ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 12/21/12 for the Period Ending 12/20/12

Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
Telephone	914-347-4300
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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 20, 2012**

Acorda Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**000-50513**	**13-3831168**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)
	420 Saw Mill River Road, Ardsley, NY	**10502**
	(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(914) 347-4300**

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:

☐ 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))

Item 8.01 Other Events

On December 21, 2012, Acorda Therapeutics, Inc. ("Acorda") issued a press release announcing that Acorda has completed the acquisition of Neuronex, Inc. ("Neuronex"), a privately held company developing a nasal spray formulation of diazepam, or DZNS, pursuant to a previously-announced merger agreement entered into on February 15, 2012. A copy of the press release issued by Acorda announcing the completion of the acquisition is attached as Exhibit 99.1 to this Current Report on Form 8-K, and incorporated by reference into this Item.

In accordance with the terms and conditions of the Neuronex merger agreement, upon execution of the merger agreement, Acorda made an initial payment of $2 million to Neuronex. Also, prior to the completion of the acquisition, Acorda provided Neuronex with $1.5 million to support certain research and development activities conducted by Neuronex.

Upon closing of the acquisition on December 20, 2012, Acorda paid an additional $6.8 million in cash consideration to acquire Neuronex, subject to a $300,000 holdback in accordance with the provisions of the Neuronex merger agreement. Under the terms of the merger agreement, the former equity holders of Neuronex will be entitled to receive from Acorda up to an additional $18 million in earnout payments upon the achievement of specified regulatory and manufacturing-related milestones with respect to the DZNS product, and up to $105 million upon the achievement of specified sales milestones with respect to the DZNS product. The former equity holders of Neuronex will also be entitled to receive tiered royalty-like earnout payments, ranging from the upper single digits to lower double digits, on worldwide net sales of DZNS products.

Neuronex licenses the patent and other intellectual property and other rights relating to the DZNS product from SK Biopharmaceuticals Co., Ltd., or SK. Pursuant to the SK license, which grants worldwide rights to Neuronex except certain specified Asian countries, Neuronex is obligated to pay SK up to $8 million upon the achievement of specified development milestones with respect to the DZNS product (including a $1 million payment upon the FDA's acceptance for review of the first NDA for the DZNS product), and up to $3 million upon the achievement of specified sales milestones with respect to the DZNS product. Also, Neuronex is obligated to pay SK a tiered, mid-single digit royalty on net sales of DZNS products. As a result of the acquisition, Acorda is be responsible for amounts payable under the SK license in addition to the earnout payments described above.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	*Description*
99.1	Press Release dated December 21, 2012

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 hereunto duly authorized.

Acorda Therapeutics, Inc.

December 21, 2012

By: David Lawrence

Name: David Lawrence
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated December 21, 2012

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces Completion of Neuronex, Inc. Acquisition

- *Diazepam Nasal Spray, Pre-NDA Stage Epilepsy Product, Added to Acorda's Neurology Pipeline*

ARDSLEY, N.Y. – December 21, 2012 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that the Company has completed the acquisition of Neuronex, Inc., a privately held company developing a nasal spray formulation of diazepam. Under the terms of the agreement, Acorda paid $6.8 million to Neuronex to complete the acquisition.

"Diazepam Nasal Spray is an important addition to our pipeline and aligns with our core strategy to develop and commercialize products that offer unique benefits to people with neurological diseases," said Ron Cohen, M.D., Acorda's President and CEO. "This product leverages our existing sales, marketing and medical organizations, which have proved highly successful in bringing novel neurological therapies to market."

Diazepam Nasal Spray is a proprietary formulation of diazepam that Acorda is developing as a treatment for the management of selected, refractory patients with epilepsy, on stable regimens of antiepileptic drugs (AEDs), who require intermittent use of diazepam to control bouts of acute repetitive seizures (ARS). Currently, the only approved outpatient treatment option for people who experience this type of seizure activity is DIASTAT ® AcuDial ™ (diazepam rectal gel), a rectally administered gel formulation of diazepam. The nasally administered formulation potentially offers patients and caregivers a more practical and socially acceptable treatment option.

"There are up to 175,000 people in the U.S. who suffer from acute repetitive seizures despite being on stable regimens of antiepileptic medications. These seizures can occur at any time and have a profound impact on a person's life," said Enrique Carrazana, M.D., Acorda's Chief Medical Officer. "As an epileptologist, I am very excited that we are developing a product which, if approved, will represent a major contribution to patient care."

