
**UNITED STATES
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): May 8, 2019

Akcea Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38137
(Commission File Number)

47-2608175
(IRS Employer
Identification No.)

22 Boston Wharf Road
9th Floor
Boston, MA
(Address of Principal Executive Offices)

02210
(Zip Code)

Registrant's Telephone Number, Including Area Code: (617) 207-0202

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

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 (see General Instructions A.2. below):

- 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.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock	AKCA	NASDAQ

Item 2.02 Results of Operations and Financial Condition.

On May 8, 2019, Akcea Therapeutics, Inc. (the “*Company*”) issued a press release announcing the Company’s financial results for the quarter ended March 31, 2019. In addition to disclosing results that are determined in accordance with Generally Accepted Accounting Principles (GAAP), the Company also discloses non-GAAP results of operations, which are adjusted from GAAP to exclude non-cash compensation related to stock awards. The Company is presenting non-GAAP information excluding non-cash compensation related to stock awards 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated May 8, 2019

SIGNATURES

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

Date: May 8, 2019

AKCEA THERAPEUTICS, INC.

By: /s/ Paula Soteropoulos
Paula Soteropoulos
Chief Executive Officer



Akcea Reports Financial Results and Highlights for First Quarter 2019

Achieved First Quarter 2019 TEGSEDI® (inotersen) Global Net Product Revenues of \$7 Million

Novartis exercised its option to license AKCEA-APO(a)-LRx

Received marketing authorization for WAYLIVRA® (volanesorsen) in E.U.

Conference Call Webcast Wednesday, May 8, 4:30 p.m. ET at www.akceatx.com

Boston, Mass., May 8th, 2019 (GLOBE NEWSWIRE) -- Akcea Therapeutics, Inc. (NASDAQ: AKCA), an affiliate of Ionis Pharmaceuticals, Inc., focused on developing and commercializing drugs to treat patients with serious and rare diseases, today reported financial results for the first quarter ended March 31, 2019. Due to the one-time license fee from Novartis, the company reported operating income for the first quarter ended March 31, 2019 on a GAAP basis of \$26 million and on a non-GAAP basis of \$45 million. Akcea had \$322 million of cash, cash equivalents and short-term investments as of March 31, 2019.

"We had a highly productive start to 2019 and are executing on our plans as a commercial organization. We are building a multi-product company with the approval of WAYLIVRA in the E.U. and continuing with our launch of TEGSEDI," said Paula Soteropoulos, chief executive officer of Akcea. "We are seeing positive momentum in the launch of TEGSEDI and continuing to make progress on our broad pipeline of products for patients with ATTR amyloidosis and cardiometabolic diseases. We remain steadfast in our goal of continuing to build Akcea into a trusted, patient-focused, global company delivering important and life-changing therapies to patients with rare and serious diseases."

"We have achieved \$7 million in product sales in our first full quarter of the TEGSEDI launch. Our strong cash balance supports our commercial and development efforts. We are able to realize a meaningful operational efficiency, including launching multiple products in the EU," said Michael MacLean, chief financial officer.

Upcoming Events

- Launch of TEGSEDI in additional E.U. countries
- Launch of WAYLIVRA in the E.U., beginning with Germany
- Report top line results from Phase 3 study of WAYLIVRA in familial partial lipodystrophy, or FPL, in the middle of this year
- Report top line results from the Phase 1/2 AKCEA-TTR-LRx study in 2H 2019
- Initiate AKCEA-TTR-LRx Phase 3 program in 2H 2019
- Report top line results from Phase 2 studies of AKCEA-ANGPTL3-LRx and AKCEA-APOCIII-LRx in 1H 2020

Recent Events

- Launched TEGSEDI in the U.S., Germany and Canada to treat patients with polyneuropathy of hATTR amyloidosis
- Received conditional marketing authorization following a positive CHMP opinion for WAYLIVRA in the E.U., earning a \$6M milestone payment from PTC Therapeutics

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- Licensed AKCEA-APO(a)-LRx to Novartis resulting in a \$150 million license fee to Akcea split equally with Ionis
 - Highlighted the long-term efficacy and safety of TEGSEDI in an oral presentation at the American Academy of Neurology (AAN) Annual Meeting
 - Completed enrollment in the Phase 2 studies of AKCEA-ANGPTL3-LRx and AKCEA-APOCIII-LRx
 - Presented at the American College of Cardiology (ACC) on the benefits of treatment with TEGSEDI

