

NOVARTIS AG  
Form 6-K  
November 12, 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 November 11, 2008

(Commission File No. 1-15024)

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**Novartis AG**

(Name of Registrant)

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(Address of Principal Executive Offices)

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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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Yes:  No:

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- Investor Relations Release -

**Rasilez®, first-in-class direct renin inhibitor, provides greater reduction in high blood pressure than ACE inhibitor ramipril in patients 65 and older**

- *New AGELESS data show Rasilez lowers systolic blood pressure by additional 2.3 mmHg in patients aged 65 and over compared to ACE inhibitor ramipril(1)*
- *70% of people over 60 have high blood pressure(2), a condition that becomes increasingly prevalent and challenging to treat with age(3)*
- *Research shows a 2 mmHg reduction in systolic blood pressure may lower a patient's risk of stroke death by 10% and risk of heart disease death by 7%(4)*
- *AGELESS, part of the ASPIRE HIGHER clinical program, is the third study to show Rasilez provides a greater reduction in blood pressure than ramipril(1),(5),(6)*

**Basel, November 11, 2008** New clinical data presented today show first-in-class direct renin inhibitor Rasilez®(1) (aliskiren), known as Tekturna® in the US, provides significantly greater blood pressure reductions in patients with high blood pressure aged 65 and over, compared to the angiotensin-converting enzyme (ACE) inhibitor ramipril(1).

Results from the AGELESS study, presented at the American Heart Association (AHA) 2008 scientific sessions, showed that Rasilez/Tekturna provides an additional reduction in systolic blood pressure of 2.3 mmHg in patients aged 65 and over compared to the ACE inhibitor ramipril after the primary endpoint of 12 weeks of treatment(1).

Seventy per cent of people aged over 60 have high blood pressure<sup>(2)</sup>. Increased systolic blood pressure (the pressure of blood flow when the heart beats) is the most frequent type of uncontrolled high blood pressure in the elderly<sup>(7)</sup> and is associated with an increased risk of cardiovascular events including stroke, myocardial infarction and heart failure<sup>(8)</sup>.

High blood pressure becomes more prevalent and challenging to treat with age, said Professor Daniel Duprez, lead author of the AGELESS study and Director of Research at the Rasmussen Center for Cardiovascular Disease Prevention, University of Minnesota. The elderly population is expected to more than double over the next thirty years. Therefore, it is important to have effective therapies such as aliskiren to treat a range of patients, including the elderly.

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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 AGELESS study conducted in 900 patients with systolic hypertension aged 65 and over showed that Rasilez/Tekturna (150 mg daily increased to 300 mg daily) lowered systolic blood pressure by 13.6 mmHg compared to a reduction of 11.3 mmHg in patients taking ramipril (5 mg daily increased to 10 mg daily) after 12 weeks of treatment ( $p < 0.0001$ ). A greater reduction of diastolic blood pressure (pressure between heart beats) was also achieved after 12 weeks of treatment with Rasilez/Tekturna compared to ramipril -4.8 mmHg vs. -3.5 mmHg, respectively) ( $p < 0.0001$ ). In the study, Rasilez was well tolerated<sup>(1)</sup>. The most frequently reported adverse events in this study for Rasilez/Tekturna included headache, dizziness, diarrhea, upper respiratory tract infection, cough, nasopharyngitis and nausea.

AGELESS is the third study to show that Rasilez lowers blood pressure more effectively than the ACE inhibitor ramipril, said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG. Rasilez provides effective blood pressure lowering that lasts beyond 24 hours in a range of patients. Through the ASPIRE HIGHER program we hope to further demonstrate significant blood pressure lowering in special populations as well as examine the organ protection potential of Rasilez.

AGELESS is part of the landmark ASPIRE HIGHER program, the largest ongoing cardio-renal outcomes program worldwide involving more than 35,000 patients in 14 trials. In addition to hypertension studies in specific patient populations, the ASPIRE HIGHER program is investigating the potential heart and kidney protection benefits of Rasilez/Tekturna.

The AGELESS data adds to the findings from three of the 14 studies in the ASPIRE HIGHER program that have also 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<sup>(9)</sup>.

The ALOFT study, recently published in *Circulation: Heart Failure*, showed that the addition of Rasilez/Tekturna to standard heart failure treatments resulted in nearly five times greater reductions in brain natriuretic protein (BNP), a marker of heart failure severity, than placebo<sup>(10)</sup>. 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<sup>(11)</sup>. In ALLAY, Rasilez/Tekturna reduced LVH as effectively as the angiotensin receptor blocker (ARB) losartan, the gold standard in reducing LVH in hypertensive patients. The combination of Rasilez/Tekturna and losartan achieved a numerically greater reduction in LVH than losartan alone, but the result was not statistically significant<sup>(11)</sup>.

Rasilez/Tekturna is approved in more than 57 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 HCT® was approved in Switzerland in October 2008 and a European Commission decision is expected for the single-pill combination in early 2009.

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 *may*, *expected*, *hope*, *potential*, *risk*, *expected*, or similar expressions, or by express or implied discussions regarding potential new indications or labelling 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 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 97,000 full-time associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

**References**

- (1) Duprez DA et al. The AGELESS Study: The Effect of Aliskiren vs Ramipril Alone or in Combination with Hydrochlorothiazide and Amlodipine in Patients  $\geq$  65 Years of Age with Systolic Hypertension. Oral Presentation at the American Heart Association 2008 Scientific Sessions.
- (2) Fagard RH. Epidemiology of Hypertension in the Elderly. *Am J Geriatr Cardiol* 2002;11:23-28.
- (3) Ostchega Y, Dillon CF, Hughes JP, et al. Trends in Hypertension Prevalence, Awareness, Treatment, and Control in Older U.S. Adults: Data from the National Health and Nutrition Examination Survey 1988 to 2004. *J Am Geriatr Soc* 2007;55:1056-1065.
- (4) Lewington S et al. Age-Specific Relevance of Usual Blood Pressure to Vascular Mortality: A Meta-Analysis of Individual Data for One Million Adults in 61 Prospective Studies. *Lancet* 2002; 360: 1903-13.
- (5) Andersen K, Weinberger MH, Egan B et al. Comparative Efficacy and Safety of Aliskiren, An Oral Direct Renin Inhibitor, and Ramipril in Hypertension: A 6-month, Randomized, Double-Blind Trial. *J Hypertens* 2008;26:589-99.
- (6) Uresin Y, Taylor AA, Kilo C et al. Efficacy and Safety of the Direct Renin Inhibitor Aliskiren and Ramipril Alone or in Combination in Patients with Diabetes and Hypertension. *J Renin Angiotensin Aldosterone Syst* 2007;8:190-8.
- (7) 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.
- (8) Sander GE. Hypertension in the Elderly. *Curr Hypertens Rep* 2004;6:469-476.
- (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.

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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: November 11, 2008

By: /s/ MALCOLM B. CHEETHAM

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