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): November 5, 2018

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 November 5, 2018, Akcea Therapeutics, Inc. (the "***Company***") issued a press release announcing the Company's financial results for the quarter ended September 30, 2018. 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 5, 2018.

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: November 5, 2018

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

Exhibit 99.1

Akcea Reports Financial Results and Highlights for Third Quarter 2018

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

$320 million to fund the company through key milestones

Conference Call Webcast Monday, November 5, 4:30 p.m. ET at www.akceatx.com

Boston, Mass., November 5, 2018 (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 third quarter ended September 30, 2018. The company reported a net loss for the three and nine months ended September 30, 2018 on a GAAP basis of $64 million and $155 million, respectively, and on a pro forma basis of $51 million and $124 million, respectively. Akcea had $320 million of cash, cash equivalents and short-term investments as of September 30, 2018.

"This is a pivotal time for Akcea and the amyloidosis community with the approval of TEGSEDI in the United States, Europe and Canada and the treatment of our first commercial patients in Germany. Today we are a commercial company launching in multiple countries as we deliver TEGSEDI to patients and families who have been suffering with this severe and debilitating disease," said Paula Soteropoulos, chief executive officer of Akcea. "We are continuing regulatory discussions to deliver WAYLIVRA to people living with FCS who have no therapeutic options. We also are advancing our pipeline of ligand conjugated antisense, or LICA, therapeutics. We reported positive Phase 2 results in September on AKCEA-APO(a)-LRx, the largest and longest study of Ionis' LICA technology to date, demonstrating significant Lp(a) lowering and a favorable safety and tolerability profile with convenient low monthly doses."

"Our financial results are in line with our expectations as we begin to execute on a multi-country launch of TEGSEDI in the U.S., E.U. and Canada and advance our pipeline of additional drugs in development," said Michael MacLean, chief financial officer of Akcea. "We believe we have sufficient cash reserves to execute on our strategic priorities through 2019. In addition, with positive Phase 2 data reported from the AKCEA-APO(a)-LRx trial, we have the opportunity to achieve a $150 million license fee in the first quarter of 2019 in the event Novartis exercises its option on the program."

Upcoming Events

- Presentation of the AKCEA-APO(a)-LRx Phase 2 results as a late-breaking clinical trial presentation at the American Heart Association Scientific Sessions.

- Potential approval and launch of WAYLIVRA™ (volanesorsen) in the E.U.; continuing discussions on a path forward for WAYLIVRA in the U.S. and Canada.
- Initiation of Phase 1 clinical studies of AKCEA-TTR-LRx.
- Decision from Novartis on whether to exercise their option to license AKCEA-APO(a)-LRx, which, if exercised, would result in a $150 million milestone payment.
- Announcement of top line results from Phase 2 studies of AKCEA-ANGPTL3-LRx and AKCEA-APOCIII-LRX and from the Phase 3 study of WAYLIVRA in familial partial lipodystrophy, or FPL.

Recent Events

- TEGSEDI approved in the US, EU and Canada.
- Announced Access and Distribution strategy for TEGSEDI, including partnership with Express Scripts' Accredo.
- Reported positive results from the Phase 2 Study of AKCEA-APO(a)-LRx.
- Received Complete Response Letter from the FDA and preliminary notification of a Notice of Noncompliance withdrawal letter from Health Canada for WAYLIVRA.
- Partnered with PTC Therapeutics to commercialize TEGSEDI and WAYLIVRA in Latin America.
- Appointed Dr. Damien McDevitt to Akcea's Board of Directors.

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 total revenue for the three and nine months ended September 30, 2018 was $19 million and $55 million, which was comprised of license revenue and research and development revenue. Akcea's license revenue for the three months and nine months ended September 30, 2018 was $12 million which was related to the collaboration and license agreement entered into with PTC Therapeutics. Akcea's research and development revenue for the three and nine months ended September 30, 2018 was $7 million and $43 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 three and nine months ended September 30, 2018 on a GAAP basis were $84 million and $213 million, respectively, and on a pro forma basis were $72 million and $182 million, respectively. These amounts compare to GAAP operating expenses of $26 million and $121 million and pro forma operating expenses of $21 million and $109 million for the same periods in 2017. These increases primarily relate to development costs, including AKCEA-TTR-LRx, and commercialization costs for TEGSEDI and WAYLIVRA in the third quarter ended September 30, 2018 compared to the same period in 2017.

