NOVARTIS AG
Form 6-K
April 28, 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 April 28, 2011

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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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

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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 for Rasilamlo®, a single-pill combination of aliskiren and amlodipine to treat high blood pressure

- *Rasilamlo combines in a single pill the only approved direct renin inhibitor, Rasilez, with the widely used calcium channel blocker amlodipine(1)*

- *Data showed Rasilamlo provides greater blood pressure reductions than Rasilez and amlodipine alone(2)*

- *Up to 85 percent of patients may need multiple medications to help control their high blood pressure underscoring the need for effective combination treatments(3),(4)*

Basel, April 28, 2011 Novartis announced today that Rasilamlo®, a single-pill combination of aliskiren and amlodipine, has received approval from the European Commission (EC) for the treatment of high blood pressure patients not controlled by either aliskiren or amlodipine alone(1). Rasilamlo combines the only approved direct renin inhibitor worldwide, Rasilez®, with the widely used calcium channel blocker amlodipine(1).

Rasilamlo has been evaluated in clinical studies involving more than 5,000 patients with mild-to-severe high blood pressure(1). Data shows that Rasilamlo provides greater blood pressure reductions than Rasilez and amlodipine alone(2).

We are pleased to announce that following today s EC approval Rasilamlo will now be available to high blood pressure patients in the EU who are not controlled by either aliskiren or amlodipine alone, said David Epstein, Division Head of Novartis Pharmaceuticals. This approval reinforces the Novartis commitment to developing new treatment options for patients with uncontrolled high blood pressure.

Data shows that up to 85% of patients will require more than one therapy to best manage their blood pressure(3),(4). However, increasing the number of medications a patient is required to take can have a negative impact on their compliance to therapy. Studies suggest that on average only 8% of patients with high blood pressure in the EU have their condition under control(5), suggesting that the use of single-pill combinations like Rasilamlo can provide a convenient new treatment option for patients with uncontrolled blood pressure.

The treatment of high blood pressure remains a challenge for many patients who require more than one medication to address their complex needs, said Professor Gordon McInnes, Professor of Clinical Pharmacology, Institute of Cardiovascular & Medical Sciences, University of Glasgow. Research has shown that patients receiving two blood pressure medications in a single-pill combination are more likely to adhere to treatment than those receiving two single medications in combination, highlighting the need for innovative new single-pill combinations to treat high blood pressure.

The single-pill combination Rasilamlo works to lower blood pressure in two ways. The Rasilez component targets the activity of the renin angiotensin aldosterone system (RAAS), an important regulator of blood pressure. Rasilez directly binds to and inhibits renin, an enzyme produced by the kidneys that starts a process that can make blood vessels narrow and lead to high blood pressure(6). The calcium channel blocker amlodipine lowers blood pressure by relaxing the blood vessel walls through the inhibition of calcium. Both of these medicines enable blood to flow more easily therefore lowering blood pressure.

It is estimated that about one billion people globally have high blood pressure(7),(8), and many of these remain either untreated or treated but not at their blood pressure target(5). High blood pressure can cause damage to the vital organs of the body, including the heart, brain and kidneys(8). However, if high blood pressure is properly controlled, the incidence of stroke and heart failure can be reduced by almost half and heart attacks by one quarter(8).

Tekturna/Rasilez is approved in over 80 countries. Tekturna was approved in the US in 2007 and in the European Union in 2007 under the trade name Rasilez. Rasilez received approval in Canada in 2008, Japan in 2009 and China in March 2010. Tekturna HCT®, a single-pill combination of aliskiren and hydrochlorothiazide (HCT), was approved in the US in 2008 for second-line treatment of high blood pressure, and in 2009 for first-line treatment of high blood pressure. The single-pill combination Rasilez HCT® was approved for add-on and replacement therapy in the European Union in 2009. In 2009, Valturna®, a single-pill combination of aliskiren and valsartan (Diovan®), was approved in the US. Tekamlo®, the single-pill combination of aliskiren and amlodipine was approved in the US in August 2010. Amturnide , the triple-combination of aliskiren, amlodipine and hydrochlorothiazide (HCTZ), was approved in the US in December 2010.

Novartis has a strong cardiovascular and metabolic portfolio, focusing on innovative treatments for high blood pressure and diabetes. These include Diovan® (valsartan), the number one selling branded blood pressure medication worldwide(9), Exforge® (valsartan/ amlodipine), a single-pill combining two leading medicines for high blood pressure; Exforge HCT® (amlodipine/valsartan/HCT); and Rasilez® (aliskiren), the first and only approved direct renin inhibitor, and four single-pill combinations of Rasilez®, Tekamlo®/Rasilamlo® (aliskiren/amlodipine), Amturnide (aliskiren/amlodipine/HCT), Tekturna HCT®/Rasilez HCT® (aliskiren/HCT) and Valturna® (aliskiren/valsartan). For the treatment of type 2 diabetes, these include Galvus® (vildagliptin, a DPP-4 inhibitor) and Eucreas® (vildagliptin and metformin).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as may, will, commitment, can, or simila expressions, or by express or implied discussions regarding potential future revenues from Rasilamlo. 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 Rasilamlo to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Rasilamlo will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Rasilamlo could be affected by, among other things, competition in general; government, industry and general public pricing pressures; 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; 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 activities 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.

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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:	April 28, 2011	By:	/s/ MALCOLM B. CHEETHAM
		Name:	Malcolm B. Cheetham
		Title:	Head Group Financial Reporting and Accounting