NOVARTIS AG
Form 6-K
May 18, 2006

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 18, 2006

(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: ý 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**: ý

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**: ý

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**: ý

Enclosures:

1. New data demonstrates efficacy of Rasilez as a potentially innovative oral direct renin inhibitor for treatment of high blood pressure (Basel, May 17, 2006)

2. Novartis announces first Phase III Exforge data, shows strong efficacy as new high blood pressure treatment with dual mechanisms of action (Basel, May 17, 2006)

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- Investor Relations Release -

New data demonstrates efficacy of Rasilez as a potentially innovative oral direct renin inhibitor for treatment of high blood pressure

Studies show investigational medicine Rasilez provides significant and sustained blood pressure reduction over 24-hour period

Potential for use both as monotherapy and in combination with other high blood pressure medicines

Direct renin inhibitors will be the first new class of high blood pressure medicines available in more than 10 years

US submission completed in April, EU submission expected by end-2006

Basel, May 17, 2006 New data for Rasilez® (aliskiren), the first orally effective direct renin inhibitor, reaffirmed that it provides a significant and sustained blood pressure response over a 24-hour period, both when used alone or in combination with the diuretic hydrochlorothiazide (HCTZ), one of the most commonly-used high blood pressure medicines.

The Rasilez data, which was presented today at the American Society of Hypertension, Inc., Annual Scientific Meeting and Exposition (ASH 2006) in New York, showed durable and persistent blood pressure lowering over the entire 24-hour dosing period. This is important because blood pressure often surges during early morning hours.

Throughout the clinical program, Rasilez has also shown significant blood pressure response when used in combination with ACE inhibitors and calcium channel blockers, with a superior response seen in trials against the ACE inhibitor ramipril. Rasilez has shown placebo-like tolerability as a monotherapy and has been well tolerated when used with other common cardiovascular as well as anti-diabetic medicines.

High blood pressure and its consequences is the world s No.1 killer, estimated to affect nearly one billion people. The overwhelming number of patients who remain uncontrolled despite current treatments speaks to the urgent need for new options, said Dr. James Shannon, MD, Head of Development at Novartis Pharma AG. These new data for Rasilez underscore our commitment to developing novel medicines to help physicians get their patients blood pressure under control.

If approved, Rasilez, developed with Speedel, will represent the first new treatment approach for people with high blood pressure in more than a decade. It acts within the renin system, which is

central to blood pressure regulation. By directly inhibiting the system s point of activation renin Rasilez decreases the system s activity, as measured by plasma renin activity (PRA).(1)

Submission in the US was completed in April 2006, while European submission remains on track for the end of 2006. The trade name Rasilez is pending FDA and other regulatory approvals.

Rasilez offers consistent 24-hour control(1)

Rasilez provides sustained blood pressure control throughout a 24-hour dosing period. This was shown in a randomized, double-blind, multicenter, placebo-controlled study with 672 people with mild-to-moderate high blood pressure given Rasilez 150 mg, 300 mg, or 600 mg once a day, or placebo.

Sustained 24-hour control is particularly important because blood pressure fluctuates during the day and often surges in the early morning hours, said lead investigator Dr. Jerry Mitchell, MD, of the Texas Center for Drug Development in Houston. Patients need to control their blood pressure around the clock, and our study shows that aliskiren can provide that control.

Ambulatory systolic and diastolic blood pressure measurements over 24 hours were lowered and statistically significant ($p<0.0001$). Also with Rasilez 300 mg, the trough-to-peak ratio for lowering diastolic blood pressure was 0.98, indicating that reductions were consistent and nearly identical over the entire 24-hour period. The trough-to-peak ratio for Rasilez 150 mg was 0.64 and for 600 mg was 0.86.

Rasilez significantly reduces blood pressure alone and in combination(2)

Rasilez provides effective blood pressure control when used alone or in combination with the diuretic (HCTZ). A randomized double-blind 8-week study of 2,776 people with high blood pressure who received Rasilez at 75 mg, 150 mg or 300 mg in various combinations with HCTZ or placebo showed that Rasilez significantly reduced mean sitting systolic ($p<0.0001$) and diastolic blood pressure ($p<0.0002$).

This study showed that aliskiren is an effective treatment for high blood pressure when given alone and provided additional blood pressure reductions when combined with HCTZ, said study author Dr. Alberto Villamil, MD, of Buenos Aires, Argentina. The additive effect is particularly promising because when aliskiren and HCTZ were used together, blood pressure dropped significantly more than with either agent alone.

Similarly, the combination of Rasilez 300 mg and HCTZ 25mg resulted in the highest percentage of responders, defined as patients who reached the goal for diastolic blood pressure of less than 90 mmHg and/or decreased blood pressure by at least 10 mmHg.

In the overall clinical program, Rasilez at doses up to 300 mg (within the expected therapeutic dose range) has consistently shown tolerability similar to placebo.

