

CURIS INC
Form 8-K
September 22, 2005

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): September 18, 2005

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.)

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

02138
(Zip Code)

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

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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))
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Item 1.01. Entry into a Material Definitive Agreement.

On September 18, 2005, Curis, Inc. (the "Company") entered into a Collaboration, Research and License Agreement (the "Agreement") with Procter & Gamble, Inc. and Procter & Gamble Pharmaceuticals, a division of The Procter & Gamble Company (collectively, "P&G"), to evaluate and develop potential treatments for hair growth regulation and skin disorders utilizing the Company's Hedgehog agonist technology.

Under the terms of the Agreement, the Company granted to P&G an exclusive, worldwide, royalty-bearing license for the development and commercialization of topical dermatological and hair growth products that incorporate the Company's Hedgehog agonist technology. Under the Agreement, the Company retains rights to veterinary applications of the technology, although P&G has a first option to negotiate a collaboration with the Company for veterinary indications in the field of dermatology, provided that the Company may not later enter into a collaboration with a third party on terms that are more favorable to such third party than those previously offered by P&G. The Company also retains rights to the technology for cardiovascular diseases and disorders in humans and for *ex vivo* use in cell therapy applications.

In accordance with the terms of the Agreement, the parties shall jointly undertake a research program with the goal of identifying one or more compounds to be developed and commercialized by P&G. The research program shall be conducted under the direction of the research steering committee, which shall be comprised of an equal number of representatives from each of the Company and P&G and shall meet at least four times per year during the research term. The research program shall have an initial term of one year and shall be subject to periodic extension at the election of P&G. The Company has agreed to initially devote to the research program at least two full time equivalent scientists. After the first twelve months of the research program, the research steering committee shall periodically review staffing needs and approve increases or decreases in the number of scientists to be devoted to the research program by the Company, provided that in no event shall P&G provide funding for fewer than two scientists during any contract year of the research program.

P&G is solely responsible for the cost of worldwide development and commercialization of any product candidates developed pursuant to the research program, provided however, that at the time that P&G determines to file the first investigational new drug application with the U.S. Food and Drug Administration for a product candidate, the Company shall have the option, at its sole discretion, to co-develop a product candidate through Phases 1 and 2 of clinical development.

Pursuant to the Agreement, P&G has agreed to make the following payments to the Company:

an initial cash payment of \$0.5 million in consideration of the licenses granted to P&G under the Agreement;

research support payments for the full time equivalent scientists devoted to the research program during the research term;

preclinical milestone payments totaling \$2.8 million, contingent upon the successful completion of certain research objectives;

up to over \$100 million in milestone payments if the collaboration continues for its full term and at least one product is commercialized by P&G worldwide in two indications and developed directly by P&G on a global basis;

a royalty on net sales of commercialized products derived from the collaboration, including any such products that P&G may license to a sublicensee; and

a higher royalty on such net product sales if the Company exercises its option to co-develop a product candidate through Phases 1 and 2 of clinical development, although the Company would have to forgo two early clinical milestone payments from P&G in order to receive such higher royalty.

Unless earlier terminated in accordance with the terms of the agreement, the Agreement shall continue until six months after the expiration of the last to expire of any patent rights covering a product being sold under the Agreement. Early termination rights are as follows:

During the first 12-months, the Agreement may not be terminated by either party, except in the case of breach, as discussed below, or failure of all, or all but one, of the licensed compounds to demonstrate acceptable results in certain tests as specified in the Agreement and the research plan. In the event of such failure, P&G may terminate the Agreement without cause and the related research obligations, with 45 days prior written notice.

Following the initial 12-month period, P&G shall have the right to terminate the Agreement without cause upon at least six (6) months prior written notice to the Company.

Upon or after the uncured breach of any material provision of the Agreement by a party, the other party may terminate the Agreement immediately upon written notice to the defaulting party.

If P&G terminates the Agreement without cause or the Company terminates the Agreement as a result of P&G's material breach, then, among other things, all licenses granted to P&G by the Company shall terminate. The Company shall have the exclusive option to acquire from P&G (with the right to license or sublicense) all data generated by P&G and all regulatory approvals and other regulatory filings and submissions, clinical data, promotional, advertising, marketing and distribution rights or contracts, and other similar information and items related to

the compounds developed during the collaboration by P&G, on commercially reasonable terms to be mutually agreed to by the parties. Upon termination of the Agreement by P&G as a result of a material breach by the Company, all rights and licenses granted by the Company to P&G under the Agreement shall terminate.

Statements made in this Form 8-K that are not historical facts, including statements regarding expectations for future contract value and future revenues, are forward-looking statements that are made pursuant to the safe harbor provisions of the Securities Litigation Reform Act of 1995. The Company undertakes no obligation to update any such forward-looking statements. Each of these statements is made as of the date hereof based only on current information and expectations that are inherently subject to change and involve a number of risks and uncertainties. Actual events or results may differ materially from those projected in any of such statements due to various factors. For a discussion of these factors, refer to the Company's annual report on Form 10-K for the year ended December 31, 2004 and the Company's most recent quarterly report on Form 10-Q for the quarter ended June 30, 2005, as well as the Company's other filings with the SEC.

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: September 22, 2005

By: /s/ Michael P. Gray

Michael P. Gray

Vice President of Finance and Chief Financial Officer

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