NOVARTIS AG
Form 6-K
July 09, 2009

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 8, 2009

(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 -

Japanese Ministry of Health approves Rasilez®, a first-in-class direct renin inhibitor (DRI), for the treatment of high blood pressure

- *Rasilez provides significant blood pressure reductions that last for 24 hours (1),(2), when taken alone or in combination with other antihypertensives(3)-(6)*

- *An estimated 40 million people in Japan, nearly a third of the population, have high blood pressure(7), 70% of whom are not achieving treatment goals(8)*

- *Rasilez s potential long-term benefits are being further investigated as part of ASPIRE HIGHER - the largest ongoing cardio-renal outcomes program*

Basel, July 8, 2009 Rasilez® (aliskiren), the first new type of high blood pressure medicine in more than a decade, has been approved for use in Japan. Rasilez directly inhibits renin(9), an enzyme that triggers a process leading to high blood pressure and organ damage. The Ministry of Health, Labour and Welfare (MHLW) in Japan approved Rasilez for the treatment of high blood pressure alone or in combination with other high blood pressure medicines.

High blood pressure is the leading risk factor for cardiovascular disease, the number one cause of death worldwide(10). In Japan an estimated 40 million people, nearly a third of the population, are affected by high blood pressure(7) with the majority of patients not reaching their blood pressure treatment goal(8).

In Japan, nearly 70% of patients are not reaching their blood pressure goal, demonstrating a strong need for therapies with a new mechanism of action, said Professor Toshiro Fujita, Chief of the Department of Nephrology and Endocrinology, University of Tokyo. It is expected that Rasilez s unique mechanism of action will provide significant blood pressure reductions that last for 24 hours.

It is estimated that nearly one billion people globally have high blood pressure(11) and many of these remain either untreated or treated but not reaching their target(11). Patients are therefore at risk of complications including heart attack, stroke, kidney failure, blindness and death, creating an unmet need for new high blood pressure therapies(11).

Rasilez, known as Tekturna® in the US(1), works by directly inhibiting renin to reduce the effects caused by an over-active renin system(9). By inhibiting renin at the point of activation, Rasilez provides significant blood pressure reductions alone or in combination with other antihypertensives(3)-(6).

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

The potential long-term benefits of Rasilez are currently being investigated further in the landmark ASPIRE HIGHER program, the largest ongoing cardio-renal outcomes program worldwide, involving more than 35,000 patients in 14 trials.

We are very excited about the approval in Japan, which provides Japanese patients access to this innovative high blood pressure treatment that directly targets renin, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. Novartis is committed to supporting the research and development of effective and innovative treatments for patients suffering high blood pressure.

Rasilez is approved in over 70 countries. Tekturna was approved in the US in March 2007 and in the European Union in August 2007 under the trade name Rasilez. Tekturna HCT, the first single-pill combination involving Tekturna, was approved in the US in January 2008. The single-pill combination Rasilez HCT was approved by the European Commission in January 2009.

Novartis is focused on improving the lives of the hundreds of thousands of people with cardiovascular and metabolic diseases. As a global leader in cardiovascular and metabolic health for nearly 50 years, Novartis provides innovative therapies and support programs to treat high blood pressure and diabetes both major public health issues. The portfolio includes the world s most-prescribed angiotensin receptor blocker, the first and only approved direct renin inhibitor, a single pill combining two leading high blood pressure medicines, and a DPP-4 inhibitor.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as estimated, potential, expected, will, committed, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Rasilez/Tekturna or regarding potential future revenues from Rasilez/Tekturna. 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 Rasilez/Tekturna to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Rasilez/Tekturna will be approved for any additional indications or labeling in any market. Nor can there be any guarantee that Rasilez/Tekturna will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Rasilez/Tekturna could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; 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 AG 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 2008, the Group s continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,000 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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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

Yanyan Chang
Novartis Division Communications
+ 41 61 324 2339 (direct)
+ 41 79 292 0959 (mobile)
yanyan.chang@novartis.com

e-mail: media.relations@novartis.com

Novartis Investor Relations

Central phone:	+41 61 324 7944
Ruth Metzler-Arnold	+41 61 324 9980
Pierre-Michel Bringer	+41 61 324 1065
John Gilardi	+41 61 324 3018
Thomas Hungerbuehler	+41 61 324 8425
Isabella Zinck	+41 61 324 7188

e-mail: investor.relations@novartis.com

North America:	
Richard Jarvis	+1 212 830 2433
Jill Pozarek	+1 212 830 2445
Edwin Valeriano	+1 212 830 2456

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 8, 2009

By: /s/ MALCOLM B. CHEETHAM

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