ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

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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): **July 8, 2013**

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 2.01 Completion of Acquisition or Disposition of Assets

On July 8, 2013, Acorda Therapeutics, Inc. ("Acorda") completed the acquisition of two neuropathic pain management assets from NeurogesX, Inc. ("NeurogesX"), including: Qutenza ®, which is approved by the U.S. Food and Drug Administration (FDA) for the management of neuropathic pain associated with postherpetic neuralgia; and NP-1998, a Phase 3 ready, prescription strength capsaicin topical solution, being assessed for the treatment of neuropathic pain. NP-1998 was previously referred to as NGX-1998.

Acorda made an approximately $8 million payment to acquire development and commercialization rights for Qutenza and NP-1998 in the United States, Canada, Latin America and certain other territories, including $7 million paid to NeurogesX and approximately $900,000 for certain assumed accounts payable. Acorda will also make up to $5 million in payments contingent upon the achievement of certain regulatory and sales milestones related to NP-1998.

A copy of the press release announcing the completion of the NeurogesX transaction is attached as Exhibit 99.1 to this Current Report on Form 8-K, and incorporated by reference into this Item.

Item 9.01 Financial Statements and Exhibits

(a) Financial Statements of Businesses Acquired

Acorda intends to file the financial statements of NeurogesX required by Item 9.01(a) of Securities and Exchange Commission Form 8-K as part of an amendment to this Current Report on Form 8-K or otherwise not later than 71 calendar days after the date this Current Report on Form 8-K is required to be filed.

(b) Pro Forma Financial Information

Acorda intends to file the pro forma financial information required by Item 9.01(b) of Securities and Exchange Commission Form 8-K as part of an amendment to this Current Report on Form 8-K or otherwise not later than 71 calendar days after the date this Current Report on Form 8-K is required to be filed.

(d) Exhibits

Exhibit No.	*Description*
99.1	Press Release dated July 9, 2013

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.

July 9, 2013

By: /s/David Lawrence
Name: David Lawrence
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated July 9, 2013

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces Acquisition of Two Neuropathic Pain Assets

- Qutenza ® (capsaicin) 8% Patch FDA-Approved Therapy for Neuropathic Pain Associated with Postherpetic Neuralgia
- Phase 3-Stage Product NP-1998 Being Assessed in Painful Diabetic Neuropathy
- Approximately $8 Million Payment for Rights in United States and Selected Markets

ARDSLEY, NY – July 9, 2013 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that it has acquired two neuropathic pain management assets from NeurogesX, Inc. (OTCBB: NGSX). Qutenza ® is approved by the U.S. Food and Drug Administration (FDA) for the management of neuropathic pain associated with postherpetic neuralgia. The Company also acquired NP-1998, a Phase 3 ready, prescription strength capsaicin topical solution, being assessed for the treatment of neuropathic pain. NP-1998 was previously referred to as NGX-1998.

“The acquisition of Qutenza and NP-1998 enables us to expand into the area of neuropathic pain management. We plan to support Qutenza with our existing medical and commercial infrastructure, which includes one of the industry’s best neurology sales forces,” said Ron Cohen, M.D., Acorda’s President and CEO. “In addition, we will leverage our neurology expertise to evaluate NP-1998 for the treatment of neuropathic pain, with an initial emphasis on painful diabetic neuropathy. This adds another potentially important, late stage product to our pipeline.”

Acorda made an approximately $8 million payment to acquire development and commercialization rights for Qutenza and NP-1998 in the United States, Canada, Latin America and certain other territories, including $7 million paid to NeurogesX and approximately $900,000 for certain assumed accounts payable . Acorda will also make up to $5 million in payments contingent upon the achievement of certain regulatory and sales milestones related to NP-1998. Astellas Pharma Europe Ltd. has exclusive commercialization rights for Qutenza in the European Economic Area (EEA) including the 27 countries of the European Union, Iceland, Norway, and Liechtenstein as well as

Switzerland, certain countries in Eastern Europe, the Middle East and Africa. Astellas also has an option to develop NP-1998 in those same territories.

