
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): August 8, 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 (§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 August 8, 2017, Akcea Therapeutics, Inc. (the “Company”) issued a press release announcing the Company’s financial results for the quarter ended June 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 August 8, 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: August 8, 2017

By: /s/ Elizabeth L. Hougen
Elizabeth L. Hougen
Chief Financial Officer

INDEX TO EXHIBITS

[99.1](#) Press Release dated August 8, 2017.



Akcea Reports Financial Results and Highlights for Second Quarter 2017

Marketing authorization application submitted to the European Medicines Agency for the approval of volanesorsen

Cash balance of approximately \$300 million to fund volanesorsen launch and cardiometabolic pipeline advancement

Strategic investment of \$75 million by Novartis and Ionis

Cambridge, Mass., August 8, 2017 (GLOBE NEWSWIRE) -- Akcea Therapeutics, Inc. (NASDAQ: AKCA), an affiliate of Ionis Pharmaceuticals, Inc., focused on developing and commercializing drugs to treat patients with serious cardiometabolic diseases caused by lipid disorders, today reported financial results for the second quarter ended June 30, 2017, and provided an update on upcoming events and key achievements.

“We recently submitted a marketing authorization application (MAA) to the European Medicines Agency (EMA) for the approval of volanesorsen in Europe and we are on track to file for regulatory approval in the U.S. and Canada in September. In anticipation of a potential 2018 launch, we are actively preparing to commercialize volanesorsen globally. We are building a small, highly specialized salesforce and a comprehensive patient support program tailored to meet the needs of patients with familial chylomicronemia syndrome (FCS) and their treating physicians,” said Paula Soteropoulos, president and chief executive officer of Akcea. “Last month, we raised over \$190 million with the completion of our initial public offering (IPO) and concurrent \$50 million strategic investment by our partner Novartis Pharma AG and \$25 million investment from Ionis Pharmaceuticals, who discovered and is co-developing the drugs in our pipeline. We now have approximately \$300 million in cash, which should allow us to advance our mature pipeline of four novel cardiometabolic drugs, including building the infrastructure necessary to commercialize our drugs globally. We believe we are well-positioned to pursue our mission to bring important medicines to patients with lipid-driven cardiometabolic diseases.”

Upcoming Events

- File for regulatory approval of volanesorsen in the U.S. and Canada in September.
- Present results from the Phase 1/2 study evaluating AKCEA-APOCIII-LR_x in healthy volunteers and patients with elevated triglycerides in the second half of 2017.
- Initiate Phase 2 studies with AKCEA-ANGPTL3-LR_x in the second half of 2017, including a study in patients with non-alcoholic fatty liver disease (NAFLD) and metabolic complications and studies in patients with rare hyperlipidemias.
- Initiate a Phase 2b dose-ranging study evaluating AKCEA-APOCIII-LR_x in patients with hypertriglyceridemia and established cardiovascular disease in the second half of 2017.

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 six months ended June 30, 2017 was \$14.1 million and \$23.7 million, respectively, all of which was 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 six months ended June 30, 2017 on a GAAP basis were \$25.4 million and \$94.9 million, respectively, and on a pro forma basis were \$21.5 million and \$87.8 million, respectively. These amounts compare to GAAP operating expenses of \$13.7 million and \$29.7 million and pro forma operating expenses of \$11.7 million and \$24.6 million for the same periods in 2016. Akcea's operating expenses increased for the six months ended June 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 six months ended June 30, 2017 and 2016 included \$12.0 million and \$4.1 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.

Net Loss

Akcea reported a net loss of \$11.9 million and \$72.3 million on a GAAP basis for the three and six months ended June 30, 2017, respectively, compared to \$13.6 million and \$29.6 million for the same periods in 2016. Akcea reported a pro forma net loss of \$8.0 million and \$65.2 million for the three and six months ended June 30, 2017 compared to \$11.6 million and \$24.4 million for the same periods in 2016. For the three and six months ended June 30, 2017, basic and diluted net loss per share were \$0.41 and \$2.50, respectively. Basic and diluted net loss per share for the same periods in 2016 were \$0.47 and \$1.02.

Balance Sheet

As of June 30, 2017, Akcea had cash, cash equivalents and short-term investments of \$118.7 million compared to \$7.9 million at December 31, 2016. Akcea's cash balance increased in the first half of 2017 due to the \$75 million upfront payment the Company received from Novartis and the \$106 million from borrowings under Akcea's line of credit with Ionis, which converted into Akcea's common stock in connection with the completion of the IPO. Akcea's second quarter cash balance did not include the \$182 million it received in net proceeds from its IPO and Novartis' strategic investment. Concurrent with the Company's IPO, the series A preferred stock that Ionis owned converted into Akcea's common stock. Akcea's working capital was \$53.6 million at June 30, 2017 compared to \$(19.3) million at December 31, 2016.

