

NOVARTIS AG
Form 6-K
October 01, 2010

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 or 15d-16 OF
THE SECURITIES EXCHANGE ACT OF 1934**

Report on Form 6-K dated September 30, 2010

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

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Form 20-F: ☒ **Form 40-F:** ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes: ☐ **No:** ☒

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes: ☐ **No:** ☒

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes: ☐ **No:** ☒

Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland
<http://www.novartis.com>

- Investor Relations Release -

Novartis Pharmaceuticals Corporation, a US subsidiary of Novartis AG, reaches settlement agreement with US Attorney's Office

- *Novartis Pharmaceuticals Corporation reaches resolution with US Attorney's Office for the Eastern District of Pennsylvania regarding civil and criminal allegations of the off-label promotion of Trileptal® as well as civil allegations relating to five other products*
- *NPC agrees to pay USD 422.5 million in criminal and civil claims; company to enter Corporate Integrity Agreement with Office of the Inspector General*
- *Payments are in line with provisions made for a potential agreement and disclosed and accounted for by Novartis*

Basel, September 30, 2010 Novartis Pharmaceuticals Corporation (NPC), a US subsidiary of Novartis AG, has reached a global resolution with the US Attorney's Office for the Eastern District of Pennsylvania (EDPA) regarding the previously disclosed investigation into civil and criminal allegations of the off-label promotion of Trileptal® as well as civil allegations relating to five other products: Diovan®, Exforge®, Sandostatin®, Tekturna® and Zelnorm®. Under the agreement, the company will pay a total of USD 422.5 million in criminal and civil claims.

Novartis had previously disclosed information regarding the EDPA investigation. This disclosure included the total monetary provisions amounting to USD 422.5 million that were set aside and disclosed in the second quarter of 2010 for the civil and criminal Trileptal investigations and the five products investigation.

In 2005, NPC received a subpoena from the EDPA related to promotional practices with respect to Trileptal. Prior to receiving the subpoena, NPC had already taken steps to correct the challenged practices and comply with new government guidance. NPC cooperated fully with the government throughout the course of this investigation, as well as the investigations of the five other products covered under the settlement. As part of this settlement totaling USD 422.5 million in criminal and civil claims, NPC will plead guilty to one misdemeanor violation of misbranding under the US Food, Drug and Cosmetic Act and pay a fine of USD 185 million for Trileptal. NPC has also resolved civil allegations under the False Claims Act related to all six drugs and agreed to pay USD 237.5 million in civil claims.

We are pleased to have reached resolution on this matter. NPC will continue its commitment to high standards of ethical business conduct and regulatory compliance in the sale and marketing of our products," said Andy Wyss, Head of Novartis Pharma North America and President of Novartis Pharmaceuticals Corporation. Our goal is to ensure that patients receive the medicines they need and we will continue to work with the

government and other organizations to improve healthcare for all Americans.

As part of the settlement, the Company will also be entering into a Corporate Integrity Agreement with the Office of the Inspector General of the US Department of Health and Human Services. Under the terms of this agreement, NPC will implement for five years additional compliance-related measures, which include additional monitoring, auditing, training, education, reporting and disclosures. This agreement will expand upon the Company's already strong commitment to sustainable performance built on a solid foundation of ethical values at all levels of business.

In addition to adhering to the principles of ethical business conduct outlined in the NPC Code of Conduct, NPC associates are guided by the specific standards for marketing activities described in the NPC Ethics & Compliance Policy. The Company is firmly committed to these guidelines and strengthens its compliance practices and policies on a continuing basis.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as "potential," "will," "commitment," "goal," "committed," or similar expressions, or by express or implied discussions regarding the potential future impact upon NPC of the compliance-related measures required by the Corporate Integrity Agreement. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantees as to the actual impact that the compliance-related measures required by the Corporate Integrity Agreement will have on NPC. In particular, management's expectations regarding the impact upon NPC of the settlement agreement and the Corporate Integrity Agreement could be affected by, among other things, unexpected difficulties in implementing or carrying out the agreements; the impact that the foregoing factors could have on the values attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis

Novartis provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2009, the Group's continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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Novartis Media Relations

Central media line : +41 61 324 2200

Eric Althoff

Novartis Global Media Relations

+41 61 324 7999 (direct)

+41 79 593 4202 (mobile)

eric.althoff@novartis.com

Anna Frable

Novartis Pharma Communications

+1 862 778 5388 (direct)

+1 732 673 5262 (mobile)

anna.frable@novartis.com

Brandi Robinson

Novartis Corporate Communications

+1 212 830 2457 (direct)

+1 862 210 0852 (mobile)

brandi.robinson@novartis.com

e-mail: media.relations@novartis.com

Novartis Investor Relations

Central phone:

+41 61 324 7944

Susanne Schaffert

+41 61 324 3769

Pierre-Michel Bringer

+41 61 324 1065

Thomas Hungerbuehler

+41 61 324 8425

Isabella Zinck

+41 61 324 7188

North America:

Richard Jarvis

+1 212 830 2433

Edwin Valeriano

+1 212 830 2456

Jill Pozarek

+1 212 830 2456

e-mail: investor.relations@novartis.com

e-mail: investor.relations@novartis.com

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, thereunto duly authorized.

Novartis AG

Date: September 30, 2010

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham
Title: Head Group Financial
Reporting and Accounting