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): February 26, 2019

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

Delaware	**001-38137**	**47-2608175**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

22 Boston Wharf Road **9th Floor** **Boston, Massachusetts**	**02210**
(Address of principal executive offices)	**(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 obligations 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, 2019, Akcea Therapeutics, Inc. (the "***Company***") issued a press release announcing the Company's financial results for the year ended December 31, 2018. 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.

99.1 Press Release dated February 26, 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 hereunto duly authorized.

AKCEA THERAPEUTICS, INC.

Date: February 26, 2019

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

Exhibit 99.1

Akcea Reports Financial Results and Highlights for Fourth Quarter and Year End 2018

TEGSEDI™ (inotersen) commercially available in United States, European Union & Canada

Achieved Fourth Quarter 2018 TEGSEDI® (inotersen) Global Net Product Revenues of $2.2 Million

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

Boston, Mass., February 26, 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 fourth quarter and year ended December 31, 2018. The company reported an operating loss for the fourth quarter and year ended December 31, 2018 on a GAAP basis of $72 million and $231 million, respectively, and on a non-GAAP basis of $59 million and $187 million, respectively. Akcea had $253 million of cash, cash equivalents and short-term investments as of December 31, 2018.

“This past year was pivotal for Akcea. With the approval and launch of TEGSEDI in the U.S., Germany and Canada, we are now a global commercial company. Our track record of execution, our broad pipeline and strategic partnership with Novartis and our foundational relationship with Ionis, are a solid foundation for our future,” said Paula Soteropoulos, chief executive officer of Akcea. “We are executing on our commercial launch and progressing our broad pipeline of products for patients with ATTR amyloidosis and cardiometabolic diseases. We are focused on 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 are very pleased with how our launch of TEGSEDI is progressing and we continue to hear enthusiasm from the hATTR amyloidosis community about TEGSEDI’s impact on quality of life in patients with polyneuropathy and the independence it brings with subcutaneous administration,” said Sarah Boyce, president of Akcea.” It is early days in the TEGSEDI launch and as we go through 2019, we look forward to building on our progress to date, to launching in additional European countries and to working with PTC to gain approval for TEGSEDI in Brazil.”

“With the launch of TEGSEDI and product sales of over $2 million in the fourth quarter, this is our first-time reporting revenue from Q4’18 product sales. We are well prepared to distribute TEGSEDI to commercial patients, including supply chain, patient on-boarding, monitoring and reimbursement. In 2019, we look forward to continuing our progress, including launching in additional countries once reimbursement is obtained, as well as advancing our pipeline,” said Michael MacLean, chief financial officer.

Upcoming Events

- Ongoing regulatory discussions on WAYLIVRA™ (volanesorsen) in the E.U. and, if approved, launch
- Upcoming oral presentation on long term efficacy and safety of TEGSEDI at the American Academy of Neurology (AAN) Annual Meeting
- Data anticipated from Phase 3 study of WAYLIVRA in familial partial lipodystrophy, or FPL, in the middle of this year
- Results from the Phase 1/2 AKCEA-TTR-L_{Rx} study and initiation of AKCEA-TTR-L_{Rx} Phase 3 program
- Top line results from Phase 2 studies of AKCEA-ANGPTL3-L_{Rx} and AKCEA-APOCIII-L_{Rx} with data anticipated in 1H of 2020

Recent Events

- TEGSEDI commercially available in the U.S., Germany and Canada to treat the polyneuropathy of hATTR amyloidosis
- Novartis exercised its option to license AKCEA-APO(a)-L_{Rx}, resulting in a $150 million license fee to Akcea split equally with Ionis
- Initiated Phase 1 clinical study of AKCEA-TTR-L_{Rx} in 2018
- Presented at the American Society of Hematology (ASH) on the benefits of treatment with TEGSEDI. Results show continued efficacy with long-term exposure in the NEURO-TTR open-label extension study
- Announced Phase 2 results on AKCEA-APO(a)-L_{Rx} in late-breaking plenary presentation at AHA Scientific Sessions
- PTC Therapeutics announced that TEGSEDI's regulatory filing was accepted by ANVISA in Brazil and received priority review.

