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): December 18, 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 8.01. Other Events.

On December 18, 2019, Akcea Therapeutics, Inc. (the "***Company***") announced that, following a strategic portfolio decision by Novartis Pharma AG ("***Novartis***") not to exercise its option, the Company has retained rights to develop and commercialize AKCEA-APOCIII-IRx. In accordance with the terms of the Strategic Collaboration, Option and License Agreement between Novartis and the Company dated January 5, 2017, Novartis' rights to develop and commercialize AKCEA-APOCIII-LRx are terminated. A copy of the press release is attached to this Report as Exhibit 99.1 and is incorporated by reference into this Item 8.01.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated December 18, 2019, issued by the Company

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: December 19, 2019

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

Exhibit 99.1

Akcea Retains Rights to AKCEA-APOCIII-LRx

Data from Phase 2 clinical trial of AKCEA-APOCIII-LRx anticipated in early 2020

BOSTON and CARLSBAD, Calif., Dec. 18, 2019 – Akcea Therapeutics, Inc. (NASDAQ: AKCA), a majority-owned affiliate of Ionis Pharmaceuticals, Inc., and Ionis Pharmaceuticals, Inc. (NASDAQ: IONS), today announced that, following a strategic portfolio decision by Novartis not to exercise its option, Akcea has retained rights to develop and commercialize AKCEA-APOCIII-LRx.

"AKCEA-APOCIII-LRx has advanced rapidly in the past year and we are excited to drive the development and commercial strategy for this drug. We plan to focus our efforts on developing AKCEA-APOCIII-LR, for familial chylomicronemia syndrome, or FCS, plus other indications that could be positively impacted by reducing APOCIII and triglycerides. We look forward to seeing the results from our Phase 2 study of AKCEA-APOCIII-LRx early in 2020," said Damien McDevitt, Ph.D., interim chief executive officer at Akcea. "Novartis remains a strategic partner for Akcea. Novartis has made AKCEA-APO(a)-LRx, also known as TQJ230, a key priority in its pipeline and has already begun the Lp(a)HORIZON Phase 3 cardiovascular CVD outcomes study."

AKCEA-APOCIII-LRx was discovered by Ionis and is being co-developed by Akcea and Ionis. It is an antisense drug developed using Ionis' advanced **LI**gand **C**onjugated **A**ntisense (LICA) technology platform. It is designed to reduce the production of apolipoprotein C-III, or apoC-III, which is potentially a key target for addressing multiple diseases including FCS and cardiovascular disease, or CVD. AKCEA-APOCIII-LRx is currently in Phase 2 clinical development to treat patients with hypertriglyceridemia and CVD. Akcea and Ionis remain on track to announce topline results from this Phase 2 clinical study in early 2020.

ABOUT AKCEA-APOCIII-LRx

AKCEA-APOCIII-LRx is a ligand conjugated antisense (LICA) drug designed to reduce the production of apolipoprotein C-III, or apoC-III. ApoC-III is a protein produced in the liver that plays a central role in the regulation of serum triglycerides. Genetically reduced levels of apoC-III are correlated to lower levels of triglycerides and lower risk of cardiovascular disease whereas elevated levels of apoC-III correlate with high triglyceride levels that have been associated with multiple metabolic abnormalities, such as insulin resistance and/or metabolic syndrome. Akcea and Ionis are developing AKCEA-APOCIII-LRx to treat hypertriglyceridemia and established cardiovascular disease with data anticipated from the Phase 2 program early in 2020.

Results from a Phase 1/2 clinical trial of AKCEA-APOCIII-LRx showed significant, dose-dependent reductions in apoC-III protein of up to 84 percent after six weeks of treatment and in triglyceride levels of up to 71 percent. Significant dose-dependent reductions of up to 30% in apolipoprotein B (apoB) and increases of up to 100% in high-density lipoprotein cholesterol (HDL-C) were also observed. Both decreased levels of apoB and increased levels of HDL-C are associated with decreased cardiovascular risk. In the Phase 1/2 study there were no serious adverse events or adverse events leading to treatment discontinuation. There were no hepatic or renal signals, injection site or flu-like reactions and no clinically significant findings in routine hematology or biochemistry, including no platelet reductions.

ABOUT IONIS PHARMACEUTICALS, INC.

As the leader in RNA-targeted drug discovery and development, Ionis has created an efficient, broadly applicable, drug discovery platform called antisense technology that can treat diseases where no other therapeutic approaches have proven effective. Our drug discovery platform has served as a springboard for actionable promise and realized hope for patients with unmet needs. We created the first and only approved treatment for children and adults with spinal muscular atrophy as well as the world's first RNA-targeted therapeutic approved for the treatment of polyneuropathy in adults with hereditary transthyretin amyloidosis. Our sights are set on all the patients we have yet to reach with a pipeline of more than 40 novel medicines designed to treat a broad range of diseases including cardiovascular diseases, neurological diseases, infectious diseases, pulmonary diseases and cancer.

To learn more about Ionis visit www.ionispharma.com and follow us on Twitter @ionispharma.

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.

AKCEA AND IONIS FORWARD-LOOKING STATEMENT

This press release includes forward-looking statements regarding the business of Akcea Therapeutics, Inc. and Ionis Pharmaceuticals, Inc. and the therapeutic and commercial potential of AKCEA-APOCIII-LRx. and AKCEA-APO(a)-LRx. Any statement describing Akcea's or Ionis' goals, expectations, financial or other projections, intentions or beliefs, including the commercial potential of AKCEA-APOCIII-LRx, AKCEA-APO(a)-LRx or other of Akcea's or Ionis' drugs in development 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 and Ionis' 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 and Ionis' forward-looking statements reflect the good faith judgment of its management, these statements are based only on facts and factors currently known by Akcea and Ionis. As a result, you are cautioned not to rely on these forward-looking statements. These and other risks concerning Akcea's and Ionis' programs are described in additional detail in Akcea's and Ionis' quarterly reports on Form 10-Q and annual reports on Form 10-K, which are on file with the SEC. Copies of these and other documents are available from each 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.

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