

NOVARTIS AG  
Form 6-K  
September 20, 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 19, 2010**

(Commission File No. 1-15024)

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**Novartis AG**

(Name of Registrant)

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**4056 Basel**

**Switzerland**

(Address of Principal Executive Offices)

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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):

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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:       **No:**

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**- Investor Relations Release -**

**Novartis study shows Onbrez® Breezhaler® is superior to salmeterol in reducing breathlessness for patients with COPD**

- *Phase III INSIST study shows once-daily Onbrez Breezhaler gave better 24-hour bronchodilation than twice-daily salmeterol(1), a current mainstay of treatment*
- *Data show Onbrez Breezhaler significantly reduced use of rescue medication in patients with chronic obstructive pulmonary disease (COPD)(1)*
- *New results provide further evidence that Onbrez Breezhaler is a highly effective treatment option for patients with this potentially life-threatening disease*

**Basel, September 19, 2010** Results of the Phase III INSIST study show that Onbrez® Breezhaler® (indacaterol) given once-daily is significantly better at improving lung function and reducing breathlessness than twice-daily salmeterol(1), one of the current mainstays of treatment for patients with chronic obstructive pulmonary disease (COPD).

Patients with COPD using the novel Onbrez Breezhaler were also able to reduce their use of rescue medication compared to those using salmeterol(1), a widely prescribed drug in the long-acting beta-2 agonist (LABA) class. Onbrez Breezhaler has been described in scientific literature as the first ultra-LABA reflecting its longer duration of action compared to older LABAs(2).

Data from the INSIST study involving 1,123 patients aged 40 years or above in seven countries were presented today at the European Respiratory Society (ERS) congress in Barcelona, Spain. Results showed that Onbrez Breezhaler 150 µg once-daily provided superior 24-hour bronchodilation to salmeterol 50 µg twice-daily at the end of 12 weeks treatment(1).

Patients with COPD require treatment that combines a sustained improvement in lung function with better clinical outcomes, said the study's principal investigator, Dr Stephanie Korn from the Pulmonary Department at Mainz University Hospital in Germany. The results of INSIST confirm that indacaterol is potentially an attractive maintenance treatment option for these patients.

COPD is a progressive, life-threatening disease associated with tobacco smoking, air pollution or occupational exposure, which causes obstruction of airflow in the lungs resulting in debilitating bouts of breathlessness. Although often considered a disease of the elderly, research

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has shown that a majority of COPD patients are under the age of 65(3), when they are likely to be at the peak of their earning power and family responsibilities.

INSIST was a 12-week, randomized, double-blind, head-to-head study involving patients with moderate-to-severe COPD (as defined by the GOLD 2007 criteria(4)). The study met its primary endpoint with Onbrez Breezhaler giving superior bronchodilation to salmeterol at week 12(1). This was assessed by measuring patients' forced expiratory volume of breath in one second (FEV1)

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from five minutes to 11 hours 45 minutes post-dose (mean difference in FEV1 area under curve 60 mL,  $p < 0.001$ )(1). Onbrez Breezhaler showed superiority for this assessment in all subgroups of patients(1).

In addition, Onbrez Breezhaler significantly increased the proportion of patients with a clinically relevant reduction in breathlessness compared to salmeterol (69.4% vs. 62.7% achieved a score of at least one in the transition dyspnea index,  $p < 0.05$ ), and the number of days on which patients did not require rescue medication (mean difference 4.4%,  $p < 0.05$ )(1). Both treatments were well tolerated in the study(1).

By demonstrating the benefits that Onbrez Breezhaler can bring to patients with COPD, this study affirms our confidence in this medicine and in the indacaterol-based combination therapies currently under development, said Trevor Mundel, MD, Global Head of Development at Novartis AG. Novartis is committed to providing innovative treatment options for patients with COPD and their physicians as part of our long-standing involvement in the field of respiratory medicine.

The INSIST study findings are supported by recently published data from the 26-week INLIGHT-2 Phase III study involving 1,002 patients with moderate-to-severe COPD(5). In this study, Onbrez Breezhaler 150 µg once-daily provided a greater improvement in lung function after 12 weeks than salmeterol 50 µg twice-daily or placebo (24-hour trough FEV1 increased by 60 mL more than salmeterol and 170 mL more than placebo, both  $p < 0.001$ )(5). Safety profiles were similar across the treatment groups and both active treatments were well tolerated(5).

Onbrez Breezhaler is approved in more than 40 countries including the European Union, Switzerland, Australia, India, Indonesia, Korea, and a number of countries in Latin America. It is indicated in Europe for the maintenance bronchodilator treatment of airflow obstruction in adult patients with COPD(6). US approval is subject to the FDA's review of additional clinical data that Novartis expects to file by the end of 2010.

In clinical studies, the most commonly reported adverse reactions with Onbrez Breezhaler were nasopharyngitis, upper respiratory tract infection, cough and headache(6).

COPD affects 210 million people worldwide(7) and is projected to be the third leading cause of death by 2020(8). The symptoms cause profound disability and COPD is a major burden on individual patients, their families, and society at large. Early diagnosis and effective treatment are a key priority, because although COPD is incurable, the disease is manageable with appropriate therapies.

## Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potentially, can, expects, confidence, development, commitment, or similar expressions, or by express or implied discussions regarding potential additional marketing approvals for Onbrez Breezhaler or regarding potential future revenues from Onbrez Breezhaler. 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 Breezhaler to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Onbrez Breezhaler will be approved for sale in any additional markets. Nor can there be any guarantee that Onbrez Breezhaler will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Onbrez Breezhaler 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

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analysis of existing clinical data; competition in general; government, industry and general public pricing pressures; the company's ability to obtain or maintain patent or other proprietary intellectual property protection;

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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 102,000 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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## References

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- (3) Data on file, Novartis Pharma AG.
- (4) Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. Updated 2007. Available at: <http://www.goldcopd.com/Guidelineitem.asp?11=2&12=1&intId=1955>. Last accessed 16 September 2010.
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- (6) Onbrez Breezhaler (indacaterol) Summary of Product Characteristics. November 2009.
- (7) WHO. Factsheet No 315: Chronic obstructive pulmonary disease (COPD), Available at: [www.who.int/mediacentre/factsheets/fs315/en/index.html](http://www.who.int/mediacentre/factsheets/fs315/en/index.html). Last accessed 16 September 2010.
- (8) Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. Updated 2009. Available at: <http://www.goldcopd.com/Guidelineitem.asp?11=2&12=1&intId=2003>. Last accessed 16 September 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, thereunto duly authorized.

**Novartis AG**

Date: September 19, 2010

By:

/s/ MALCOLM B. CHEETHAM

Name:

Malcolm B. Cheetham

Title:

Head Group Financial  
Reporting and Accounting

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