Financial Results

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

Revenue

Akcea's total revenue for the first quarter ended March 31, 2019 was \$164 million, which was comprised of product revenue and research and development and license revenue. Revenue from sales of TEGSEDI in the first quarter ended March 31, 2019 was \$7 million. Akcea's research and development and license revenue for the first quarter ended March 31, 2019 was \$157 million. Research and development and license revenue was primarily related to the \$150 million license fee the company earned as a result of Novartis' exercise of its option to license AKCEA-APO(a)-LRx. Additionally, Akcea recognized research and development revenue related to the amortization of the upfront payment the company received upon the initiation of the collaboration agreement.

Expenses

Akcea's operating expenses, inclusive of the reimbursement due from Ionis through the companies' profit/loss share arrangement, for the three months ended March 31, 2019 on a GAAP basis were \$138 million, and on a non-GAAP basis were \$119 million. These amounts compare to GAAP operating expenses of \$47 million and non-GAAP operating expenses of \$41 million for the same period in 2018. These increases primarily relate to the one-time \$75 million sublicense fee paid to Ionis as a result of Novartis' exercise of its option to license AKCEA-APO(a)-LRx, higher development costs, including for AKCEA-TTR-LRx, and commercialization costs for TEGSEDI and WAYLIVRA in the first quarter ended March 31, 2019 compared to the same period in 2018.

Net Income (Loss)

Akcea reported net income of \$27 million on a GAAP basis for the three months ended March 31, 2019, compared to a net loss of \$30 million for the same period in 2018. Akcea reported non-GAAP net income of \$46 million for the three months ended March 31, 2019, compared to a non-GAAP net loss of \$23 million for the same period in 2018. This increase in non-GAAP net income was primarily due to the \$150 million license fee the company earned as a result of Novartis' exercise of its option to license AKCEA-APO(a)-LRx and commercial product revenue which was partially offset by the sublicense fee to Ionis of \$75 million, increased operating expenses related to commercialization costs for TEGSEDI and WAYLIVRA and higher development costs.

For the three months ended March 31, 2019, basic net income per share of common stock owned by Ionis and others was \$0.35 and \$0.15, respectively. For the three months ended March 31, 2019, diluted net income per share of common stock owned by Ionis and others was \$0.34 and \$0.15, respectively. For the three months ended March 31, 2018, basic and diluted net loss per share of common stock owned by Ionis and others was \$0.44. All amounts are on a GAAP basis.

Balance Sheet

As of March 31, 2019, Akcea had cash, cash equivalents and short-term investments of \$322 million compared to \$253 million at December 31, 2018, which the Company believes is sufficient to fund global commercial efforts and to fund progression of Akcea's current pipeline to decision events.

Conference Call

At 4:30 p.m. Eastern Time today, May 8, 2019, 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 4357317 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, Inc., an affiliate of Ionis Pharmaceuticals, Inc. (NASDAQ: IONS), is a biopharmaceutical company focused on developing and commercializing drugs to treat patients with serious and rare diseases. Akcea is commercializing TEGSEDI® (inotersen) and advancing a mature pipeline of novel drugs, including WAYLIVRA® (volanesorsen), AKCEA-APO(a)-LRx, AKCEA-ANGPTL3-LRx, AKCEA-APOCIII-LRx, and AKCEA-TTR-LRx, with the potential to treat multiple diseases. All six drugs were discovered by and are being co-developed with Ionis, a leader in antisense therapeutics, and are based on Ionis' proprietary antisense technology. TEGSEDI is approved in the U.S., E.U. and Canada. WAYLIVRA is approved in the E.U. and is currently in Phase 3 clinical development for the treatment of people with familial partial lipodystrophy, or FPL. Akcea is building the infrastructure to commercialize its drugs globally. Akcea is a global company headquartered in Boston, Massachusetts. Additional information about Akcea is available at www.akceatx.com and you can follow us on twitter at @akceatx.

FORWARD-LOOKING STATEMENT

This press release includes forward-looking statements regarding the business of Akcea Therapeutics, Inc. and the therapeutic and commercial potential of TEGSEDI® (inotersen), WAYLIVRA® (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 10-K, 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 Therapeutic® TEGSEDI® and WAYLIVRA® are trademarks of Akcea Therapeutics, Inc.

