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 30, 2009**

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 30, 2009, Acorda Therapeutics, Inc. ("Acorda") entered into a Collaboration and License Agreement (the "Collaboration Agreement") with Biogen Idec International GmbH ("Biogen Idec"), a Swiss subsidiary of Biogen Idec Inc. Under the Collaboration Agreement, Acorda and Biogen Idec have agreed to collaborate on the development and commercialization of products containing aminopyridines, including Fampridine-SR, initially directed to the treatment of multiple sclerosis. The Collaboration Agreement includes a sublicense of Acorda's rights under its license agreement with Elan Pharma International Limited ("Elan"), a subsidiary of Elan Corporation, plc. Acorda and Biogen Idec have also entered into a supply agreement (the "Supply Agreement") pursuant to which Acorda, through its supply agreement with Elan, will supply Biogen Idec with its requirements for the licensed products. Biogen Idec, Inc. has guaranteed the performance of Biogen Idec's obligations under the Collaboration Agreement and the Supply Agreement.

Under the Collaboration Agreement, Biogen Idec, itself or through its affiliates, has the exclusive right to commercialize licensed products in all countries outside of the United States, with Acorda retaining the right to commercialize licensed products in the United States. Each party will have the exclusive right to develop licensed products for its commercialization territory, although the parties may also decide to jointly carry out mutually agreed future development activities under a cost-sharing arrangement. If Biogen Idec does not participate in the development of licensed products for certain indications or forms of administration, it may lose the right to develop and commercialize the licensed products for such indication or form of administration. Biogen Idec may sublicense its rights to certain unaffiliated distributors. During the term of the Collaboration Agreement and for two years after the Collaboration Agreement terminates, neither party nor its affiliates may, other than pursuant to the Collaboration Agreement, research, develop, manufacture or commercialize any competing product, defined as one that contains aminopyridine or any other compound that acts at least in part through direct interaction with potassium channels to improve neurological function in multiple sclerosis, spinal cord injury or other demyelinating conditions, except that Acorda may exploit the licensed products anywhere in the world following termination of the Collaboration Agreement.

In consideration for the rights granted to Biogen Idec under the Collaboration Agreement, Biogen Idec has paid Acorda $110 million in cash. Acorda is also eligible to receive up to $400 million from Biogen Idec should specified regulatory and sales milestones be met. There can be no guarantee that any such milestones will in fact be met.

Acorda will also receive double-digit tiered royalties on sales of licensed products by Biogen Idec, its affiliates or certain distributors outside of the United States. Such royalties for products combining a licensed compound with at least one other clinically active therapeutic, prophylactic or diagnostic ingredient are determined based on the contribution of the licensed compound to the overall sales or value of the combination product. Biogen Idec may offset against the royalties payable to Acorda a portion of certain royalties which it may need to pay to third parties. In addition, Biogen Idec will pay, in consideration for its purchase and sale of the licensed products, all amounts due from Acorda to Elan for ex-US sales, including royalties owed.

The collaboration between Acorda and Biogen Idec will be governed by a joint steering committee consisting of an equal number of representatives from each party. In the event of a dispute at the joint steering committee level, Biogen Idec will generally having final decision-making authority with respect to the development and commercialization of licensed products outside of the United States and Acorda will generally have final decision-making authority with respect to the development and commercialization of licensed products in the United States.

Biogen Idec will exclusively purchase from Acorda all of Biogen Idec's, its affiliates' and sublicensees' requirements of the licensed products. The purchase price paid by Biogen Idec for licensed products under the

Collaboration Agreement and Supply Agreement reflects the prices owed to Acorda's suppliers under Acorda's supply arrangements with Elan or other suppliers.

