NOVARTIS AG
Form 6-K
May 16, 2008

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 May 15, 2008

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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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):

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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 -

New data show Tekturna HCT® is twice as effective at reducing blood pressure than the diuretic HCT alone

- *Recently launched in the US, Tekturna HCT is a single-tablet combination of Tekturna®*(1) *and the diuretic HCT for the treatment of high blood pressure*(1)

- *Both Tekturna HCT and Tekturna provide effective blood pressure lowering with good tolerability*[(1),(2),(3)]

- *Tekturna, first-in-class direct renin inhibitor, provides blood pressure reductions that last beyond 24 hours*[(2),(4)]

Basel, May 15, 2008 New clinical data presented at the American Society of Hypertension (ASH) show that Tekturna HCT® 300/25 mg, a single-tablet combination of the direct renin inhibitor Tekturna® (aliskiren) and the diuretic hydrochlorothiazide (HCT)[(1)], is twice as effective at reducing blood pressure compared to HCT 25 mg alone[(3)]. High blood pressure is estimated to affect nearly one in four adults worldwide and remains uncontrolled in nearly 70% of people who have this condition in the United States[(5)].

Results of the eight-week study showed that treatment with Tekturna HCT 300/25 mg or 150/25 mg once a day reduced systolic and diastolic blood pressure by 16.7/10.7 mmHg and 12.9/8.5 mmHg respectively compared to 7.1/4.8 mmHg ($p<0.001$)[(3)] in patients with high blood pressure not adequately responding to HCT alone. Tekturna HCT was well tolerated with fewer occurrences of hypokalemia (low potassium levels in the blood) compared to HCT alone[(3)]. Tekturna HCT should not be used in patients who have a low urine output or have allergies to sulfa type drugs.

Most patients need two or more medicines to reach their target blood pressure[(5)]; therefore a single tablet that combines more than one medicine may help make managing blood pressure more convenient[(3)].

High blood pressure, or hypertension, is a serious global problem and we are clearly in need of treatments to help patients reach their target blood pressure levels, said Alan Gradman, MD, Division of Cardiovascular Diseases at the Western Pennsylvania Hospital in Pittsburgh, USA. The data show that Tekturna HCT is an effective and convenient treatment option for patients who have high blood pressure and, as a consequence, have a higher risk of heart attack, heart failure and stroke.

Additional data presented at ASH reconfirm the ability of the first-in-class direct renin inhibitor Tekturna, known as Rasilez® outside the US, to provide significant blood pressure reductions that

(1) Tekturna® is the US trade name for aliskiren. Aliskiren is known as Rasilez® outside the US.

last beyond 24 hours following a missed dose[2]. Tekturna/Rasilez 300 mg effectively lowered blood pressure beyond the 24-hour dosing interval after a missed dose better than either the angiotensin II receptor blocker (ARB) irbesartan 300 mg or angiotensin-converting enzyme (ACE) inhibitor ramipril 10 mg[2]. This is an important consideration when treating patients with hypertension because many high blood pressure medicines fail to work around the clock, especially during the early morning hours when blood pressure often surges.

Tekturna provides effective blood pressure lowering that lasts beyond 24 hours a critical benefit for patients, especially during the morning hours when blood pressure rises, said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG. Eighty percent of blood pressure reductions are maintained for four days after the last dose of Tekturna is given.

New data also presented at ASH included a *post hoc* analysis of a subset of patients with stage 2 high blood pressure. Tekturna/Rasilez (150-300 mg) provided highly effective systolic and diastolic blood pressure reductions greater than 22.3/12.7 mmHg and achieved superior blood pressure control compared to ramipril (5-10 mg). Stage 2 high blood pressure is a more severe stage of the disease where patients have systolic blood pressure at or above 160 mmHg[6].

Systolic and diastolic blood pressure represent the maximal (when the heart is pumping) and minimal (when the heart is at rest) pressure within the cardiovascular system, respectively. High blood pressure is generally defined as a consistent systolic pressure of 140 mmHg and higher or a diastolic pressure of 90 mmHg and higher[5].

Tekturna/Rasilez is being studied in the landmark ASPIRE HIGHER clinical trial program to assess the effect of direct renin inhibition in a variety of conditions, including diabetic kidney disease and heart failure. ASPIRE HIGHER is the largest ongoing cardio-renal outcomes program and involves more than 35,000 patients in 14 studies, including three new mega-trials.

Tekturna/Rasilez acts by directly inhibiting renin, an enzyme that triggers a process leading to high blood pressure and organ damage. Tekturna/Rasilez is approved in more than 40 countries[2],[4]. Tekturna® was approved in the US in March 2007 and also in the European Union in August 2007 under the trade name Rasilez®. Tekturna HCT®, the first single-dose combination involving Tekturna, was approved in the US in January 2008. Tekturna/Rasilez was discovered by Novartis and developed in collaboration with Speedel.

Novartis is focused on improving the lives of the hundreds of millions 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 core of the Novartis portfolio is its cardiovascular medications for the treatment of high blood pressure and diabetes. These include 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 novel DPP-4 inhibitor. Novartis is dedicated to helping physicians and patients improve cardiovascular and metabolic health through effective medicines, programs and an ongoing commitment to research.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as estimated , can , may , risk , or similar expressions, or by express or implied discussions regarding potential new indications or labelling for Tekturna HCT or Tekturna/Rasilez or regarding potential future revenues from Tekturna HCT or Tekturna/Rasilez. Such forward-looking

statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with these products to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that these products will be submitted or approved for any additional indications or labelling in any market. Nor can there be any guarantee that these products will achieve any particular levels of revenue in the future. In particular, management s expectations regarding these products 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, 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 growth areas in healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, and consumer health products. Novartis is the only company with leading positions in these areas. In 2007, the Group s continuing operations (excluding divestments in 2007) achieved net sales of USD 38.1 billion and net income of USD 6.5 billion. Approximately USD 6.4 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,000 full-time associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

References

(1) Tekturna HCT US Prescribing Information.
(2) Palatini P, Jung P, Schlyakhto E et al. Blood Pressure Reduction Following A Simulated Missed Dose Of Aliskiren, Irbesartan, or Ramipril: A Comparative Ambulatory Blood Pressure Monitoring Study. Poster Presentation at American Society of Hypertension 23rd Annual Scientific Meeting 2008.
(3) Blumenstein M, Romaszko J, Calderon A et al. Antihypertensive Efficacy And Tolerability Of Aliskiren/Hydrochlorothiazide (HCTZ) Fixed-Dose Combination Tablets In Patients With Hypertension Who Are Not Adequately Responsive To HCTZ. Poster Presentation at American Society of Hypertension 23rd Annual Scientific Meeting 2008.
(4) Oh BH, Mitchell J, Herron JR 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.
(5) Chobanian AV, Bakris GL, Black HR, et al. Seventh Report of the Joint National Committee on Prevention, Detection Evaluation and Treatment of High Blood Pressure. *Hypertens* 2003;42:1206-1251.
(6) Andersen K, Weinberger MH, Egan B et al. Aliskiren Monotherapy Lowers Blood Pressure More Effectively Than Ramipril Monotherapy in Patients with Stage 2 Hypertension: Subgroup Analysis of a 6-Month, Double-Blind Trial. Poster Presentation at American Society of Hypertension 23rd Annual Scientific Meeting 2008.

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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: May 15, 2008

By: /s/ MALCOLM B. CHEETHAM

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