NOVARTIS AG
Form 6-K
September 04, 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 September 3, 2008

(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

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: 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 -

Rasilez®*(1)*, first-in-class direct renin inhibitor, lowers high blood pressure more effectively than diuretic in obese patients

- *Data presented at European Society of Cardiology congress confirm Rasilez is effective in difficult-to-treat patients with obesity, heart failure and diabetes(1),(2),(3)*

- *Data from ALOFT study shows Rasilez reduces marker of heart failure severity when added to optimal therapy in chronic heart failure patients with diabetes(2)*

- *Findings important as 70% of patients with high blood pressure are overweight or obese(4) and 23 million people worldwide have chronic heart failure(5)*

- *Heart and kidney protection potential of Rasilez independent of blood pressure lowering ability being further studied in ASPIRE HIGHER clinical program*

Basel, September 3, 2008 New clinical data analysis confirms that the first-in-class direct renin inhibitor Rasilez® (aliskiren), known as Tekturna® in the US, provides significantly greater blood pressure reductions in obese patients with high blood pressure compared to the diuretic hydrochlorothiazide (HCT) alone(1).

The *post hoc* analysis presented at the European Society of Cardiology (ESC) 2008 annual congress showed that Rasilez/Tekturna 300 mg monotherapy provided reductions in mean sitting systolic blood pressure (when the heart is pumping) of 16.7 mmHg compared to 12.2 mmHg for HCT, and diastolic (when the heart is at rest) blood pressure reductions of 12.3 mmHg compared to -9.1 mmHg for HCT ($p<0.001$)(1).

These findings are significant as 70% of patients with high blood pressure are overweight or obese (body mass index $\geq$30 kg/m²)(4). Obese patients with high blood pressure have an increased risk of cardiovascular and kidney disease(6). Approximately 58% of diabetes and 21% of ischemic heart disease is attributable to a body mass index above 21(7).

Sixty-five percent of people with high blood pressure worldwide still do not have the condition under control and as the rate of obesity and diabetes continues to rise there is a definite need for new treatments to help bring patients to goal, said Professor Aldo Maggioni of the Italian Association of Hospital Cardiologists Research Center, Florence, Italy. In addition to providing effective blood pressure reductions in the general hypertensive population these data further

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

confirm that aliskiren is effective and well tolerated in difficult to treat patients who are obese and in patients with heart failure who also have kidney disease or diabetes.

Two subgroup analyses of the ALOFT study (ALiskiren Observation of Heart Failure Treatment) were also presented. Rasilez/Tekturna, when added to standard therapy in heart failure patients with or without diabetes, provided a 25% reduction in brain natriuretic peptide (BNP), an indicator of heart failure severity, from baseline compared with placebo(2). Rasilez/Tekturna was well tolerated when added to standard therapy in chronic heart failure patients, including those with diabetes and kidney disease (eGFR < 60 mL/min/1.73m²)(2),(3).

BNP is a substance released from the heart s lower ventricles in response to increased wall tension. The level of BNP in the bloodstream increases when heart failure symptoms worsen, and decreases when the heart failure condition is stable.

Approximately 23 million people worldwide have chronic heart failure for which the leading risk factor is high blood pressure(5). If high blood pressure is properly controlled, the incidence of heart failure and stroke can be reduced by almost half, and heart attacks by one quarter(8).

In addition to providing powerful blood pressure reductions that last beyond 24 hours both as monotherapy and in combination, Rasilez continues to demonstrate the potential to protect organs such as the heart and kidneys, said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG. We are pleased to report that studies from the ASPIRE HIGHER program, including data from ALOFT and AVOID, have already paved the way for an enhanced European Union label for Rasilez.

ASPIRE HIGHER is the largest ongoing cardio-renal outcomes program worldwide and is investigating the potential heart and kidney protection benefit of Rasilez/Tekturna.

Findings from three of the 14 studies in the ASPIRE HIGHER program have already been reported. The AVOID study, published recently in *The New England Journal of Medicine*, showed that Rasilez/Tekturna reduced albuminuria, a key indicator of kidney disease, by an additional 20% in type 2 diabetic patients with kidney disease and high blood pressure who were already taking the maximum standard treatment(9).

