CARACO PHARMACEUTICAL LABORATORIES LTD
Form 8-K
July 16, 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

July 10, 2009

(Date of report)

CARACO PHARMACEUTICAL LABORATORIES, LTD.

(Exact name of registrant as specified in its charter)

| Michigan | 1-31773 | 38-2505723 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission file number) | (I.R.S. employer identification no.) |

1150 Elijah McCoy Drive, Detroit, Michigan 48202

(Address of principal executive offices)

(313) 871-8400

(Registrant’s telephone number, including area code)

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:

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 140.14a-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))

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

**Settlement Agreement**

On July 10, 2009, Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") entered into a settlement agreement ("Settlement Agreement") with Forest Laboratories, Inc. and Forest Laboratories Holdings Ltd. ("Forest"), H. Lundbeck A/S ("Lundbeck") and Sun Pharmaceutical Industries Limited and its affiliates, ("Sun Pharma"), regarding the pending patent litigation arising from the filing by Caraco of an ANDA application to market a generic version of Forest's Lexapro® brand escitalopram oxalate product.

Among other things, with respect to Caraco, the litigation settlement involves the following provisions:

1. Forest and Lundbeck have agreed to provide licenses to Caraco for any patents related to Lexapro® with respect to the marketing of Caraco's generic version of the product as of the dates that any third party generic enters the market with final approval from the FDA other than an authorized generic or the first filer with Hatch-Waxman related exclusivity.

2. By July 24, 2009, Forest shall make a nonrefundable payment to Caraco as reimbursement of a portion of Caraco's attorneys fees related to the litigation.

3. Pursuant to an Asset Purchase Agreement (the "Asset Purchase Agreement"), Caraco will take over the commercialization and sale of several products from Forest's Inwood business, as disclosed in greater detail below under "Asset Purchase Agreement."

In connection with the settlement agreement, Lundbeck and Sun Pharma will enter into a certain Patent License Agreement (the "Patent License Agreement").

The Settlement Agreement, Asset Purchase Agreement and Patent License Agreement have been submitted to the Federal Trade Commission ("FTC") and the Department of Justice ("DOJ") pursuant to the Medicare Modernization Act. The Asset Purchase Agreement is scheduled to close no sooner than 40 days after the submission to the FTC and DOJ, which the parties hope will provide the FTC and DOJ with sufficient time to review the transaction. As the transaction must be submitted to the FTC and DOJ, there is a possibility that the transaction may either be revised or not consummated. If the transaction is not consummated, the litigation may, as applicable, be continued from the point that it left off or reinstituted.

The foregoing description of the settlement does not purport to be complete and is qualified in its entirety by reference to the text of the Settlement Agreement, a copy of which Caraco intends to file with its Quarterly Report on Form 10-Q for the quarter ending September 30, 2009, requesting confidential treatment for certain portions.

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**Asset Purchase Agreement**

As disclosed above, as part of the Settlement Agreement, Caraco and Forest entered into an Asset Purchase Agreement dated July 10, 2009. Under the Asset Purchase Agreement, Caraco will take over the commercialization and sale of several products from Forest's Inwood business. Caraco's rights to market the products are subject to certain restrictions on its commercialization of competing products.

Caraco will pay Forest an advance against royalties and royalties on net sales of the products. Under the Asset Purchase Agreement, Forest and other third parties are to manufacture and supply the products. The Asset Purchase Agreement contemplates that Caraco intends to manufacture certain of such products at its own facilities in the future. In the event that Forest is unable to supply such products or in the event that Forest is unable to deliver certain products at closing, Caraco is entitled to certain consideration from Forest.

The closing of the transaction is subject to the satisfaction or waiver of certain conditions as specified in the Asset Purchase Agreement. As noted above under "Settlement Agreement," the transaction must be submitted to the FTC and DOJ; accordingly, there is a possibility that the transaction may either be revised or not consummated.

The foregoing description of the Asset Purchase Agreement does not purport to be complete and is qualified in its entirety by reference to the text of the Asset Purchase Agreement, a copy of which Caraco intends to file with its Quarterly Report on Form 10-Q for the quarter ending September 30, 2009, requesting confidential treatment for certain portions.

**Agreement With Alkaloida Chemical Company ZRT**

On July 10, 2009, Caraco entered into an agreement with Alkaloida Chemical Company ZRT, a Hungarian corporation ("Alkaloida") and indirect subsidiary of Sun Pharma, pursuant to which Alkaloida will provide for certain products an exclusive, non-transferable license to Caraco to manufacture and market the products in the United States, its territories and possessions, including Puerto Rico. The license for a product is for a period of five (5) years from the commencement of marketing of the product, however, Caraco may extend the license for a further five (5) year period. Alkaloida is required to deliver the product technology for a product as soon as it is developed or available or as agreed to by Caraco and Alkaloida.

Caraco is required, at its own expense, to perform an intellectual property analysis to determine whether a product will infringe on the intellectual property of any third party, to conduct all product tests, including bioequivalency studies, and to make all ANDA submissions to the FDA. Caraco is responsible for the costs of manufacturing and marketing each product. Alkaloida shall receive royalties on the net sales of each product. If marketing does not commence within one year of ANDA approval, subject to certain conditions, Caraco will be liable for certain payments to Alkaloida.



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Caraco is to own the ANDAs with respect to the products. Alkaloida has a right of first refusal if Caraco intends to sell an ANDA. Subject to the licenses, Alkaloida owns and retains all right, title and interest to the intellectual property rights of each product.

During the term of the agreement, Caraco is prohibited from, directly or indirectly, manufacturing, selling, distributing or marketing products of a third party with the same formulae and dosage strength as the products subject to the agreement.

If a third party infringes the intellectual property rights relating to a product, Caraco has the sole right to determine what action to take. Caraco shall bear the costs of such action, however, if an action is unsuccessful, Alkaloida shall reimburse a portion of such costs. Among other things, Alkaloida is required to indemnify Caraco for product liability arising from the development of a product, and Caraco is required to indemnify Alkaloida if a product infringes a third party's intellectual property rights under U.S. law.

The agreement expires five years from the date of approval of the first ANDA, unless renewed or extended for consecutive one (1) year periods, however, the licenses remain valid pursuant to the terms of the agreement. Under certain conditions, the agreement may be terminated in its entirety or with respect to one or more products. The agreement is governed by and construed in accordance with the laws of the State of Michigan. The agreement was approved by Caraco's Independent Committee comprised of Caraco's four independent directors.

The foregoing description of the agreement between Caraco and Alkaloida does not purport to be complete and is qualified in its entirety by reference to the text of the agreement, a copy of which Caraco intends to file with its Quarterly Report on Form 10-Q for the quarter ending September 30, 2009, requesting confidential treatment for certain portions.

**SIGNATURES**

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

CARACO PHARMACEUTICAL LABORATORIES, LTD.

(Registrant)

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| Date: | July 16, 2009 | By: | /s/ Daniel H. Movens |
| | | | Daniel H. Movens |
| | | | Chief Executive Officer |