NOVARTIS AG
Form 6-K
September 23, 2010

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 22, 2010

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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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:

Form 20-F: x Form 40-F: o

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- Investor Relations Release -

Novartis gains FDA approval for Gilenya , a novel first-line multiple sclerosis treatment shown to significantly reduce relapses and delay disability progression

- *Gilenya is the first approved oral treatment indicated for relapsing forms of MS in the US, a major advance for people with this disease*

- *Gilenya showed superior efficacy by reducing relapses by 52% at one year compared with interferon beta-1a IM, a commonly prescribed treatment*

- *Two-year, placebo-controlled study showed that Gilenya significantly reduced the risk of disability progression*

- *Well-studied safety and tolerability profile with over 2,600 clinical trial patients*

Basel, September 22, 2010 Today, Novartis announced that the US Food and Drug Administration (FDA) approved the oral multiple sclerosis (MS) treatment Gilenya (fingolimod) 0.5 mg daily, a first-line treatment for relapsing forms of multiple sclerosis the most common forms of the disease. The FDA approval makes Gilenya the first oral treatment indicated for relapsing forms of MS available in the US.

Today is a significant and encouraging day for people with relapsing forms of MS in the US, said Nicholas LaRocca, Vice President of Healthcare Delivery and Policy Research at the National Multiple Sclerosis Society. A new treatment option that offers significant efficacy in the convenience of a capsule is a welcome alternative to frequent injections for individuals living with this chronic disease.

Gilenya reduces the frequency of MS relapses (flare-ups) and helps slow the build-up of some of the physical problems caused by MS. In clinical trials, Gilenya has a well-studied safety and tolerability profile, which has been characterized in over 2,600 clinical trial patients, some of whom are in their seventh year of treatment, with more than 4,500 patient years of experience.

Through a novel mechanism of action, Gilenya can significantly improve clinical outcomes among patients with relapsing forms of MS, said Fred Lublin, MD, Saunders Family Professor of Neurology, The Corinne Goldsmith Dickinson Center for Multiple Sclerosis, Mount Sinai School of Medicine. Gilenya provides significant efficacy and manageable safety when used in accordance with approved labeling, making it a valuable advancement for relapsing MS patients and the physicians who treat them.

The Gilenya approval was based on the largest clinical trial program ever submitted to date to the FDA for a new MS drug and included combined data from clinical studies showing significant efficacy in reducing relapses, the risk of disability progression, and the number of brain lesions

detected by magnetic resonance imaging (MRI), a measure of disease activity, in people with relapsing forms of MS.

We are proud to have worked successfully with the MS community toward a shared goal of bringing a novel efficacious treatment to people with relapsing forms of MS, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. We are actively pursuing regulatory approval in Europe and the rest of the world.

Gilenya is the first in a new class of drugs called sphingosine 1-phosphate receptor (S1PR) modulators. In MS, the immune system damages the covering that protects nerve fibers in the central nervous system (CNS), which includes the brain and spinal cord. Gilenya s novel mechanism is unknown, but it is thought to work by reducing the immune system s attack on the CNS by retaining certain white blood cells (lymphocytes) in the lymph nodes. This prevents the white blood cells from reaching the CNS, where they could potentially attack the protective covering around the nerve fibers, resulting in less inflammatory damage to the nerve cells. The white blood cell retention is reversible if Gilenya treatment is stopped.

About Gilenya

Gilenya is a prescription medicine used to treat relapsing forms of MS in adults. Gilenya can decrease the number of MS flare-ups (relapses). Gilenya does not cure MS, but it can help slow the build up of physical problems that MS causes.

The FDA regulatory application included data showing Gilenya 0.5 mg reduced relapses by 52% ($P<0.001$) at one year compared with interferon beta-1a IM (Avonex®), one of the most commonly prescribed treatments for MS. Gilenya also reduced disease activity as measured by the number of new and newly enlarged T2 lesions on MRI scans compared to interferon beta-1a IM (1.6 vs 2.6, respectively, $P=0.002$) at one year. Data from a two-year placebo-controlled study showed a reduction in relapse rate (54% reduction $P<0.001$, compared with placebo) and risk of disability progression among Gilenya patients (30% reduction confirmed at three-month follow-up visit $P=0.02$, compared with placebo).

In both studies, treatment with Gilenya also resulted in statistically significant reductions in brain lesion activity as measured by MRI.

Gilenya was submitted to the European Medicines Agency (EMA) and to the US Food and Drug Administration for review in December 2009. The EMA regulatory review and other filings worldwide are ongoing.

Gilenya Important Safety Information

Gilenya may cause serious side effects such as slow heart rate (bradycardia or bradyarrhythmia), infections, macular edema, breathing and liver problems.

