
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): November 6, 2017

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 (Section 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (Section 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 November 6, 2017, Akcea Therapeutics, Inc. (the “Company”) issued a press release announcing the Company’s financial results for the quarter ended September 30, 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. 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 November 6, 2017.

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: November 6, 2017

By: /s/ Paula Soteropoulos

Paula Soteropoulos
President and Chief Executive Officer

INDEX TO EXHIBITS

[99.1](#) Press Release dated November 6, 2017.

Akcea Reports Financial Results and Highlights for Third Quarter 2017

Submitted marketing authorization applications in the US, EU and Canada for volanesorsen in FCS

Expanded leadership team to support global commercial launch of volanesorsen

Conference Call Webcast Monday, November 6, 4:30 p.m. ET at www.akceatx.com

Cambridge, Mass., November 6, 2017 (GLOBE NEWSWIRE) -- Akcea Therapeutics, Inc. (NASDAQ: AKCA), an affiliate of Ionis Pharmaceuticals, Inc., today reported financial results for the third quarter ended September 30, 2017. Akcea is focused on developing and commercializing drugs to treat patients with serious cardiometabolic diseases caused by lipid disorders. The Company reported an operating loss for the three and nine months ended September 30, 2017 on a GAAP basis of \$12.6 million and \$83.7 million, respectively, and on a pro forma basis of \$7.9 million and \$71.9 million, respectively. Akcea had \$286.1 million of cash, cash equivalents and short-term investments as of September 30, 2017.

“We filed for marketing authorizations in the US, EU and Canada positioning ourselves for the potential 2018 launch of volanesorsen in our three top markets. We are building a strong commercial organization and expanding our global presence to enable delivery of volanesorsen to patients with FCS who currently have no other treatment options for this devastating disease,” said Paula Soteropoulos, president and chief executive officer of Akcea. “In addition, we continued to enroll on track on our Phase 2b study of AKCEA-APO(a)-LR_x and announced positive results of a Phase 1/2 study of AKCEA-APOCIII-LR_x demonstrating the continued advancement of our novel pipeline of therapeutics for patients with both broad and rare cardiometabolic diseases.”

“We raised net proceeds of \$182 million in our recent initial public offering and the concurrent private placement with Novartis which provided us with funding sufficient to execute on the initial launch of volanesorsen in 2018 and to progress our pipeline to critical data milestones. Our costs incurred in the reported period are in line with our expectations,” said Michael MacLean, chief financial officer of Akcea.

Upcoming Events

- Launch volanesorsen in 2018 in patients with FCS in US, EU and Canada, if approved.
- Report top line results in 2018 from a Phase 2b trial of AKCEA-APO(a)-LR_x in patients with high lipoprotein(a), also known as Lp(a).
- Initiate this year a Phase 2 study of AKCEA-ANGPTL3-LR_x in patients with rare hyperlipidemias.
- Initiate this year a Phase 2 study of AKCEA-ANGPTL3-LR_x in patients with non-alcoholic fatty liver disease (NAFLD) with metabolic complications.
- Initiate this year a Phase 2b dose-ranging study evaluating AKCEA-APOCIII-LR_x in patients with hypertriglyceridemia and established cardiovascular disease.
- Present at a number of medical conferences including an oral presentation on the volanesorsen APPROACH study at the American Pancreatic Association.

Recent Key Highlights

- Submitted marketing authorization filings to the US FDA, European Medicines Agency and Health Canada for the approval of volanesorsen for the treatment of patients with FCS.
- Received Priority Review for the volanesorsen regulatory filings in Canada.
- Received Promising Innovative Medicine (PIM) designation for volanesorsen in the United Kingdom which is an early indication that a medicinal product is a promising candidate with the potential to treat a life-threatening or seriously debilitating condition.
- Announced positive results from the Phase 1/2 study evaluating AKCEA-APOCIII-LR_x in healthy volunteers and patients with elevated triglycerides.
- Presented final results from the IN-FOCUS study demonstrating the significant burden of illness for patients with FCS at the National Organization of Rare Diseases Summit.
- Raised over \$180 million through our initial public offering (IPO), including the underwriters' full exercise of their overallotment option, and concurrent private placement with Novartis.
- Expanded the leadership team in the US and established a global presence in Canada, United Kingdom, Germany and France.

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 three and nine months ended September 30, 2017 was \$13.4 million and \$37.2 million, respectively. Akcea's 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 Ionis' common stock at a premium. Since Akcea is providing the services under the Novartis collaboration, Akcea is also amortizing into revenue the \$33.4 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 \$33.4 million non-cash charge related to the premium Novartis paid to acquire Ionis' common stock as described in Operating Expenses below.

Operating Expenses

Akcea's operating expenses for the three and nine months ended September 30, 2017 on a GAAP basis were \$26.0 million and \$120.9 million, respectively, and on a pro forma basis were \$21.3 million and \$109.1 million, respectively. These amounts compare to GAAP operating expenses of \$19.9 million and \$49.7 million for the same periods in 2016. Akcea's operating expenses increased for the nine months ended September 30, 2017 compared to the same period in 2016 primarily due to \$48.4 million of sublicensing expenses related to the Company's collaboration with Novartis. The \$48.4 million is comprised of \$15 million the Company paid to Ionis related to the \$75 million upfront payment and a \$33.4 million non-cash charge related to the premium Novartis paid to acquire Ionis' common stock. Akcea's operating expenses for the nine months ended September 30, 2017 and 2016 included \$7.9 million and \$5.8 million, respectively, of expenses for development and support services Ionis provided to Akcea. Akcea expects its G&A expenses to continue to increase as the Company continues to prepare to launch volanesorsen and build out its corporate functions. As Akcea continues to build its internal corporate functions, Akcea will rely less on Ionis for support services and the associated charges should decrease.

