ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

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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): **June 27, 2011**

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.)

15 Skyline Drive, Hawthorne, NY	**10532**
(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 1.01 Entry into a Material Definitive Agreement

On June 27, 2011, Acorda Therapeutics, Inc. (" **Acorda** ") entered into a License Agreement (the " **License Agreement** ") with Medtronic, Inc. and its affiliate Warsaw Orthopedic, Inc. (" **Medtronic** ") pursuant to which Acorda licensed from Medtronic worldwide development and commercialization rights to certain formulations of magnesium with a biomembrane sealing agent, such as polyethylene glycol (the " **Licensed Products** "), which will be referred to as AC105. Acorda plans to study AC105 as an acute treatment for patients who have suffered neurological trauma, such as spinal cord injury (SCI) and traumatic brain injury (TBI).

Under the License Agreement, Acorda has a license to develop and commercialize the Licensed Products in all countries worldwide. Acorda's rights are exclusive in all fields for certain formulations (" **Exclusive Products** "). With respect to Licensed Products that are not Exclusive Products, Acorda has non-exclusive rights in certain specified fields, including pain and musculoskeletal indications, and has exclusive rights in all other fields, including the treatment of TBI, stroke, and all other traumatic and ischemic central nervous system indications (the " **Exclusive Fields** "). Acorda's license includes sublicensing rights, subject to Medtronic's consent in certain cases. During the term of the License Agreement and, except in certain circumstances for one year thereafter, neither Medtronic nor any of its affiliates may research, develop, manufacture or commercialize any Exclusive Product in any field or any other Licensed Product in the Exclusive Fields.

In consideration for the rights granted to Acorda under the License Agreement, Acorda has paid to Medtronic an upfront $3 million cash license fee. Medtronic is also eligible to receive up to $32 million from Acorda if specified regulatory and development milestones are met. There can be no guarantee that any such milestones will in fact be met. Acorda will also pay to Medtronic a single-digit royalty on sales of Licensed Products by Acorda or its affiliates. Acorda may offset, against a portion of the royalties payable to Medtronic, a portion of any royalties Acorda may pay under certain third party licenses.

Acorda must use its commercially reasonable efforts to develop and commercialize a Licensed Product in at least one of the major markets specified in the License Agreement. Prior to the launch of a Licensed Product in such a major market, Medtronic can terminate Acorda's exclusivity if Acorda has failed to conduct material and good faith development and commercialization activities for a major market in the prior 6 months. However, Medtronic's right to terminate exclusivity is subject to Acorda's right to propose and implement a development and commercialization plan that satisfies the requirements of the License Agreement.

The License Agreement will terminate upon the expiration of Acorda's royalty payment obligations, which occurs, on a Licensed Product-by-Licensed Product and country-by-country basis, upon the latest of (a) the tenth anniversary of the first commercial sale of such Licensed Product, (b) expiration of the last-to-expire patent covering a Licensed Product, and (c) in the case of a Licensed Product that is not covered by a patent but that is subject to exclusivity under an orphan drug law for all indications for which regulatory approval has been received, the earlier of (i) the end of the regulatory exclusivity afforded by the orphan drug law for any indication for which the Licensed Product has received regulatory approval, and (ii) the date on which another drug receives regulatory approval for any indication for which the Licensed Product has received regulatory approval. Because the date of the first commercial sale of a Licensed Product is uncertain, and because a number of patent applications are pending that, if issued, would extend the term of the License Agreement, the term of the License Agreement in each country and with respect to each Licensed Product is uncertain. Upon termination of all royalty obligations for a Licensed Product in a country, the license becomes fully paid-up, irrevocable and perpetual for that product in that country.

The License Agreement may be terminated by either party in the event of an uncured material breach by the other party. Also, Medtronic may terminate the License Agreement if Acorda fails to comply with applicable law in connection with the exploitation of any Licensed Product and such non-compliance remains uncured after notice by Medtronic. To the extent permitted by law, each party may terminate the License Agreement if the other party is subject to bankruptcy or similar proceedings. Except in limited circumstances following a breach by Medtronic of the License Agreement, Medtronic's liability to Acorda is limited to amounts previously paid to Medtronic.

