
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

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

Date of report (Date of earliest event reported): February 26, 2018

AKCEA THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware

(State or Other Jurisdiction of Incorporation)

001-38137
(Commission File No.)

47-2608175
(IRS Employer Identification No.)

55 Cambridge Parkway
Suite 100
Cambridge, Massachusetts 02142
(Address of Principal Executive Offices and Zip Code)

Registrant's telephone number, including area code: **(617) 207-0202**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

Item 2.02 Results of Operations and Financial Condition.

On February 26, 2018, Akcea Therapeutics, Inc. (the “Company”) issued a press release announcing the Company’s financial results for the quarter and fiscal year ended December 31, 2017. In addition to disclosing results that are determined in accordance with Generally Accepted Accounting Principles (GAAP), the Company also discloses pro forma or non-GAAP results of operations, which are adjusted from GAAP to exclude non-cash compensation related to stock awards. The Company is presenting pro forma information excluding non-cash compensation because the Company believes it is useful for investors in assessing the Company’s operating results compared to the prior year. A copy of the release is furnished with this report as an exhibit pursuant to “Item 2.02. Results of Operations and Financial Condition” of Form 8-K in accordance with SEC Release Nos. 33-8216 and 34-47583.

The information in this Current Report on Form 8-K and the Exhibit attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release dated February 26, 2018.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Akcea Therapeutics, Inc.

Dated: February 27, 2018

By: /s/ Paula Soteropoulos

Paula Soteropoulos
President and Chief Executive Officer

INDEX TO EXHIBITS

[99.1](#) Press Release dated February 26, 2018.



Akcea Reports Financial Results and Highlights for Fourth Quarter and Year End 2017

Preparing for mid-2018 approval and launch of volanesorsen for FCS in the US, EU and Canada

Advancing the pipeline with four Phase 2 trials underway and data planned from two studies in 2018

Conference Call Webcast Monday, February 26, 4:30 p.m. ET at www.akceatx.com

Cambridge, Mass., February 26, 2018 (GLOBE NEWSWIRE) -- Akcea Therapeutics, Inc. (NASDAQ: AKCA), an affiliate of Ionis Pharmaceuticals, Inc., today reported financial results for the fourth quarter and year ended December 31, 2017. Akcea is focused on developing and commercializing drugs to treat patients with serious cardiometabolic diseases. The company reported an operating loss for the fourth quarter and year ended December 31, 2017 on a GAAP basis of \$25 million and \$109 million, respectively, and on a pro forma basis of \$19 million and \$91 million, respectively. Akcea had \$260 million of cash, cash equivalents and short-term investments as of December 31, 2017.

“With our marketing submissions accepted in the US, EU and Canada, we continue to focus our efforts on the regulatory process and on preparation for the mid-2018 launch of volanesorsen quickly after our potential approvals,” said Paula Soteropoulos, president and chief executive officer of Akcea. “In addition, we completed enrollment on our Phase 2b study of AKCEA-APO(a)-LR_x and initiated three Phase 2 studies with AKCEA-APOCIII-LR_x and AKCEA-ANGPTL3-LR_x expanding the number of indications across both broad and rare diseases that we are pursuing with our novel pipeline of therapeutics.”

“We are on track with the build out of our commercial infrastructure and the development timelines laid out at the IPO. The costs incurred in 2017 associated with the tremendous progress we have made on both fronts are in line with our expectations and we believe we have sufficient funds to achieve our planned critical milestones through 2019,” said Michael MacLean, chief financial officer of Akcea.

Upcoming Events

- Approval and launch of volanesorsen in mid-2018 in patients with FCS in US, EU and Canada.
- Report top line results in the second half of 2018 from a Phase 2b trial of AKCEA-APO(a)-LR_x in patients with high lipoprotein(a), also known as Lp(a).
- Report top line results in 2018 from an exploratory Phase 2 study of AKCEA-ANGPTL3-LR_x in patients with rare hyperlipidemias.

Recent Key Highlights

- Acceptance of marketing applications to the US Food and Drug Administration, European Medicines Agency and Health Canada for the approval of volanesorsen for the treatment of patients with FCS.

- Substantial progress on the build out of the commercial organization including hiring the US field team and key positions in commercial operations, medical affairs, patient support and market access.
- Completed enrollment in the Phase 2b study of AKCEA-APO(a)-LR_x.
- Initiated a Phase 2b study of AKCEA-APOCIII-LR_x in patients with Hypertriglyceridemia and Established Cardiovascular Disease.
- Initiated a Phase 2 program of AKCEA-ANGPTL3-LR_x in rare hyperlipidemias and a Phase 2 study of AKCEA-ANGPTL3-LR_x in patients with nonalcoholic fatty liver disease (NAFLD) with metabolic complications.

Financial Results

All pro forma amounts referred to in this press release exclude non-cash compensation expense related to equity awards. Please refer to the reconciliation of pro forma and GAAP measures, which is provided later in this release.

