NOVARTIS AG
Form 6-K
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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 24, 2010

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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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: xForm 40-F: o

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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: o**No**: x

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- Investor Relations Release -

Novartis receives EU approval recommendation for TOBI® Podhaler®, a fast and simple therapy that helps reduce treatment burden for cystic fibrosis patients

- *CHMP supports approval of TOBI Podhaler, a new dry powder form of tobramycin for treating chronic P. aeruginosa lung infection in cystic fibrosis patients over six*

- *Data show new formulation reduces administration time by 72% compared to TOBI, with same efficacy(1) and using more convenient, patient-friendly device*

- *Cystic fibrosis is a life-threatening genetic disease primarily affecting children and young adults complex daily treatment reduces their ability to lead normal lives*

Basel, September 24, 2010 TOBI® Podhaler® (tobramycin inhalation powder), a fast and convenient inhaled therapy(1) for use by patients with cystic fibrosis (CF), has been recommended for approval in the European Union. The Committee for Medicinal Products for Human Use (CHMP), which reviews medicines for the European Commission, issued a positive opinion for TOBI Podhaler as a suppressive therapy for chronic *Pseudomonas aeruginosa* (Pa) infections in CF patients aged six years and older.

TOBI Podhaler combines a number of innovations that significantly improve the delivery of tobramycin, which is an established effective treatment for Pa lung infection in patients with cystic fibrosis, said Professor Stuart Elborn, Professor of Respiratory Medicine at Queens University, Belfast, and President of the European Cystic Fibrosis Society. This therapy should help patients to lead more independent lives an important factor considering the relatively young age of many people with this disease.

The CHMP based its positive opinion on data showing that TOBI Podhaler provides the same efficacy(2) as TOBI® (tobramycin solution) with a comparable safety profile(2). TOBI is the most widely used inhaled antibiotic for chronic Pa infections in CF(3). TOBI Podhaler has a unique dry powder formulation, developed using novel PulmoSphere® technology to produce particles that are light and porous for deep delivery into the lung. This means treatment can be given with a portable, patient-friendly device, in contrast to TOBI which is administered with a nebulizer.

Data show that patients using TOBI Podhaler completed their tobramycin treatment in five to six minutes instead of 20 minutes with TOBI, a reduction of 72%(1). Nebulized treatments require additional time for assembly and disinfection, unlike TOBI Podhaler, which also does away with the need for refrigeration of the active compound and a power source for the delivery device. A study found that patients treated with TOBI Podhaler had significantly higher treatment satisfaction than those treated with TOBI(1).

Due to the complexity of existing anti-Pa treatment, most patients do not fully adhere to their therapy(4),(5),(6). In addition, many patients do not clean their nebulizers properly and these are often

contaminated(7),(8),(9),(10). With TOBI Podhaler, the inhaler device is disposable and the dry formulation potentially reduces the risk of bacterial contamination.

TOBI Podhaler shows how we are applying innovative technologies to better meet the needs of patients and their families, said David Epstein, Division Head of Novartis Pharmaceuticals. TOBI Podhaler also underscores our long-term commitment to improving the quality of care for patients with diseases such as cystic fibrosis and helping them to lead longer and more active lives.

Cystic fibrosis (CF) is a life-threatening genetic disease that affects the internal organs, especially the lungs and digestive system, by clogging them with thick mucus making it hard to breathe and digest food. A total of 70,000 patients have been diagnosed with CF worldwide(11). Symptoms usually develop within the first year of life and only half of CF patients live to over 35 years of age(12). In 90% of cases, death is due to a progressive decline in lung function often made worse by chronic *Pseudomonas aeruginosa* infection(13).

The first launch of TOBI came in 1997 and it is now approved in 46 countries including the US and EU for the treatment of *Pseudomonas aeruginosa* in CF patients aged six years old and above.

TOBI Podhaler was submitted for EU approval in December 2009 and is not yet approved in any country. The European Commission generally follows the recommendations of the CHMP and is expected to make a decision within three months.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as recommendation, recommended, should, potentially, commitment, expected, or similar expressions, or by express or implied discussions regarding potential marketing approvals for TOBI Podhaler or regarding potential future revenues from TOBI Podhaler. 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 TOBI Podhaler to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that TOBI Podhaler will be approved for sale in any market. Nor can there be any guarantee that TOBI Podhaler will achieve any particular levels of revenue in the future. In particular, management s expectations regarding TOBI Podhaler 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 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; 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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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 24, 2010	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting