NOVARTIS AG
Form 6-K
July 05, 2011

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 July 1, 2011

(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:

Form 20-F: x Form 40-F: o

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: o **No**: x

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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: o **No**: x

Novartis International AG

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- Investor Relations Release -

Novartis receives approval in Japan for Onbrez® Inhalation Capsules, a novel once-daily bronchodilator therapy for patients with COPD

- *Onbrez is the only once-daily long-acting beta2-agonist (LABA) approved in Japan for treatment of chronic obstructive pulmonary disease*

- *Clinical data show that Onbrez provides rapid and sustained improvement in lung function lasting for 24 hours, and improves breathlessness and quality of life(1)-(6)*

- *COPD is a progressive lung disease causing disability and death that could affect up to 5.3 million people in Japan(7)*

Basel, July 1, 2011 Novartis announced today that it has received regulatory approval in Japan for Onbrez® Inhalation Capsules (indacaterol) 150 mcg once-daily for the treatment of chronic obstructive pulmonary disease (COPD). Onbrez is the only once-daily COPD therapy to combine improvements in lung function lasting for 24 hours(1),(2),(3) with a rapid onset of action within five minutes of the first dose(4),(5).

Indacaterol is a novel bronchodilator that offers a unique combination of fast- and long-acting properties, said Senior Professor Atsushi Nagai of the First Department of Medicine at Tokyo Women s Medical University. In addition to the convenience of once-daily dosing, it has shown benefits in terms of reduced breathlessness and improved quality of life, and could provide a promising new treatment option for Japanese patients with COPD.

Onbrez, delivered using the Breezhaler® device, belongs to the long-acting beta2-agonist (LABA) class of medicines which help to reduce the symptoms of breathlessness, cough and sputum in COPD patients by increasing bronchodilation, or airflow into the lungs. The Japanese Ministry of Health, Labor and Welfare (MHLW) has approved Onbrez for relief of symptoms due to airway obstruction in COPD (chronic bronchitis and emphysema).

The submission was supported by a clinical trial program that included three local clinical studies. The pivotal 12-week Phase III study was conducted in Japan and five other Asian countries and involved 347 patients with moderate-to-severe COPD(6). This study showed that Onbrez given once-daily produced significant improvements in lung function (measured by trough FEV1, or forced expiratory volume of breath in one second) compared to placebo, as well as reducing breathlessness and improving quality of life(6). The incidence of adverse events was lower than for placebo(6). Altogether, these three studies involved a total of 388 Japanese patients.

We are pleased that the health authorities in Japan have recognized the positive benefit-risk profile of Onbrez for patients suffering from this serious and life-threatening disease, said David Epstein, Head of the Pharmaceuticals Division of Novartis. Investing in Japan and building upon

our leading presence is a key priority for us, and we welcome the fact that patients there will have access to this important medicine.

COPD is a chronic, progressive lung disease that is commonly caused by tobacco smoking, air pollution or occupational exposure, and results in airflow obstruction and debilitating bouts of breathlessness. Although the latest figures show only 173,000 people have been diagnosed with COPD in Japan(8), epidemiological data suggest that the total number of patients could be as high as 5.3 million(7). There are concerns that the number of patients could grow in Japan where smoking rates are high and many people are starting to smoke at an increasingly early age.

Indacaterol was first approved in November 2009 in the European Union under the brand-name Onbrez® Breezhaler® and has now been approved in more than 60 countries, including Turkey in May 2011. It is available in more than 30 countries with additional launches planned during 2011. In the US, the Food and Drug Administration (FDA) is expected to complete its review of the new drug application by July 2011. If approved in the US the brand name will be Arcapta Neohaler .

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as could, promising, priority, will, launches, planned, expected, proposed, or similar expressions, or by express or implied discussions regarding potential additional marketing approvals for Onbrez, or the timing or any such approvals, or regarding potential future revenues from Onbrez. 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 with Onbrez to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Onbrez will be approved for sale in any additional markets, or at any particular time. Nor can there be any guarantee that Onbrez will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Onbrez could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; competition in general; government, industry and general public pricing pressures; 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, eye care, cost-saving generic pharmaceuticals, consumer health products, preventive vaccines and diagnostic tools. Novartis is the only company with leading positions in these areas. In 2010, the Group s continuing operations achieved net sales of USD 50.6 billion, while approximately USD 9.1 billion (USD 8.1 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 119,000 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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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: July 1, 2011

By: /s/ MALCOLM B. CHEETHAM

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