DERMA SCIENCES, INC.
Form 8-K
November 08, 2007

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): November 2, 2007

Derma Sciences, Inc.

(Exact name of registrant as specified in its charter)

Pennsylvania	1-31070	23-2328753
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS employer identification number)

214 Carnegie Center, Suite 300
Princeton, NJ 08540
(609) 514-4744
(Address including zip code and telephone number, of principal executive offices)

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 (*see* General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 November 2, 2007, Derma Sciences, Inc. (the Registrant) entered into a license agreement (the License Agreement) with the University of Southern California (USC) pursuant to which the Registrant acquired exclusive rights to 49 United States and foreign patents and non-exclusive rights to one patent, together with trade secrets and know-how, related to an angiotensin analog (the patents, trade secrets and know-how, collectively, the Angiotensin Analog Technology). The Angiotensin Analog Technology relates to a topical application for the treatment of chronic wounds such as diabetic ulcers, leg ulcers associated with venous insufficiency, pressure ulcers (bed sores), burns and surgical scars.

Not later than November 12, 2007 and December 2, 2007, the Registrant will pay to or on behalf of USC initial license fees of $539,348 and $300,000, respectively. The Registrant will pay USC royalties relative to sales of products employing the Angiotensin Analog Technology (the Angiotensin Analog Products or Products) at the rates of 6.5% and 8.5% in respect of revenues less than $100 Million and revenues equal to or greater than $100 Million, respectively. In addition, the Registrant will make milestone payments to USC of up to $9,625,000 predicated upon obtaining approval of the United States Food and Drug Administration (FDA) of various indications for the Angiotensin Analog Products as well as the attainment of various sales objectives. Further, the Registrant is obligated to spend at least $1,250,000 on direct marketing of the initial Angiotensin Analog Product within twelve months of the FDA s approval thereof.

The Compound employing the Angiotensin Analog Technology (Angiotensin Analog Compound or Compound) is classified as a drug the sale of which is conditioned upon FDA approval. The process of obtaining FDA approval for the Angiotensin Analog Compound consists of subjecting the Compound to a series of pre-clinical and clinical studies, these latter known as phase 1, phase 2 and phase 3 studies.

Pre-clinical studies typically involve animal models and are designed to determine a drug s initial dosing, beneficial effects (efficacy) and side effects. Phase 1 studies seek to refine dosing, document how the drug is metabolized and excreted and further identify side effects. Phase 1 studies typically involve a small number of healthy volunteers.

Phase 2 studies typically include more participants who have the condition that the drug is designed to treat. In phase 2 studies, researchers gather further safety data and preliminary evidence of the drug s efficacy and develop research methods for future studies. If the phase 2 studies indicate that the drug may be effective and its risks or side effects are acceptable, the drug moves to phase 3.

In phase 3 studies the drug is studied in a larger number of individuals with the disease. Phase 3 studies further test the drug s efficacy, monitor side effects and compare the drug s effects to one or more standard treatments or a placebo.

The Angiotensin Analog Compound has successfully undergone pre-clinical and phase 1 clinical studies. The phase 2 clinical studies will begin immediately and are expected to be concluded by the end of 2009. If the phase 2 clinical studies are successful, phase 3 clinical studies are expected to begin in January, 2010 and, barring unforeseen events, are expected to be

completed by the end of 2012. In the event the phase 3 clinical studies are successful, evaluation of the clinical studies by the FDA is expected to be completed by the end of 2013.

The Registrant s costs incident to conducting phase 2 and phase 3 clinical studies relative to the Angiotensin Analog Compound are expected to aggregate approximately $1.3 Million and $10.0 Million, respectively. The Registrant is under no obligation to undertake or complete phase 2 or phase 3 studies. Should it elect not to do so, the Registrant may either sublicense the Angiotensin Analog Technology to one or more pharmaceutical concerns or release the Technology to USC. In this latter event, USC would reimburse the Registrant for certain of its costs incident to clinical studies that have theretofore been performed.

The foregoing description of the License Agreement is qualified in its entirety by reference to the License Agreement a copy of which has been attached hereto as Exhibit 10.01.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

10.01 License Agreement

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DERMA SCIENCES, INC.

By: /s/ John E. Yetter
John E. Yetter, CPA
Vice President and Chief Financial Officer

Date: November 8, 2007

EXHIBIT INDEX

10.01 License Agreement