NOVARTIS AG
Form 6-K
September 29, 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 September 27, 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

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: o **No**: x

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
Novartis Global Communications
CH-4002 Basel
Switzerland
http://www.novartis.com

- Investor Relations Release -

New Novartis data show potential of respiratory portfolio to help COPD patients maintain active and productive lives

- *Studies show investigational once-daily NVA237 provides superior 24-hour bronchodilation and increases exercise endurance relative to placebo(1),(2)*

- *Additional data show NVA237 significantly prolonged time to first moderate/ severe COPD exacerbation and reduced associated hospitalizations(3)*

- *NVA237 submitted for EU approval under brand-name Seebri® Breezhaler® for treatment of chronic obstructive pulmonary disease (COPD)*

Basel, September 27, 2011 Novartis has presented new Phase III data at the European Respiratory Society (ERS) congress demonstrating the potential for its portfolio of once-daily inhaled therapies to help patients with chronic obstructive pulmonary disease (COPD) to maintain more active and productive lives.

The GLOW1 and GLOW3 studies show that investigational NVA237 (glycopyrronium bromide) significantly increased patients lung function compared to placebo with a fast onset of action at first dose, as well as improving exercise endurance. NVA237 is a new drug in the long-acting anti-muscarinic (LAMA) class which has recently been submitted for approval in the European Union under the brand-name Seebri® Breezhaler®.

These results illustrate the potential benefits of NVA237 for COPD patients and are especially encouraging as we move ahead with plans to develop a fixed-dose combination with Onbrez® Breezhaler®, our once-daily therapy in the LABA class, said David Epstein, Division Head of Novartis Pharmaceuticals. This investigational combination of two bronchodilators with complementary modes of action is designed to give COPD patients access to the two leading classes of therapy in a single inhaler for the first time.

The studies, presented at the ERS congress in Amsterdam, The Netherlands, underscore the company s commitment to developing innovative medicines to treat this life-threatening disease. Although COPD is often thought of as a disease of the elderly, 50% of patients are estimated to

be below the age of 65, and are likely to be at the peak of their earning power and family responsibilities(4),(5),(6).

The GLOW1 study met its primary endpoint by showing that NVA237 50 mcg once-daily produced a significant improvement in lung function of 108 mL in trough FEV1(1) after 12 weeks in patients with moderate-to-severe COPD compared to placebo ($p<0.001$)(1). Moreover, NVA237 had a rapid onset of action, with a 93 mL improvement in FEV1 compared to placebo at five minutes post-dose following the first dose on the first day of treatment ($p<0.001$)(1).

(1) Forced expiratory volume of breath in one second

NVA237 also significantly prolonged the time to first moderate/severe COPD exacerbation compared to placebo, and reduced the percentage of associated hospitalizations(3). Significant improvement in breathlessness was seen at 26 weeks compared to placebo, accompanied by a significant improvement in health-related quality of life and reduction in the use of rescue medication(7).

The GLOW3 study investigated the effects of NVA237 50 mcg once-daily on exercise endurance in moderate-to-severe COPD patients. The study met its primary endpoint by showing a significant 21% improvement in exercise endurance versus placebo at the end of the study (i.e. day 21), with a significant 10% increase from day one (both $p<0.001$)(2).

Both studies showed that NVA237 was well-tolerated, with a similar incidence of adverse events for patients treated with NVA237 and placebo(1),(2),(3),(7).

These results provide important new insights into the potential effects of NVA237 in improving lung function and relieving symptoms such as breathlessness, said Dr Kai-Michael Beeh of the insaf Respiratory Research Institute in Wiesbaden, Germany, the principal investigator of the GLOW3 study. The improvements in exercise endurance are significant as exercise limitation is a considerable burden for COPD patients, affecting everyday activities such as climbing the stairs. These trials show that NVA237 may provide a future option that could positively impact the way COPD is treated.

New analyses of Onbrez Breezhaler data at ERS

New pooled analyses of data were also presented confirming the efficacy of Onbrez Breezhaler (indacaterol), a long-acting beta2-agonist (LABA) approved in more than 70 countries for the maintenance treatment of COPD.

One pooled analysis examined the efficacy of Onbrez Breezhaler in patients with moderate or less, and severe or worse COPD (defined as stages I-II and III IV respectively in the GOLD guidelines(8)). This showed that Onbrez Breezhaler 150 and 300 mcg once-daily significantly improved lung function in both subgroups at six months compared to placebo ($p<0.001$)(9). The analysis also showed that in the more severe subgroup, Onbrez Breezhaler 300 mcg was significantly more effective than 150 mcg in improving breathlessness compared to baseline, as assessed using the Transition Dyspnea Index (TDI) ($p<0.05$)(9).

A second pooled analysis showed that Onbrez Breezhaler 150 and 300 mcg improved lung function regardless of patients background use of ICS. In patients not using ICS, the improvements in lung function were 180 and 170 mL with Onbrez Breezhaler 150 and 300 mcg respectively compared to placebo ($p<0.001$)(10).

