NOVARTIS AG
Form 6-K
July 05, 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 July 1, 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

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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 -

Novartis receives FDA approval for Arcapta Neohaler , a novel once-daily bronchodilator for chronic obstructive pulmonary disease

- *Arcapta is the only once-daily long-acting beta2-agonist (LABA) approved in US for maintenance treatment of airflow obstruction in patients with COPD*

- *Clinical studies with Arcapta showed sustained improvement in lung function; improvements were seen at 5-minutes after first dose(1)*

- *Arcapta is approved with data demonstrating improvements in health-related quality of life*

- *COPD is a progressive and life-threatening lung disease that affects more than 12 million Americans(2) and is a major cause of long-term disability(3)*

Basel, July 1, 2011 Novartis announced today that the US Food and Drug Administration (FDA) has approved once-daily Arcapta Neohaler (indacaterol inhalation powder) 75 mcg for the long-term maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema(1). Arcapta is not indicated for acute deteriorations of COPD or to treat asthma.

The decision makes Arcapta, formerly known as QAB149, the first once-daily therapy in the long-acting beta2-agonist (LABA) class to be approved in the US for maintenance treatment of airflow obstruction in COPD patients.

With millions of Americans known to be affected by COPD, the approval of Arcapta is good news for patients, said John W. Walsh, president and co-founder of the US-based COPD Foundation. A new once-daily medicine is a welcome addition to the treatment options for people suffering with this serious and debilitating disease.

Arcapta 75 mcg was studied in a total of 641 COPD patients in two key Phase III trials lasting 12 weeks. Results at week 12 showed that Arcapta significantly improved lung function at 24 hours compared to placebo(1). Lung function improvements were seen five minutes after the first dose and consistently maintained over 12 weeks. (1). Arcapta also significantly reduced the need for patients to use daily rescue medication(1). Additionally, Arcapta improved health-related quality of life compared to placebo, as measured with the St George s Respiratory Questionnaire (SGRQ)(1). The SGRQ is widely used in clinical trials to measure symptoms, activities, and impact of COPD on daily life as reported by patients(1).

The clinical trial program supporting US submission evaluated safety in 2,516 patients who received Arcapta for at least 12 weeks at doses of 75 mcg or more(1), with results supporting the

safety and tolerability profile of Arcapta. The most common adverse reactions in 449 patients taking Arcapta 75 mcg (i.e. those reported in more than 2% of patients and with higher incidence than placebo) were cough, nasopharyngitis, headache, nausea and oropharyngeal pain.

Novartis is focused on bringing innovative, safe and effective COPD medicines to patients and physicians, said Trevor Mundel, MD, Global Head of Development in the Pharmaceuticals Division of Novartis. Indacaterol is the cornerstone of our respiratory portfolio and this US approval represents a significant clinical and regulatory milestone.

Indacaterol was first approved in November 2009 in the European Union under the brand-name Onbrez® Breezhaler®. It is now approved in more than 60 countries for the treatment of COPD, and is available in more than 30 countries with additional launches planned during 2011. The Arcapta US launch is planned for the first quarter of 2012.

COPD is a progressive and life-threatening lung disease that makes it difficult to breathe(4). More than 12 million people in the US are affected, while another estimated 12 million people are believed to have the disease but remain undiagnosed(2). COPD ranks as the third leading cause of death in the US(5),(6) and is a major cause of serious long-term disability(3). Worldwide, COPD is estimated to affect a total of 210 million people(7).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as milestone, planned, or similar expressions, or by express or implied discussions regarding the development and marketing of potential future respiratory product, regarding future launches of indacaterol, or regarding potential future revenues from indacaterol. 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 Novartis will successfully develop or bring to market any additional respiratory products. Nor can there be any guarantee that indacaterol will be launched in any particular countries, or at any particular time. Neither can there be any guarantee that indacaterol will achieve any particular levels of revenue in the future. In particular, management s expectations regarding indacaterol could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally, including unexpected reimbursement difficulties or delays; competition in general; government, industry and general public pricing pressures; 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; 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 119,000 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) Arcapta Neohaler PI, Draft, April 24, 2011

(2) National Heart, Lung, and Blood Institute. Morbidity & Mortality: 2009 Chart Book on Cardiovascular, Lung, and Blood Diseases. Bethesda, Maryland: U.S Department of Health and Human Services, NIH, NHLBI. October 2009.

(3) Sin DD, Stafinski T, NG YC, Bell NR, Jacobs P. The impact of chronic obstructive pulmonary disease on work loss in the United States. Am J Respir Crit Care Med. 2002; 165: 704-707.

(4) Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. Updated 2009.

(5) Minino AM, Xu J, Kochanek KD. Centers for Disease Control, Division of Vital Statistics. Deaths: Preliminary Data for 2008. National Vital Statistics System. December 2010; 59(2).

(6) Perez I. New CDC report puts COPD in #3 spot in mortality rates. COPD Foundation. December 9, 2010. http://www.copdfoundation.org/PressRoom/tabid/170/language/en%E2%80%90US/Default.aspx?News=114%00%00. Accessed January 21, 2011.

(7) 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 11 May 2011.

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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

Mark Grossien

Novartis Pharma Communications

+41 61 696 5780 (direct)

+41 79 489 7688 (mobile)

mark.grossien@novartis.com

e-mail: media.relations@novartis.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	Edwin Valeriano	+1 212 830 2456
e-mail: investor.relations@novartis.com		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: July 1, 2011	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting