NOVARTIS AG
Form 6-K
April 05, 2005

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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 March, 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**

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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. PTK/ZK CONFIRM 1 Study Shows Positive Drug Effects in Phase III Study in Metastatic Colorectal Cancer, Filing Now Anticipated for Early 2007 (Basel, March 21, 2005)

2. Novartis investigational renin inhibitor Aliskiren offers once-daily, dose-dependent blood pressure reductions (Basel, March 10, 2005)

3. Femara® approved in Germany as the only hormonal therapy given after standard tamoxifen for post-menopausal woman with early breast cancer (Basel, March 7, 2005)

4. Novartis shareholders approve eighth consecutive dividend increase and fifth share buyback program (Basel, March 1, 2005)

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Investor Relations Release

PTK/ZK CONFIRM 1 Study Shows Positive Drug Effects in Phase III Study in Metastatic Colorectal Cancer, Filing Now Anticipated for Early 2007

Pre-planned analysis of progression-free survival as assessed by investigators achieved statistical significance while analysis of primary endpoint of progression-free survival assessed by central review did not achieve statistical significance

Independent data monitoring board recommends CONFIRM 1 trial to continue to allow analysis of overall survival (Second Primary Endpoint)

Basel, March 21, 2005 Novartis Pharma AG and Schering AG announced today that the analysis of progression free survival (PFS) as assessed by central radiology review in the CONFIRM 1 trial with the investigational drug PTK/ZK did not achieve statistical significance. However, a separate pre-planned analysis of progression-free survival as assessed by the investigators achieved statistical significance.

Further analysis of the data including more detailed evaluations of subpopulations are ongoing to fully assess the potential benefit of PTK/ZK. In the study, PTK/ZK was given in combination with the chemotherapy regimen oxaliplatin/5FU/LV, called FOLFOX-4, compared with FOLFOX-4 alone in previously untreated patients.

Based on a review of the CONFIRM 1 results, an independent data monitoring board recommended the Phase III clinical trial program to continue to allow analysis of overall survival endpoints. This is expected in 2nd half of 2006.

Another ongoing phase III trial, CONFIRM 2, compares the PTK/ZK combination regimen to FOLFOX-4 alone in patients with metastatic colorectal cancer who have progressed after irinotecan-based chemotherapy. An interim analysis is planned in mid- 2005 and final overall survival data are expected in mid-2006.

Novartis and Schering now anticipate filing for approval with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMEA) in early 2007. The CONFIRM 1 data will be submitted as a late-breaking abstract to the American Society of Clinical Oncology (ASCO) meeting in Orlando, Florida, May 13-17, 2005.

"The recommendation by the independent monitoring board to continue the Phase III program, and the investigator assessment of progression encourage us to further explore the potential benefit of PTK/ZK in patients suffering from metastatic colorectal cancer and other cancers," said David Epstein, CEO of Specialty Medicines and president of Novartis Oncology. "Novartis and Schering look forward to the complete data analysis of the ongoing Phase III program."

About PTK/ZK

PTK/ZK, an investigational oral multi-VEGF receptor tyrosine kinase inhibitor, blocks tumor angiogenesis and lymphangiogenesis by inhibiting all known VEGF receptors. Targeting all the VEGF

receptors rather than a single VEGF type may provide a new approach for inhibiting tumor growth and spread.

Safety Data

In the CONFIRM 1 trial, the side effect profile was generally consistent with effects of anti-angiogenic therapy including hypertension and thrombo-embolic events. A review of the safety data will be submitted for presentation at ASCO. To date, in Phase I/II trials, PTK/ZK treatment has been generally well tolerated in more than 500 patients with up to 24 months of uninterrupted treatment. The most frequently reported adverse events were nausea, fatigue, vomiting and dizziness and the majority of these were mild to moderate. PTK/ZK should not be administered to women who are pregnant or lactating or to anyone not practicing adequate contraception.

