

ALLERGAN INC
Form 8-K
September 01, 2010

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

August 30, 2010

Date of Report (Date of Earliest Event Reported)

ALLERGAN, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State of Incorporation)

1-10269
(Commission File Number)

95-1622442
(IRS Employer

Identification Number)

2525 Dupont Drive

Irvine, California 92612

(Address of Principal Executive Offices) (Zip Code)

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(714) 246-4500

(Registrant's Telephone Number, Including Area Code)

N/A

(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.

On September 1, 2010, Allergan, Inc. (the "Company") announced that it reached resolution with the United States Department of Justice (the "DOJ") regarding the previously reported government investigation into the Company's past U.S. sales and marketing practices relating to certain therapeutic uses of *Botox*®. The Company hereby incorporates by reference the press release dated September 1, 2010 and filed as Exhibit 99.1 to this report (the "Settlement Press Release").

A copy of the agreement setting forth the terms and conditions of the civil settlement described in the Settlement Press Release (the "Federal Settlement Agreement") is filed as Exhibit 10.1 to this report and incorporated by reference herein. The Company, together with its subsidiary Allergan USA, Inc. ("Allergan USA"), entered into the Federal Settlement Agreement on August 31, 2010 with the United States of America, acting through the DOJ and the United States Attorney's Office for the Northern District of Georgia (the "USAO") and on behalf of the Office of Inspector General of the Department of Health and Human Services ("OIG-HHS"), the TRICARE Management Activity, the United States Office of Personnel Management, the United States Department of Veterans Affairs, and Office of Workers' Compensation Programs of the United States Department of Labor; and the relators in the *qui tam* actions identified in the Federal Settlement Agreement.

A copy of the Corporate Integrity Agreement described in the Settlement Press Release (the "Corporate Integrity Agreement") is filed as Exhibit 10.2 to this report and incorporated by reference herein. The Company entered into the Corporate Integrity Agreement with OIG-HHS on August 30, 2010. Failure to comply with its obligations under the Corporate Integrity Agreement could result in the Company incurring financial penalties or being excluded from participation in federal health care programs.

The proposed terms and conditions of the Company's plea to the misdemeanor misbranding charge referenced in the Settlement Press Release are set forth in a written agreement with the USAO (the "Plea Agreement") that the Company expects will be executed contemporaneously with the plea hearing in the United States District Court for the Northern District of Georgia (the "Court"). The plea hearing has not yet been scheduled. The recommended sentence in the Plea Agreement is subject to approval by the Court, and there can be no assurance that the Court will approve the Plea Agreement or regarding the timing of any such approval. The form of the Plea Agreement is filed as Exhibit 10.3 to this report and incorporated by reference herein.

The Federal Settlement Agreement provides for payment by the Company of a settlement amount of \$225 million, plus accrued interest, consisting of (1) a federal settlement amount of \$210.15 million, plus applicable accrued interest, payable to the United States within seven business days after the later of (a) execution of the Federal Settlement Agreement and (b) approval by the Court of the Plea Agreement and (2) a state settlement amount of \$14.85 million, plus applicable accrued interest, a designated portion of which state settlement amount and accrued interest would be payable to each U.S. state including as a state, for this purpose, the District of Columbia that enters into a separate state settlement agreement with the

Company and Allergan USA. If the Court does not accept the Company's guilty plea under, or impose the sentence contemplated by, the Plea Agreement, each of the Company or the United States may, at its option, elect to have the Federal Settlement Agreement become null and void and be rescinded.

The Plea Agreement provides for a sentence, to be imposed by the Court, requiring the Company to pay to the United States \$375 million, consisting of a \$350 million criminal fine and \$25 million in satisfaction of a forfeiture obligation, within 10 business days of the date of sentencing.

Both the Federal Settlement Agreement and the Plea Agreement are conditioned on the Company's dismissal with prejudice of the declaratory judgment action filed by the Company in October 2009 in the United States District Court for the District of Columbia, captioned Allergan, Inc. v. United States, et al., 1:09-cv-01879, in which the Company sought a ruling that it could proactively share truthful scientific and medical information with the medical community to assist physicians in evaluating the risks and benefits if they choose to use *Botox*® off-label to treat certain forms of spasticity.

The description of the Federal Settlement Agreement, the Corporate Integrity Agreement and the Plea Agreement in this Item 1.01 is not complete and is qualified in its entirety by the terms of the Federal Settlement Agreement, the Corporate Integrity Agreement and the form of Plea Agreement, copies of which are filed as Exhibit 10.1, 10.2 and 10.3, respectively, hereto and incorporated herein by reference. If the Court does not approve the Plea Agreement, there can be no assurance that the Federal Settlement Agreement will take effect as currently contemplated or at all or that any charges or claims to which the Plea Agreement, the Federal Settlement Agreement or the government investigation relates would ultimately be resolved in a manner consistent with, or not materially more adverse to the Company than, the terms and conditions that would apply under the Plea Agreement, the Federal Settlement Agreement and related state settlement agreements and the Corporate Integrity Agreement as described in this report.

Item 2.06. Material Impairments.

