

Edgar Filing: Revance Therapeutics, Inc. - Form 10-Q

Revance Therapeutics, Inc.
Form 10-Q
November 04, 2016

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 September 30, 2016

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 No. 001-36297

Revance Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware 77-0551645
(State or other jurisdiction of (I.R.S. Employer
incorporation or organization) Identification Number)

7555 Gateway Boulevard
Newark, California 94560
(510) 742-3400
(Address, including zip code, and telephone number,
including area code, of registrant's principal executive
offices)

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 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 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 Smaller reporting company

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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

Number of shares outstanding of the registrant's common stock, par value \$0.001 per share, as of October 26, 2016:
28,515,070

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“Revance Therapeutics,” the Revance logos and other trademarks or service marks of Revance appearing in this quarterly report on Form 10-Q are the property of Revance Therapeutics, Inc. This Form 10-Q contains additional trade names, trademarks and service marks of others, which are the property of their respective owners. We do not intend our use or display of other companies’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

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PART I. FINANCIAL INFORMATION

ITEM 1. Condensed Consolidated Financial Statements

Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

(Unaudited)

	September 30, 2016	December 31, 2015
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 130,481	\$ 201,615
Short-term investments	70,770	50,688
Restricted cash, current portion	—	35
Prepaid expenses and other current assets	7,428	1,625
Total current assets	208,679	253,963
Property and equipment, net	17,385	19,708
Long-term investments	—	1,751
Restricted cash, net of current portion	580	400
Other non-current assets	213	—
TOTAL ASSETS	\$ 226,857	\$ 275,822
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	\$ 2,871	\$ 2,657
Accruals and other current liabilities	11,306	6,245
Financing obligations, current portion	3,339	3,135
Total current liabilities	17,516	12,037
Financing obligations, net of current portion	2,836	5,346
Derivative liability associated with Medicis settlement	2,009	1,414
Deferred rent	3,681	3,773
Other non-current liabilities	100	—
TOTAL LIABILITIES	26,142	22,570
Commitments and Contingencies (Note 10)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value \$0.001 per share — 5,000,000 shares authorized both as of September 30, 2016 and December 31, 2015; no shares issued and outstanding both as of September 30, 2016 and December 31, 2015.	—	—
Common stock, par value \$0.001 per share — 95,000,000 shares authorized both as of September 30, 2016 and December 31, 2015; 28,515,161 and 28,288,464 shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively	29	28
Additional paid-in capital	595,411	585,537
Accumulated other comprehensive income (loss)	16	(40)
Accumulated deficit	(394,741)	(332,273)
TOTAL STOCKHOLDERS' EQUITY	200,715	253,252
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 226,857	\$ 275,822

The accompanying notes are an integral part of these unaudited Condensed Consolidated Financial Statements.

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REVANCE THERAPEUTICS, INC.

Condensed Consolidated Statement of Operations and Comprehensive Loss

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Revenue	\$75	\$75	\$225	\$225
Operating expenses:				
Research and development	10,296	13,016	37,851	32,573
General and administrative	7,502	5,827	21,975	18,183
Loss on impairment	—	—	1,949	—
Total operating expenses	17,798	18,843	61,775	50,756
Loss from operations	(17,723)	(18,768)	(61,550)	(50,531)
Interest income	306	68	940	144
Interest expense	(256)	(390)	(857)	(834)
Change in fair value of derivative liability associated with Medicis settlement	(167)	13	(595)	60
Other expense, net	(138)	(98)	(406)	(221)
Net loss	(17,978)	(19,175)	(62,468)	(51,382)
Unrealized gain/(loss) on available for sale securities	(132)	22	56	10
Comprehensive loss	\$(18,110)	\$(19,153)	\$(62,412)	\$(51,372)
Net loss attributable to common stockholders (Note 13):				
Basic	\$(17,978)	\$(19,175)	\$(62,468)	\$(51,382)
Diluted	\$(17,978)	\$(19,175)	\$(62,468)	\$(51,382)
Net loss per share attributable to common stockholders:				
Basic	\$(0.64)	\$(0.81)	\$(2.22)	\$(2.17)
Diluted	\$(0.64)	\$(0.81)	\$(2.22)	\$(2.17)
Weighted-average number of shares used in computing net loss per share attributable to common stockholders:				
Basic	28,160,458	23,755,199	28,085,541	23,625,869
Diluted	28,160,458	23,755,199	28,085,541	23,625,869

The accompanying notes are an integral part of these unaudited Condensed Consolidated Financial Statements.

