

NOVARTIS AG  
Form 6-K  
October 08, 2008

# 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 October 7, 2008**

**(Commission File No. 1-15024)**

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**Novartis AG**

(Name of Registrant)

**Lichtstrasse 35**

**4056 Basel**

**Switzerland**

(Address of Principal Executive Offices)

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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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Yes: ☐ **No:** ☒

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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 -**

**New Phase II data on NVA237, a novel once-daily treatment for COPD, show promising efficacy and tolerability with potentially faster onset than tiotropium**

- *NVA237 demonstrated sustained 24-hour bronchodilation with efficacy comparable to tiotropium and potentially faster onset of action(1)*
- *Data show NVA237 was well tolerated with good overall safety profile and no clinically relevant cardiovascular findings(2)*
- *Chronic obstructive pulmonary disease (COPD) affects 210 million people worldwide(3) projected to be the third leading cause of death by 2030(4)*

**Basel, October 7, 2008** New Phase II data show that NVA237 (glycopyrronium bromide), a novel inhaled long-acting muscarinic antagonist (LAMA), provides sustained 24-hour bronchodilation in patients with moderate-to-severe COPD(1). NVA237 showed similar efficacy and duration of action to tiotropium with potentially a more rapid onset of action(1).

In addition, studies lasting up to 28 days showed that NVA237 was safe and well tolerated with no clinically relevant cardiovascular findings(1),(2). The results were presented at the annual congress of the European Respiratory Society (ERS) in Berlin, Germany.

Chronic obstructive pulmonary disease (COPD) is a progressive lung disease that currently affects 210 million people worldwide(3) and is projected to be the third leading cause of death by 2030(4). While there is no cure, bronchodilators such as LAMAs make breathing easier by enlarging the patient's airways, and are recognized in international guidelines as first-line treatment for COPD(5).

COPD is a complex and debilitating disease that can have a devastating impact on patients and their families, said Prof. Claus Vogelmeier of the University Hospital Giessen and Marburg, Germany. There is a need for new therapies that give instant relief from debilitating symptoms such as shortness of breath, and provide a sustained benefit that can help to improve patients' quality of life.

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Novartis is developing a comprehensive range of therapies for patients with respiratory diseases. NVA237 is an important element in the portfolio of once-daily inhaled drugs and is also being investigated as a possible fixed-dose combination with the novel once-daily long-acting beta2-agonist QAB149, currently in Phase III development.

One of the randomized, double-blind, placebo-controlled studies compared NVA237 (12.5, 25, 50 and 100µg once-daily) with placebo and open-label tiotropium(1). In the study involving 83 patients,

all doses of NVA237 showed rapid onset of action and sustained 24-hour bronchodilation over the seven-day treatment period(1).

Clinically relevant improvements (i.e. >120mL more than placebo) in forced expiratory volume in one second (FEV1), a standard measure of lung function, were observed with both the 50 and 100µg doses of NVA237(1). Early post-dose spirometry data suggested a more rapid onset of action than tiotropium(1). During the study, NVA237 was well tolerated with a good overall safety profile(1).

The other study evaluated the safety and tolerability of NVA237 (100 and 200µg once-daily) in 250 patients during 28 days of treatment(2). In this study both doses were safe and well tolerated, with no clinically significant changes seen in vital signs or other cardiac monitoring(2). NVA237 provided sustained 24-hour bronchodilation over the study period(2). The authors concluded that NVA237 should be further evaluated for the treatment of COPD(2).

The results of the latest studies are consistent with previous clinical studies with NVA237 which demonstrated a potentially faster onset of action than tiotropium (five minutes versus 20-30 minutes)(6) and a good overall safety and tolerability profile(7),(8).

Novartis is committed to the development of innovative, once-daily inhaled products that provide immediate and sustained bronchodilation to relieve the symptoms of airway obstruction, said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG. Our extensive late-stage portfolio of once-daily and fixed-dose combination inhaled products is designed to address the unmet need in respiratory diseases, and we look forward to moving forward with the development of these therapies as rapidly as possible.

NVA237 was licensed to Novartis in 2005 by Sosei Group Corporation and Vectura Group plc.

## Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as promising, potentially, planned, projected, can, possible, suggested, committed, designed to, look forward to, or similar expressions, or by express or implied discussion regarding potential approvals to market NVA237 or regarding potential future revenues from NVA237. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with NVA237 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that NVA237 will be approved for sale in any market. Nor can there be any guarantee that NVA237 will achieve any particular levels of revenue in the future. In particular, management's expectations regarding NVA237 could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; 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 AG 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 2007, the Group's continuing operations (excluding divestments in 2007) achieved net sales of USD 38.1 billion and net income of USD 6.5 billion. Approximately USD 6.4 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,000 full-time associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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## References

- (1) Overend et al. Dose-ranging study to assess the efficacy and tolerability of NVA237, a once daily long-acting muscarinic antagonist, in patients with COPD. Presented at ERS, 4-8 October 2008 (Poster 3606).
- (2) Vogelmeier et al. Safety and tolerability of NVA237, a once-daily long-acting muscarinic antagonist, in patients with COPD. Presented at ERS, 4-8 October (Oral presentation 2735).
- (3) World Health Organization. Factsheet No 315 Chronic obstructive pulmonary disease (COPD). <http://www.who.int/mediacentre/factsheets/fs315/en/index.html> (accessed 26 September 2008)
- (4) World Health Organization. Chronic obstructive pulmonary disease (COPD). <http://www.who.int/respiratory/copd/en/> (accessed 26 September 2008)
- (5) Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2007. <http://www.goldcopd.org> (accessed 26 September 2008)
- (6) Kuna et al. Eur Respir J 2007;30(Suppl. 51):354s, (P2135).
- (7) Gunawardena et al. Proceedings of the American Thoracic Society 2006;3:A117; Gunawardena et al. Eur Respir J 2006;28(Suppl. 50):527s (P3050).
- (8) Singh et al. Proceedings of the American Thoracic Society 2006;3:A113; Singh et al. Eur Respir J 2006;28(Suppl. 50):527s (P3051).

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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: October 7, 2008

By: /s/ MALCOLM B. CHEETHAM

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