Net Loss

Akcea reported a net loss of \$14.1 million and \$86.4 million on a GAAP basis for the three and nine months ended September 30, 2017, respectively, compared to \$19.8 million and \$49.4 million for the same periods in 2016. Akcea reported a pro forma net loss of \$9.4 million and \$74.6 million for the three and nine months ended September 30, 2017 compared to \$17.3 million and \$41.7 million for the same periods in 2016. For the three and nine months ended September 30, 2017, basic and diluted net loss per share of common stock for the period since our IPO were \$0.27 and \$2.72, respectively.

Balance Sheet

As of September 30, 2017, Akcea had cash, cash equivalents and short-term investments of \$286.1 million compared to \$7.9 million at December 31, 2016. Akcea's third quarter cash balance includes \$182.4 million in net proceeds from the recent IPO and the concurrent private placement from Novartis' strategic investment. In addition, during 2017 Akcea received \$75 million related to the upfront payment from Novartis and \$106 million from borrowings under Akcea's line of credit with Ionis. Concurrent with the IPO, the Company was able to streamline its capital structure through the conversion of both Ionis' line of credit and series A preferred stock into Akcea's common stock. Akcea's working capital was \$214.4 million at September 30, 2017 compared to \$(19.3) million at December 31, 2016.

Conference Call

At 4:30 p.m. Eastern Time today, November 6, 2017, 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 855-237-2439, passcode 99468373 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 its final prospectus for its initial public offering and its most recent quarterly report on Form 10-Q, which are on file with the SEC.

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
Condensed Consolidated Statements of Operations
(In Thousands, Except Per Share Data)

	Three months ended, September 30,		Nine months ended, September 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
R&D Revenue	\$ 13,449	\$ -	\$ 37,173	\$ -
Expenses:				
Research and development	17,640	17,005	100,921	39,739
General and administrative	8,373	2,897	19,963	9,911
Total operating expenses	26,013	19,902	120,884	49,650
Loss from operations	(12,564)	(19,902)	(83,711)	(49,650)
Other income (expense):				
Investment income	760	93	1,118	270
Interest expense	(224)	-	(1,731)	-
Loss before income tax expense	(12,028)	(19,809)	(84,324)	(49,380)
Income tax expense	(2,066)	-	(2,066)	-
Net loss	\$ (14,094)	\$ (19,809)	\$ (86,390)	\$ (49,380)
Net income (loss) per share of preferred stock, basic and diluted	\$ 0.05	\$ (0.69)	\$ (1.77)	\$ (1.71)
Net loss per share of common stock, basic and diluted	\$ (0.27)	-	\$ (2.72)	-

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, September 30,		Nine months ended, September 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
As reported operating expenses according to GAAP	\$ 26,013	\$ 19,902	\$ 120,884	\$ 49,650
Excluding compensation expense related to equity awards	(4,692)	(2,515)	(11,814)	(7,683)
Pro forma operating expenses	<u>\$ 21,321</u>	<u>\$ 17,387</u>	<u>\$ 109,070</u>	<u>\$ 41,967</u>
As reported loss from operations according to GAAP	\$ (12,564)	\$ (19,902)	\$ (83,711)	\$ (49,650)
Excluding compensation expense related to equity awards	(4,692)	(2,515)	(11,814)	(7,683)
Pro forma loss from operations	<u>\$ (7,872)</u>	<u>\$ (17,387)</u>	<u>\$ (71,897)</u>	<u>\$ (41,967)</u>
As reported net loss according to GAAP	\$ (14,094)	\$ (19,809)	\$ (86,390)	\$ (49,380)
Excluding compensation expense related to equity awards	(4,692)	(2,515)	(11,814)	(7,683)
Pro forma net loss	<u>\$ (9,402)</u>	<u>\$ (17,294)</u>	<u>\$ (74,576)</u>	<u>\$ (41,697)</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>September 30,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Assets:		
Cash, cash equivalents and short-term investments	\$ 286,131	\$ 7,857
Other current assets	1,749	1,209
Licenses, net	1,251	1,341
Other assets	218	277
Total assets	<u>\$ 289,349</u>	<u>\$ 10,684</u>
Liabilities and stockholders' deficit:		
Accounts payable	\$ 2,012	\$ 476
Payable to Ionis	9,501	24,355
Accrued compensation	2,307	2,505
Accrued liabilities	3,452	1,041
Current portion of deferred contract revenue	54,043	-
Other current liabilities	2,142	33
Long-term portion of deferred rent	14	21
Line of credit with Ionis	-	-
Long-term deferred contract revenue	18,035	-
Stockholders' equity (deficit)	197,843	(17,747)
Total liabilities and stockholders' equity	<u>\$ 289,349</u>	<u>\$ 10,684</u>

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