

FOREST LABORATORIES INC  
Form 8-K  
September 20, 2010

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

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Pursuant to Section 13 OR 15 (d) of The Securities Exchange Act of 1934

September 15, 2010

Date of Report (Date of earliest event reported)

FOREST LABORATORIES, INC.  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation)

1-5438  
(Commission File Number)

11-1798614  
(IRS Employer Identification No.)

909 Third Avenue  
New York, New York  
(Address of principal executive  
offices)

10022-4731  
(Zip Code)

(212) 421-7850  
(Registrant's telephone number, including area code)

None

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(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 15, 2010, Forest Laboratories, Inc. (the “Company”) announced that it has finalized a previously reported agreement-in-principle to resolve all aspects of the investigations led by the United States Department of Justice (“DOJ”) and the United States Attorney’s Office for the District of Massachusetts that began in January 2004 relating to past marketing, sales, and other activities in connection with Celexa®, Lexapro®, and a formulation of Levothroid® that the Company ceased distributing in 2003. As part of this resolution, the Company and its wholly-owned subsidiary Forest Pharmaceuticals, Inc. (“FPI”) have entered into a Settlement Agreement, and FPI entered into a Plea Agreement. The Company also entered into a Corporate Integrity Agreement that applies to the operations of the Company, FPI and other Company subsidiaries. Each of these agreements is described below. The Settlement Agreement and Plea Agreement are subject to approval by the U.S. District Court for the District of Massachusetts, and the required payments described below are covered by the previously disclosed \$313 million plus interest in reserves that the Company had set aside in connection with the investigations.

1. Plea Agreement

FPI has agreed to plead guilty to a single felony charge of obstructing an agency proceeding, which relates to misstatements by certain Company plant employees to FDA inspectors during a November 2003 plant inspection, pursuant to a plea agreement (the “Plea Agreement”). In addition, pursuant to the Plea Agreement, FPI has also agreed to plead guilty to two strict liability, no-intent misdemeanor violations of the Food, Drug and Cosmetic Act relating to (1) the distribution of an unapproved new drug, Levothroid®, between August 2001 and August 2003 (following an FDA determination that the levothyroxine supplement drug class required NDA registration) and (2) the off-label promotion of Celexa® as a treatment for pediatric patients (for which Celexa® had not been approved) between 1998 and 2002. Neither misdemeanor charge includes as an element false or deceptive conduct. As part of the resolution of the criminal investigation, the Company has agreed to pay to the United States a fine of approximately \$150 million and a forfeiture payment of \$14 million.

2. Settlement Agreement

The Company and FPI also entered into a settlement agreement (the “Settlement Agreement”) to resolve civil claims asserted by DOJ under the False Claims Act and in qui tam lawsuits relating to allegations concerning (1) the distribution of Levothroid® without an NDA between August 2001 and August 2003, (2) off-label promotion of Celexa® and Lexapro® for pediatric use between 1998 and 2005 (prior to the FDA approval of Lexapro for the treatment of major depressive disorder in adolescents in March 2009), and (3) alleged payments of kickbacks to physicians. While the Settlement Agreement calls for the Company to make payments to the federal government and state Medicaid programs totaling approximately \$149 million plus interest, the Company expressly denies the allegations made in connection with the civil claims being settled. The Settlement Agreement will resolve the allegations contained in the civil complaint filed by the United States in February 2009, as well as the complaints filed by qui tam relators, and those complaints all will be dismissed.

### 3. Corporate Integrity Agreement

Also in connection with the Settlement Agreement, the Company has entered into a Corporate Integrity Agreement (“CIA”) with the Office of Inspector General of the U.S. Department of Health and Human Services. The CIA requires the Company to maintain its current compliance program and to undertake a set of defined corporate integrity obligations (which apply to the Company, FPI, and certain other operating subsidiaries) for a period of five years. The CIA also provides for an independent third-party review organization to assess and report on the Company’s compliance program.

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Item 9.01 Financial Statements and Exhibits.

- (a) Not Applicable.
- (b) Not Applicable.
- (c) Not Applicable.
- (d) Exhibits:

The following exhibits are furnished herewith:

Exhibit No.	Exhibit Description
99	Press release of Forest Laboratories, Inc. dated September 15, 2010.

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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.

Date: September 20, 2010

Forest Laboratories, Inc.  
(Registrant)

/s/ Francis I. Perier, Jr.  
Francis I. Perier, Jr.  
Senior Vice President - Finance and  
Chief Financial Officer

Exhibit Index

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