The foregoing release contains certain forward-looking statements that can be identified by terminology such as "progression-free survival," "are ongoing," "are anticipated," "could be used," "are expected," "will reassess," "further assess the potential benefit," "will explore," "look forward," "are awaiting," "will continue," "has the potential," or similar expressions, or by discussions regarding the potential that PTK/ZK will be approved for marketing, or regarding any potential revenues from PTK/ZK. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with PTK/ZK to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that PTK/ZK will be approved for sale in any market. In particular, management's expectations regarding commercialization of PTK/ZK could be affected by, among other things, uncertainties relating to clinical trials; new clinical data; 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; government, industry and general public pricing pressures; as well as other risks and factors referred to in the Company'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

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MEDIA RELEASE COMMUNIQUE AUX MEDIAS MEDIENMITTEILUNG

Novartis investigational renin inhibitor Aliskiren offers once-daily, dose-dependent blood pressure reductions

Study also demonstrates a safety and tolerability profile for Aliskiren comparable to placebo

Basel, March 10, 2005 Data published in the March issue of the journal *Circulation*[1] indicates a significant dose-dependent response with the antihypertensive agent Aliskiren vs. placebo and another antihypertensive, irbesartan. Aliskiren (SPP100) is potentially the first in a new class of orally active renin inhibitors in development for treating hypertension with the potential for improved end organ protection.

"These data support results from earlier studies and provide additional evidence regarding Aliskiren's potential as a useful antihypertensive agent for people with mild-to-moderate hypertension," said lead investigator Alan Gradman, MD, Chief, Division of Cardiovascular Diseases, The Western Pennsylvania Hospital, Pittsburgh, Penn.

In the eight-week study investigators compared the antihypertensive efficacy and safety of Aliskiren with an active comparator, the angiotensin receptor II blocker irbesartan and placebo. Six hundred and fifty-two patients with mild-to-moderate hypertension (mean sitting diastolic blood pressure ≥95 and <110 mm Hg) were randomized to oral once-daily Aliskiren at 150, 300, or 600 mg doses, irbesartan 150 mg or placebo. All doses of Aliskiren effectively lowered trough (level before next dose is administered) mean sitting diastolic blood pressure (DBP) and systolic blood pressure (SBP). DBP reductions for Aliskiren 150 mg, 300 mg, 600 mg were 9.3mm, 11.8mm, and 11.5mm Hg respectively while SBP reductions were 11.4mm, 15.8mm, and 15.7mm respectively. As with other Aliskiren trials, this study demonstrated dose-dependent efficacy up to the 300 mg dose of Aliskiren.

According to Joerg Reinhardt, Head of Development, Novartis Pharma AG, "People with cardiovascular disease/hypertension are still not being adequately treated to prevent detrimental outcomes. With its unique effect on renin, Aliskiren may offer a new treatment option that goes beyond blood pressure lowering and that will potentially offer further protection for the heart and kidney as well. We continue to be encouraged and look forward to exploring the full potential of the agent."

Suppression of the renin angiotensin system (RAS) using angiotensin converting enzyme inhibitors and angiotensin II receptor blockers has been widely shown to treat hypertension and reduce cardiovascular events. Aliskiren's novel mechanism of action offers a new way to address the RAS by inhibiting renin and reducing plasma renin activity (PRA), thereby optimizing RAS suppression. Other therapies which act on the RAS provide incomplete suppression due to indirect pathways and compensatory feedback mechanisms which in turn result in increased PRA.

Aliskiren treatment was well tolerated at all doses in the study. The most commonly reported events were headache, dizziness and diarrhea. The incidence of adverse events and discontinuations due to adverse events was relatively low and was similar to that observed with the placebo or irbesartan treatment.

The phase III clinical trial program for Aliskiren as monotherapy and in combination with other antihypertensive therapies is ongoing. The development of Aliskiren is driven by Novartis' cardiovascular and metabolic research and development program. Novartis is a worldwide leader in cardiovascular care and in the treatment of a variety of metabolic disorders.

Novartis discovered Aliskiren and licensed it to Speedel, a privately-held biopharmaceutical company in 2000. After completion of phase I and II trials by Speedel, Novartis exercised a call-back option in 2002 and is now solely responsible for development and commercialization of Aliskiren.

