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, 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, MA		**02210**
(Address of Principal Executive Offices)		**(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))

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**

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, 2019, Akcea Therapeutics, Inc. (the "***Company***") issued a press release announcing the Company's financial results for the quarter ended September 30, 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 excludenon-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 Form8-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.

Exhibit Number	Description
99.1	Press Release dated November 5, 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.

AKCEA THERAPEUTICS, INC.

Date: November 5, 2019

By: /s/Damien McDevitt
Damien McDevitt
Interim Chief Executive Officer

Exhibit 99.1

Akcea Reports Financial Results and Highlights for Third Quarter 2019

Reported Third Quarter 2019 Global Net Product Revenues of $12 Million

WAYLIVRA® (volanesorsen) launched in the E.U.

Entered into a worldwide licensing agreement with Pfizer, Inc. for AKCEA-ANGPTL3-LRx

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

Boston, Mass., November 5th, 2019 (GLOBE NEWSWIRE) — Akcea Therapeutics, Inc. (NASDAQ: AKCA), a majority-owned 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, 2019. The company reported a net loss for the three and nine months ended September 30, 2019 on a GAAP basis of $31 million and $42 million, respectively. On a non-GAAP basis, the company reported a net loss of $35 million and $12 million, respectively, for the three months and nine months ended September 30, 2019. Akcea had $253 million of cash, cash equivalents and short-term investments as of September 30, 2019.

"With the launch of WAYLIVRA in the E.U., steady progress on the launch of TEGSEDI, data coming from our innovative pipeline and the imminent initiation of multiple Phase 3 programs, we have a solid foundation in place for clinical and commercial success. Furthermore, we are building on that success by potentially expanding our pipeline through the acquisition of new assets from Ionis as well as evaluating medicines to license from third parties," said Damien McDevitt, interim chief executive officer of Akcea. "Through our collaborations with Pfizer, Novartis and PTC Therapeutics and our own commercial and development efforts, we remain focused on bringing life-changing therapies to patients with serious and rare diseases globally. I am proud to be leading this experienced and passionate team as we build for the future."

"We generated $12 million in product sales from TEGSEDI and WAYLIVRA in the third quarter as we continue to expand the number of countries where our products are commercially available," said Mike MacLean, chief financial officer of Akcea. "With the launch of WAYLIVRA in Germany and the ongoing launch of TEGSEDI, we are now a multi-product commercial company. We are excited to continue these commercial and development efforts and to explore bringing further economic opportunities to the company. We ended the quarter with $253 million in cash and short-term investments. Upon closing of the Pfizer license agreement in Q4, we anticipate that we will have significant funds available to support our strategic initiatives."

Upcoming Events

- Launch of TEGSEDI in additional E.U. countries and PTC Therapeutics launching in Latin America
- Launch of WAYLIVRA in additional E.U. countries
- Initiate AKCEA-TTR-LRx Phase 3 program in 4Q 2019
- Novartis to treat first patients in Phase 3 trial for AKCEA-APO(a)-LRx
- Report top line results from Phase 2 studies of AKCEA-ANGPTL3-LRx and AKCEA-APOCIII-LRx in early 2020

Business Updates

- Appointed Damien McDevitt, Ph.D. as interim CEO
- Promoted Kyle Jenne to Chief Commercial Officer
- Appointed Michael Yang and Joseph "Skip" Klein, III to the board of directors
- Licensed worldwide rights to Pfizer, Inc. for AKCEA-ANGPTL3-LRx

Commercial Achievements

- Treated first commercial patients with TEGSEDI in the United Kingdom following acceptance by both the National Institute for Health and Care Excellence, or NICE, and the Scottish Medicines Consortium, or SMC
- Successfully completed initial free pricing period and finalized pricing negotiations in Germany and Austria;
- Successfully completed pricing negotiations with the New Therapies Council in Sweden and launching there imminently
- PTC Therapeutics announced approval of TEGSEDI in Brazil in October 2019; With this achievement, Akcea earned a $4 million milestone payment which will be split 60% to Ionis and 40% to Akcea per the TEGSEDI profit share
- Launched WAYLIVRA in Germany to treat patients with genetically confirmed Familial Chylomicronemia Syndrome, or FCS, who have a history of pancreatitis; also launched an ATU, or a reimbursed early access program, in France

Pipeline Achievements

- Reported positive top line results from the Phase 1/2 study ofAKCEA-TTR-LRx
- New England Journal of Medicine published results from the Phase 3 APPROACH study of WAYLIVRA in patients with FCS
- Reported top line results from the BROADEN study of WAYLIVRA in familial partial lipodystrophy, or FPL, which met the primary endpoint and a key secondary endpoint

Financial Results

All non-GAAP amounts referred to in this press release excludenon-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 three and nine months ended September 30, 2019 was $21 million and $211 million, respectively, which was comprised of product revenue, licensing revenue, and research and development revenue. Revenue from sales of TEGSEDI and WAYLIVRA in the three and nine months ended September 30, 2019 was $12 million and $29 million, respectively. Licensing revenue for the nine months ended September 30, 2019 was $6 million. Licensing revenue was recognized upon regulatory approval for WAYLIVRA from the European Commission pursuant to our license agreement with PTC Therapeutics. Akcea's research and development and license revenue for the three and nine months ended September 30, 2019 was $9 million and $176 million, respectively. 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 and nine months ended September 30, 2019 on a GAAP basis were $53 million and $256 million, respectively, and on a non-GAAP basis were $57 million and $227 million, respectively. These amounts compare to GAAP operating expenses of $84 million and $213 million and non-GAAP operating expenses of $72 million and $182 million for the same periods in 2018. The decrease in operating expenses for the three months ended September 30, 2019 compared to the same period in 2018 was primarily due a decrease in development activities related to TEGSEDI and WAYLIVRA. The increase in operating expenses for the nine months ended September 30, 2019 compared to the same period in the prior year is primarily due to the one-time $75 million sublicense fee due to Ionis as a result of Novartis' exercising its option to license AKCEA-APO(a)-LRX and increased operating expenses related to commercialization costs for TEGSEDI and WAYLIVRA.