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 fourth quarter and year ended December 31, 2018 was $10 million and $65 million, which was comprised of product revenue, license revenue and research and development revenue. Revenue from sales of TEGSEDI in the fourth quarter ended December 31, 2018 was $2 million. Akcea did not have license revenue during the fourth quarter 2018. Akcea's license revenue for the year ended December 31, 2018 was $12 million, which Akcea earned when it entered into a collaboration and license agreement with PTC Therapeutics. Akcea's research and development revenue for the fourth quarter and year ended December 31, 2018 was $8 million and $51 million, respectively. Research and development revenue to date is entirely related to the Company's collaboration with Novartis, executed in 2017, and the associated amortization of the $75 million upfront payment and the purchase of Ionis stock by Novartis at a premium of $33 million. On January 1, 2018, Akcea adopted ASC 606, *Revenue from Contracts with Customers*, and recorded a cumulative effect adjustment to equity of approximately $12 million.

Expenses

Akcea's expenses for the fourth quarter and year ended December 31, 2018 on a GAAP basis were $82 million and $296 million, respectively, and on a non-GAAP basis were $69 million and

$251 million, respectively. These amounts compare to GAAP operating expenses of $43 million and $164 million and non-GAAP operating expenses of $37 million and $146 million for the same periods in 2017. These increases primarily relate to development costs to advance the Company's pipeline, including AKCEA-TTR-L_{Rx}, and commercialization costs for TEGSEDI.

Net Loss

Akcea reported a net loss of $71 million and $226 million on a GAAP basis for the fourth quarter and year ended December 31, 2018, respectively, compared to $20 million and $122 million for the same periods in 2017. Akcea reported a non-GAAP net loss of $58 million and $182 million for the fourth quarter and year ended December 31, 2018, respectively, compared to $14 million and $104 million for the same periods in 2017. This increase in non-GAAP net loss was primarily due to increased operating expenses largely related to development costs to advance the Company's pipeline, including AKCEA-TTR-L_{Rx}, and commercialization costs for TEGSEDI. For the fourth quarter of 2018, basic and diluted net loss per share of common stock owned by Ionis and others was $0.79. For the year ended December 31, 2018, basic and diluted net loss per share of common stock owned by Ionis and others was $2.74 and $2.87, respectively. For the fourth quarter of 2017, basic and diluted net loss per share of common stock owned by Ionis and others was $0.30. For the year ended December 31, 2017, basic and diluted net loss per share of preferred stock was $1.80 and net loss per share of common stock owned by Ionis and others was $3.08.

Balance Sheet

As of December 31, 2018 Akcea had cash, cash equivalents and short-term investments of $253 million compared to $260 million at December 31, 2017 which the Company believes is sufficient to execute on key milestones through 2019.

Conference Call

At 4:30 p.m. Eastern Time today, February 26, 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 7364489 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., is a biopharmaceutical company focused on developing and commercializing drugs to treat patients with serious and rare diseases. Akcea is advancing a mature pipeline of novel drugs, including TEGSEDI™, WAYLIVRA™ (volanesorsen), AKCEA-APO(a)-L_{Rx}, AKCEA-ANGPTL3-L_{Rx}, AKCEA-APOCIII-L_{Rx}, and AKCEA-TTR-L_{Rx}, all 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 under regulatory review for the treatment of familial chylomicronemia syndrome, or FCS, 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.

