

CURIS INC
Form 8-K
August 10, 2009

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): August 6, 2009

Curis, Inc.

(Exact name of registrant as specified in charter)

Delaware
(State or other jurisdiction
of incorporation)

000-30347
(Commission File Number)

04-3505116
(IRS Employer
Identification No.)

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45 Moulton Street, Cambridge, MA
(Address of principal executive offices)

02138
(Zip Code)

Registrant's telephone number, including area code: (617) 503-6500

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.

License Agreement with Debiopharm S.A.

On August 6, 2009, Curis, Inc. entered into a license agreement with Debiopharm S.A., a Swiss corporation pursuant to which Curis has granted to Debiopharm a worldwide, exclusive royalty-bearing license, with the right to grant sublicenses, to develop, manufacture, market and sell any product containing Curis Hsp90 inhibitor technology, including its lead Hsp90 compound under development, CUDC-305. Debiopharm will assume all future development responsibility and incur all future costs related to the development, registration and commercialization of products under the agreement. The agreement is effective as of August 5, 2009.

Pursuant to the terms of the agreement, Curis has agreed to use its reasonable commercial efforts to transfer to Debiopharm, know how, information and materials necessary for Debiopharm to continue the development of products in accordance with the development plan outlined in the agreement. Furthermore, at no cost to Debiopharm, Curis will provide a reasonable amount of technical, scientific and intellectual property support to the development plan, as requested by Debiopharm, during the first six months of the agreement.

Pursuant to the terms of the agreement, Debiopharm has agreed to undertake reasonable commercial efforts to implement the development plan in the timeframes described in the agreement in order to develop, register and commercialize the product in specified markets and will be solely responsible for all the costs relating thereto. Debiopharm will retain final decision making authority on all development, commercialization, marketing, manufacturing and regulatory matters relating to the product; provided, however, that Debiopharm will provide Curis the opportunity to review and comment on protocols for clinical trials of which Debiopharm or its affiliate will be the sponsor and proposed labeling for the product and further, that Debiopharm shall consider Curis comments with respect to such clinical trial protocols and product labeling in good faith.

If at any time Debiopharm definitively and formally suspends its research or development efforts for the product, or definitively and formally makes an internal determination to suspend research and development of the product, for a period exceeding 60 days, Debiopharm will notify Curis giving reasons and a statement of its intended actions.

Debiopharm is required to make IND or CTA filings within prescribed periods of time after specified conditions have been met by Curis, subject to the extension of such timeframes under specified circumstances. In any event, Debiopharm agrees to use reasonable commercial efforts to file an IND or CTA in a major market as promptly as practicable and agrees to use commercially reasonable efforts to develop at least one compound.

As consideration for the exclusive license rights provided in the agreement, and subject to the terms of the agreement, Debiopharm has agreed to pay Curis up to an aggregate of \$90 million comprised of the following:

an up-front license fee, to be paid within 30 days after Debiopharm's receipt of an invoice from Curis, provided that Curis has transferred to Debiopharm certain information specified in the agreement (Curis expects this payment to occur approximately 30 days following execution of the agreement);

a payment upon the first regulatory approval in a major market country of an open IND or CTA to initiate human clinical trials;

a payment upon the administration of CUDC-305 in the 5th patient in the first phase I clinical trial; and

additional contingent payments assuming the successful achievement of additional specified clinical development and regulatory approval objectives.

In addition, Debiopharm will pay Curis:

a specified percentage of all sublicensing payments received by Debiopharm and its affiliates from sublicensees;

a specified percentage of royalties Debiopharm and its affiliates receive from sublicensees; and

a specified percentage of royalties on net sales of products by Debiopharm or its affiliates.

The agreement is effective as of August 5, 2009, and unless terminated earlier will expire, on a country-by-country basis, on the later of (i) the expiration of the last-to-expire valid claim of the Curis patents and joint patents relating to the products, and (ii) the 10th anniversary of the first commercial sale of the product in such country. Pursuant to the agreement, either party can terminate the agreement upon notice under prescribed circumstances, and the agreement specifies the consequences to each party for such early termination.

Debiopharm may terminate the agreement prior to its expiration as follows:

At any time for any scientific, technical, administrative or commercial reasons upon 90 days' prior written notice to Curis.

If Debiopharm is permanently enjoined from exercising its license under the agreement pursuant to a patent infringement action brought by a third party, or if neither Debiopharm nor Curis undertakes the defense or settlement of a third party suit alleging infringement within the six-month period after notice of such suit, then Debiopharm may terminate the agreement in the country where such suit was filed upon thirty days' prior written notice to Curis.

Curis may terminate the agreement prior to its expiration as follows:

If Debiopharm fails to file an IND or CTA in a specified market on or before the applicable IND/CTA filing deadline set forth in the agreement, Curis may terminate the agreement on thirty days' written notice to Debiopharm unless Debiopharm makes such filing before the end of such thirty day period.

If Debiopharm does not correct a failure to use reasonable commercial efforts as set forth in the agreement, Curis may terminate the agreement on thirty days' written notice to Debiopharm unless Debiopharm cures such failure before the end of such thirty day period.

Either party may terminate the agreement prior to its expiration:

subject to certain conditions, upon ninety days' (or forty-five days' in the case of failure to make payment of amounts due under the agreement) prior written notice to the other party in the event of the material breach of any term or condition of the agreement by the other party, unless the breaching party has cured such breach by the end of the applicable cure period; and

immediately upon written notice to the other party if the other party or its affiliate directly, or through assistance granted to a third party, challenges, whether as a claim, a cross-claim, counterclaim, or defense, the validity or enforceability of any of such party's patents before any court, arbitrator, or other tribunal or administrative agency in any jurisdiction.

The agreement also sets forth certain customary terms regarding each party's intellectual property ownership rights, representations and warranties, indemnification obligations, confidentiality rights and obligations, patent prosecution, maintenance and defense rights and obligations, and the agreement of Curis, subject to certain exceptions, not to develop an Hsp90 inhibitor or product containing an Hsp90 inhibitor that competes with the product being developed under the agreement. In addition, Curis has agreed to indemnify, defend and hold harmless Debiopharm's sublicensees from and against any and all losses to which any sublicensee may become subject as a result of any claim by a third party solely to the extent such losses arise out of or result from Curis' breach of certain representation and warranties set forth in the agreement or breach of the foregoing non-compete.

The foregoing is a summary of the agreement, does not purport to be complete and is qualified in its entirety by reference to the agreement, which Curis intends to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ended September 30, 2009.

SIGNATURE

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.

Curis, Inc.

Date: August 10, 2009

By: /s/ MICHAEL P. GRAY
Michael P. Gray

Chief Operating Officer and Chief Financial Officer