

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:

Edgar Filing: NOVARTIS AG - Form 6-K

**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:

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

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**

Novartis Global Communications

CH-4002 Basel

Switzerland

<http://www.novartis.com>

**- 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<sup>1,2</sup>, alone or in combination with other antihypertensives<sup>3-6</sup>*
- *High blood pressure is the leading preventable cause of death in China<sup>7</sup>, affecting some 153 million adults<sup>8</sup> and resulting in over two million deaths annually<sup>7</sup>*
- *76% of individuals receiving treatment for high blood pressure in China are not achieving optimal goals<sup>7</sup>, 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 medicines<sup>9</sup>. Rasilez blocks the activity of renin, an enzyme that triggers a process that may lead to high blood pressure<sup>10</sup>.

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 worldwide<sup>11</sup>. In China, an estimated 153 million adults are affected by high blood pressure<sup>8</sup>, with the majority of patients not reaching their optimal treatment goal<sup>7</sup>. 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 year<sup>7</sup>.

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<sup>12,13</sup>, and many of these remain either untreated or treated but not reaching their target<sup>12</sup>. High blood pressure causes damage to the vital organs of the body including the heart, brain and kidneys<sup>12</sup>. 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<sup>12</sup>.

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 pressure<sup>10</sup>. By inhibiting renin at the point of activation, Rasilez provides significant blood pressure reductions alone or in combination with other antihypertensives<sup>3-6</sup>.

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 worldwide<sup>14</sup>, 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>.

---

## References

- (1) Oh BH, et al. Aliskiren, an Oral Renin Inhibitor, Provides Dose-Dependent Efficacy and Sustained 24-hour Blood Pressure Control in Patients with Hypertension. *J Am Coll Cardiol* 2007;49:1157-63.
- (2) Palatini P, et al. Blood Pressure Reduction Following A Simulated Missed Dose Of Aliskiren, Irbesartan, or Ramipril: A Comparative Ambulatory Blood Pressure Monitoring Study. Presentation at American Society of Hypertension 2008.
- (3) Uresin Y, et al. Aliskiren Monotherapy Lowers Blood Pressure More Effectively than Ramipril Monotherapy in Patients with Diabetes and Grade 2 Hypertension: Subgroup Analysis of an 8-week, Double-Blind Trial. *J Hypertens* 2008;26(Suppl 1):S479 PS33/THU/62.
- (4) Oparil S, et al. Efficacy and Safety of Combined use of Aliskiren and Valsartan in Patients with Hypertension: A Randomised, Double-Blind Trial. *Lancet* 2007;370:221-29.
- (5) Drummond W, et al. Antihypertensive Efficacy of the Oral Direct Renin Inhibitor Aliskiren as Add-on Therapy in Patients not Responding to Amlodipine Monotherapy. *J Clin Hypertens* 2007;9:742-50.
- (6) Gradman A, et al. Aliskiren in Combination with Hydrochlorothiazide is Effective and well Tolerated during Long-Term Treatment of Hypertension. Presentation at the American Society of Hypertension 2007.
- (7) Jiang H, et al. Premature Deaths Attributable to Blood Pressure in China: A Prospective Cohort Study. *Lancet* 2009;374:1765-72.
- (8) Wu Y, et al. Prevalence, Awareness, Treatment, and Control of Hypertension in China: Data from the China National Nutrition and Health Survey 2002. *Circulation* 2008;118:2679-86.
- (9) Rasilez Package Insert in China.
- (10) Rasilez Summary of Product Characteristics (SmPC) for European Union.
- (11) World Health Organization. Cardiovascular disease factsheet. Available at: <http://www.who.int/mediacentre/factsheets/fs317/en/index.html>. Last accessed July 2010.
- (12) Chobanian AV, et al. Seventh Report of the Joint National Committee on prevention, detection, evaluation, and treatment of high blood pressure. *Hypertension* 2003;42:1206-51.
- (13) Kearney P, et al. Global Burden of Hypertension: Analysis of Worldwide Data. *Lancet* 2005;365:217-23.

(14) IMS Midas Worldwide Sales Data. December 2009.

###

4

---

**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

**Rebecca Fisher-Pollard**

Novartis Pharma Communications

+ 41 61 324 91 66 (direct)

+ 41 79 426 46 84 (mobile)

rebecca.fisher-pollard@novartis.com

e-mail: media.relations@novartis.com

For Novartis multimedia content, please visit [www.thenewsmarket.com/Novartis](http://www.thenewsmarket.com/Novartis)

For questions about the site or required registration, please contact: [journalisthelp@thenewsmarket.com](mailto:journalisthelp@thenewsmarket.com).

**Novartis Investor Relations**

**Central phone:**

Susanne Schaffert

Pierre-Michel Bringer

Thomas Hungerbuehler

Isabella Zinck

+41 61 324 7944

+41 61 324 3769

+41 61 324 1065

+41 61 324 8425

+41 61 324 7188

**North America:**

Richard Jarvis

Jill Pozarek

Edwin Valeriano

+1 212 830 2433

+1 212 830 2445

+1 212 830 2456

e-mail: investor.relations@novartis.com

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 20, 2010

By: /s/ MALCOLM B. CHEETHAM

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