Qutenza is a dermal patch containing 8% prescription strength capsaicin that is applied once every three months for the management of neuropathic pain associated with postherpetic neuralgia, also known as post-shingles nerve pain. The drug was approved by the U.S. Food and Drug Administration in 2010, and had net sales of $2.6 million in 2011. NeurogesX discontinued active promotion of the product in March 2012; net sales were approximately $2.4 million through the end of the third quarter of 2012. Acorda plans to support Qutenza in the United States using the Company's existing commercial organization, including its specialty neurology sales force of approximately 100 sales professionals, as well as its medical and safety reporting infrastructure.

NP-1998 is a topical solution containing 20% prescription strength capsaicin under clinical development as a treatment for pain associated with neuropathic pain conditions such as painful diabetic neuropathy (PDN).

Astellas is currently conducting clinical trials of Qutenza including a Phase 3 trial to assess its use in the treatment of pain associated with PDN. Under the terms of the agreement, Acorda will have rights to review data from that trial, and the companies may also collaborate and/or share costs of future clinical trials.

Postherpetic Neuralgia (PHN) or Post-Shingles Nerve Pain

Postherpetic neuralgia (PHN), also known as post-shingles nerve pain, is chronic pain resulting from shingles, a viral infection caused by the same virus that causes chickenpox. There are approximately one million new cases of shingles in the United States each year.

Shingles is characterized by an outbreak of rash or blisters on the skin and nerve pain that typically resolves within several weeks. However, up to one-third of people who have a shingles outbreak experience PHN, which can continue for months or years after the shingles rash has healed.

About Painful Diabetic Neuropathy (PDN)

Diabetes is a group of diseases marked by high levels of blood glucose resulting from defects in insulin production, insulin action or both. According to the National Institute of Diabetes and Digestive Kidney Diseases (NIDDK), more than 23 million people in the U.S. have diabetes.

Painful diabetic neuropathy is a common complication of diabetes characterized by chronic pain that results from damage to nerves due to poor circulation and high blood sugar. People with diabetes can develop nerve problems at any time, but risk rises with age and longer duration of diabetes. Diabetic neuropathies also appear to be more common in people who have problems controlling their blood glucose, as well as those with high levels of blood fat and blood pressure, and those who are overweight.

Qutenza Important Safety Information

Qutenza ® is indicated for the management of neuropathic pain associated with postherpetic neuralgia.

Treatment with Qutenza must be performed only by a healthcare provider. You should never apply or remove Qutenza yourself.

Warnings and Precautions:

- Qutenza is not for use near eyes or mucous membranes. Do not sniff or inhale near the Qutenza patch as this may cause you to cough or sneeze.
- Do not touch the Qutenza patch with your hands. If you touch the patch, it may cause burning and stinging; if this occurs, tell your healthcare provider.
- Even though a numbing medicine is used on the skin before applying Qutenza, some patients may still experience substantial pain during the treatment. Tell your healthcare provider if you are experiencing pain; a cool compress or medicine for the pain can be provided to help lessen your discomfort.
- Qutenza can cause serious side effects including pain and increases in blood pressure during or right after treatment.
- Your healthcare provider should check your blood pressure during treatment with Qutenza.
- Patients who have high blood pressure that is not well controlled by medicine, or who have had recent heart problems, stroke, or other vascular problems, may be at increased risk and should discuss with their doctor whether Qutenza is right for them.

Side Effects:

- In clinical studies, the most common drug-related side effects of Qutenza, which occurred in 5% or more of patients, included redness, pain, small bumps, and itching. These side effects occurred at the patch application site.
- You should tell your doctor if any side effects bother you or do not go away.

These are not all the side effects of Qutenza. For more information, ask your healthcare provider or pharmacist or visit www.qutenza.com.

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 Actavis, Inc. under its agreement with Acorda.

Acorda has one of the leading pipelines in the industry 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 potential for 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, GGF2 for treatment of heart failure and rHIgM22, a remyelinating monoclonal antibody, for the treatment of MS. GGF2 is also being investigated in preclinical studies as a treatment for neurological conditions such as stroke and peripheral nerve damage. Chondroitinase, an enzyme that encourages nerve plasticity in spinal cord injury, is in preclinical development.

Acorda 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 or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market Diazepam Nasal Spray 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; failure 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 & Exchange Commission. Acorda 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 release are made only as of the date hereof, and Acorda disclaims

any intent or obligation to update any forward-looking statements as a result of developments occurring after the date of this release.