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

	Three months ended December 31,		Year ended December 31,	
	2018	2017	2018	2017
		(as revised)		*(as revised)*
	(unaudited)			
Revenue:				
Commercial revenue				
Product revenue	$ 2,237	$ -	$ 2,237	$ -
Licensing revenue	-	-	12,000	-
Total commercial revenue	2,237	-	14,237	-
R&D revenue	7,960	21,688	50,630	43,401
Total revenue	10,197	21,688	64,867	43,401
Expenses:				
Cost of sales and license	2,789	-	11,733	-
Research and development	33,532	25,968	130,340	126,890
Selling, general and administrative	45,934	17,018	153,610	36,981
Total expenses	82,255	42,986	295,683	163,871
Loss from operations	(72,058)	(21,298)	(230,816)	(120,470)
Other income (expense):				
Investment income	1,542	819	5,631	1,813
Interest expense	-	-	-	(1,731)
Other income (expense)	(41)	(19)	(189)	104
Loss before income tax expense	(70,557)	(20,498)	(225,374)	(120,284)
Income tax expense	-	791	(447)	(1,275)
Net loss	$(70,557)	$ (19,707)	$(225,821)	$(121,559)
Net loss per share of preferred stock, basic and diluted	$ -	$ -	$ -	$ (1.80)
Weighted-average shares of preferred stock outstanding, basic and diluted	-	-	-	15,748
Net loss per share of common stock owned by Ionis, basic and diluted	$ (0.79)	$ (0.30)	$ (2.74)	$ (3.08)
Weighted-average shares of common stock outstanding owned by Ionis, basic and diluted	67,130	45,448	59,812	20,669
Net loss per share of common stock owned by others, basic and diluted	$ (0.79)	$ (0.30)	$ (2.87)	$ (3.08)
Weighted-average shares of common stock outstanding owned by others, basic and diluted	21,870	21,094	21,553	9,593

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 December 31,		Year ended December 31,	
	2018	**2017**	**2018**	**2017**
		(as revised)		*(as revised)*
	(unaudited)			
As reported operating expenses according to GAAP	$ 82,255	$ 42,986	$ 295,683	$ 163,871
Excluding compensation expense related to equity awards	(13,043)	(5,725)	(44,282)	(17,539)
Non-GAAP operating expenses	$ 69,212	$ 37,261	$ 251,401	$ 146,332
As reported loss from operations according to GAAP	$ (72,058)	$ (21,298)	$ (230,816)	$ (120,470)
Excluding compensation expense related to equity awards	(13,043)	(5,725)	(44,282)	(17,539)
Non-GAAP loss from operations	$ (59,015)	$ (15,573)	$ (186,534)	$ (102,931)
As reported net loss according to GAAP	$ (70,557)	$ (19,707)	$ (225,821)	$ (121,559)
Excluding compensation expense related to equity awards	(13,043)	(5,725)	(44,282)	(17,539)
Non-GAAP net loss	$ (57,514)	$ (13,982)	$ (181,539)	$ (104,020)

Reconciliation of GAAP to non-GAAP Basis

As illustrated in the Selected Financial Information in this press release, non-GAAP operating expenses, non-GAAP loss from operations, and non-GAAP 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 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)

	December 31, 2018	2017 (as revised)
Assets:		
Cash and cash equivalents	$ 86,454	$ 58,367
Short-term investments	166,155	201,763
Accounts receivable	4,597	5,413
Other current assets	10,029	1,302
Property, plant and equipment, net	5,696	77
Licenses, net	88,914	1,221
Deposits and other assets	3,416	661
Total assets	$ 365,261	$ 268,804
Liabilities and stockholders' equity (deficit):		
Accounts payable	$ 12,068	$ 2,381
Payable to Ionis Pharmaceuticals, Inc.	18,901	14,365
Accrued compensation	8,583	4,083
Accrued liabilities	14,787	7,570
Current portion of deferred revenue	25,354	58,192
Other current liabilities	968	1,875
Long-term portion of deferred rent	4,442	12
Long-term portion of deferred revenue	3,434	12,501
Stockholders' equity	276,724	167,825
Total liabilities and stockholders' equity	$ 365,261	$ 268,804

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