NOVARTIS AG
Form 6-K
May 03, 2005

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 for the month of April 2005

(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 study finds Coartem® (artemether-lumefantrine) is the most effective malaria treatment in areas of high resistance to conventional anti-malarials (Basel, April 26, 2005)

2. Novartis provides progress update on plans to integrate Hexal and Eon Labs with Sandoz (Basel, April 26, 2005)

3. Novartis receives European marketing authorization for Aclasta® (Basel, April 21, 2005)

4. Novartis announces agreement to develop and commercialize new treatment for chronic obstructive pulmonary disease (Basel, April 13, 2005)

5. Novartis provides update on regulatory developments regarding its pending acquisitions of Hexal AG and Eon Labs (Basel, April 08, 2005)

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MEDIA RELEASE **COMMUNIQUE AUX MEDIAS** **MEDIENMITTEILUNG**

New study finds Coartem® (artemether-lumefantrine) is the most effective malaria treatment in areas of high resistance to conventional anti-malarials

USD 170 million financing commitment from Global Fund will help secure the majority of 2005-2006 Coartem supply

Novartis continues unprecedented production scale-up to meet rapidly increasing demand estimates

Basel, April 26, 2005 A new study published in *The Lancet* suggests that the combination of artemether and lumefantrine, available from Novartis under the brand name Coartem, is the most effective available treatment for malaria in children in areas of Africa where resistance to conventional anti-malarial drugs is high. Developed and produced by Novartis and its Chinese partners, Coartem is currently the only fixed-dose artemisinin-based combination therapy pre-qualified by the World Health Organization (WHO) for procurement by United Nations agencies.

Recently, the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria approved a grant of USD 170 million to seven African nations for the procurement of Coartem over the next two years.

These new clinical data confirm that Coartem is the current gold standard to treat malaria in areas of high resistance to conventional anti-malarials and is as such a life-saving drug, said Dr. Daniel Vasella, Chairman and CEO of Novartis. When combined with the most recent financing commitment from the Global Fund, these results underpin our efforts to rapidly ramp up the production of Coartem.

Since 2001, Novartis has supplied more than six million treatments of artemether-lumefantrine on a non-profit basis for distribution to the public sector in malaria-endemic developing countries. Production of Coartem, currently the leading artemisinin-based combination therapy (ACT), has increased from 100,000 treatments in 2002 to a projected 30 million treatments in 2005. The original 2001 agreement between Novartis and the WHO forecast demand for Coartem at just over two million treatments in 2005. Since then, non-binding demand forecasts provided by WHO have continuously increased, including a six-fold jump in the 2005 demand forecast between December 2003 and March 2004. In this three month period, the WHO demand forecast surged from 10 million to 60 million treatments.

Results of new study by the London School of Hygiene and Tropical Medicine

In the April 23, 2005 edition of *The Lancet*, Dr. T. K. Mutabingwa and colleagues at the London School of Hygiene and Tropical Medicine reported on a randomised trial of anti-malarial drug

combinations for children (aged 4 59 months) with uncomplicated malaria in Muheza, Tanzania. This area has a high prevalence of resistance to sulfadoxinepyrimethamine and chloroquine. Children were randomly allocated three days of amodiaquine (n=270), amodiaquine+sulfadoxine-pyrimethamine (n=507), amodiaquine+artesunate (n=515), or a three-day six-dose regimen of artemether-lumefantrine (n=519). Drugs were taken orally, at home, unobserved by medical staff. The primary endpoint was parasitological failure by day 14 assessed blind to treatment allocation. Secondary endpoints included day 28 follow-up and gametocyte carriage.

Analysis was by intention to treat. Of 3,158 children screened, 1,811 were randomly assigned treatment and 1,717 (95%) reached the 14-day follow-up. The amodiaquine group was stopped early by the data and safety monitoring board because it reached a pre-determined stopping rule of more than 40% parasitological failure by day 14. By day 14, the parasitological failure rates were 103 of 248 (42%) for amodiaquine, 97 of 476 (20%) for amodiaquine+sulfadoxinepyrimethamine, 54 of 491 (11%) for amodiaquine+artesunate, and seven of 502 (1%) for artemether-lumefantrine. By day 28, the parasitological failure rates were 182 of 239 (76%), 282 of 476 (61%), 193 of 472 (40%), and 103 of 485 (21%), respectively. The difference between individual treatment groups and the next best treatment combination was significant (p0.001) in every case. Recrudescence rates by day 28, after correction by genotyping, were 48.4%, 34.5%, 11.2%, and 2.8%, respectively.

