

NOVARTIS AG  
Form 6-K  
April 21, 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 April 21, 2006**

**(Commission File No. 1-15024)**

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## **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:

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**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

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Enclosures:

1. New drug application for Rasilez®, an innovative oral renin inhibitor to treat high blood pressure, accepted for US regulatory review (Basel, April 20, 2006 )
  2. Novartis acquisition of Chiron approved by Chiron shareholders (Basel, April 19, 2006)
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**- Investor Relations Release -**

®

New drug application for **Rasilez**®, an innovative oral renin inhibitor to treat high blood pressure, accepted for US regulatory review



## Edgar Filing: NOVARTIS AG - Form 6-K

*Renin inhibitors would be the first new class of high blood pressure medicines available in more than 10 years*

*US submission includes data from more than 6,000 patients on Rasilez in 34 trials*

*Clinical trials showed Rasilez use as a monotherapy produced significant blood pressure reductions sustained over 24 hours*

*Seeking approval use as a monotherapy and in combination with other high blood pressure medicines*

**Basel, April 20, 2006** Novartis announced today that the US Food and Drug Administration (FDA) accepted its application for Rasilez (aliskiren) as a treatment for high blood pressure. As a renin inhibitor, Rasilez would represent the first new treatment approach for people with high blood pressure in more than a decade. European submission remains on track for 2006.

The US submission included data from more than 6,000 people with high blood pressure. These data showed that when used alone, Rasilez produced significant blood pressure reductions sustained over 24 hours.(1)

The sustained 24-hour blood pressure control achieved with once-daily Rasilez is good news for people with high blood pressure, said Dr. James Shannon, MD, Head of Development at Novartis Pharma AG. This innovative medicine has the potential to redefine future treatment standards, and studies are now underway to evaluate potential long-term benefits beyond blood pressure control.

Throughout the clinical program, Rasilez showed placebo-like tolerability when used alone. When used with ACE inhibitors, calcium channel blockers or a diuretic, Rasilez delivered additional blood pressure reductions, helping people already on therapy to reach their blood pressure goals. Rasilez was well tolerated when used with the most common cardiovascular and anti-diabetic medicines.

We continue to need new therapeutic approaches to control blood pressure, said Dr. Michael Weber, MD, Professor of Medicine at SUNY Downstate Medical Center in New York. Renin inhibition has long been considered a logical and highly desired treatment approach. The Rasilez data show that inhibiting renin directly is effective in reducing blood pressure, and in this case, over 24 hours.

### **Renin inhibition: a unique mechanism of action**

Rasilez, developed with Speedel, is a first-of-its-kind treatment in the long search for effective oral renin inhibition. It acts within the renin system, which is central to blood pressure regulation. By suppressing the system's point of activation – renin – Rasilez decreases the activity of the renin system, as measured by plasma renin activity (PRA).

### **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.(2) 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.(3) Meanwhile, many existing treatments fail to provide sustained 24-hour blood pressure control, particularly during the early morning hours.

The trade name Rasilez is currently pending regulatory, including FDA, approval.

This release contains certain forward-looking statements, relating to the Group's business, which can be identified by the use of forward-looking terminology such as "would", "has the potential to redefine", "potential long-term benefits", or similar expressions, or by express or implied discussions 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,

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which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics 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 91,000 people and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

### References

1. Data on file: Novartis study SPP100 A2308
2. American Heart Association. International Cardiovascular Disease Statistics fact sheet.  
[www.americanheart.org](http://www.americanheart.org)
3. Datamonitor, Treatment algorithms. Hypertension, 2003

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Novartis acquisition of Chiron approved by Chiron shareholders

***Novartis to establish additional growth platform through creation of new Vaccines & Diagnostics division***



***Acquisition further strengthens Novartis pipeline, expands oncology franchise***



## Edgar Filing: NOVARTIS AG - Form 6-K

**Basel, April 19, 2006** Novartis announced today that shareholders of Chiron Corporation voted to approve its acquisition of Chiron, paving the way for the creation of a new division at Novartis focusing on vaccines and diagnostics.

At a special shareholder meeting held today in Emeryville, California, over 85% of the total 198 million votable shares were cast in favor of the proposed transaction, while 12% were not voted, according to a preliminary count.

Under the terms of the transaction, which is expected to close on April 20, Novartis will acquire all outstanding shares of Chiron that Novartis does not already own for USD 48 per share. The all-cash deal represents a total value of USD 5.4 billion. Annual cost synergies totaling USD 200 million are anticipated within three years after closing, with 50% expected to be achieved in the first 18 months.

The merger certificate has been filed, with the merger to become effective as of 12:01 a.m. Eastern Daylight Time on Thursday, April 20, 2006.