The ALOFT study, recently published in the *Circulation: Heart Failure,* showed that the addition of Rasilez/Tekturna to standard heart failure treatments resulted in nearly five times greater reductions in BNP, a marker of heart failure severity, than the standard therapy alone(10). The ALLAY study demonstrated that Rasilez/Tekturna reduced left ventricular hypertrophy (LVH), a marker of cardiac damage associated with an increased risk of cardiovascular events(11). In ALLAY, the combination of Rasilez/Tekturna and the angiotensin receptor blocker (ARB) losartan achieved a numerically greater reduction in LVH than losartan alone, but the result was not statistically significant(11).

Rasilez/Tekturna is approved in 55 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. Rasilez/Tekturna 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 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 novel DPP-4 inhibitor. Novartis is dedicated to helping physicians and patients 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 can , potential or similar expressions, or by express or implied discussions regarding potential new indications or labelling for Rasilez/Tekturna or regarding potential future revenues fromRasilez/Tekturn. 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 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 labelling 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 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; competition in general; government, industry and general public pricing pressures; the effect that the foregoing factors could have on the values attributed to the 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 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) Schmieder RE, Philipp T, Gueredíaga J et al. Aliskiren-Based Therapy Lowers Blood Pressure More Effectively than Hydrochlorothiazide-Based Therapy in Obese Hypertensive Patients: Subgroup Analysis of a 52-week, Randomized, Double-Blind Trial. Oral Presentation at European Society of Cardiology 2008 Annual Congress.

(2) Maggioni AP, Latini R, McMurray JJ et al. Efficacy and Tolerability of Aliskiren Added to Optimized Medical Therapy in Diabetic Patients with Heart Failure. Poster Presentation at the European Society of Cardiology 2008 Annual Congress.

(3) Maggioni AP, McMurray JJ, Latini R et al. Safety and Tolerability Profile of Aliskiren When Added to Optimized Medical Therapy in Patients with Heart Failure and Renal Dysfunction. Oral Presentation at the European Society of Cardiology 2008 Annual Congress.

(4) Davy KP, and Hall JE. Obesity and Hypertension: Two Epidemics or One? *Am J Physiol Regul Integr Comp Physiol. 2004* May;286(5):R803-13.

(5) American Heart Association. The Prevention of Heart Failure. Accessed August 14, 2008. Available at http://pt.wkhealth.com/pt/re/chf/addcontent.7847092.htm;jsessionid=LkGSnwkN4gQzJVS9Qvn2yWXlhx5whz5sKh8VgyrqYp93TJLJGh8T!-927161468!

(6) Zhang R and Reisin E. Obesity-Hypertension: The Effects on Cardiovascular and Renal Systems. *Am J Hypertens*. 2000;13,1308 1314.

(7) World Heart Federation: Cardiovascular Disease Risk Factors: Obesity. Available at http://www.world-heart-federation.org/cardiovascular-health/cardiovascular-disease-risk-factors/obesity/.

(8) 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. *Hypertension*. 2003;42:1206-1251.

(9) Parving H-H et al. Aliskiren Combined with Losartan in Type 2 Diabetes and Nephropathy. *N Eng J Med*. 2008;358:2433-46.

(10) McMurray J, Pitt B, Latini R, et al. Effects of the Oral Direct Renin Inhibitor Aliskiren in Patients with Symptomatic Heart failure. *Circulation: Heart Failure*. 2008;1:17-24.

(11) Solomon S, Appelbaum E, Manning WJ, et al. Effect of the Direct Renin Inhibitor Aliskiren, Either Alone or in Combination with Losartan, Compared to Losartan, on Left Ventricular Mass in Patients With Hypertension and Left Ventricular Hypertrophy: The ALiskiren Left Ventricular Assessment of Hypertrophy (ALLAY) Trial. Oral presentation at American College of Cardiology 57th Scientific Sessions 2008.

# # #

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

Navjot Rai

Novartis Pharma Communications

+41 61 324 6498 (direct)

+41 79 777 6400 (mobile)

navjot.rai@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: September 3, 2008

By: /s/ MALCOLM B. CHEETHAM

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