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REVANCE THERAPEUTICS, INC.

Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$(62,468)	\$(51,382)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,068	1,586
Amortization of premium on investment	1,029	364
Amortization of discount on debt and capital leases	—	5
Amortization of debt issuance cost	—	39
Change in fair value of derivative liability associated with Medicis settlement	595	(60)
Stock-based compensation expense	8,984	7,314
Effective interest on financing obligations	315	226
Loss on disposal of fixed assets	—	29
Loss on impairment	1,949	—
Acquisition of in-process research and development	2,000	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(5,852)	(134)
Other non-current assets	—	24
Accounts payable	200	(477)
Accruals and other liabilities	5,821	3,096
Deferred rent	—	152
Net cash used in operating activities	(46,359)	(39,218)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(1,152)	(2,849)
Proceeds from maturities of investments	139,050	—
Proceeds from sales of investments	1,000	—
Purchases of investments	(159,754)	(54,087)
Payment for acquisition of in-process research and development	(1,800)	—
Change in restricted cash	(145)	75
Net cash used in investing activities	(22,801)	(56,861)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock, net of deferred at-the-market offering costs	—	10,154
Principal payments made on capital leases and financing obligations	(2,622)	(1,768)
Net settlement of restricted stock awards to settle employee taxes	(359)	(762)
Principal payments made on notes payable	—	(2,652)
Proceeds from sale and leaseback financing	—	9,831
Proceeds from the exercise of stock options and employee stock purchase plan	1,250	738
Payment of registration statement costs	(243)	—
Net cash provided by (used in) financing activities	(1,974)	15,541
NET DECREASE IN CASH AND CASH EQUIVALENTS	(71,134)	(80,538)
CASH AND CASH EQUIVALENTS — Beginning of period	201,615	171,032
CASH AND CASH EQUIVALENTS — End of period	130,481	90,494

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:

Cash paid for interest	542	564
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REVANCE THERAPEUTICS, INC.

	Nine Months Ended September 30,	
	2016	2015
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:		
Property and equipment purchases included in accounts payable and accruals and other current liabilities	29	95
Deferred offering costs	—	84
Holdback related to acquisition of in-process research and development	200	—
Write-off of fixed assets	—	28
The accompanying notes are an integral part of these unaudited Condensed Consolidated Financial Statements.		

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REVANCE THERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. The Company and Basis of Presentation

Revance Therapeutics, Inc., or the Company, was incorporated in Delaware on August 10, 1999 under the name Essentia Biosystems, Inc. The Company commenced operations in June 2002 and on April 19, 2005, changed its name to Revance Therapeutics, Inc. The Company is a clinical-stage biotechnology company focused on the development, manufacturing and commercialization of novel botulinum toxin products for multiple aesthetic and therapeutic indications, for dermatology, neurology and other specialties. The Company is leveraging its proprietary botulinum toxin, DaxibotulinumtoxinA, combined with its patented TransMTS® peptide technology to address unmet needs in the large and growing neurotoxin market. The Company's proprietary TransMTS® technology is used in two investigational drug product candidates, DaxibotulinumtoxinA for Injection (RT002), or RT002 injectable, and DaxibotulinumtoxinA Topical Gel, or RT001 topical. Currently, RT002 injectable is in clinical development, and RT001 topical is in preclinical development. The Company holds worldwide rights for all indications of RT002 injectable and RT001 topical and the pharmaceutical uses of the TransMTS® technology platform.

