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): October 4, 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 1.01 Entry into a Material Definitive Agreement.

On October 4, 2019 (the "***Execution Date***"), Akcea Therapeutics, Inc. (the "***Company***") entered into a license agreement (the "***Agreement***") with Pfizer Inc. ("***Pfizer***") for the development and commercialization of AKCEA-ANGPTL3-LRx (the "***Product***"). In addition to customary closing conditions, consummation of the transaction contemplated by the Agreement is subject to obtaining clearance required under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

Under the terms of the Agreement, the Company granted Pfizer an exclusive license, with the right to grant certain sublicenses, under the Company's intellectual property to develop, manufacture, commercialize and otherwise exploit the Product worldwide. The Company has the right, at its option, to participate in commercialization activities with Pfizer in the United States and certain additional markets on pre-defined terms and based on meeting pre-defined criteria. In addition, each party has agreed not to, independently or with any third party, develop or commercialize any competing oligonucleotide product for the same gene target as the Product for a period of five years from the Execution Date.

At closing, as payment for the grant of rights to Pfizer under the Agreement, Pfizer will pay the Company a $250 million upfront license fee, which will be split equally with Ionis Pharmaceuticals, Inc. ("***Ionis***") in accordance with the Development, Commercialization and License Agreement between the Company and Ionis dated December 18, 2015. Akcea will settle its $125 million obligation to Ionis through the issuance of its common stock. In addition, the Company is eligible to receive development, regulatory and sales milestone payments of up to $1.3 billion and tiered, double-digit royalties on annual worldwide net sales of the Product. The royalty payments are subject to reduction in certain circumstances as set forth in the Agreement.

The Agreement continues until the expiration of the last to expire royalty term with respect to all Products in all countries worldwide. Prior to the first commercial sale of the Product in the United States, either party may terminate the Agreement on written notice to the other party if the other party is in material breach of its obligations thereunder and has not cured such breach within 30 days after notice in the case of a payment breach or 90 days after notice in the case of any other breach. In addition, at any time following payment by Pfizer of the upfront license fee, Pfizer may terminate the Agreement for convenience by providing 90 days written notice to the Company.

The foregoing description of the Agreement is a summary only and is qualified in its entirety by reference to the terms of the Agreement, a copy of which will be filed with the Company's Annual Report on Form 10-K for the year ended December 31, 2019.

On October 7, 2019, the Company issued a press release in which it announced that it entered into the Agreement. A copy of the press release is attached to this Report as Exhibit 99.1 and is incorporated herein by reference.

Item 3.02 Unregistered Sales of Equity Securities.

The information set forth in Item 1.01 of this Current Report is incorporated herein by reference.

Akcea will satisfy its obligation to pay Ionis the $125.0 million sublicense fee through the issuance of its common stock (the "***Common Stock***") at $18.1862 per share calculated using the trailing 20 trading day average measured from the Execution Date, which will result in 6,873,344 shares of Common Stock being issued to Ionis. The Common Stock will be sold pursuant to a stock purchase agreement and the closing of such sale is expected to occur in the fourth quarter of 2019 following Akcea's receipt of the $250 million license fee from Pfizer. The sale of the Common Stock is exempted from registration pursuant to Rule 144 of the Securities Act of 1933.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release, dated October 7, 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: October 8, 2019

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

Exhibit 99.1

Akcea and Pfizer Inc. Announce Licensing Agreement for investigative antisense therapy AKCEA-ANGPTL3-LRx

Akcea and Ionis to earn $250 million license fee

BOSTON, Mass. and NEW YORK, NY, October 7, 2019 – Akcea Therapeutics, Inc. (NASDAQ: AKCA), a majority-owned affiliate of Ionis Pharmaceuticals, Inc. (NASDAQ: IONS) and Pfizer Inc. (NYSE:PFE), today announced that the companies have entered into a worldwide exclusive licensing agreement for AKCEA-ANGPTL3-LRx, an investigational antisense therapy being developed to treat patients with certain cardiovascular and metabolic diseases.

AKCEA-ANGPTL3-LRx is designed to reduce the production of angiopoietin-like 3 (ANGPTL3) protein in the liver, a key regulator of triglycerides, cholesterol, glucose and energy metabolism. AKCEA-ANGPTL3-LRx is currently being evaluated in a Phase 2 study in patients with Type 2 diabetes, hypertriglyceridemia and non-alcoholic fatty liver disease (NAFLD).

"AKCEA-ANGPTL3-LRx has the potential to treat people suffering from certain cardiovascular and metabolic diseases. Given the unmet medical need for this patient population and the broad market potential, we believe Pfizer's expertise and breadth of experience in cardiovascular and metabolic diseases makes it well suited to accelerate clinical development of AKCEA-ANGPTL3-LRx, and to deliver it to patients in need of additional therapies for these life threatening diseases," said Damien McDevitt, Ph.D., interim chief executive officer at Akcea.