The foregoing release contains forward-looking statements that can be identified by terminology such as "potentially", "potential", "may offer", "look forward", or similar expressions, or by discussions regarding potential regulatory approvals for or potential future revenue from Aliskiren. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Aliskiren to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Aliskiren will be approved for any indications or labelling in any market. Neither can there be any guarantee that Aliskiren will ever be sold or achieve any particular level of revenue in any market. In particular, management's expectations regarding Aliskiren could be affected by, among other things, additional analysis of Aliskiren 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; government, industry, and general public pricing pressures, and other risks and factors referred to in the Company'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

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References

1 Gradman AH, Schmieder RE, Lins RL, et al. Aliskiren, a Novel Orally Effective Renin Inhibitor, Provides Dose-Dependent Antihypertensive Efficacy and Placebo-Like Tolerability in Hypertensive Patients. *Circulation*. 2005;111:1012-1018.

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Investor Relations Release

Femara® approved in Germany as the only hormonal therapy given after standard tamoxifen for post-menopausal woman with early breast cancer

Marks first major market under EU Mutual Recognition Procedure

New extended adjuvant setting option approved in more than 40 countries worldwide

Landmark MA-17 trial demonstrated significant 42% reduction in the risk of distant breast cancer recurrence post-tamoxifen (extended adjuvant)

Basel, March 7, 2005 Novartis announced today that Femara® (letrozole) has received marketing authorization via the Mutual Recognition Procedure in Germany, a major European market, for the treatment of postmenopausal women who have completed five years of standard adjuvant (post-surgery) tamoxifen therapy (extended adjuvant).

More than 40 countries, including the US, Switzerland and the United Kingdom, have issued approvals for Femara for the extended adjuvant indication. This approval is based on the landmark MA-17 study, an independent, internationally conducted trial that included more than 5,100 postmenopausal women which was coordinated by the National Cancer Institute of Canada Clinical Trials Group at Queens University in Kingston, Ontario, and supported by Novartis. Initial results were published in the New England Journal of Medicine in October 2003.

The study showed that Femara reduced the risk of cancer coming back, or disease-free survival, by 42%. This is particularly important because when breast cancer recurs, it very often has spread beyond the breast (metastatic disease), which can have serious consequences. Femara also greatly reduced the chance of breast cancer returning to another part of the body, or distant metastases, by 39%. The appearance of distant metastasis is a well-recognized predictor of mortality.

"This new treatment option represents new hope for postmenopausal women throughout Europe," said Henning Mouridsen, MD, Rigshospitalet Department of Oncology, Copenhagen, Denmark. "Femara is the only aromatase inhibitor proven beneficial after five years of standard tamoxifen treatment, providing a much needed therapy for women with early breast cancer, who, before now, had no options after tamoxifen."

The term *extended adjuvant* describes the period following standard adjuvant (post-surgery) treatment with tamoxifen. Even years after breast cancer diagnosis and primary treatment, the ongoing risk of breast cancer recurrence remains significant for all patients. Approximately one-third of women with estrogen receptor-positive early breast cancer experience a recurrence and over half of those recurrences occur more than five years after surgery. While tamoxifen is beneficial for five years post-surgery, if used beyond that, the risks associated with it outweigh the benefits. Femara is the only clinically proven therapy to effectively address the unmet medical need to reduce the ongoing risk of breast cancer recurrence following standard tamoxifen treatment.

"We look forward to more approvals for this indication throughout the EU in the near future," said Diane Young, Vice President and global head of Clinical Development at Novartis Oncology. "The availability of Femara as a new post-tamoxifen treatment option will offer more women the chance to live free of breast cancer recurrence."

Novartis is pursuing this indication in all member states of the EU. Following completion of the MRP process, EU member states are expected to use the final endorsed Summary of Product Characteristics to implement marketing authorizations locally.