Since commencing operations in 2002, the Company has devoted substantially all of its efforts and resources to identifying and developing product candidates for the aesthetic and therapeutic pharmaceutical markets, recruiting personnel and raising capital, and preclinical and clinical development of, and manufacturing capabilities for, RT002 injectable and RT001 topical. The Company has never been profitable and has not yet commenced commercial operations.

The Company has incurred losses and negative cash flows from operations since its inception. The Company has not generated significant revenue from product sales to date and will continue to incur significant research and development and other expenses related to its ongoing operations. For the three and nine months ended September 30, 2016, the Company had a net loss of \$18.0 million and \$62.5 million, respectively, and used \$46.4 million of cash for operating activities during the nine months ended September 30, 2016. As of September 30, 2016, the Company had a working capital surplus of \$191.2 million and an accumulated deficit of \$394.7 million. The Company has funded its operations since inception primarily through the sale and issuance of common stock, convertible preferred stock, notes payable, and convertible notes. As of September 30, 2016, the Company had capital resources consisting of cash, cash equivalents, and investments of \$201.3 million. The Company believes that its existing cash, cash equivalents and investments will allow the Company to fund its operating plan through at least the next 12 months.

Basis of Presentation

The accompanying unaudited Condensed Consolidated Financial Statements, in the opinion of management, include all adjustments which the Company considers necessary for the fair statement of the Condensed Consolidated Results of Operations and Comprehensive Loss and Condensed Consolidated Statement of Cash Flows for the interim periods covered and the Condensed Consolidated Financial Position of the Company at the date of the balance sheets. The December 31, 2015 Condensed Consolidated Balance Sheet was derived from audited financial statements, but does not include all disclosures required by generally accepted accounting principles in the United States of America, or US GAAP. The interim results presented herein are not necessarily indicative of the results of operations that may be expected for the full fiscal year ending December 31, 2016, or any other future period.

The Condensed Consolidated Financial Statements should be read in conjunction with the Company's audited Consolidated Financial Statements contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, which was filed with the Securities and Exchange Commission, or SEC, on March 4, 2016. The Condensed Consolidated Financial Statements of the Company include the Company's accounts and those of the Company's wholly-owned subsidiary and have been prepared in conformity with US GAAP.

2. Summary of Significant Accounting Policies

Significant accounting policies are described in Note 2 to the Consolidated Financial Statements in Item 15 of the Company's Annual Report on Form 10-K for the year ended December 31, 2015. There have been no changes to the Company's significant accounting policies during the three and nine months ended September 30, 2016, except as described below.

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REVANCE THERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements — (Continued)
(Unaudited)

Use of Estimates

The preparation of Condensed Consolidated Financial Statements in conformity with US GAAP requires management to make estimates and assumptions that affect the amounts reported in the Condensed Consolidated Financial Statements and accompanying notes. Such management estimates include accruals, stock-based compensation, the fair value of derivative liability associated with the Medicis settlement, and the valuation of deferred tax assets. The Company bases its estimates on historical experience and also on assumptions that it believes are reasonable, however, actual results could significantly differ from those estimates.

Accounting Pronouncements

On August 26, 2016, the FASB issued Accounting Standards Update (ASU) 2016-15, Statement of Cash Flows (Topic 230). The amendments in ASU 2016-15 affect all entities that are required to present a statement of cash flows and provide guidance and clarity on certain cash flow classification aspects. This update addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. The ASU is effective for public companies for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years. Early adoption is permitted for any entity in any interim or annual period. If an entity adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. An entity that elects early adoption must adopt all of the amendments in the same period. The adoption of this standard is not expected to have a material impact on the Company's financial statements.

On March 30, 2016, the FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting (Topic 718). The amendments in ASU 2016-09 affect all entities that issue share-based payment awards to their employees and involve multiple aspects of the accounting for share-based payment transactions, including income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The ASU is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted for any entity in any interim or annual period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. An entity that elects early adoption must adopt all of the amendments in the same period. The Company is currently evaluating the impact that the standard will have on its financial statements and plans to adopt the ASU in the first quarter of 2017.