Revenue

Akcea's revenue for the fourth quarter and year ended December 31, 2017 was \$18 million and \$55 million, respectively. Akcea's 2017 revenue is entirely related to the Company's collaboration with Novartis. In January 2017, Akcea and Novartis entered into a strategic collaboration and Novartis paid Akcea a \$75 million upfront payment, which Akcea is amortizing into revenue. As part of the strategic collaboration, Novartis also purchased shares of Ionis' common stock at a premium. Since Akcea is providing the services under the Novartis collaboration, Akcea is also amortizing into revenue the \$33 million premium. Under its license agreement with Ionis, Akcea paid a \$15 million sublicense fee to Ionis related to the \$75 million upfront payment and recorded a \$33 million non-cash charge related to the premium Novartis paid to acquire Ionis' shares of common stock as described in Operating Expenses below.

Operating Expenses

Akcea's operating expenses for the fourth quarter and year ended December 31, 2017 on a GAAP basis were \$43 million and \$164 million, respectively, and on a pro forma basis were \$37 million and \$146 million, respectively. These amounts compare to GAAP operating expenses of \$34 million and \$84 million, and pro forma operating expenses of \$31 million and \$73 million, respectively for the same periods in 2016. Akcea's operating expenses increased for the year ended December 31, 2017 compared to the same period in 2016 primarily due to \$48 million of sublicensing expenses related to the Company's collaboration with Novartis. The \$48 million is comprised of \$15 million the Company paid to Ionis related to the \$75 million upfront payment and a \$33 million non-cash charge related to the premium Novartis paid to acquire Ionis' common stock. Akcea's operating expenses related to development and support services Ionis provided to Akcea was \$102 million and \$64 million for the years ended December 31, 2017 and 2016, respectively.

Net Loss

Akcea reported a net loss of \$23 million and \$110 million on a GAAP basis for the fourth quarter and year ended December 31, 2017, respectively, compared to \$34 million and \$83 million for the same periods in 2016. Akcea reported a pro forma net loss of \$18 million and \$92 million for the fourth quarter and year ended December 31, 2017 compared to \$31 million and \$73 million for the same periods in 2016. For the fourth quarter of 2017, basic and diluted net loss per share of common stock was \$0.35. For the year ended December 31, 2017, basic and diluted net loss per share of preferred stock and common stock were \$1.55 and \$2.82, respectively.

Balance Sheet

As of December 31, 2017, Akcea had cash, cash equivalents and short-term investments of \$260 million compared to \$8 million at December 31, 2016. Akcea's year-end cash balance includes \$182 million in net proceeds from the recent IPO and the concurrent private placement from Novartis' strategic investment. Akcea's cash position will allow the Company to achieve planned milestones in commercial and development operations through 2019.

Conference Call

At 4:30 p.m. Eastern Time today, February 26, 2018, Akcea will conduct a live webcast conference call to discuss this earnings release and related activities. Interested parties may listen to the call by dialing 844-866-6320, passcode 8789648 or access the webcast at www.akceatx.com. A webcast replay will be available for a limited time at the same address.

ABOUT AKCEA THERAPEUTICS

Akcea Therapeutics, an affiliate of Ionis Pharmaceuticals, Inc. (NASDAQ: IONS), is a biopharmaceutical company focused on developing and commercializing drugs to treat patients with serious cardiometabolic diseases caused by lipid disorders. Akcea is advancing a mature pipeline of four novel drugs, including volanesorsen, AKCEA-APO(a)-LR_x, AKCEA-ANGPTL3-LR_x and AKCEA-APOCIII-LR_x, all with the potential to treat multiple diseases. All four drugs were discovered by and are being co-developed with Ionis, a leader in antisense therapeutics, and are based on Ionis' proprietary antisense technology. The most advanced drug in its pipeline, volanesorsen, is under regulatory review in the U.S., EU and Canada for the treatment of familial chylomicronemia syndrome, or FCS, and is currently in Phase 3 clinical development for the treatment of familial partial lipodystrophy, or FPL. Akcea is building the infrastructure to commercialize its drugs globally with a focus on lipid specialists as the primary call point. Akcea is located in Cambridge, Massachusetts. Additional information about Akcea is available at www.akceatx.com.

FORWARD-LOOKING STATEMENT

This press release includes forward-looking statements regarding the business of Akcea Therapeutics, Inc. and the therapeutic and commercial potential of volanesorsen and other products in development. Any statement describing Akcea's goals, expectations, financial or other projections, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those inherent in the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs. Akcea's forward-looking statements also involve assumptions that, if they never materialize or prove correct, could cause its results to differ materially from those expressed or implied by such forward-looking statements. Although Akcea's forward-looking statements reflect the good faith judgment of its management, these statements are based only on facts and factors currently known by Akcea. As a result, you are cautioned not to rely on these forward-looking statements. These and other risks concerning Akcea's programs are described in additional detail in Akcea's annual report on Form S-1, and its most recent quarterly report on Form 10-Q, which are on file with the SEC. Copies of these and other documents are available from the Company.

In this press release, unless the context requires otherwise, "Ionis", "Akcea," "Company," "Companies," "we," "our," and "us" refers to Ionis Pharmaceuticals and/or Akcea Therapeutics.