Onbrez Breezhaler is the only COPD treatment to offer clinically relevant 24-hour bronchodilation combined with a rapid onset of action within five minutes of the first dose. In July 2011, Novartis announced approval of the 75 mcg once-daily dose in the US under the brand name Arcapta Neohaler , and of the 150 mcg once-daily dose in Japan under the brand name Onbrez® Inhalation Capsules.

COPD is a progressive disease associated with tobacco smoking, air pollution or occupational exposure, which causes obstruction of airflow in the lungs resulting in debilitating bouts of breathlessness. It affects an estimated 210 million people worldwide(11) and is predicted to be the third leading cause of death by 2020(8).

NVA237 was licensed to Novartis in April 2005 by Vectura and its co-development partner Sosei.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, encouraging, plans, designed, commitment, could, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Onbrez Breezhaler, potential marketing approvals for NVA237 or a potential fixed-dose combination product, or regarding potential future revenues from such products. 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 guarantee that Onbrez Breezhaler will be submitted or approved for any additional indications or labeling in any market. Nor can there be any guarantee that NVA237 or a potential fixed-dose combination product will be submitted or approved in any market, or at any particular time. Neither can there be any guarantee that any of the products referred to in this release will achieve any particular levels of revenue in the future. In particular, management s expectations regarding such products 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; 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; 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 121,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis.

References

(1) D Urzo, A. NVA237 once-daily provides rapid, clinically meaningful and sustained 24-h bronchodilation in patients with COPD: The GLOW1 trial. European Respiratory Society (ERS) Annual Congress 2011. Abstract No. P866. Presented 25th September 2011, 12:50-14:40, Hall 2-19.

(2) Beeh, K. Once-daily NVA237 improves exercise endurance from first dose in patients with COPD: The GLOW3 Trial. European Respiratory Society (ERS) Annual Congress 2011. Abstract No. 4497. Late-breaking abstract. Presented 27th September 2011, 16:00, Forum.

(3) D Urzo, A. NVA237 once daily reduces the percentage of patients with exacerbations of COPD and associated hospitalizations: The GLOW1 trial. European Respiratory Society (ERS) Annual Congress 2011. Abstract No. 3427. Presented 27th September 2011, 12:00, Room 3.2.

(4) Fletcher, M, *et al.* COPD Uncovered: An International survey on the impact of chronic obstructive pulmonary disease (COPD) on a working age population. BMC Public Health 2011, 11:612.

(5) Buist AS, McBurnie MA, Vollmer WM, Gillespie S, Burney P, Mannino DM, *et al*. International variation in the prevalence of COPD [the BOLD Study]: a population-based prevalence study. Lancet. 2007;370[9589]:741-50.

(6) de Marco R, Accordini S, Cerveri I, Corsico A, Sunyer J, Neukirch F, *et al*. An international survey of chronic obstructive pulmonary disease in young adults according to GOLD stages. Thorax. 2004;59[2]:120-5.

(7) van Noord, JA. NVA237 once daily improves dyspnea and health-related quality of life (HRQoL) in patients with COPD: The GLOW1 trial. European Respiratory Society (ERS) Annual Congress 2011. Abstract No. P867. Presented 25th September 2011, 12:50-14:40, Hall 2-19.

(8) Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. Updated 2010. http://www.goldcopd.org/uploads/users/files/GOLDReport_April112011.pdf. Last accessed 24 August 2011.

(9) Korn, S. Efficacy of indacaterol is maintained in patients with moderate or less and severe or worse COPD. European Respiratory Society (ERS) Annual Congress 2011. Abstract No. P860. Presented 25th September, 2011, 12:50-14:40, Hall 2-19.

(10) Dahl, R. Efficacy of indacaterol in COPD is maintained irrespective of inhaled corticosteroid (ICS) use. European Respiratory Society (ERS) Annual Congress 2011. Abstract No. P861. Presented 25th September, 2011, 12:50-14:40, Hall 2-19.

(11) Global Alliance against Chronic Respiratory Diseases (GARD). Global surveillance, prevention and control of chronic respiratory diseases: a comprehensive approach. Available at: http://www.who.int/gard/publications/GARD%20Book%202007.pdf Last accessed 24 August 2011.

# # #

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

John Taylor
Novartis Pharma Communications
+41 61 324 6715 (direct)
+41 79 593 4279 (mobile)
john.taylor@novartis.com

e-mail: media.relations@novartis.com

For Novartis multimedia content, please visit www.thenewsmarket.com/Novartis
For questions about the site or required registration, please contact: journalisthelp@thenewsmarket.com.

Novartis Investor Relations

Central phone:	+41 61 324 7944		
Susanne Schaffert	+41 61 324 7944	**North America:**	
Pierre-Michel Bringer	+41 61 324 1065	Richard Jarvis	+1 212 830 2433
Thomas Hungerbuehler	+41 61 324 8425	Jill Pozarek	+1 212 830 2445

Isabella Zinck +41 61 324 7188

e-mail: investor.relations@novartis.com

Edwin Valeriano +1 212 830 2456

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 27, 2011	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting