NOVARTIS AG
Form 6-K
August 30, 2012

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 30, 2012

(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

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis QVA149 Phase III study meets primary endpoint in reducing exacerbations in COPD patients, filing in EU and Japan by end of year

- *SPARK demonstrated QVA149 statistically significantly reduced rate of moderate-to-severe exacerbations compared to glycopyrronium 50 mcg(1)*

- *Study showed QVA149 statistically significantly reduced overall exacerbation rates compared to glycopyrronium 50 mcg and open-label tiotropium 18 mcg(1)*

- *SPARK is the final study of the IGNITE Phase III clinical trial program intended for initial regulatory filings*

Basel, August 30, 2012 Novartis announced today that the fifth QVA149 (indacaterol maleate / glycopyrronium bromide) Phase III study, SPARK, met its primary endpoint of a reduced rate of moderate-to-severe COPD exacerbations compared to glycopyrronium bromide (Seebri® Breezhaler®)(1). SPARK is the final study intended for initial regulatory filings of QVA149 in Europe and Japan, which are expected in Q4 2012. US filing of QVA149 is expected at the end of 2014. To date, the first five studies of the IGNITE QVA149 Phase III clinical trials program have all met their primary endpoints of efficacy, safety, exercise endurance, and reduction of exacerbations(1)-(5).

We are very pleased that SPARK showed a reduction of exacerbations, further demonstrating that QVA149 could improve the lives of patients with COPD, said Tim Wright, Head of Development, Novartis Pharmaceuticals. We are looking forward to filing QVA149 initially in Europe and Japan, which will bring us another step closer to providing a full range of innovative COPD medicines to help physicians select the right treatment for the right patient at the right time.

SPARK met its primary endpoint by demonstrating that patients treated with once-daily (QD) investigational QVA149 for 64 weeks demonstrated a clinically meaningful and statistically significant lower rate of moderate-to-severe COPD exacerbations compared to patients treated with QD glycopyrronium 50 mcg (p=0.038)(1). The study also showed that the rate of moderate-to-severe exacerbations was numerically lower (p=0.096) in patients on QVA149 compared to open-label (OL) tiotropium 18 mcg(1).

A further analysis of the data demonstrated that QVA149 was statistically significantly more effective in reducing the overall rate of all exacerbations (mild, moderate and severe) compared to glycopyrronium 50 mcg (p=0.001) and OL tiotropium 18 mcg (p=0.002)(1). The adverse

event (AE) profile of QVA149 was similar to both glycopyrronium 50 mcg and OL tiotropium 18 mcg(1).

The management of COPD exacerbations is important to both patients and physicians, as exacerbations can impose a significant burden of morbidity, mortality, reduced quality of life and healthcare costs(6),(7). Frequent exacerbations are linked to an accelerated decline in lung function(8),(9) and patients are also known to have a poorer quality of life(10). Admissions to hospital due to exacerbations are increasing(11) and patients with more

severe underlying disease account for around 70% of the direct medical costs of COPD(12).

SPARK was a 64-week, multi-center, randomized, double-blind, parallel-group, active controlled study designed to evaluate the effect of QVA149 (indacaterol maleate 110 mcg / glycopyrronium 50 mcg) QD versus glycopyrronium 50 mcg and QD OL tiotropium 18 mcg on moderate-to-severe COPD exacerbations in 2,224 patients with severe to very severe COPD(1).

QVA149 is an investigational inhaled, once-daily, fixed-dose combination of the long-acting beta2-adrenergic agonist (LABA) indacaterol maleate, and the investigational long-acting muscarinic antagonist (LAMA) glycopyrronium bromide, being investigated for the treatment of COPD in the Phase III IGNITE clinical trial program. IGNITE is one of the largest international clinical trial programs in COPD comprising 10 studies in total with more than 7,000 patients across 42 countries(1)-(5),(13)-(20). The first five studies (ILLUMINATE, SHINE, BRIGHT, ENLIGHTEN, SPARK) have already completed in 2012 with three additional studies (BLAZE, ARISE, BEACON) expected to complete by the end of the year. The studies are designed to investigate efficacy, safety and tolerability, exercise endurance, exacerbations, breathlessness and quality of life(1)-(5),(13)-(17).

About the Novartis COPD portfolio

Novartis is committed to addressing the unmet medical needs of COPD patients and improving their quality of life by providing innovative medicines and devices.

In addition to investigational QVA149, the Novartis COPD portfolio also includes Onbrez® Breezhaler® (indacaterol maleate) and glycopyrronium bromide (Seebri® Breezhaler®).

Onbrez® Breezhaler® (indacaterol maleate) is a QD LABA that is currently the only COPD treatment on the market to offer clinically relevant 24-hour bronchodilation combined with a rapid onset of action of five minutes at first dose, as demonstrated in the INERGIZE Phase III trial program(21)-(24). Onbrez® Breezhaler® has also shown significant improvement in breathlessness scores compared to placebo and OL tiotropium 18 mcg(21). Onbrez® Breezhaler® was first launched in the EU in 150 mcg and 300 mcg once-daily doses. Most recently, Novartis launched the 75 mcg once-daily dose in the US under the brand name ArcaptaTM NeohalerTM. It is also available as a 150 mcg once-daily dose in Japan under the brand name Onbrez® Inhalation Capsules.