Neither party may assign the License Agreement without the prior written consent of the other, except to an affiliate or to a third party acquirer of the party or its business relating to Licensed Products.

The foregoing is a summary description of certain terms of the License Agreement, does not purport to be complete, and is qualified in its entirety by reference to the full text of the License Agreement (which Acorda intends to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending June 30, 2011, with confidential terms redacted).

A copy of the press release issued by Acorda announcing the License Agreement 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

(d) Exhibits

Exhibit No.	*Description*
99.1	Press Release dated July 1, 2011

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 1, 2011

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

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated July 1, 2011

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Licenses Rights to Investigational Treatment for Spinal Cord Injury and Traumatic Brain Injury

$3 Million Upfront Payment to Medtronic for Worldwide Development and Commercialization Rights for Compound Poised for Phase 2 Clinical Development

HAWTHORNE, NY, July 1, 2011 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that it has licensed worldwide development and commercialization rights to a proprietary magnesium formulation from Medtronic, Inc. (NYSE: MDT), which will be referred to as AC105. Acorda plans to study AC105 as an acute treatment for patients who have suffered neurological trauma, such as a spinal cord injury (SCI) and traumatic brain injury (TBI).

"Acorda has significant experience in the area of spinal cord injury and other neurological injury research. We are excited to leverage that expertise to continue the clinical development of AC105, potentially providing a new therapy to people who suffer debilitating central nervous system injuries," said Ron Cohen, M.D., Acorda's President and CEO. "The acquisition of AC105 is an important addition to our existing pipeline, providing a clinical stage compound to complement GGF2, which is in early Phase 1 clinical trials for the treatment of heart failure, as well as our preclinical programs in remyelination and spinal cord injury."

Acorda made a $3 million upfront payment to Medtronic and will make up to $32 million in regulatory and development milestone payments. A single-digit sales royalty will also be paid by Acorda to Medtronic if AC105 is commercialized by Acorda. Acorda's development and commercialization rights are exclusive in all fields (including SCI, TBI and stroke) for certain formulations of the licensed compound. For other formulations, Acorda's rights are exclusive for indications of interest to Acorda, including SCI, TBI, stroke and all other traumatic and ischemic central nervous system indications, while Medtronic has non-exclusive (with Acorda) development rights in specific areas, including certain areas of pain and musculoskeletal indications.

“Spinal cord injuries and traumatic brain injuries often result in severe, lifelong disability. This places an enormous burden on the person suffering the injury, their caregivers and the healthcare system. The situation is compounded because most spinal cord injuries and traumatic brain injuries occur in young people, leading to long-term care and quality of life issues,” said Andrew R. Blight, Ph.D., Acorda’s Chief Scientific Officer. “There are currently no FDA-approved therapies for either SCI or TBI, so we are excited to continue research on AC105 to determine its value in improving outcomes for people who suffer these very serious injuries.”

In preclinical studies, AC105 demonstrated neuroprotective properties and improvement of locomotor function in SCI and cognitive function in TBI when therapy was initiated within four hours of injury. Medtronic conducted Phase 1 trials in healthy volunteers and Acorda is planning a Phase 2 clinical trial program in SCI, with the potential for subsequent studies in other central nervous system indications, such as TBI and stroke. The U.S. Food and Drug Administration (FDA) granted Fast Track designation on February 12, 2009 for AC105 to improve functional recovery of acute SCI patients. Acorda expects to apply for FDA orphan drug designation for the acute treatment of SCI and will explore orphan drug designations in Europe and in other parts of the world given its worldwide development and commercialization rights.

