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): August 6, 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 August 6, 2019, Akcea Therapeutics, Inc. (the "***Company***") issued a press release announcing the Company's financial results for the quarter ended June 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 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.

Exhibit Number	Description
99.1	Press Release dated August 6, 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: August 6, 2019

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

Exhibit 99.1

Akcea Reports Financial Results and Highlights for Second Quarter 2019

Achieved Second Quarter 2019 TEGSEDI® (inotersen) Global Net Product Revenues of $10 Million

Conference Call Webcast Tuesday, August 6, 4:30 p.m. ET at www.akceatx.com

Boston, Mass., August 6th, 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 second quarter ended June 30, 2019. The company reported a net loss for the three and six months ended June 30, 2019 on a GAAP basis of $37 million and $10 million, respectively. On a non-GAAP basis, the company reported a net loss of $23 million for the three months ended June 30, 2019 and reported net income of $23 million for the six months ended June 30, 2019. Akcea had $296 million of cash, cash equivalents and short-term investments as of June 30, 2019.

"We continue to see momentum building in the launch of TEGSEDI and growth in the number of patients diagnosed with hATTR and symptoms of polyneuropathy. This is also a pivotal time for the FCS community as we prepare for the commercial launch of WAYLIVRA in the E.U., the only therapy approved for those with FCS," said Paula Soteropoulos, Chief Executive Officer of Akcea. "The rest of our pipeline is also progressing. We are on track for two Phase 3 initiations by the end of this year for AKCEA-APO(a)-LRx with Novartis and AKCEA-TTR-LRx with Ionis, and two Phase 2 data readouts from AKCEA-ANGPTL3-LRx and AKCEA-APOCIII-LRx in early 2020. We remain focused on delivering innovative solutions that improve the lives of those affected by serious and rare diseases."

"We reported product sales of $10 million from the ongoing multi-country launch of TEGSEDI in the second quarter. With $296 million in cash, cash equivalents, and short-term investments, growing revenue from TEGSEDI and future revenue potential from WAYLIVRA in the E.U., we are in a strong financial position to fund the progression of our current operations into 2021. We are uniquely positioned with two products on the market, as well as a pipeline of drugs for both broad and rare diseases that represent meaningful economic opportunities for the company," said Mike MacLean, Chief Financial Officer of Akcea.

Upcoming Events

- Launch WAYLIVRA in Germany to treat patients with genetically confirmed Familial Chylomicronemia Syndrome, or FCS
- Launch of TEGSEDI in additional E.U. countries and in Latin America through PTC Therapeutics
- Launch of WAYLIVRA in additional E.U. countries
- 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
- Novartis to initiate 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 1H 2020

Recent Events

- Launched TEGSEDI in the U.S., Germany and Canada to treat patients with polyneuropathy of hATTR amyloidosis
- Received final Highly Specialized Technologies (HST) Guidance for TEGSEDI from the National Institute for Health and Care Excellence (NICE), now being implemented by the National Health System in England
- Announced expanded partnership with Ambry Genetics on the hATTR Compass™ program, a genetic testing program that enables diagnosis and treatment for Hereditary ATTR Amyloidosis (hATTR)
- Received conditional marketing authorization following a positive CHMP opinion for WAYLIVRA in the E.U., earning a $6M milestone payment from PTC Therapeutics
- 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
- Licensed AKCEA-APO(a)-LRx to Novartis resulting in a $150 million license fee to Akcea split equally with Ionis
- Completed enrollment in the Phase 2 studies of AKCEA-ANGPTL3-LRx and AKCEA-APOCIII-LRx

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 three and six months ended June 30, 2019 was $27 million and $190 million, respectively, which was comprised of product revenue, licensing revenue, and research and development and license revenue. Revenue from sales of TEGSEDI in the three and six months ended June 30, 2019 was $10 million and $17 million, respectively. Licensing revenue for the three and six months ended June 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 six months ended June 30, 2019 was $11 million and $168 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 six months ended June 30, 2019 on a GAAP basis were $65 million and $203 million, respectively, and on a non-GAAP basis were $51 million and $170 million, respectively. These amounts compare to GAAP operating expenses of $82 million and $129 million and non-GAAP operating expenses of $70 million and $111 million for the same periods in 2018. The decrease in operating expenses for the three months ended June 30, 2019

compared to the same period in 2018 was primarily due to the completion of clinical activities related to the end of phase 2 meeting for AKCEA-APO(a)-LRx, and a decrease in development activities related to TEGSEDI and WAYLIVRA. The increase in operating expenses for the six months ended June 30, 2019 compared to the same period in the prior year is primarily due to the one-time $75 million sublicense fee paid to Ionis as a result of Novartis exercising its option to license and higher development costs for AKCEA-TTR-LRx and AKCEA-ANGPTL3-LRx.