Glycopyrronium bromide (Seebri® Breezhaler®) is an investigational LAMA developed as a once-daily inhaled maintenance therapy for the treatment of COPD. Phase III data from the GLOW1, 2 and 3 studies demonstrated that glycopyrronium bromide increased patients lung function over a 24-hour period compared to placebo with a fast onset of action at first dose, and improved exercise endurance versus placebo(25)-(27). Glycopyrronium bromide was licensed to Novartis in April 2005 by Vectura and its co-development partner Sosei.

All of the Novartis COPD portfolio products are being developed for delivery via the Breezhaler® device, a single-dose dry powder inhaler (SDDPI), which has low air flow resistance, making it particularly suitable for patients with airflow limitation, such as COPD patients. The Breezhaler® device allows patients to hear, feel and see that they have taken the drug correctly(18).

About COPD

COPD is a progressive disease associated mainly with tobacco smoking, air pollution or occupational exposure, which can cause obstruction of airflow in the lungs resulting in debilitating bouts of breathlessness. It affects an estimated 210 million people worldwide(28) and is predicted to be the third leading cause of death by 2020(29). Although COPD is often thought of as a disease of the elderly, 50% of patients are estimated to be

within the ages of 50 and 65, which means that half of the COPD population are likely to be impacted at the peak of their earning power and family responsibilities(30).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as intended, expected, could, looking forward to, will, being investigated, designed, committed, launched, or similar expressions, or by express or implied discussions regarding potential regulatory submissions or approvals for QVA149 or regarding potential future revenues from QVA149. 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 QVA149 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that QVA149 will be submitted or approved for sale in any market, or at any particular time. Nor can there be any guarantee that QVA149 will achieve any particular levels of revenue in the future. In particular, management s expectations regarding QVA149 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; unexpected manufacturing issues; 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 innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2011, the Group achieved net sales of USD 58.6 billion, while approximately USD 9.6 billion (USD 9.2 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 126,000 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) ClinicalTrials.gov. Effect of QVA149 Versus NVA237 and Tiotropium on Chronic Obstructive Pulmonary Disorder (COPD) Exacerbations (SPARK). NCT01120691. http://www.clinicaltrials.gov/ct2/show/NCT01120691?term=NCT01120691.&rank=1. Last accessed 21 August 2012.

(2) ClinicalTrials.gov. QVA149 versus Fluticasone/Salmeterol in Patients With Chronic Obstructive Pulmonary Disease (COPD) (ILLUMINATE). NCT01315249 http://www.clinicaltrials.gov/ct2/show/NCT01315249?term=NCT01315249&rank=1. Last accessed 21 August 2012.

(3) ClinicalTrials.gov. A Study to Assess the Efficacy, Safety and Tolerability of Once-daily QVA149 in Patients With Moderate to Severe Chronic Obstructive Pulmonary Disease (COPD) (SHINE). NCT01202188. http://www.clinicaltrials.gov/ct2/show/NCT01202188?term=NCT01202188&rank=1. Last accessed 21 August 2012.

(4) ClinicalTrials.gov. Effect of QVA149 on Exercise Tolerance in Patients With Chronic Obstructive Pulmonary Disease (COPD) (BRIGHT). NCT01294787. http://www.clinicaltrials.gov/ct2/show/NCT01294787?term=NCT01294787.&rank=1. Last accessed 21 August 2012.

(5) ClinicalTrials.gov. A Study to Assess the Long-term Safety of QVA149 (ENLIGHTEN). NCT01120717. http://www.clinicaltrials.gov/ct2/show/NCT01120717?term=NCT01120717&rank=1. Last accessed 21 August 2012.

(6) Simoens S *et al.* Clinical and economic analysis of antimicrobial therapy of chronic obstructive pulmonary disease exacerbations. *Int J Clin Pract.* 2007;**61**:200-206.

(7) Hurst J et al. Chronic obstructive pulmonary disease: the clinical management of an acute exacerbation. Postgrad Med J. 2004;**80**:497-505.

(8) Kanner R, *et al.* Lower respiratory illness promote FEV1 decline in current smokers but not ex-smokers with mild chronic obstructive pulmonary disease. Results from the Lung Health Study. *Am J Respir Crit Care Med* 2001;**164**:358-64.

(9) Donaldson G *et al.* Relationship between exacerbation frequency and lung function decline in chronic obstructive pulmonary disease. *Thorax.* 2002;**57**:847-52.

(10) Seemungal TAR *et al.* Effect of exacerbation on quality of life in patients with chronic obstructive pulmonary disease. *Am J Respir Crit Care Med.* 1998;**157**:1418-22.

(11) Lung and Asthma Information Agency. Trends in hospital admissions for lung disease. Fact sheet 2001/4. London: St George s Hospital Medical School.

(12) Sullivan S *et al.* The economic burden of COPD. Chest. 200;117(suppl):5S-9S.