The authors concluded that there are few options for treating malaria where there is a high level of resistance to sulfadoxinepyrimethamine and amodiaquine.

Unprecedented scale-up underway

The rapid scale-up underway at Novartis to meet public sector demand for Coartem is unprecedented in commercial drug production for a new chemical entity. The effort will require operation of two large scale manufacturing plants to produce more than 1.9 billion Coartem tablets which equates to 120 million treatments in 2006.

We have already significantly increased our investments in Coartem production, including in the cultivation of *Artemisia annua* and the extraction of artemisinin, which is currently in short supply due to the annual planting cycle, Dr. Vasella added. We are confident that we will succeed in increasing the available volumes to 30 million treatments by the end of the year and to 120 million treatments in 2006. While we provide Coartem at cost, our efforts would be in vain without the Global Fund s financial aid allowing governments of malaria endemic countries to purchase the drug.

Novartis said its investments are focused on expanding manufacturing infrastructure, increasing and diversifying the supplier base for the production of raw material and transitioning a largely wild crop to commercial plantation cultivation. For the first time, significant volumes of artemisinin will be produced in Africa following the 2005 harvest.

Novartis said its ability to meet 2005 Coartem production goals remains dependent upon the availability of sufficient supplies of the key natural raw material *Artemisia annua* and the extraction product artemisinin, and, most importantly, the timely receipt of firm Coartem orders from affected countries.

Firm financing commitments for the purchase of ACTs is perhaps the highest return investment in improving public health that donor organizations can make today, said Professor Bob Snow, a leading scientist in the field of malaria research and public health, from Kenya Medical Research Institute, Nairobi and University of Oxford, UK. Millions of lives can be saved through swift and

decisive action that bridges the gap between enormous public demand and the realities of commercial supply for artemether-lumefantrine and other ACTs.

Novartis communicated its 2006 production goal of 120 million treatments to leading representatives of the WHO, the Global Fund for HIV/AIDS, Tuberculosis and Malaria, African health ministries and other key stakeholders in the battle against malaria at its annual Coartem Advisory Board meeting held last month in Dakar, Senegal.

About Coartem

Coartem is a highly effective and well tolerated anti-malarial that achieves cure rates of up to 95%, even in areas of multi-drug resistance. It is indicated for the treatment of falciparum malaria, the most dangerous form of malaria. Coartem is the only pre-qualified, fixed-dose ACT combining artemether, an artemisinin derivative, and lumefantrine. This fixed-dose combination is of great benefit to patients as it facilitates treatment compliance and supports optimal clinical effectiveness.

Artemisinin is a compound extracted from the sweet wormwood plant and has been used for centuries in traditional Chinese medicine to treat fever. An artemisinin-based combination therapy is a combination of two or more drugs (one of which is an artemisinin derivative) with different modes of action and different targets. Studies have shown that using two or more drugs in combination has the potential to delay the development of resistance in areas of low transmission. Artemisinin-based combination therapies in particular have been found to be highly effective treatments for malaria and their potential to delay resistance in areas of intense transmission is under investigation.

Coartem was co-developed by Novartis in collaboration with Chinese partners who also supply the active ingredients (artemether and lumefantrine). The final Coartem tablets are produced in China by Novartis. Coartem is currently registered in 79 countries worldwide and more than six million patients have benefited from this innovative treatment since its first registration in October 1998. Coartem has been extensively studied in multi-center clinical trials involving more than 3,000 patients.

This release contains certain forward-looking statements that can be identified by the use of forward-looking terminology, such as continues , will help secure , projected , will require , will succeed , would be , will be , has the potential , or similar expressions, or by express or im discussions regarding Novartis ability to meet its projected production goals of Coartem. 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 the actual results with Coartem to be materially different from any future results, performance, or achievements expressed or implied by such statements. There can be no guarantee that Novartis will be able to achieve any particular level of Coartem production in the future. Any such results can be affected by, among other things, the ability to obtain the necessary raw materials, uncertainties relating to regulatory actions or government regulation generally, as well as factors discussed in the Company s Form 20-F filed 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 described herein as 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

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Group s businesses achieved sales of USD 28.2 billion and a pro forma net income of USD 5.6 billion. The Group invested approximately USD 4.2 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 81 400 people and operate in over 140 countries around the world.

Novartis was recently honored with the 2005 Excellence in Corporate Philanthropy Award from the Committee to Encourage Corporate Philanthropy. In 2004, over 4.25 million patients around the world benefited from Novartis programs valued at USD 570 million. These initiatives range from drug donation and research programs to combat neglected diseases like malaria, tuberculosis and leprosy in developing nations to patient assistance programs that help cancer patients receive the most innovative and effective treatments available. For further information please consult http://www.novartis.com.