About Spinal Cord Injury

Spinal cord injury (SCI) refers to any injury to the spinal cord that is caused by trauma, such as a motor vehicle accident, fall or sports injury. According to the National Spinal Cord Injury Statistical Center (NSCISC), there are between 183,000 and 230,000 people in the United States, and approximately 2 million people worldwide living with a spinal cord injury. Each year, there are 11,000 new injuries reported in the United States. Males account for the majority of spinal cord injury patients with 50-70% of those occurring in those aged 15-35.

The costs of living with SCI can be considerable and can vary greatly due to the severity of injury. Long-term complications from SCI can include neurologic impairments in any body system controlled by the affected nerves. Average annual medical cost for an SCI patient is $15,000-30,000 per year and the annual direct and indirect costs of SCI are estimated at $9.7 billion in the U.S. alone. There are currently no FDA-approved therapies indicated to treat, mitigate, or reverse SCI.

About Traumatic Brain Injury

Traumatic brain injury (TBI) is caused by a blow or jolt to the head or a penetrating head injury that disrupts the normal function of the brain. TBI can cause a wide range of functional short- or long-term changes affecting thinking, sensation, language, or emotion. TBI can also cause epilepsy and increase the risk for conditions such as

Alzheimer’s disease, Parkinson’s disease, and other brain disorders that become more prevalent with age.

According to World Health Organization, traumatic brain injury (TBI) will surpass many diseases as the major cause of death and disability by the year 2020. With an estimated 10 million people worldwide affected annually by TBI, the burden of mortality and morbidity that this condition imposes on society, makes TBI a pressing public health and medical problem.

In the U.S., approximately 1.6 million people sustain a traumatic brain injury annually and TBI results in approximately 52,000 fatalities and 275,000 hospitalizations every year. Approximately one-third of all hospitalized TBI survivors have long-term disability. TBI is a contributing factor to one third (30.5%) of all injury-related deaths in the United States. Direct medical costs and indirect costs such as lost productivity of TBI totaled an estimated $60 billion in the United States in 2000. There are currently no FDA-approved therapies indicated to treat, mitigate, or reverse TBI.

About Stroke

Stroke is a disease that affects the arteries leading to and within the brain. It is the third leading cause of death in the United States. A stroke occurs when a blood vessel that carries oxygen and nutrients to the brain is either blocked by a clot or bursts. When that happens, the brain cannot get the blood and oxygen it needs to survive. According to the Centers for Disease Control, strokes are suffered by 15 million people worldwide each year. Of these, 5 million die and another 5 million are permanently disabled. In the United States, approximately 795,000 Americans each year suffer a new or recurrent stroke with more than 137,000 people per year killed by stroke in the U.S. alone. The CDC estimates that Americans paid about $73.7 billion in 2010 for stroke-related medical costs and disability.

About Acorda Therapeutics

Acorda Therapeutics is a biotechnology company developing therapies for multiple sclerosis, spinal cord injury and related nervous system disorders. The Company is commercializing and marketing AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg, in the United States. AMPYRA is a potassium channel blocker approved as a treatment to improve walking in patients with multiple sclerosis (MS); this was demonstrated by an improvement in walking speed. AMPYRA was developed using Elan’s Matrix Drug Absorption System (MXDAS ®) technology and is manufactured by Elan based on a supply agreement with Acorda.

Acorda also markets ZANAFLEX CAPSULES ® (tizanidine hydrochloride) , a short-acting drug for the management of spasticity. The Company's pipeline includes a number of products in development for the treatment, regeneration and repair of the spinal cord and brain.

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 Acorda Therapeutics' ability to successfully market and sell Ampyra in the United States and to successfully market Zanaflex Capsules; third party payors (including governmental agencies) may not reimburse for the use of Ampyra 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; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain regulatory approval of Ampyra outside of the United States and our dependence on our collaboration partner Biogen Idec in connection therewith; competition; failure to protect Acorda Therapeutics' 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; the ability to obtain additional financing to support Acorda Therapeutics' operations; and, unfavorable results from our preclinical programs. 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 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.