Key Achievements

- Submitted a marketing authorization application (MAA) to the European Medicines Agency (EMA) for the approval of volanesorsen for the treatment of patients with familial chylomicronemia syndrome (FCS).
- Raised over \$190 million in the Company's initial public offering, including the underwriters' full exercise of their overallotment option, Novartis' \$50 million strategic investment and \$25 million strategic investment from Ionis, who discovered and is co-developing the drugs in Akcea's pipeline. The IPO generated over \$180 million in net proceeds.
- Established a strategic collaboration with Novartis, a leader in cardiovascular medicines, worth up to more than \$1.6 billion plus royalties for the development and commercialization of AKCEA-APO(a)-LR_x and AKCEA-APOCIII-LR_x for large populations of patients who have high cardiovascular risk due to inadequately treated lipid disorders.
- Successfully completed the Phase 3 program of volanesorsen for the treatment of FCS.
- Expanded the Company's independent board of directors with the appointments of Elaine Hochberg, Sandford Smith, Edward Fitzgerald and Christopher Gabrieli, as chairman of the board.
- Initiated a Phase 2b dose-ranging study with AKCEA-APO(a)-LR_x in patients with elevated Lp(a) and established cardiovascular disease to support the design of the Phase 3 cardiovascular outcome study.
- Published key preclinical findings with angiopoietin-like 3 (ANGPTL3)-targeting drugs and Phase 1/2 clinical study results with AKCEA-ANGPTL3-LR_x in the *New England Journal of Medicine*.
- Published results from the IN-FOCUS (Investigation of Findings and Observations Captured in Burden of Illness Survey in FCS Patients) survey, the largest survey in patients with FCS, demonstrating the considerable daily and life-long burden of disease for these patients.

ABOUT AKCEA THERAPEUTICS

Akcea Therapeutics, an affiliate of Ionis Pharmaceuticals, Inc., 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 with the potential to treat multiple diseases, including volanesorsen, AKCEA-APO(a)-LR_x, AKCEA-ANGPTL3-LR_x and AKCEA-APOCIII-LR_x. All four drugs were discovered and are being co-developed by Ionis, a leader in antisense therapeutics, based on Ionis' proprietary antisense technology. The most advanced drug in its pipeline, volanesorsen, is under regulatory review in the EU 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 financial position, outlook and 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, which is on file with the SEC.

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

Akcea Therapeutics™ is a trademark of Ionis Pharmaceuticals, Inc. Ionis Pharmaceuticals™ 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, June 30,		Six months ended, June 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
R&D Revenue	\$ 14,128	\$ -	\$ 23,725	\$ -
Expenses:				
Research and development	18,487	10,944	83,282	22,734
General and administrative	6,915	2,762	11,590	7,014
Total operating expenses	<u>25,402</u>	<u>13,706</u>	<u>94,872</u>	<u>29,748</u>
Loss from operations	(11,274)	(13,706)	(71,147)	(29,748)
Other income (expense):				
Investment income	295	91	358	177
Interest expense	(965)	-	(1,507)	-
Net loss	<u>\$ (11,944)</u>	<u>\$ (13,615)</u>	<u>\$ (72,296)</u>	<u>\$ (29,571)</u>
Basic and diluted net loss per share	<u>\$ (0.41)</u>	<u>\$ (0.47)</u>	<u>\$ (2.50)</u>	<u>\$ (1.02)</u>
Shares used in computing basic and diluted net loss per share	<u>28,885</u>	<u>28,885</u>	<u>28,885</u>	<u>28,885</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, June 30,		Six months ended, June 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
As reported operating expenses according to GAAP	\$ 25,402	\$ 13,706	\$ 94,872	\$ 29,748
Excluding compensation expense related to equity awards	(3,942)	(1,978)	(7,122)	(5,168)
Pro forma operating expenses	<u>\$ 21,460</u>	<u>\$ 11,728</u>	<u>\$ 87,750</u>	<u>\$ 24,580</u>
As reported loss from operations according to GAAP	\$ (11,274)	\$ (13,706)	\$ (71,147)	\$ (29,748)
Excluding compensation expense related to equity awards	(3,942)	(1,978)	(7,122)	(5,168)
Pro forma loss from operations	<u>\$ (7,332)</u>	<u>\$ (11,728)</u>	<u>\$ (64,025)</u>	<u>\$ (24,580)</u>
As reported net loss according to GAAP	\$ (11,944)	\$ (13,615)	\$ (72,296)	\$ (29,571)
Excluding compensation expense related to equity awards	(3,942)	(1,978)	(7,122)	(5,168)
Pro forma net loss	<u>\$ (8,002)</u>	<u>\$ (11,637)</u>	<u>\$ (65,174)</u>	<u>\$ (24,403)</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. 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>June 30,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Assets:		
Cash, cash equivalents and short-term investments	\$ 118,668	\$ 7,857
Other current assets	3,939	1,209
Licenses, net	1,281	1,341
Other assets	216	277
Total assets	<u>\$ 124,104</u>	<u>\$ 10,684</u>
Liabilities and stockholders' deficit:		
Other current liabilities	\$ 3,648	\$ 4,055
Payable to Ionis	11,244	24,355
Current portion of deferred contract revenue	54,155	-
Long-term portion of deferred rent portion	18	21
Line of credit with Ionis	107,507	-
Long-term deferred contract revenue	30,515	-
Stockholders' deficit	(82,983)	(17,747)
Total liabilities and stockholders' equity	<u>\$ 124,104</u>	<u>\$ 10,684</u>

Media and Investor Contacts:

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