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- Investor Relations Release -

Novartis provides progress update on plans to integrate Hexal and Eon Labs with Sandoz

Holzkirchen, Germany, named as new Sandoz Global Headquarters site

70% of Country General Managers have been nominated

Basel, April 26, 2005 Novartis reports on key milestones in the integration planning to merge Hexal AG and Eon Labs, Inc. with Sandoz.

In the few weeks since the acquisitions were announced in February, we have made great progress in developing our plans to integrate the three companies, said Dr. Andreas Rummelt, CEO of Sandoz. At the same time, we sustained the momentum in our business, achieving our targets and addressing the needs of patients and physicians who want high-quality, low-cost generics.

Integration planning activities are under way to ensure the completion of the transaction and successful operation of the combined company after the closings, which are expected to be completed in the second half of 2005. In the meantime, all three companies continue to operate separately as independent, directly competing companies.

The goal of our integration planning is to be fully prepared to operate as one unified, aligned company immediately following regulatory approvals, Dr. Rummelt said.

Action steps that have been completed include the creation of an Integration Steering Committee and Integration Office to lead all integration-related activities. Approximately 70% of Country General Managers have been nominated as part of a process that will be completed by early May. All candidates are assessed by top executives of Sandoz and Hexal based on their business performance, experience and leadership skills.

Specific strategies based on publicly available data have been charted out for each country. This includes the decision under which brand the new company will operate in the various countries. In this context, it has been decided to maintain both the Hexal and Sandoz names in Germany.

Holzkirchen, Germany, has been chosen as the new location of the global headquarters for Sandoz.

The primary reason for this choice was the proximity to major operational sites of the Hexal commercial, development and production functions in Holzkirchen and the Sandoz production site in Kundl, Austria. The emerging biotechnology industry in Munich was an additional factor. The

importance of Germany the No.2 generics market in the world and one of the fastest-growing markets and government support on the local and state levels also played an important role. Approximately 150 employees will be located in the global headquarters in Holzkirchen, which also will be the site for regional commercial operations as well as the Hexal German commercial operations of the new company.

The Austrian Government was very supportive in facilitating the implementation of the headquarters of the new company in Vienna, but the proximity to operations in the end outweighed all of the advantages of maintaining the headquarters in Vienna.

However, the Kundl site in Tyrol, which currently employs approximately 2,700 people, will remain the headquarters of the Anti-infectives business unit. In addition, Novartis is evaluating the possibility of further strengthening the biopharmaceutical operations by investing in a plant expansion and adding approximately 50 new jobs at this site. The final decision will depend on the outcome of ongoing discussions with the Tyrolean government. The departure of the Sandoz headquarters from Vienna will have no impact on the activities of the pharma research center in Vienna.

Selected Technical Operations functions will be transferred to the global headquarters of Novartis in Basel, Switzerland, in order to take advantage of the existing infrastructure and of possible synergies with Logistics, Purchasing and Finance functions. The company expects to add some 30 positions in Basel.

About Novartis

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Sandoz, a Novartis company, is a world leader in generic pharmaceuticals and develops, manufactures and markets these medicines as well as pharmaceutical and biotechnological active ingredients. Decades of experience and know-how make Sandoz a renowned partner in pharmaceuticals, biogenerics and anti-infectives. Altogether, Sandoz employs 13,000 people in over 110 countries and reported sales of USD 3.0 billion in 2004.

Disclaimer

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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 ability to obtain governmental approvals for the transaction on the proposed terms and schedule; 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; and general economic conditions and normal business uncertainty and competition and its 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 if any events, conditions or circumstances on which any such forward looking statement is based.

Securityholders of Eon are urged to read the tender offer statement relating to the tender offer when such document becomes available. The tender offer statement will contain important information. Eon Securityholders will be able to obtain a free copy of the tender offer statement and other filed documents when they become available at the SEC s internet site (http://www.sec.gov).

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- Investor Relations Release -

Novartis receives European marketing authorization for Aclasta®

First long-lasting treatment for Paget s disease delivered as a 15 minute intravenous infusion

Basel, April 21, 2005 Novartis announced today that it has signed a global development and commercialization agreement with Vectura Group plc and Arakis Ltd. for AD 237, an inhaled, long-acting, anti-muscarinic agent for the treatment of chronic obstructive pulmonary disease (COPD).

Novartis will be responsible for further development of AD 237 both as monotherapy and in combination with QAB149, its once-daily, long-acting beta2 agonist currently in Phase II clinical development.