"Pfizer is committed to delivering breakthrough medicines to patients who are waiting," said Mikael Dolsten, Chief Scientific Officer and President, Worldwide Research & Development and Medical, Pfizer. "AKCEA-ANGPTL3-LRx is a novel mechanism that will nicely complement ourmid-stage internal medicine pipeline of potential first-in-class therapies, and we believe that our deep expertise in cardiovascular and metabolic diseases will help allow this program to reach its maximum potential – which is to offer patients a new treatment option for areas of unmet medical need."

Under terms of the agreement, Akcea and Ionis will receive a $250 million upfront license fee, which will be split equally between the two companies. Akcea will settle its $125 million obligation to Ionis in Akcea common stock. The companies are also eligible to receive development, regulatory and sales milestone payments of up to $1.3 billion

and tiered, double-digit royalties on annual worldwide net sales following marketing approval of AKCEA-ANGPTL3-LRx. Future milestone payments and royalties will be split equally between Akcea and Ionis. Pfizer is responsible for all development and regulatory activities and costs beyond those associated with the ongoing Phase 2 study. Prior to regulatory filing for marketing approval, Akcea has the right, at its option to participate in certain commercialization activities with Pfizer in the U.S. and certain additional markets on pre-defined terms and based on meeting pre-defined criteria.

This transaction is subject to clearance under the Hart-Scott Rodino Antitrust Improvements Act and other customary closing conditions.

ABOUT AKCEA-ANGPTL3-LRx

AKCEA-ANGPTL3-LRx is an investigational antisense therapy being developed to treat patients with certain cardiovascular and metabolic diseases. This antisense medicine is designed to reduce the production of angiopoietin-like 3 (ANGPTL3) protein in the liver, a key regulator of triglycerides, cholesterol, glucose and energy metabolism. AKCEA-ANGPTL3-LRx was developed using Ionis' advanced**LI**gand **C**onjugated **A**ntisense (LICA) technology platform. The potential therapeutic benefits of ANGPTL3 reduction are supported by the discovery that people with a genetic deficiency in ANGPTL3 have reduced levels of low-density lipoprotein cholesterol (LDL-C) and triglycerides, and a decreased risk of diabetes and cardiovascular disease[1]. In a Phase 1/2 study, patients treated with AKCEA-ANGPTL3-LRx achieved robust, dose-dependent reductions of ANGPTL3, triglycerides, LDL-cholesterol and total cholesterol with a positive safety and tolerability profile[2]. AKCEA-ANGPTL3-LRx is currently being evaluated in a Phase 2 study in patients with Type 2 diabetes, hypertriglyceridemia and non-alcoholic fatty liver disease (NAFLD). AKCEA-ANGPTL3-LRx was discovered by Ionis and has been co-developed by Akcea and Ionis.

ABOUT AKCEA THERAPEUTICS, INC.

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 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 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.

Pfizer Inc.: Breakthroughs that Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality,

safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

AKCEA FORWARD-LOOKING STATEMENT

This press release includes forward-looking statements regarding the business of Akcea Therapeutics, Inc. and the therapeutic and commercial potential of AKCEA-ANGPTL3-LRx and other products in development. Any statement describing Akcea's goals, expectations, financial or other projections, intentions or beliefs, including the commercial potential of AKCEA-ANGPTL3-LRx or other of Akcea's 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 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 quarterly report on Form 10-Q and annual report on Form 10-K, 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, "Pfizer", "Akcea," "Company," "Companies," "we," "our," and "us" refers to Pfizer and/or Akcea Therapeutics.

PFIZER DISCLOSURE NOTICE: *The information contained in this release is as of October 7, 2019. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.*

This release contains forward-looking information about a worldwide exclusive licensing agreement among Pfizer, Akcea Therapeutics, Inc. and Ionis Pharmaceuticals, Inc., and AKCEA-ANGPTL3-LRx, an investigational antisense therapy being developed to treat patients with certain cardiovascular and metabolic diseases, including its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any jurisdictions for AKCEA-ANGPTL3-LRx; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether AKCEA-ANGPTL3-LRx will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of AKCEA-ANGPTL3-LRx; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form10-K for the fiscal year ended December 31, 2018 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

Akcea Investor Contact:

Kathleen Gallagher
Vice President, Corporate Communications and Investor Relations
(617)-207-8509
kgallagher@akceatx.com

Bill Berry
Berry & Company
T: 212 253-8881
bberry@berrypr.com

Lynn Granito
Berry & Company
T: 212 253-8881
lgranito@berrypr.com

Pfizer Media Relations:

Patricia Kelly
212-733-3810
patricia.kelly@pfizer.com

Pfizer Investor Relations:

Chuck Triano
212-733-3901
charles.e.triano@pfizer.com

References

1. JAMA Cardiol. 2018 Oct 1;3(10):957-966.
2. N Engl J Med. 2017 Jul 20;377(3):222-232.