On August 31, 2010, the Company concluded that the intangible assets and a related prepaid royalty asset associated with the *Sanctura*® franchise (the *Sanctura*® Assets), which the Company acquired in connection with its October 2007 acquisition of Esprit Pharma Holding Company, Inc. and certain subsequent licensing and commercialization transactions, have become impaired. The Company determined that an impairment charge was required with respect to the *Sanctura*® Assets because the estimated undiscounted future cash flows over their remaining useful life were not sufficient to recover the current carrying amount of the *Sanctura*® Assets and the carrying amount exceeded the estimated fair value of those assets due to a recent reduction in expected future financial performance for the *Sanctura*® franchise resulting from lower than anticipated acceptance by patients, physicians and payers. As a result, the Company's third quarter and full year 2010 financial results are expected to include an aggregate non-cash pretax impairment charge of approximately \$340 million to \$350 million related to the *Sanctura*® Assets. The Company has not yet completed its analysis of the fair value of the *Sanctura*® Assets and expects to complete that analysis by the end of its third fiscal quarter. The

amount of the impairment charge is dependent upon a final determination of the fair value of the *Sanctura*® Assets. This non-cash impairment charge will have no effect on the Company's cash balances, cash flows from operating activities or ongoing operations, and the Company will continue to market and sell the *Sanctura*® product line.

Item 8.01. Other Events.

On September 1, 2010, the Company announced that it reached a resolution with the DOJ regarding the previously reported government investigation into the Company's past U.S. sales and marketing practices relating to certain therapeutic uses of *Botox*®. The Company hereby incorporates by reference (1) the press release dated September 1, 2010 and filed as Exhibit 99.1 to this report and (2) the disclosure in Item 1.01 of this report.

* * * * *

Statements made by the Company in this report that are not historical facts, including statements relating to the implementation and effect of the agreements described in Items 1.01 and 8.01 of this report, the estimated timing and amount of the pre-tax charges in connection with the global settlement with the DOJ, the timing of the payment of the global settlement costs and the timing, amount and impact of the impairment charge discussed in Item 2.06 of this report, are forward-looking statements. All forward-looking statements in this report reflect the Company's current analysis of existing trends and information and represent the Company's judgment only as of the date of this report. These statements are not guarantees of future performance and rely on a number of assumptions concerning future events, many of which are outside of the Company's control, and involve known and unknown risks and uncertainties that could cause the Company's actual results, performance or achievements to differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, among other things, the risk that the Court may not approve the Plea Agreement, the actual amount of interest and attorneys' fees for which the Company will be liable in connection with the global settlement with the DOJ, the outcome of further analysis of the valuation of the Company's *Sanctura*® and *Sanctura XR*® business, the results of any pending or future litigation and the Company's compliance with the Corporate Integrity Agreement. Additional such risks and uncertainties are described in press releases issued by the Company, including the press release filed as Exhibit 99.1 to this report, as well as the Company's public filings with the Securities and Exchange Commission, including the discussion under the heading

Risk Factors in the Company's Form 10-K for the fiscal year ended December 31, 2009 and Forms 10-Q for the quarters ended March 31, 2010 and June 30, 2010. Except as required under the federal securities laws and the rules and regulations of the U.S. Securities and Exchange Commission, the Company does not have any intention or obligation to update publicly any forward-looking statements made in this report, whether as a result of new information, future events, changes in assumptions or otherwise. The reader is cautioned not to rely on these forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

- 10.1 Settlement Agreement, dated August 31, 2010, among the United States of America, acting through the United States Department of Justice and the United States Attorney's Office for the Northern District of Georgia and on behalf of the Office of Inspector General of the Department of Health and Human Services, the TRICARE Management Activity, the United States Office of Personnel Management, the United States Department of Veterans Affairs, and Office of Workers' Compensation Programs of the United States Department of Labor; the relators identified therein; and Allergan, Inc. and Allergan USA, Inc.
- 10.2 Corporate Integrity Agreement, dated August 30, 2010, between the Office of Inspector General of the Department of Health and Human Services and Allergan, Inc.
- 10.3 Form of Plea Agreement between the United States Attorney's Office for the Northern District of Georgia as counsel for the United States and Allergan, Inc.
- 99.1 Press Release dated September 1, 2010

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.

ALLERGAN, INC.

Date: September 1, 2010

By: /s/ Matthew J. Maletta
Name: Matthew J. Maletta
Title: Vice President,
Associate General Counsel and Secretary

Exhibit Index

Exhibit	Description of Exhibit
10.1	Settlement Agreement, dated August 31, 2010, among the United States of America, acting through the United States Department of Justice and the United States Attorney's Office for the Northern District of Georgia and on behalf of the Office of Inspector General of the Department of Health and Human Services, the TRICARE Management Activity, the United States Office of Personnel Management, the United States Department of Veterans Affairs, and Office of Workers' Compensation Programs of the United States Department of Labor; the relators identified therein; and Allergan, Inc. and Allergan USA, Inc.
10.2	Corporate Integrity Agreement, dated August 30, 2010, between the Office of Inspector General of the Department of Health and Human Services and Allergan, Inc.
10.3	Form of Plea Agreement between the United States Attorney's Office for the Northern District of Georgia as counsel for the United States and Allergan, Inc.
99.1	Press Release dated September 1, 2010