With the close of this transaction, Novartis will gain access to attractive strategic growth platforms in the dynamic vaccines market and the rapidly expanding diagnostics business. At the same time, Chiron will add to our pharmaceuticals pipeline, especially in our oncology franchise, said Dr. Daniel Vasella, Chairman and CEO of Novartis. With innovative medicines at our core, complemented by generic drugs, over-the-counter treatments and now preventive medicines in the form of vaccines, Novartis offers a full spectrum of treatments, benefiting patients and physicians around the world.

### **Vaccines & Diagnostics to focus on ensuring supply and accelerating innovation**

Novartis is creating a new division called Novartis Vaccines & Diagnostics, consisting of two businesses: Novartis Vaccines and a diagnostics business that will retain the Chiron name.

We are committed to investing the significant skills and capital needed to build a global leader in the increasingly important vaccines and diagnostics markets and contribute to meeting emerging public health needs, said Dr. Joerg Reinhardt, CEO of Novartis Vaccines & Diagnostics. Novartis will strive to ensure that we provide our customers and patients with a safe and effective supply of vaccines, especially at a time when the world faces the potential threat of a global flu pandemic. By combining our skills and resources we will enhance manufacturing reliability and capacity while accelerating our ability to innovate.

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Leveraging the solid manufacturing capabilities and skills of Novartis, the company will continue to prioritize the completion of ongoing manufacturing remediation efforts. Novartis Vaccines & Diagnostics will focus on continued improvements in quality assurance and making the necessary investments to upgrade manufacturing capabilities while exploring new technologies to increase the capacity and reliability of the manufacturing process.

While the Chiron blood testing business is already strong in the US, Novartis sees an opportunity to strengthen its position globally. To grow this business Novartis plans to make additional investments in R&D, and explore opportunities to expand in molecular diagnostics.

#### **BioPharmaceuticals assets integrated with Pharmaceutical and research networks**

Chiron's BioPharmaceutical business will be integrated into Novartis Pharmaceuticals, where Chiron's products and pipeline will complement the in-market and development portfolios of Novartis in the respiratory, infectious diseases and oncology franchises. Included in Chiron's portfolio are products for the treatment of cystic fibrosis, renal/skin cancer and skin infections. Chiron's early-stage research will be incorporated into the Novartis Institutes for BioMedical Research (NIBR), which will maintain Chiron's existing research center in Emeryville, California.

This communication is for information purposes only. It shall not constitute an offer to purchase, sell or exchange, or the solicitation of an offer to purchase, sell or exchange any securities of Novartis or Chiron. The distribution of this news release may, in some countries, be restricted by law or regulation. Accordingly, persons who come into possession of this document should inform themselves of and observe these restrictions.

This document contains forward-looking statements within the meaning of the US Private Securities Litigation Reform Act. Forward-looking statements are statements that are not historical facts and are generally identified by the words "will", "expected", "anticipated", or similar expressions, or by express or implied discussions regarding strategies, plans and expectations (including synergies). These statements include, but are not limited to, financial projections and estimates and their underlying assumptions, statements regarding the benefits of the business transactions described herein, including future financial and operating results. Such statements reflect the current plans, expectations, objectives, intentions or views of management with respect to future events, are based on the current beliefs and expectations of management, and are subject to significant risks, uncertainties and assumptions. Management's expectations could be affected by, among other things, competition in general, the general economic environment and other risks such as, but not limited to, those referred to in Novartis AG's Form 20-F on file with the U.S. Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may differ materially from those set forth or implied by the forward-looking statements.

The following factors, among others, could cause actual results to differ materially from those set forth in the forward-looking statements: the risk that the businesses will not be integrated successfully; the risk that the cost savings and any other synergies from the transaction may not be fully realized or may take longer to realize than expected; disruption from the transaction making it more difficult to maintain relationships with customers, employees or suppliers; social and political conditions such as war, political unrest and terrorism or natural disasters; general economic conditions and normal business uncertainty and competition and their effect on pricing, spending, third-party relationships and revenues. These forward-looking statements speak only as of the date of this press release and no undertaking has been made to update or revise them if there are changes in expectations or in any events, conditions or circumstances on which any such forward-looking statement is based.

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# # #

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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: April 21, 2006 By: /s/ MALCOLM B. CHEETHAM  
Name: Malcolm B. Cheetham  
Title: Head Group Financial  
Reporting and Accounting

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This announcement will also be available on HSBC's website at [www.hsbc.com/sea](http://www.hsbc.com/sea)

Enquiries to:

Loren Wulfsohn  
Shareholder Services Team  
+ 44 (0) 207 991 8918

#### SIGNATURE

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.

HSBC Holdings plc

By:

Name: Ben J S Mathews

Title: Group Company Secretary

Date: 12 September 2016