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 27, 2018

AKCEA THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-38137	**47-2608175**
(Commission File No.)	(IRS Employer Identification No.)

55 Cambridge Parkway
Suite 100
Cambridge, Massachusetts 02142
(Address of Principal Executive Offices and 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 obligation 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 (Section 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (Section 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 August 27, 2018, Akcea Therapeutics, Inc. (the "***Company***"), an affiliate of Ionis Pharmaceuticals, Inc., announced that the Company received a Complete Response Letter from the Division of Metabolism and Endocrinology Products of the U.S. Food and Drug Administration regarding the New Drug Application for WAYLIVRA™ (volanesorsen). 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 August 27, 2018, issued by the Company

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Akcea Therapeutics, Inc.

Dated: August 27, 2018

By: /s/ Paula Soteropoulos

Paula Soteropoulos
Chief Executive Officer

Exhibit 99.1

Akcea and Ionis Receive Complete Response Letter for WAYLIVRA from FDA

CAMBRIDGE, Mass. and CARLSBAD, Calif. August 27, 2018 (GLOBENEWSWIRE)
- Akcea Therapeutics, Inc. (NASDAQ:AKCA) an affiliate of Ionis Pharmaceuticals, Inc., and Ionis Pharmaceuticals, Inc. (NASDAQ:IONS), today announced that they received a Complete Response Letter (CRL) from the Division of Metabolism and Endocrinology Products of the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for WAYLIVRA™(volanesorsen).

“We are extremely disappointed with the FDA’s decision. FCS is an ultra-rare and debilitating disease. Our disappointment extends to the patient and physician community who currently do not have a treatment available to them. We continue to feel strongly that WAYLIVRA demonstrates a favorable benefit/risk profile in people with FCS as was reflected in the positive outcome from our Advisory Committee hearing in May. We will continue to work with the FDA to confirm the path forward,” said Paula Soteropoulos, chief executive officer of Akcea Therapeutics.

Familial chylomicronemia syndrome (FCS) is an ultra-rare, devastating hereditary disease that causes unpredictable and potentially fatal acute pancreatitis, chronic complications due to permanent organ damage, and a severe impact on daily living. The hallmark of FCS is extremely elevated triglycerides.

Results from the Phase 3 APPROACH trial, the largest study ever conducted in patients with FCS, show that in comparison to placebo, treatment with WAYLIVRA reduced triglycerides by 77% (-94% when compared to placebo). The Endocrine Society and current clinical practice guidelines recommend triglyceride reduction as the goal of treatment for FCS. The most common adverse events in the APPROACH study were injection site reactions and reductions in platelet levels.

“We are fully supportive of WAYLIVRA and the many patients, physicians and researchers who are working to provide the first therapeutic option for FCS, a truly life-altering disease that deserves a treatment,” said Brett P. Monia, Ph.D., chief operating officer of Ionis Pharmaceuticals.

ABOUT WAYLIVRA AND FCS
WAYLIVRA, a product of Ionis’ proprietary antisense technology, is designed to reduce the production of ApoC-III, a protein produced in the liver that plays a central role in the regulation of plasma triglycerides and may also affect other metabolic parameters.

WAYLIVRA is also under regulatory review in the E.U. and Canada for the treatment of people with familial chylomicronemia syndrome (FCS).

FCS is an ultra-rare disease caused by impaired function of the enzyme lipoprotein lipase (LPL) and characterized by severe hypertriglyceridemia, or triglyceride levels that can be greater than 10 times normal values, and the risk of unpredictable and potentially fatal acute pancreatitis. Because of limited LPL function, people with FCS cannot breakdown chylomicrons, lipoprotein particles that are 90% triglycerides. In addition to pancreatitis, people with FCS are at risk of chronic complications due to permanent organ damage, including chronic pancreatitis and pancreatogenic diabetes. They can experience daily symptoms including abdominal pain, generalized fatigue and impaired cognition that affect their ability to work. People with FCS also experience major emotional and psychosocial effects including anxiety, social withdrawal, depression and brain fog. There is no effective therapy for FCS currently available. Additional information on FCS is available at www.fcsfocus.com, and through the FCS Foundation at http://www.livingwithfcs.org and the LPLD Alliance at www.lpldalliance.org. For a full list of organizations supporting the FCS community worldwide, please click here.

WAYLIVRA is also currently in Phase 3 clinical development for the treatment of patients with familial partial lipodystrophy, or FPL. Akcea anticipates reporting top-line data from this study in 2019.

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)-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 E.U. for the treatment of stage 1 or stage 2 polyneuropathy in adult patients with hereditary transthyretin amyloidosis (hATTR) and is currently under regulatory review in the U.S. and Canada. WAYLIVRA is also under regulatory review in the E.U. and Canada 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 a global company headquartered in Cambridge, Massachusetts. Additional information about Akcea is available at www.akceatx.com.

ABOUT IONIS PHARMACEUTICALS, INC.

Ionis is the leading company in RNA-targeted drug discovery and development focused on developing drugs for patients who have the highest unmet medical needs, such as those patients with severe and rare diseases. Using its proprietary antisense technology, Ionis has created a large pipeline of first-in-class or best-in-class drugs, with over 40 drugs in development. SPINRAZA® (nusinersen) has been approved in global markets for the treatment of spinal muscular atrophy (SMA). Biogen is responsible for commercializing SPINRAZA. TEGSEDI™ (inotersen) and WAYLIVRA™ (volanesorsen) are two antisense drugs that Ionis discovered and successfully advanced through Phase 3 studies. TEGSEDI is approved in the E.U. for the treatment of stage 1 or stage 2 polyneuropathy in adult patients with hereditary transthyretin amyloidosis, or hATTR, and is currently under regulatory review in the U.S. and Canada. WAYLIVRA is also under regulatory review for marketing approval in the E.U. and Canada for the treatment of patients with familial chylomicronemia syndrome, or FCS. WAYLIVRA is also in a Phase 3 study in patients with familial partial lipodystrophy, or FPL. Akcea Therapeutics, an affiliate of Ionis focused on developing and commercializing drugs to treat patients with serious and rare diseases, will commercialize TEGSEDI and WAYLIVRA, if approved. Ionis' patents provide strong and extensive protection for its drugs and technology. Additional information about Ionis is available at www.ionispharma.com.

AKCEA'S 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 WAYLIVRA™ (volanesorsen). Any statement describing Akcea's or Ionis' goals, expectations, financial or other projections, intentions or beliefs, including the commercial potential of WAYLIVRA 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 Ionis' and Akcea's programs are described in additional detail in Ionis' and Akcea's 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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