In addition to the closing payment to Neuronex, Acorda will provide additional payments of up to $18 million based on achievement of certain regulatory and manufacturing-related milestones, and up to $105 million based on specified sales milestones. Tiered upper single-digit to lower double-digit royalty-like earnout payments on sales will be paid if the product is approved. In addition, Acorda will assume responsibility for regulatory and sales milestone payments of up to $11 million and single-digit royalties to third parties, based on existing Neuronex licensing agreements.

Acorda made an initial option payment of $2.0 million to Neuronex in the first quarter of 2012, and provided $1.5 million in ensuing quarters to support certain research and development activities conducted by Neuronex prior to completing the acquisition.

Acorda plans to submit a 505(b)(2)-type New Drug Application (NDA) for Diazepam Nasal Spray to the U.S. Food and Drug Administration (FDA) in 2013. A 505(b)(2) application allows for an NDA that relies on medical literature and FDA's finding of safety and effectiveness for a previously approved drug product.

About Epilepsy and Acute Repetitive Seizures (ARS)
Epilepsy is a neurological condition that produces seizures affecting a variety of mental and physical functions. Seizures are symptoms of abnormal brain activity, and occur when a brief, strong surge of electrical activity affects part or all of the brain. The Centers for Disease Control and Prevention (CDC) estimates that approximately 2.3 million Americans have active epilepsy.

Acute repetitive seizures (ARS) are characterized by recognizable, recurring episodes of seizure clusters.

About Acorda Therapeutics
Acorda Therapeutics is a biotechnology company focused on developing therapies that restore function and improve the lives of people with MS, spinal cord injury and other neurological conditions.

Acorda markets AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg, in the United States as a treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an improvement in walking speed. AMPYRA is marketed outside the United States as FAMPYRA ® (prolonged-release fampridine tablets) by Biogen Idec under a licensing agreement from Acorda. AMPYRA and FAMPYRA are manufactured under license from Alkermes Pharma Ireland Limited.

The Company also markets ZANAFLEX CAPSULES ® (tizanidine hydrochloride) and Zanaflex tablets, a short-acting drug for the management of spasticity. Acorda also receives sales royalties on tizanidine hydrochloride capsules, an authorized generic version of ZANAFLEX CAPSULES distributed by Watson Pharmaceutics, Inc. under its agreement with Acorda.

Acorda has an industry-leading pipeline of novel neurological therapies. The Company is developing Diazepam Nasal Spray for treatment of certain epileptic seizures. It is also studying AMPYRA to improve a range of functional impairments caused by MS, as well as its use in other neurological conditions, including cerebral palsy and post-stroke deficits. In addition, Acorda is developing clinical stage compounds AC105 for acute treatment of spinal cord injury and GGF2 for treatment of heart failure. GGF2 is also being investigated in preclinical studies as a treatment for neurological conditions such as stroke and spinal cord injury. Additional development programs include rHIgM22, a remyelinating monoclonal antibody for the treatment of MS, and chondroitinase, an enzyme that encourages nerve plasticity in spinal cord injury.

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, regarding management's expectations, beliefs, goals, plans or prospects should be considered forward-looking. These statements are subject to risks and uncertainties that could cause actual results to differ materially, including our ability to successfully market and sell Ampyra in the U.S.; third party payers (including governmental agencies) may not reimburse for the use of Ampyra or our other products at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions; the risk of unfavorable results from future studies of Ampyra or from our other research and development programs, including Diazepam Nasal Spray (“DZNS”) or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market DZNS or other products under development; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain regulatory approval of or to successfully market Fampyra outside of the U.S. and our dependence on our collaboration partner Biogen Idec in connection therewith; competition, including the impact of generic competition on Zanaflex Capsules revenues; failure to protect our intellectual property, to defend against the intellectual property claims of others or to obtain third party intellectual property licenses needed for the commercialization of our products; f ailure to comply with regulatory requirements could result in adverse action by regulatory agencies; and the ability to obtain additional financing to support our operations. These and other risks are described in greater detail in Acorda Therapeutics' filings with the Securities and Exchange Commission. Acorda Therapeutics may not actually achieve the goals or plans described in its forward-looking statements, and investors should not place undue reliance on these statements. Forward-looking statements made in this press release are made only as of the date hereof, and Acorda Therapeutics disclaims any intent or obligation to update any forward-looking statements as a result of developments occurring after the date of this press release.

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