The Collaboration Agreement will terminate upon the expiration of Biogen Idec's royalty payment obligations, which occurs, on a licensed product-by-licensed product and country-by-country basis, upon the latest of expiration of the last-to-expire patent covering a licensed product, a specified number of years following first commercial sale of such licensed product, the expiration of regulatory exclusivity; and the existence of certain levels of sales by competing products. The Collaboration Agreement and the Supply Agreement will automatically terminate upon the termination of the license agreement between Acorda and Elan in its entirety or with respect to all countries outside of the United States. Acorda cannot terminate the license agreement between Acorda and Elan without Biogen Idec's prior written consent under certain circumstances. Biogen Idec may terminate the Collaboration Agreement in its entirety or on a country-by-country basis at any time upon 180 days' prior written notice to Acorda, subject to Acorda's right to accelerate such termination. The Collaboration Agreement may also be terminated by either party if the other party fails to cure a material breach under the Collaboration Agreement, which termination will be limited to a particular country or region under certain circumstances. However, if Biogen Idec has the right to terminate the Collaboration Agreement due to Acorda's material uncured breach, Biogen Idec may instead elect to keep the Collaboration Agreement in effect, but decrease the royalty rates payable to Acorda by a specified percentage. Acorda may also terminate the Collaboration Agreement if Biogen Idec does not commercially launch a licensed product within a specified time period after receiving regulatory approval for such licensed product or otherwise fails to meet certain commercialization obligations. In addition, Acorda may terminate the Collaboration Agreement under certain circumstances if (i) Biogen, its affiliates or sublicensees challenge certain of Acorda's patents or (ii) there is a change in control of Biogen Idec or its parent company or certain dispositions of assets by Biogen Idec, its parent or affiliated companies, followed by a change in the sales and marketing personnel responsible for the licensed products in Biogen Idec's territory of more than a specified percentage within a certain period of time after such change in control or disposition. The Supply Agreement may be terminated by either party if the other party fails to cure a material breach under the Supply Agreement. In addition, the Supply Agreement will terminate automatically upon termination of the Collaboration Agreement, and the Collaboration Agreement will terminate automatically if the Supply Agreement is terminated for any reason other than Acorda's material breach. To the extent permitted by law, each party may terminate the Collaboration Agreement and the Supply Agreement if the other party is subject to bankruptcy proceedings.

If the Supply Agreement is terminated by Biogen Idec for Acorda's uncured material breach, Acorda will waive its right for Elan to exclusively supply the licensed products to Acorda solely to permit Biogen Idec to negotiate terms with Elan for the supply of licensed products to Biogen Idec. If the Supply Agreement is otherwise terminated, Biogen Idec will not have any future obligations to purchase licensed products from Acorda and Acorda will not have any future obligations to supply to Biogen Idec. If the Collaboration Agreement is terminated, Biogen Idec will assign to Acorda all regulatory documentation and other information necessary or useful to exploit the licensed products in the terminated countries and will grant Acorda a license under Biogen Idec's and its affiliates' relevant patent rights, know-how and trademarks to exploit the licensed products in the terminated countries. Such assignment and license will be at no cost to Acorda unless the Collaboration Agreement is terminated by Biogen Idec for Acorda's material uncured breach, in which case the parties will negotiate a payment to Biogen Idec to reflect the net value of such assigned and licensed rights.

Neither party may assign the agreements without the prior written consent of the other, except to an affiliate or, in certain cases, to a third party acquirer of the party.

In connection with the entry into this collaboration, Acorda, Biogen Idec and Elan have entered into a consent agreement (the "Consent"). Under the Consent, Elan consented to Acorda's sublicense of rights to Biogen Idec, and Acorda, Biogen Idec and Elan have agreed to set up a committee to coordinate activities under the agreements between Acorda and Elan with respect to the development, supply and commercialization of the

licensed products for Biogen Idec's territory. The Consent also amends the agreements between Acorda and Elan by, among other things, permitting Acorda to allow Biogen Idec grant sublicenses to certain unaffiliated distributors, permitting Acorda to allow Biogen Idec to package the licensed products and requiring Elan to facilitate the qualification of an alternate supplier of the licensed products under certain circumstances.

The foregoing is a summary description of certain terms of the Collaboration Agreement, the Supply Agreement and the Consent and does not purport to be complete, and it is qualified in its entirety by reference to the full text of the Collaboration Agreement, the Supply Agreement and the Consent which Acorda intends to file as exhibits to its Quarterly Report on Form 10-Q for the quarter ending June 30, 2009, with confidential terms redacted..