Developed to date through a joint venture between Arakis and Vectura, AD 237 is a once-daily, long-acting muscarinic antagonist (LAMA) with a fast onset of action. The compound is in Phase II trials for the treatment of COPD and studies have thus far demonstrated that it is well-tolerated and effective over 24 hours after a single dose. AD 237 has been developed using Vectura s proprietary PowderHale® inhalation technology for delivering product to the lung and optimizing fine particle fraction delivery through a commercially available dry-powder inhaler device.

With this agreement, our late stage pipeline now contains two promising bronchodilator drugs, QAB149 and AD 237 for the treatment of COPD, said Joerg Reinhardt, Head of Development, Novartis Pharma AG. Both products have significant therapeutic potential, either as single agents or combination therapies. Respiratory disease is one of our key therapeutic areas of focus, and we are delighted to expand our franchise and provide patients with important new therapeutic solutions.

COPD, the world s fourth largest cause of death, is an irreversible and chronic obstruction of the airways which is caused primarily by smoking. It is estimated that the disease is prevalent in 4% of the population in the USA, Europe and Japan, and that at least one in 15 smokers suffers from it. Symptoms include chronic bronchitis and emphysema or both conditions, which slowly progress and eventually lead to a largely irreversible loss of lung function. The current market for COPD drug therapy is estimated to be worth $4 billion per annum and is predicted to grow to $10 billion by 2010.

Under the terms of the agreement Arakis and Vectura will receive an initial payment and additional milestone payments based upon the achievement of agreed clinical, regulatory and commercialisation targets. In addition, royalties on product sales will be paid for both the

monotherapy and combination products. All payments by Novartis will be shared equally by Arakis and Vectura.

The foregoing press release contains forward-looking statements that can be identified by the use of forward-looking terminology such as will , promising , potential , is estimated , is predicted , or similar expressions, or by express or implied discussions regarding the potential development and commercialization of AD 237 and QAB149. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that the agreement that is the subject of this release will lead to commercialization of AD 237 or QAB149 in any market. Any such commercialization can be affected by, among other things, uncertainties relating to product development and clinical trials; regulatory actions or delays or government regulation generally; the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in general; government, industry, and general public pricing pressures; as well as factors discussed in the Company s Form 20-F filed with the 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 described herein as anticipated, believed, estimated or expected. Novartis is providing this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

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- Investor Relations Release -

Novartis announces agreement to develop and commercialize new treatment for chronic obstructive pulmonary disease

In-licensing deal strengthens late stage pipeline of bronchodilators

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- Investor Relations Release -

Novartis provides update on regulatory developments regarding its pending acquisitions of Hexal AG and Eon Labs

Basel, April 08, 2005 Novartis announced today that it has made submissions to European and US regulatory authorities seeking approval to acquire the generic pharmaceutical companies Hexal AG of Germany and Eon Labs, Inc. of the US.

Novartis filed on April 4, 2005, for European Commission approval under the Merger Control Regulation for the acquisition of privately-held Hexal AG.

A submission for US regulatory approval was made on March 7, 2005. Novartis received a request on April 6, 2005, for additional information (commonly referred to as a second request) from the US Federal Trade Commission. Such a request is not unusual in transactions of this size and nature in the pharmaceutical industry. The effect of this second request is to extend the waiting period imposed by the Hart-Scott-Rodino Antitrust Improvements Act of 1976 until 30 days after Novartis and Eon have substantially complied with the request, unless that period is extended voluntarily by the parties or terminated sooner by the FTC.

The tender process to acquire the publicly-held shares of Eon Labs is planned to start in coordination with the regulatory process.

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Securityholders of Eon are urged to read the tender offer statement relating to the tender offer when such document becomes available. The tender offer statement will contain important information. n Securityholders will be able to obtain a free copy of the tender offer statement and other filed documents when they become available at the SEC s internet site (http://www.sec.gov).

About Novartis

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2004, the Group s businesses achieved sales of USD 28.2 billion and a net income of USD 5.8 billion. The Group invested approximately USD 4.2 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 81,400 people and operate in over 140 countries around the world. Further information is available at www.novartis.com.

Sandoz, a Novartis company, is a world leader in generic pharmaceuticals and develops, manufactures and markets these medicines as well as pharmaceutical and biotechnological active ingredients. Decades of experience and know-how make Sandoz a renowned partner in pharmaceuticals, biogenerics and industrial products. Altogether, Sandoz employs approximately 13,000 people in over 110 countries and reported sales of USD 3.0 billion in 2004.

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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 2, 2005

By: /s/ MALCOLM B. CHEETHAM

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