Ionis Pharmaceuticals™ is a trademark of Ionis Pharmaceuticals, Inc. Akcea Therapeutics™ is a trademark of Ionis Pharmaceuticals, Inc.

AKCEA THERAPEUTICS, INC.
SELECTED FINANCIAL INFORMATION
Consolidated Statements of Operations
(In Thousands, Except Per Share Data)

	Three months ended, December 31,		Years ended, December 31,	
	2017	2016	2017	2016
	(unaudited)			
R&D Revenue	\$ 18,035	\$ -	\$ 55,209	\$ -
Expenses:				
Research and development	25,969	28,713	126,890	68,459
General and administrative	17,017	5,142	36,981	15,053
Total operating expenses	<u>42,986</u>	<u>33,855</u>	<u>163,871</u>	<u>83,512</u>
Loss from operations	(24,951)	(33,855)	(108,662)	(83,512)
Other income (expense):				
Investment income	819	24	1,813	295
Interest expense	-	-	(1,731)	-
Other income (expense)	<u>(19)</u>	<u>-</u>	<u>104</u>	<u>-</u>
Loss before income tax expense	(24,151)	(33,831)	(108,476)	(83,217)
Income tax benefit (expense)	<u>791</u>	<u>-</u>	<u>(1,275)</u>	<u>-</u>
Net loss	<u>\$ (23,360)</u>	<u>\$ (33,831)</u>	<u>\$ (109,751)</u>	<u>\$ (83,217)</u>
Net loss per share of preferred stock, basic and diluted	<u>\$ -</u>	<u>\$ (1.17)</u>	<u>\$ (1.55)</u>	<u>\$ (2.88)</u>
Weighted-average shares of preferred stock outstanding, basic and diluted	<u>-</u>	<u>28,884,540</u>	<u>15,748,009</u>	<u>28,884,540</u>
Net loss per share of common stock, basic and diluted	<u>\$ (0.35)</u>	<u>\$ -</u>	<u>\$ (2.82)</u>	<u>\$ -</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>66,541,629</u>	<u>-</u>	<u>30,262,768</u>	<u>-</u>

AKCEA THERAPEUTICS, INC.
Reconciliation of GAAP to Pro Forma Basis:
Condensed Consolidated Operating Expenses, Loss From Operations, and Net Loss
(In Thousands)

	Three months ended, December 31,		Years ended, December 31,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
As reported operating expenses according to GAAP	\$ 42,986	\$ 33,855	\$ 163,871	\$ 83,512
Excluding compensation expense related to equity awards	(5,725)	(2,467)	(17,539)	(10,149)
Pro forma operating expenses	<u>\$ 37,261</u>	<u>\$ 31,388</u>	<u>\$ 146,332</u>	<u>\$ 73,363</u>
As reported loss from operations according to GAAP	\$ (24,951)	\$ (33,855)	\$ (108,662)	\$ (83,512)
Excluding compensation expense related to equity awards	(5,725)	(2,467)	(17,539)	(10,149)
Pro forma loss from operations	<u>\$ (19,226)</u>	<u>\$ (31,388)</u>	<u>\$ (91,123)</u>	<u>\$ (73,363)</u>
As reported net loss according to GAAP	\$ (23,360)	\$ (33,831)	\$ (109,751)	\$ (83,217)
Excluding compensation expense related to equity awards	(5,725)	(2,467)	(17,539)	(10,149)
Pro forma net loss	<u>\$ (17,635)</u>	<u>\$ (31,364)</u>	<u>\$ (92,212)</u>	<u>\$ (73,068)</u>

Reconciliation of GAAP to Pro Forma Basis

As illustrated in the Selected Financial Information in this press release, pro forma operating expenses, pro forma loss from operations, and pro forma net loss were adjusted from GAAP to exclude compensation expense related to equity awards, which are non-cash expenses. Akcea has regularly reported non-GAAP measures for operating results as pro forma results. These measures are provided as supplementary information and are not a substitute for financial measures calculated in accordance with GAAP. Akcea reports these pro forma results to better enable financial statement users to assess and compare its historical performance and project its future operating results and cash flows. Further, the presentation of Akcea's pro forma results is consistent with how Akcea's management internally evaluates the performance of its operations.

AKCEA THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(In Thousands)

	<u>December 31,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Assets:		
Cash and cash equivalents	\$ 58,367	\$ 7,857
Short-term investments	201,763	-
Contract receivable	5,413	-
Other current assets	1,302	1,209
Licenses, net	1,221	1,341
Other assets	738	277
Total assets	<u>\$ 268,804</u>	<u>\$ 10,684</u>
Liabilities and stockholders' equity (deficit):		
Accounts payable	\$ 2,381	\$ 476
Payable to Ionis	14,365	24,355
Accrued compensation	4,083	2,505
Accrued liabilities	7,570	1,041
Current portion of deferred contract revenue	50,579	-
Other current liabilities	1,875	33
Long-term portion of deferred rent	12	21
Long-term deferred contract revenue	8,306	-
Stockholders' equity (deficit)	179,633	(17,747)
Total liabilities and stockholders' equity (deficit)	<u>\$ 268,804</u>	<u>\$ 10,684</u>

Media and Investor Contact:

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