

NOVARTIS AG
Form 6-K
July 21, 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 July 20, 2010

(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:

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Form 20-F: ☒ **Form 40-F:** ☐

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: ☐ **No:** ☒

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Yes: ☐ **No:** ☒

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: ☐ **No:** ☒

Novartis International AG

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- Investor Relations Release -

Novartis receives approval in China for Rasilez, a first-in-class direct renin inhibitor for high blood pressure, the leading preventable cause of death in China

- *Rasilez provides significant blood pressure reductions lasting 24 hours and beyond^{1,2}, alone or in combination with other antihypertensives³⁻⁶*
- *High blood pressure is the leading preventable cause of death in China⁷, affecting some 153 million adults⁸ and resulting in over two million deaths annually⁷*
- *76% of individuals receiving treatment for high blood pressure in China are not achieving optimal goals⁷, creating a strong need for more effective therapies*

Basel, July 20, 2010 Rasilez® (aliskiren), a first-in-class direct renin inhibitor, has received regulatory approval in China for the treatment of high blood pressure alone or in combination with other high blood pressure medicines⁹. Rasilez blocks the activity of renin, an enzyme that triggers a process that may lead to high blood pressure¹⁰.

We are pleased that our continued investment in China enables us to bring treatment options to patients that address the needs of this growing market, said David Epstein, Division Head of Novartis Pharmaceuticals. By adapting our development timelines for Rasilez we have been able to provide patients in China with timely access to this novel therapy for high blood pressure.

High blood pressure is the leading risk factor for cardiovascular disease, the number one cause of death worldwide¹¹. In China, an estimated 153 million adults are affected by high blood pressure⁸, with the majority of patients not reaching their optimal treatment goal⁷. The country's leading preventable cause of death, high blood pressure leads to more than one million premature deaths and over two million total deaths in China each year⁷.

Modifications in lifestyle and diet have led to high blood pressure becoming a significant and growing problem in China, said Yong Huo, M.D. President-elect Chinese Society of Cardiology, Department of Cardiology, Peking University First Hospital. Because the disease has no apparent symptoms, awareness as well as treatment and control of the condition are very low. As a result, there is a clear need for innovative high blood pressure treatments in China to enable more patients to successfully manage their condition.

It is estimated that over one billion people globally have high blood pressure^{12, 13}, and many of these remain either untreated or treated but not reaching their target¹². High blood pressure causes damage to the vital organs of the body including the heart, brain and kidneys¹². 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 quarter¹².

Rasilez, known as Tekturna®* in the US, works by directly inhibiting the activity of renin, an enzyme produced by the kidneys that starts a process in the renin-angiotensin-aldosterone system which narrows blood vessels, and may lead to high blood pressure¹⁰. By inhibiting renin at the point of activation, Rasilez provides significant blood pressure reductions alone or in combination with other antihypertensives³⁻⁶.

Rasilez/Tekturna is approved in over 80 countries. Tekturna was approved in the US in March 2007 and in the European Union in August 2007 under the trade name Rasilez. In July 2009, Rasilez also received approval in Japan. Tekturna HCT®, a single-pill combination of aliskiren and hydrochlorothiazide, was approved in the US in January 2008 for second-line treatment of high blood pressure, and in July 2009 for first-line treatment of high blood pressure. The single-pill combination Rasilez HCT® was approved in the European Union in January 2009. In September 2009, Valturna®, a single-pill combination of aliskiren and valsartan (Diovan®), was approved in the US. Other single-pill combinations with aliskiren are currently in development including a single-pill combination with amlodipine.

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 blood pressure medication worldwide¹⁴, 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 two single-pill combinations of Rasilez®, 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).

* Rasilez® is the trade name for aliskiren throughout the world, except in the US where it is known as Tekturna®.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as in development, or similar expressions, or by express or implied discussions regarding potential additional approvals for Rasilez, or regarding the potential development of other single-pill combinations with aliskiren, or regarding potential future revenues from Rasilez or combination products containing aliskiren. 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 Rasilez will be approved for sale in any additional markets. Nor can there be any guarantee that Novartis will successfully develop any additional single-pill combination products containing aliskiren. Neither can there be any guarantees that Rasilez will achieve any particular levels of revenue in the future. In particular, management's expectations regarding such products 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 100,000 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: July 20, 2010

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham
Title: Head Group Financial
Reporting and Accounting