The foregoing release contains forward-looking statements which can be identified by the use of terminology such as potentially innovative , potential , will , expected , promising , if approved will , submission remains on track or similar expressions, or by express or implied disc regarding the potential regulatory approval of Rasilez, or potential future revenue from Rasilez. Such statements reflect the current views of the Novartis group of companies with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that any current or future regulatory filings will satisfy the FDA s or other health authorities requirements, that Rasilez will be approved for any indications in any market, that Rasilez will be brought to market in the US or in any other country, nor that it will reach any particular sales levels. In particular, management s expectations regarding the approval and commercialization of Rasilez could be affected by, among other things, additional analysis of clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or

delays or government regulation generally; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; increased government, industry, and general public pricing pressures; 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 (NYSE: NVS) is a world leader in offering medicines to protect health, treat disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. Novartis is the only company with leadership positions in both patented and generic pharmaceuticals. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics, human vaccines and leading self-medication OTC brands. In 2005, the Group s businesses achieved net sales of USD 32.2 billion and net income of USD 6.1 billion. Approximately USD 4.8 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 96,000 people and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

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References

(1). Mitchell J, Oh B, Herron J, Chung J, Khan M, Satlin A. Once-daily aliskiren provides effective, smooth 24-hour blood pressure control in patients with hypertension. Abstract to be presented at American Society of Hypertension (ASH) 21st Annual Meeting and Exposition.

(2) Villamil A, Chrysant S, Calhoun D. Schober B, Hsu H, Zhang J. The novel oral renin inhibitor aliskiren provides effective blood pressure control in patients with hypertension when used alone or in combination with hydrochlorothiazide. Abstract to be presented at American Society of Hypertension (ASH) 21st Annual Meeting and Exposition.

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- Investor Relations Release -

Novartis announces first Phase III Exforge data, shows strong efficacy as new high blood pressure treatment with dual mechanisms of action

Exforge provides strong blood pressure reductions, including up to 43 mmHg in patients with moderate-to-severe high blood pressure

Majority of patients taking Exforge reach recommended blood pressure goal

US and EU submissions completed in first quarter of 2006

Basel, May 17, 2006 The first Phase III data for Exforge® (amlodipine besylate/valsartan) showed patients with high blood pressure treated with the investigational medicine experienced strong reductions of blood pressure some even up to 43 mmHg with excellent tolerability.

The Exforge data, which were presented at the American Society of Hypertension, Inc., Annual Scientific Meeting and Exposition (ASH 2006) in New York, also showed that the two complementary mechanisms of action helped more than 80% of patients studied reach their recommended blood pressure goals. Exforge was shown to be safe and well tolerated in the overall clinical trial program involving 5,000 patients.

Exforge is the first high blood pressure medication to combine the most commonly prescribed branded high blood pressure medicines in their respective classes the calcium channel blocker (CCB) amlodipine besylate and the angiotensin receptor blocker (ARB) valsartan. Submissions for US and EU approval were completed earlier in 2006.

Many patients need three or more medicines to control their high blood pressure, which is considered the world s leading killer. Exforge has been shown to be a highly effective and well tolerated blood pressure-lowering agent in a broad range of patients, particularly those who have the most severe high blood pressure and are among the most challenging to treat, said Dr. James Shannon, MD, Head of Development at Novartis

Pharma AG.

Exforge has the potential to be an optimal way to use amlodipine due to a lower incidence of peripheral edema (fluid retention) in patients taking Exforge compared to those taking amlodipine alone. The single-tablet combination also provides the additional efficacy and potential end-organ protection of valsartan, the active ingredient in Diovan®.

Up to 43 mmHg systolic blood pressure drop in most severe patients

In the Phase III study(1), high blood pressure patients (considered to have diastolic blood pressure of 110 mmHg or more but less than 120 mmHg) who were treated with Exforge experienced an average drop of 35.8 mmHg in systolic blood pressure compared to 31.8 mmHg with the combination of the ACE-inhibitor lisinopril and the diuretic hydrochlorothiazide (HCTZ).

Although the study was primarily designed to evaluate the overall safety profile of amlodipine besylate/valsartan, patients with systolic blood pressures of at least 180 mmHg and treated with Exforge achieved an average reduction of 43.0 mmHg compared to 31.2 mmHg with the lisinopril/HCTZ combination.

The results also showed that 80% of patients treated with Exforge for six weeks reached the recommended goal of mean sitting diastolic blood pressure of less than 90 mmHg.

Reductions in average blood pressure ranging from 35 mmHg to 43 mmHg were significant with amlodipine besylate/valsartan, said Dr. Don Poldermans, MD, of the Erasmus Medisch Centrum in the Netherlands. We were particularly impressed by the drug s efficacy in patients having a systolic blood pressure over 180 mmHg. These findings are important in patients with uncontrolled hypertension since every decrease of 20/10 mmHg in blood pressure halves the risk of cardiovascular events.

About high blood pressure

High blood pressure and its consequences is the world s No. 1 killer and is estimated by the American Heart Association to affect one in four adults around one billion people globally. Despite extensive use of current therapies, about 70% of all people with high blood pressure do not reach target blood pressure levels. Many people require three or more medicines to control their blood pressure. Meanwhile, many existing treatments fail to provide sustained 24-hour blood pressure control, particularly during the early morning hours.

The foregoing release contains forward-looking statements which can be identified by the use of terminology such as has the potential or similar expressions, or by express or implied discussions regarding the potential regulatory approval of Exforge, or potential future revenue from Exforge. Such statements reflect the current views of the Novartis group of companies with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that any current or future regulatory filings will satisfy the FDA s or other health authorities requirements, that Exforge will be approved for any indications in any market, that Exforge will be brought to market in the US or in any other country, nor that it will reach any particular sales levels. In particular, management s expectations regarding the approval and commercialization of Exforge could be affected by, among other things, additional analysis of clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; increased government, industry, and general public pricing pressures; 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.

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Reference

(1). Comparative safety and blood pressure (BP)-lowering efficacy of a combination of amlodipine + valsartan and lisinopril + hydrochlorothiazide in patients with stage 2 hypertension; ASH 2006

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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 18, 2006

By: /s/ MALCOLM B. CHEETHAM

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