A copy of the press release issued in connection with the parties' announcement of the Agreement is attached hereto as 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*

99.1 Press release dated July 1, 2009.

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, 2009

By: */s/ David Lawrence*

Name: David Lawrence
Title: Chief Financial Officer

Exhibit Index

Exhibit No.	Description
99.1	Press Release dated July 1, 2009.

Exhibit 99.1

ACORDA THERAPEUTICS CONTACT:
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BIOGEN IDEC CONTACTS:
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Investor: Eric Hoffman (617) 679-2812

FOR IMMEDIATE RELEASE

Biogen Idec and Acorda Therapeutics Announce Collaboration Agreement to Develop and Commercialize MS Therapy Fampridine-SR in Markets Outside the U.S.

- Acorda to Continue to Develop and Commercialize Fampridine-SR in the U.S.
- Upfront Payment of $110 Million; Potential Deal Value Over $500 Million
- Acorda to Host Conference Call at 8:30 a.m. Eastern Time Today

CAMBRIDGE, MA and HAWTHORNE, NY, July 1, 2009 — Biogen Idec (NASDAQ: BIIB) and Acorda Therapeutics, Inc. (NASDAQ: ACOR) today announced that they have entered into an exclusive collaboration and license agreement to develop and commercialize Fampridine-SR, a multiple sclerosis (MS) therapy, in markets outside the United States. Fampridine-SR is a novel, oral sustained-release compound being developed to improve walking ability in people with MS. The parties have also entered into a related supply agreement. The transaction represents a sublicensing of an existing license agreement between Acorda and Elan Pharma International Limited, a subsidiary of Elan Corporation plc (NYSE: ELN).

Under the terms of the agreement, Biogen Idec will commercialize Fampridine-SR and any aminopyridine products developed under the agreement in ex-U.S. markets worldwide and will also have responsibility for regulatory activities and future clinical development of Fampridine-SR in those markets. Acorda will receive an upfront payment of $110 million and additional payments of up to $400 million based on the successful achievement of future regulatory and sales milestones. Biogen Idec will make tiered, double-digit royalty payments to Acorda on ex-U.S. sales, and, in addition, the consideration that Biogen Idec pays for products will reflect all amounts due from Acorda to Elan for ex-US sales, including royalties owed. The parties can also carry out future joint development activities under a cost-sharing arrangement.

Elan will continue to manufacture commercial supply of Fampridine-SR, based on its existing supply agreement with Acorda. Under the existing agreements with Elan, Acorda will pay Elan seven percent of the upfront and milestone payments that Acorda receives from Biogen Idec.

“Biogen Idec has outstanding capabilities in commercializing neurology and oncology products and is known globally for its reputation as an innovative leader in the field of multiple sclerosis. We are delighted to be working with them to make Fampridine-SR, if approved, available to people living with MS in Europe, Canada, Australia and other areas of the world,” said Ron Cohen, M.D., President and CEO of Acorda. “We believe that Biogen Idec’s international expertise in MS and neurology also will help us optimize future development of Fampridine-SR and maximize its value in markets outside the U.S.”

“We are very pleased to partner with Acorda, a leader in the development of therapies for spinal cord, MS, and related nervous system disorders, to help make Fampridine-SR available to MS patients outside of the United States,” said Jim Mullen, President and CEO of Biogen Idec. “As we look to expand our global MS leadership, we believe Fampridine-SR has the potential to become an important oral therapy that may help improve the walking ability of a wide range of patients — including patients with relapsing forms of MS, as well as primary and secondary progressive MS.”

MS is a chronic disease of the central nervous system that affects approximately two million people worldwide.

Acorda previously announced that the European Medicines Agency (EMEA) notified the Company that Fampridine-SR is eligible to be submitted for a Marketing Authorization Application (MAA) via the Agency’s Centralized Procedure as a new active substance. The Centralized Procedure provides for a single, coordinated review that is conducted by the EMEA on behalf of all European Union (EU) member states.