(13) ClinicalTrials.gov. The Effect of QVA149 on Dyspnea in Patients With Chronic Obstructive Pulmonary Disease (COPD) (BLAZE). NCT01490125. http://www.clinicaltrials.gov/ct2/show/NCT01490125?term=NCT01490125.&rank=1. Last accessed 21 August 2012.

(14) ClinicalTrials.gov. Long Term Safety and Tolerability of QVA149 Versus Tiotropium in Japanese Patients With Chronic Obstructive Pulmonary Disease (COPD) (ARISE). NCT01285492. http://www.clinicaltrials.gov/ct2/show/NCT01285492?term=NCT01285492.&rank=1. Last accessed 21 August 2012.

(15) ClinicalTrials.gov. Comparison of Safety and Efficacy of the Combination Product QVA149A Against the Concurrent Administration of the Individual Components, QAB149 and NVA237, in Patients With Chronic Obstructive Pulmonary Disease (COPD) (BEACON). http://www.clinicaltrials.gov/ct2/show/NCT01529632?term=BEACON&rank=6. Last accessed 22 August 2012.

(16) ClinicalTrials.gov. Comparison of Long-term Safety of the Combination Product QVA149A Against Placebo and Standard of Care Treatment in Chronic Obstructive Pulmonary Disease Patients With Moderate to Severe Airflow Limitation (GLISTEN). http://www.clinicaltrials.gov/ct2/show/NCT01610037?term=GLISTEN&rank=1. Last accessed 22 August 2012.

(17) ClinicalTrials.gov. The Effect of QVA149 on Health Related Quality of Life in Patients With Chronic Obstructive Pulmonary Disease (COPD) (QUANTIFY). http://clinicaltrials.gov/ct2/show/NCT01574651?term=QUANTIFY&rank=1. Last accessed 22 August 2012.

(18) Onbrez® Breezhaler® (indacaterol) EU Summary of Product Characteristics May 31, 2011 http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001114/human_med_001219.jsp&mid=WC0b01ac058001d124. Last accessed 21 August 2012.

(19) FDA Access Data. Spiriva® HandiHaler® Medical Review Part 2, pages 37-38. http://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/21-395_Spiriva.cfm. Last accessed 21 August 2012.

(20) FDA Access Data. Advair Medical Review Nov. 17, 2003, Page 133. http://www.accessdata.fda.gov/drugsatfda_docs/nda/2003/021077_S003_ADVAIR_DISKUS.pdf. Last accessed 21 August 2012.

(21) Donohue JF, Fogarty C, Lötvall J, *et al*. Once-daily bronchodilators for chronic obstructive pulmonary disease: Indacaterol versus tiotropium. *Am J Respir Crit Care Med.* 2010;**182**:155-162.

(22) Dahl R, Chung KF, Buhl R, *et al*. Efficacy of a new once-daily long-acting inhaled beta2-agonist indacaterol versus twice-daily formoterol in COPD. *Thorax.* 2010;**65**(6):473-9.

(23) Kornmann O, Dahl R, Centanni S, *et al*. Once-daily indacaterol vs twice-daily salmeterol for COPD: a placebo-controlled comparison. *Eur Respir J.* 2011;**37**:273-279.

(24) Balint B, Watz H, Amos C, *et al.* Onset of action of indacaterol in patients with COPD: Comparison with salbutamol and salmeterol-fluticasone. *Int J Chron Obstruct Pulmon Dis.* 2010;**5**:311-318.

(25) D Urzo A, *et al*. Efficacy and safety of once-daily NVA237 in patients with moderate-to-severe COPD: the GLOW1 trial. *Respiratory Research* 2011;**12**:156 (7 December 2011).

(26) Kerwin E, *et al.* Efficacy and safety of NVA237 versus placebo and tiotropium in patients with moderate-to-severe COPD over 52 weeks: The GLOW2 study. *Eur Resp J.* 2012. Published on July 26, 2012 (doi:10.1183/09031936.00040712). Last accessed 21 August 2012.

(27) Beeh K, Drollmann A, Di Scala L, Smith R. Once-daily NVA237 improves exercise endurance from first dose in patients with COPD: the GLOW3 trial. *Int J Chron Obstruct Pulmon Dis*. 2012;7:503-513.

(28) 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 21 August 2012.

(29) Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. Updated 2011. http://www.goldcopd.org/guidelines-global-strategy-for-diagnosis-management.html. Last accessed 21 August 2012.

(30) Fletcher MJ *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.

# # #

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

Christina Clinton
Novartis Pharma Communications
+41 61 324 8682(direct)
+41 79 483 4819 (mobile)
christina.clinton@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
Pierre-Michel Bringer	+41 61 324 1065
Thomas Hungerbuehler	+41 61 324 8425
Isabella Zinck	+41 61 324 7188

e-mail: investor.relations@novartis.com

North America:	
Helen Boudreau	+1 212 830 2404
Jill Pozarek	+1 212 830 2445
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:	August 30, 2012	By:	/s/ MALCOLM B. CHEETHAM
		Name:	Malcolm B. Cheetham
		Title:	Head Group Financial Reporting and Accounting