Net Loss

Akcea reported net loss of $37 million and $10 million on a GAAP basis for the three and six months ended June 30, 2019, compared to a net loss of $62 million and $92 million for the same periods in 2018. Akcea reported non-GAAP net loss of $23 million for the three months ended June 30, 2019, compared to a non-GAAP net loss of $50 million for the same period in 2018. Akcea reported non-GAAP net income of $23 million for the six months ended June 30, 2019, compared to a non-GAAP net loss of $73 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 and increased operating expenses related to commercialization costs for TEGSEDI and WAYLIVRA.

For the three and six months ended June 30, 2019, basic and diluted net loss per share of common stock owned by Ionis was $0.40 and $0.06, respectively. For the three and six months ended June 30, 2019, basic and diluted net loss per share of common stock owned by others was $0.40 and $0.26, respectively. For the three and six months ended June 30, 2018, basic and diluted net loss per share of common stock owned by Ionis was $0.72 and $1.19, respectively. For the three and six months ended June 30, 2018, basic and diluted net loss per share of common stock owned by others was $0.85 and $1.33, respectively.

Balance Sheet

As of June 30, 2019, Akcea had cash, cash equivalents and short-term investments of $296 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, August 6, 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 5993687 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 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(unaudited)		(unaudited)	
Revenue:				
Product revenue, net	$ 9,865	$ —	$ 16,619	$ —
Licensing revenue	6,036	—	6,036	—
Total commercial revenue	15,901	—	22,655	—
R&D and license revenue	10,722	18,321	167,784	35,429
Total revenue	26,623	18,321	190,439	35,429
Expenses:				
Cost of sales and license	5,783	—	8,227	—
Research and development	20,271	39,457	119,890	67,427
Selling, general and administrative	50,740	42,287	95,342	61,752
Net loss share from commercial activities under arrangement with Ionis Pharmaceuticals, Inc.	(11,465)	—	(20,521)	—
Total expenses	65,329	81,744	202,938	129,179
Loss from operations	(38,706)	(63,423)	(12,499)	(93,750)
Other income (expense):				
Investment income	1,571	1,546	2,795	2,414
Other income (expense)	(28)	45	(140)	(123)
Loss before income tax expense	(37,163)	(61,832)	(9,844)	(91,459)
Income tax expense	(160)	(214)	(292)	(214)
Net loss	$ (37,323)	$ (62,046)	$ (10,136)	$ (91,673)
Net loss per share of common stock owned by Ionis, basic and diluted	$ (0.40)	$ (0.72)	$ (0.06)	$ (1.19)
Weighted-average shares of common stock outstanding owned by Ionis, basic and diluted	70,221,338	60,832,494	69,406,181	53,182,685
Net loss per share of common stock owned by others, basic and diluted	$ (0.40)	$ (0.85)	$ (0.26)	$ (1.33)
Weighted-average shares of common stock outstanding owned by others, basic and diluted	22,573,900	21,492,157	22,351,368	21,332,650

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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(unaudited)		(unaudited)	
As reported operating expenses according to GAAP	$ 65,329	$ 81,744	$202,938	$129,179
Excluding compensation expense related to equity awards	14,363	12,126	32,923	18,509
Non-GAAP operating expenses	$ 50,966	$ 69,618	$170,015	$110,670
As reported loss from operations according to GAAP	$(38,706)	$(63,423)	$ (12,499)	$ (93,750)
Excluding compensation expense related to equity awards	14,363	12,126	32,923	18,509
Non-GAAP income (loss) from operations	$(24,343)	$(51,297)	$ 20,424	$ (75,241)
As reported net loss according to GAAP	$(37,323)	$(62,046)	$ (10,136)	$ (91,673)
Excluding compensation expense related to equity awards	14,363	12,126	32,923	18,509
Non-GAAP net income (loss)	$(22,960)	$(49,920)	$ 22,787	$ (73,164)

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)

	June 30, 2019	December 31, 2018
	(unaudited)	
Assets:		
Cash and cash equivalents	$150,234	$ 86,454
Short-term investments	145,374	166,155
Accounts receivable	9,193	4,597
Receivable from Ionis Pharmaceuticals, Inc.	7,911	—
Inventory	8,286	85
Other current assets	6,713	9,944
Property, plant and equipment, net	5,443	5,696
Operating lease right-of-use assets	11,534	—
Intangible assets, net	86,006	88,914
Deposits and other assets	3,426	3,416
Total assets	$434,120	$ 365,261
Liabilities and stockholders' equity:		
Accounts payable	$ 7,936	$ 12,068
Payable to Ionis Pharmaceuticals, Inc.	—	18,901
Accrued compensation	7,521	8,583
Accrued liabilities	17,569	14,787
Current portion of deferred revenue	15,830	25,354
Other current liabilities	1,713	968
Long-term portion of lease liabilities	14,909	4,442
Long-term portion of deferred revenue	—	3,434
Stockholders' equity	368,642	276,724
Total liabilities and stockholders' equity	$434,120	$ 365,261

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