On February 25, 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases. The ASU will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the impact that the standard will have on its financial statements.

On January 5, 2016, the FASB issued ASU 2016-01, Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities, which addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. The updated standard is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017 and early adoption is not permitted. The Company is currently evaluating the impact that the standard will have on its financial statements.

In August 2014, the FASB issued Accounting Standard Update No. 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40), which will require management to assess an entity's ability to continue as a going concern at each annual and interim period. Related footnote disclosures will be required if conditions give rise to substantial doubt about an entity's ability to continue as a going concern within one year of the report issuance date. If conditions do not give rise to substantial doubt, no disclosures will be required specific to going concern uncertainties. The guidance defines substantial doubt using a likelihood threshold of "probable" similar to the current use of that term in U.S. GAAP for loss contingencies and provides example indicators. The guidance is effective for reporting periods ending after December 15, 2016, and early adoption is permitted. The Company does not expect adoption of this standard to have a material impact on the Company's financial statements.

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REVANCE THERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements — (Continued)
(Unaudited)

3. In-Process Research and Development

On June 2, 2016, the Company entered into an asset purchase agreement with Botulinum Toxin Research Associates, Inc., or BTRX (the "BTRX Purchase Agreement"). Under the BTRX Purchase Agreement, the Company acquired all rights, title and interest in a portfolio of botulinum toxin-related patents and patent applications from BTRX and was granted the right of first negotiation and first refusal with respect to other botulinum toxin-related patents owned or controlled by BTRX. In exchange, the Company agreed to an upfront expenditure of \$2.0 million of which \$1.8 million was paid immediately with the remaining \$0.2 million due and payable over the next two years. The Company also agreed to pay up to an additional \$16.0 million in aggregate upon satisfaction of specified milestones relating to the Company's product revenue, intellectual property, and clinical and regulatory events.

The Company concluded that the BTRX Purchase Agreement did not meet the criteria of a business combination pursuant to the guidance prescribed in Accounting Standards Codification Topic 805, Business Combinations. The Company accounted for the initial \$2.0 million expenditure as research and development expense, as future alternative use of the acquired assets was deemed contingent upon the successful outcome of existing research and development activities as of the transaction date.

4. Medicis Settlement

In July 2009, the Company and Medicis Pharmaceutical Corporation, or Medicis, entered into a license agreement granting Medicis worldwide aesthetic and dermatological rights to the Company's investigational, injectable botulinum toxin type A product candidate. In October 2012, the Company entered into a settlement and termination agreement with Medicis. The terms of the settlement provided for the reacquisition of the rights related to all territories of RT002 injectable and RT001 topical from Medicis and for consideration payable by the Company to Medicis of up to \$25.0 million, comprised of (i) an upfront payment of \$7.0 million, which was paid in 2012, (ii) a proceeds sharing arrangement payment of \$14.0 million due upon specified capital raising achievements by the Company, of which \$6.9 million was paid in 2013 and \$7.1 million in 2014, and (iii) \$4.0 million to be paid upon the achievement of regulatory approval for RT002 injectable or RT001 topical by the Company, or Product Approval Payment. Medicis was subsequently acquired by Valeant Pharmaceuticals International, Inc. in December 2012.

The Company determined that the settlement provisions related to the proceeds sharing arrangement payment in (ii) above and Product Approval Payment in (iii) above were derivative instruments that require fair value accounting as a liability and periodic fair value remeasurements until settled.

The proceeds sharing arrangement payment derivative in (ii) above was settled upon completion of our initial public offering, or IPO. As of September 30, 2016, the Company determined the fair value of its liability for the Product Approval Payment was \$2.0 million, which was measured by assuming a term of 3.5 years, a risk-free rate of 0.95% and a credit risk adjustment of 9.00%. The Company's assumption for the expected term is based on an expe