Gilenya can cause a patient s heart rate to slow down, especially after the first dose. The heart rate will usually slow down the most about six hours after a patient takes their first dose of Gilenya. Patients might feel dizzy or tired or be aware of a slow or irregular heartbeat if their heart rate slows down. A doctor will watch patients for the first six hours after they take the first dose to see if they have any serious side effects. A patient s slow heart rate will usually return to normal within about one month after they start taking Gilenya. Patients should call their doctor if at any time they have dizziness, tiredness or a slow or irregular heartbeat.

Gilenya can increase a patient s risk of serious infections. Gilenya lowers the number of white blood cells (lymphocytes) in the blood. This will usually go back to normal within two months of stopping treatment. A patient s doctor may perform a blood test before they start taking Gilenya. Patients should call their doctor right away if they have fever, tiredness, body aches, chills, nausea or vomiting.

Macular edema can cause some of the same vision symptoms as an MS attack (optic neuritis). Patients may not notice any symptoms with macular edema. Macular edema usually starts in the first three to four months after taking Gilenya. A doctor should test a patient s vision before they start taking Gilenya and three to four months after they start taking Gilenya, or any time they notice vision changes during treatment. Risk of macular edema may be higher if a patient has diabetes or has had an inflammation of the eye called uveitis. Patients should call their doctor right away if they have blurriness, shadows or a blind spot in the center of their vision, sensitivity to light or unusually colored vision.

Some patients who take Gilenya have shortness of breath. Patients should call their doctor right away if they have trouble breathing.

Gilenya may cause liver problems. A doctor should do blood tests to check a patient s liver before they start taking Gilenya. Patients should call their doctor right away if they have nausea, vomiting, stomach pain, loss of appetite, tiredness, dark urine, or their skin or the whites of their eyes turn yellow.

Gilenya may harm an unborn baby. Women should talk to their doctor if they are pregnant or planning to become pregnant. Women who can become pregnant should use effective birth control while on Gilenya and for at least two months after stopping. If a patient becomes pregnant while taking Gilenya or if they become pregnant within two months after stopping Gilenya, they should tell their doctor right away. Women who take Gilenya should not breastfeed, as it is not known if Gilenya passes into breast milk.

Patients should tell their doctor about all their medical conditions, including if they have had or now have an irregular or abnormal heartbeat, a heart rate of less than 55 beats a minute, a fever, infection or if they are unable to fight infections, eye problems, diabetes, breathing or liver problems, or high blood pressure. Patients should especially tell their doctor if they have had chicken pox or have recently received the vaccine for chicken pox. A doctor may do a test for chicken pox virus and patients may need to get the vaccine for chicken pox and wait one month before starting Gilenya.

Patients should tell their doctor about all the medicines they take, including medicines for heart problems or high blood pressure, vaccines, other medicines to control their immune system or treat cancer, or ketoconazole (an antifungal) by mouth.

The most common side effects with Gilenya were headache, flu, diarrhea, back pain, abnormal liver tests and cough.

Gilenya Risk Evaluation and Mitigation Strategy (REMS)

Gilenya has been approved in the US with a Risk Evaluation and Mitigation Strategy (REMS) to inform patients and healthcare providers on the safe use and serious risks of Gilenya in treating relapsing forms of MS. The approved REMS includes a medication guide for patients, and a letter and safety information guide for healthcare providers. Additionally, Novartis will initiate a five-year, worldwide post-authorization safety study to monitor selected safety-related outcomes and a voluntary pregnancy registry, the findings from which will be used to give healthcare providers important information for treating and counseling patients with MS that are pregnant or may become pregnant.

About Multiple Sclerosis

While there is still much to be understood about multiple sclerosis, it is thought to be an autoimmune disease of the central nervous system that is chronic, progressive and often disabling. It affects over 400,000 Americans and more than 2.1 million people worldwide(1). The most common forms of the disease, relapsing forms of MS, are characterized by exacerbations or

flare-ups interspersed with periods of disease remission. Typically, MS strikes in early adulthood between the ages of 20 and 50 and affects women twice as frequently as men.

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Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as risk, encouraging, can, potentially, ongoing, may, will, or similar expressions, or by express or implied discussions regarding potential approvals to sell Gilenya in additional markets or regarding potential future revenues from Gilenya. 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 Gilenya to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Gilenya will be approved for sale in any additional markets. Nor can there be any guarantee that Gilenya will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Gilenya 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.

(1) http://www.nationalmssociety.org/about-multiple-sclerosis/what-we-know-about-ms/who-gets-ms/index.aspx

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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 22, 2010	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting