

NOVARTIS AG
Form 6-K
August 24, 2009

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 August 24, 2009

(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

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- Investor Relations Release -

Novartis receives approval in EU for Xolair® to treat children age 6 to 11 years suffering from severe persistent allergic asthma

- *Landmark study shows Xolair reduces asthma attacks by 50 percent at one year(1) with a good overall safety and tolerability profile in children age 6 to 11 years(2),(3),(4)*
- *Severe asthma is uncontrolled in over 50 percent of young patients(5), often leading to hospitalization(5), missed school days(6) and need for oral corticosteroids(5)*
- *Approved as add-on therapy, Xolair offers a new treatment approach to nearly 35,000 children in the EU with uncontrolled severe persistent allergic asthma(7)*

Basel, 24 August, 2009 Novartis announced today that the European Commission (EC) has approved Xolair® (omalizumab) as add-on therapy for severe persistent allergic asthma in children age 6 to 11 years. Xolair is the only approved therapy that targets an underlying mechanism of asthma and is already approved for use in patients aged 12 years and older.

Asthma is a chronic lung disease, characterized by recurrent attacks of breathlessness, that is estimated to affect 10 percent of children in Europe(8). It is also the most common cause of school absenteeism(6) and often leads to the need for oral corticosteroid use in children(5). Despite conventional therapy, severe asthma remains uncontrolled in more than 50 percent of children with this condition(5).

When a chronic and serious disease like asthma affects children, it can have life-changing and even life-threatening consequences, said Joe Jimenez, CEO of the Novartis Pharmaceuticals Division. This EC approval of Xolair offers young asthma patients new hope against this disease, in line with the Novartis commitment to develop innovative respiratory health solutions that meet patients' and physicians' needs.

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EC approval was based in part on a landmark study, presented at the European Respiratory Society Annual Congress in 2008, showing that Xolair reduced asthma attacks by 34 percent after 24 weeks of treatment(2) and provided an overall reduction of 50 percent at one year in patients age 6 to 11 years(1). Xolair also demonstrated a good overall safety and tolerability profile, consistent with that observed in the adult and adolescent population(6).

In another study, Xolair, when used in children age 6 to 11, was shown to significantly reduce the need for oral corticosteroids(9). Children taking Xolair also missed 46 percent fewer school days(9).

Xolair, a humanized monoclonal antibody, is a unique treatment which blocks the action of immunoglobulin E (IgE), an antibody involved in the underlying mechanism of allergic asthma. By targeting IgE, Xolair can prevent the onset of debilitating symptoms, such as shortness of breath and wheezing, in severely affected patients. Xolair was approved as add-on therapy in the EU in

2005 for patients 12 years and older with severe persistent allergic asthma. Xolair is currently approved in 63 countries and has been used to treat more than 62,000 patients.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as can, hope, commitment, or similar expressions, or by express or implied discussions regarding potential future revenues from Xolair. 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 Xolair to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Xolair will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Xolair 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; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; 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, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in each of these areas. In 2008, the Group's continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 99,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

References

- (1) EU summary of product characteristics (SmPC) for XOLAIR (August 2009).
- (2) Kulus M, Bridges T, Fowler Taylor A, et al. A randomized controlled study of omalizumab in children with moderate-to-severe persistent allergic asthma. Poster presented at the 18th European Respiratory Society Congress, October 4 - 8 2008, Berlin, Germany.
- (3) Milgrom H, Wasserman RL, Fowler-Taylor A, et al. Add-on omalizumab significantly reduces exacerbation rates in children with inadequately controlled moderate-to-severe allergic (IgE-mediated) asthma. Poster presented at American Thoracic Society (ATS) International Conference, San Diego, California, USA. May 15 - 20, 2009.
- (4) Milgrom H, Fink J, Fowler-Taylor A, et al. Safety of omalizumab in children with inadequately controlled moderate-to-severe allergic (IgE-mediated) asthma. Poster presented at American Thoracic Society (ATS) International Conference, San Diego, California, USA. May 15 - 20, 2009.

- (5) Chipps BE, Szeffler SJ, Simons FE, et al. Demographic and clinical characteristics of children and adolescents with severe or difficult-to-treat asthma. J Allergy Clin Immunol 2007;119:1156-63.
- (6) Chipps BE. Asthma in infants and children. Clin Cornerstone 2008;8:44-61.
- (7) Data on file: Novartis Quantitative Research based on feedback from 300 Paediatricians in EU.
- (8) <http://www.euro.who.int/childhealthenv/Risks/AsthmaTop> (accessed 3 August 2009).
- (9) Milgrom H, Berger W, Nayak A, et al. Treatment of childhood asthma with anti-immunoglobulin E antibody (omalizumab). Pediatrics 2001;108;2:1-10.

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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: August 24, 2009

By: /s/ MALCOLM B. CHEETHAM

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