Acorda will continue to develop and commercialize Fampridine-SR independently in the U.S. The U.S. Food and Drug Administration (FDA) is currently reviewing a New Drug Application (NDA) for Fampridine-SR. The NDA was assigned Priority Review and a Prescription Drug User Fee Act (PDUFA) date of October 22, 2009; the PDUFA date is the target date for the FDA to complete its review of Fampridine-SR.

Conference Call and Audiocast

Ron Cohen, President and Chief Executive Officer of Acorda Therapeutics, will host a conference call today at 8:30 a.m. ET.

To participate in the conference call, please dial 800-706-7745 (domestic) or 617-614-3472 (international) and reference the access code 68235234. The presentation will be available via a live webcast at http://phx.corporate-ir.net/phoenix.zhtml?p=irol-eventDetails&c=194451&eventID=2303543.

A replay of the call will be available from 11:30 a.m. ET on July 1, 2009 until midnight on August 1, 2009. To access the replay, please dial 888-286-8010 (domestic) or 617-801-6888 (international) and reference the access code 96152771. The archived webcast will be available for 30 days in the Investor Relations section of the Acorda website at http://www.acorda.com.

About Fampridine-SR

Fampridine-SR is a sustained-release tablet formulation of the investigational drug fampridine (4-aminopyridine or 4-AP). Fampridine has completed two successful Phase 3 clinical trials demonstrating improved walking ability in people with MS. It has been found to improve impulse conduction in nerve fibers in which the insulating layer, called myelin, has been damaged. Fampridine-SR was developed using Elan’s proprietary Oral Controlled Release MXDAS ™ (MatriX Drug Absorption System) Technology and will be manufactured by Elan based on an existing supply agreement with Acorda.

About Acorda Therapeutics

Acorda Therapeutics is a biotechnology company developing therapies for spinal cord injury, multiple sclerosis and related nervous system disorders. The Company’s marketed products include 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.

About Biogen Idec

Biogen Idec creates new standards of care in therapeutic areas with high unmet medical needs. Founded in 1978, Biogen Idec is a global leader in the discovery, development, manufacturing, and commercialization of innovative therapies. Patients in more than 90 countries benefit from Biogen Idec's significant products that address diseases such as lymphoma, multiple sclerosis, and rheumatoid arthritis. For product labeling, press releases and additional information about the company, please visit www.biogenidec.com

About Elan Drug Technologies

Elan Drug Technologies (EDT) is the world's leading drug delivery provider and is a business unit of Elan Corporation plc. EDT developed Fampridine-SR, using one of their proprietary Oral Controlled Release Technologies, the MXDAS ™ (MatriX Drug Absorption System) Technology. Products are developed by EDT through Elan Pharma International Limited and other Elan affiliates. EDT aims to deliver clinically meaningful benefits to patients by using their extensive experience and proprietary delivery technologies in partnership with pharmaceutical companies. More information is available at www.elandrugtechnologies.com

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 delays in obtaining or failure to obtain regulatory approval of Fampridine-SR, the risk of unfavorable results from future studies of Fampridine-SR, adverse safety events, dependence on a third party to supply Fampridine-SR, Acorda Therapeutics' and Biogen Idec's ability to successfully market and sell Fampridine-SR, if approved, competitive pressures, the availability of reimbursement from third party payors, failure to protect intellectual property or to defend against the intellectual property claims of others, and Acorda Therapeutics' ability to obtain additional financing to support its operations.. These and other risks are described in greater detail in Acorda Therapeutics' and Biogen Idec's respective filings with the Securities and Exchange Commission. Acorda Therapeutics and Biogen Idec may not actually achieve the goals or plans described in any forward-looking statements included in this press release, and investors should not place undue reliance on these statements. Any forward-looking statements speak only as of the date of this press release. Acorda Therapeutics and Biogen Idec disclaim any intent or obligation to update any forward-looking statements as a result of developments occurring after the date of this press release.