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

	Three Months Ended March 31,	
	2019	2018
	(unaudited)	
Revenue:		
Product revenue, net	\$ 6,754	\$ -
R&D and license revenue	157,062	17,108
Total revenue	163,816	17,108
Expenses:		
Cost of sales and license	2,444	-
Research and development	99,619	27,970
Selling, general and administrative	44,602	19,465
Net loss share from commercial activities under arrangement with Ionis Pharmaceuticals, Inc.	(9,056)	-
Total expenses	137,609	47,435
Income (loss) from operations	26,207	(30,327)
Other income (expense):		
Investment income	1,224	868
Other expense	(112)	(168)
Income (loss) before income tax expense	27,319	(29,627)
Income tax expense	(132)	-
Net income (loss)	\$ 27,187	\$ (29,627)
Net income (loss) per share of common stock owned by Ionis, basic	\$ 0.35	\$ (0.44)
Weighted-average shares of common stock outstanding owned by Ionis, basic	68,581,967	45,447,879
Net income (loss) per share of common stock owned by others, basic	\$ 0.15	\$ (0.44)
Weighted-average shares of common stock outstanding owned by others, basic	22,126,363	21,171,372
Net income (loss) per share of common stock owned by Ionis, diluted	\$ 0.34	\$ (0.44)
Weighted-average shares of common stock outstanding owned by Ionis, diluted	68,581,967	45,447,879
Net income (loss) per share of common stock owned by others, diluted	\$ 0.15	\$ (0.44)
Weighted-average shares of common stock outstanding owned by others, diluted	25,545,975	21,171,372

AKCEA THERAPEUTICS INC.
Reconciliation of GAAP to Non-GAAP Basis:
Condensed Consolidated Operating Expenses, Loss from Operations, and Net Loss
(In Thousands)

	Three Months Ended March 31,	
	2019	2018
	(unaudited)	
As reported operating expenses according to GAAP	\$ 137,609	\$ 47,435
Excluding compensation expense related to equity awards	18,560	6,384
Non-GAAP operating expenses	<u>\$ 119,049</u>	<u>\$ 41,051</u>
As reported income (loss) from operations according to GAAP	\$ 26,207	\$ (30,327)
Excluding compensation expense related to equity awards	18,560	6,384
Non-GAAP income (loss) from operations	<u>\$ 44,767</u>	<u>\$ (23,943)</u>
As reported net income (loss) according to GAAP	\$ 27,187	\$ (29,627)
Excluding compensation expense related to equity awards	18,560	6,384
Non-GAAP net income (loss)	<u>\$ 45,747</u>	<u>\$ (23,243)</u>

Reconciliation of GAAP to non-GAAP Basis

As illustrated in the Selected Financial Information in this press release, non-GAAP operating expenses, non-GAAP income (loss) from operations, and non-GAAP net income (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 non-GAAP results. These measures are provided as supplementary information and are not a substitute for financial measures calculated in accordance with GAAP. Akcea reports these non-GAAP 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 non-GAAP results is consistent with how Akcea's management internally evaluates the performance of its operations.

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

	March 31, 2019	December 31, 2018
	(unaudited)	
Assets:		
Cash and cash equivalents	\$ 201,027	\$ 86,454
Short-term investments	120,765	166,155
Accounts receivable	10,269	4,597
Receivable from Ionis Pharmaceuticals, Inc.	7,206	-
Other current assets	11,618	10,029
Property, plant and equipment, net	5,336	5,696
Operating lease right-of-use-assets	11,602	-
Intangible assets, net	87,468	88,914
Deposits and other assets	3,426	3,416
Total assets	\$ 458,717	\$ 365,261
Liabilities and stockholders' equity:		
Accounts payable	\$ 6,153	\$ 12,068
Payable to Ionis Pharmaceuticals, Inc.	-	18,901
Accrued compensation	6,300	8,583
Accrued liabilities	17,255	14,787
Current portion of deferred revenue	21,539	25,354
Other current liabilities	1,863	968
Long-term portion of lease liabilities	15,018	4,442
Long-term portion of deferred revenue	1,725	3,434
Stockholders' equity	388,864	276,724
Total liabilities and stockholders' equity	\$ 458,717	\$ 365,261

Media and Investor Contact:

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