Net Loss

Akcea reported a net loss of $64 million and $155 million on a GAAP basis for the three and nine months ended September 30, 2018, respectively, compared to $18 million and $102 million for the same periods in 2017. Akcea reported a pro forma net loss of $51 million and $124 million for the three and nine months ended September 30, 2018, respectively, compared to $13 million and $90 million for the same periods in 2017. This increase in pro forma net loss was primarily due to increased operating expenses related to development and commercialization costs for TEGSEDI and WAYLIVRA. For the three and nine months ended September 30, 2018, basic and diluted net loss per share of common stock owned by Ionis was $0.73 and $1.93, respectively. For the three and nine months ended September 30, 2018, basic and diluted net loss per share of common stock owned by others was $0.73 and $2.07, respectively.

Balance Sheet

As of September 30, 2018 Akcea had cash, cash equivalents and short-term investments of $320 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, November 5, 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 (855) 237-2439, passcode 1381717 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 six novel drugs, including TEGSEDI™ (inotersen), WAYLIVRA™ (volanesorsen), AKCEA-APO(a)-LRx, AKCEA-ANGPTL3-LRx, AKCEA-APOCIII-LRx, and AKCEA-TTR-LRx, 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.

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, which is on file with the SEC. Copies of this 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
Condensed Consolidated Statements of Operations
(In Thousands, Except Per Share Data)

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	
Revenue:				
Licensing Revenue	$ 12,000	$ —	$ 12,000	$ —
R&D Revenue	7,241	9,906	42,670	21,712
Total Revenue	19,241	9,906	54,670	21,712
Expenses:				
Cost of sales and license	8,944	—	8,944	—
Research and development	29,381	17,640	96,808	100,921
Selling, general and administrative	45,924	8,373	107,676	19,963
Total expenses	84,249	26,013	213,428	120,884
Loss from operations	(65,008)	(16,107)	(158,758)	(99,172)
Other income (expense):				
Investment income	1,675	687	4,089	994
Interest expense	—	(224)	—	(1,731)
Other income (expense)	(25)	73	(148)	124
Loss before income tax expense	(63,358)	(15,571)	(154,817)	(99,785)
Income tax expense	(233)	(2,066)	(447)	(2,066)
Net loss	$ (63,591)	$ (17,637)	$ (155,264)	$ (101,851)
Net loss per share of preferred stock, basic and diluted	$ —	$ (0.01)	$ —	$ (2.16)
Weighted-average shares of preferred stock outstanding, basic and diluted	—	5,651,323	—	21,055,031
Net loss per share of common stock owned by Ionis, basic and diluted	$ (0.73)	$ (0.33)	$ (1.93)	$ (3.12)
Weighted-average shares of common stock outstanding owned by Ionis, basic and diluted	65,538,467	36,555,903	57,346,539	12,319,205
Net loss per share of common stock owned by others, basic and diluted	$ (0.73)	$ (0.33)	$ (2.07)	$ (3.12)
Weighted-average shares of common stock outstanding owned by others, basic and diluted	21,671,415	16,966,712	21,446,813	5,717,720

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,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	
As reported operating expenses according to GAAP	$ 84,249	$ 26,013	$ 213,428	$ 120,884
Excluding compensation expense related to equity awards	(12,730)	(4,692)	(31,239)	(11,814)
Pro forma operating expenses	$ 71,519	$ 21,321	$ 182,189	$ 109,070
As reported loss from operations according to GAAP	$(65,008)	$(16,107)	$(158,758)	$ (99,172)
Excluding compensation expense related to equity awards	(12,730)	(4,692)	(31,239)	(11,814)
Pro forma loss from operations	$(52,278)	$(11,415)	$(127,519)	$ (87,358)
As reported net loss according to GAAP	$(63,591)	$(17,637)	$(155,264)	$(101,851)
Excluding compensation expense related to equity awards	(12,730)	(4,692)	(31,239)	(11,814)
Pro forma net loss	$(50,861)	$(12,945)	$(124,025)	$ (90,037)

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)

	September 30, 2018	December 31, 2017
	(unaudited)	
Assets:		
Cash and cash equivalents	$ 116,206	$ 58,367
Short-term investments	204,109	201,763
Contract receivable	636	5,413
Other current assets	8,397	1,302
Property, plant and equipment, net	5,757	77
Licenses, net	40,969	1,221
Deposits and other assets	3,054	661
Total assets	$ 379,128	$ 268,804
Liabilities and stockholders' equity (deficit):		
Accounts payable	$ 3,071	$ 2,381
Payable to Ionis Pharmaceuticals, Inc.	23,888	14,365
Accrued compensation	8,848	4,083
Accrued liabilities	21,151	7,570
Current portion of deferred revenue	32,347	58,192
Other current liabilities	1,295	1,875
Long-term portion of deferred rent	4,653	12
Long-term portion of deferred revenue	2,464	12,501
Stockholders' equity	281,411	167,825
Total liabilities and stockholders' equity	$ 379,128	$ 268,804

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