Net Loss

Akcea reported net loss of $31 million and $42 million on a GAAP basis for the three and nine months ended September 30, 2019, compared to a net loss of $64 million and $155 million for the same periods in 2018. Akcea reported non-GAAP net loss of $35 million for the three months ended September 30, 2019, compared to a non-GAAP net loss of $51 million for the same period in 2018. Akcea reportednon-GAAP net loss of $12 million for the nine months ended September 30, 2019, compared to a non-GAAP net loss of $124 million for the same period in 2018. This decrease innon-GAAP net loss 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 and increased operating expenses related to commercialization costs for TEGSEDI and WAYLIVRA.

For the three and nine months ended September 30, 2019, basic and diluted net loss per share of common stock owned by Ionis was $0.34 and $0.40, respectively. For the three and nine months ended September 30, 2019, basic and diluted

net loss per share of common stock owned by others was $0.34 and $0.60, respectively. 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, 2019, Akcea had cash, cash equivalents and short-term investments of $253 million compared to $253 million at December 31, 2018. With this substantial liquidity, the Company believes it is well positioned to continue to execute on its strategy and broaden its pipeline.

Conference Call

At 4:30 p.m. Eastern Time today, November 5, 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 9046648 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., a majority-owned 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 WAYLIVRA® (volanesorsen), as well as advancing a mature pipeline of novel drugs, including 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 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(unaudited)		(unaudited)	
Revenue:				
Product revenue, net	$ 11,944	$ —	$ 28,563	$ —
Licensing revenue	136	12,000	6,172	12,000
Total commercial revenue	12,080	12,000	34,735	12,000
R&D and license revenue	8,544	7,241	176,329	42,670
Total revenue	20,624	19,241	211,064	54,670
Expenses:				
Cost of sales and license	2,401	8,944	10,629	8,944
Research and development	24,797	29,381	144,687	96,808
Selling, general and administrative	34,905	45,924	130,247	107,676
Net loss share from commercial activities under arrangement with Ionis Pharmaceuticals, Inc.	(8,889)	—	(29,410)	—
Total expenses	53,214	84,249	256,153	213,428
Loss from operations	(32,590)	(65,008)	(45,089)	(158,758)
Other income (expense):				
Investment income	1,487	1,675	4,282	4,089
Other expense	(136)	(25)	(276)	(148)
Loss before income tax expense	(31,239)	(63,358)	(41,083)	(154,817)
Income tax expense	(259)	(233)	(551)	(447)
Net loss	$ (31,498)	$ (63,591)	$ (41,634)	$ (155,264)
Net loss per share of common stock owned by Ionis, basic and diluted	$ (0.34)	$ (0.73)	$ (0.40)	$ (1.93)
Weighted-average shares of common stock outstanding owned by Ionis, basic and diluted	70,221,338	65,538,467	69,680,886	57,346,539
Net loss per share of common stock owned by others, basic and diluted	$ (0.34)	$ (0.73)	$ (0.60)	$ (2.07)
Weighted-average shares of common stock outstanding owned by others, basic and diluted	22,821,555	21,671,415	22,509,819	21,446,813

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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(unaudited)		(unaudited)	
As reported operating expenses according to GAAP	$ 53,214	$ 84,249	$256,153	$ 213,428
Excluding compensation expense related to equity awards	(3,464)	12,730	29,459	31,239
Non-GAAP operating expenses	$ 56,678	$ 71,519	$226,694	$ 182,189
As reported loss from operations according to GAAP	$(32,590)	$(65,008)	$ (45,089)	$(158,758)
Excluding compensation expense related to equity awards	(3,464)	12,730	29,459	31,239
Non-GAAP income (loss) from operations	$(36,054)	$(52,278)	$ (15,630)	$(127,519)
As reported net loss according to GAAP	$(31,498)	$(63,591)	$ (41,634)	$(155,264)
Excluding compensation expense related to equity awards	(3,464)	12,730	29,459	31,239
Non-GAAP net income (loss)	$(34,962)	$(50,861)	$ (12,175)	$(124,025)

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 arenon-cash expenses. Akcea has regularly reported non-GAAP measures for operating results asnon-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)

	September 30, 2019	December 31, 2018
	(unaudited)	
Assets:		
Cash and cash equivalents	$ 129,329	$ 86,454
Short-term investments	123,362	166,155
Accounts receivable	10,653	4,597
Receivable from Ionis Pharmaceuticals, Inc.	647	—
Inventory	8,641	85
Other current assets	5,809	9,944
Property, plant and equipment, net	5,277	5,696
Operating lease right-of-use assets	11,300	—
Intangible assets, net	84,529	88,914
Deposits and other assets	3,620	3,416
Total assets	$ 383,167	$ 365,261
Liabilities and stockholders' equity:		
Accounts payable	$ 5,711	$ 12,068
Payable to Ionis Pharmaceuticals, Inc.	—	18,901
Accrued compensation	9,382	8,583
Accrued liabilities	15,211	14,787
Current portion of deferred revenue	10,840	25,354
Other current liabilities	1,977	968
Long-term portion of lease liabilities	14,558	4,442
Long-term portion of deferred revenue	—	3,434
Stockholders' equity	325,488	276,724
Total liabilities and stockholders' equity	$ 383,167	$ 365,261

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