Aromatase inhibitors, such as Femara, are recommended by the American Society of Clinical Oncology (ASCO) as the treatment of choice for postmenopausal women with early breast cancer, as cited in the "ASCO Technology Assessment on the Use of Aromatase Inhibitors as Adjuvant Therapy for Postmenopausal Women With Hormone Receptor Positive Breast Cancer: Status Report 2004." Aromatase inhibitors also were recommended as a viable treatment option at the International Consensus Conference on the Optimal Primary Therapy of Early Breast Cancer, formed at the Primary Therapy of Early Breast Cancer Meeting in St. Gallen, Switzerland, in January. The recommendations, developed by consensus with input from expert oncologists from Europe and North America, are expected to be published in the *Journal of Clinical Oncology* in summer 2005.

About Femara

Femara is a leading once-a-day oral aromatase inhibitor that is indicated for first-line treatment of postmenopausal women with hormone receptor-positive or hormone receptor-unknown locally advanced or metastatic breast cancer and for the treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy, and as neo-adjuvant (pre-operative) therapy. Femara is approved for extended adjuvant treatment of early breast cancer in postmenopausal women who have completed standard adjuvant tamoxifen therapy in more than 40 countries worldwide, now including member countries of the EU as well as the United States. Femara is currently available in more than 80 countries worldwide. Not all indications are available in every country.

Contraindications and adverse events

In the clinical trials supporting the metastatic settings, the most frequently reported adverse reactions were hot flushes, nausea and fatigue. In the extended adjuvant setting, the following adverse events irrespective of causality were reported significantly more often with Femara than with placebo hot flushes (50.7% vs. 44.3%), arthralgia/arthritis (28.5% vs. 23.2%) and myalgia (10.2% vs. 7.0%). The majority of these adverse events were observed during the first year of treatment. There was a higher but non-significant incidence of osteoporosis and bone fractures in patients who received Femara than in patients who received placebo (7.5% vs. 6.3% and 6.7% vs. 5.9%, respectively).

The foregoing release contains forward-looking statements that can be identified by terminology such as "represents new hope," "look forward to," "will offer," "are expected to," "near future," or similar expressions, or by express or implied discussions regarding potential additional marketing approvals or future sales of Femara. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Femara to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Femara will receive any additional marketing approvals in any other countries, or that it will reach any particular sales levels. In particular, management's expectations regarding commercialization of Femara could be affected by, among other things, additional analysis of Femara 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 the Company's current 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 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.

Additional information on Femara

Additional information regarding Femara or Novartis Oncology can be found on the websites *www.femara.com* or *www.novartisoncology.com.* Additional media information can be found at *www.novartisoncologyvpo.com.*

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Investor Relations Release

Novartis shareholders approve eighth consecutive dividend increase and fifth share buyback program

2004 marks ninth year of record results since the company was established

Driven by dynamic business performance in 2004, annual dividend increases to CHF 1.05 per share (+5%)

New share buyback program of up to CHF 4 billion and reduction of share capital return further liquidity to shareholders

High single digit growth rates for Group and Pharmaceuticals expected to drive further market share gains in 2005

Basel, March 1, 2005 Novartis shareholders today approved all proposals of the Board of Directors, including the eighth consecutive annual dividend increase to CHF 1.05 per share and a fifth share buyback program designed to return capital to shareholders.

The 2'506 shareholders present at the Annual General Meeting held in Basel represented 974'750'130 voting shares and 35.10% of the 2'777'210'000 shares issued.

Chairman's Address

Dr. Daniel Vasella, Chairman and CEO of Novartis, told shareholders that their company's continued success was the result of a clear and consistently implemented strategy focused on healthcare and innovation, including extensive investments in research and development and in marketing to bring new and more effective treatments to patients and physicians. Dr. Vasella credited the expertise and commitment of Novartis associates in increasing productivity and driving strong business results.

Dr. Vasella said dynamic growth in sales and operating income at both the Group and Pharmaceutical Division level was driven by the exceptional performance of the Oncology and Cardiovascular franchises, which posted gains of +28% and +21% respectively. He said Novartis continued to demonstrate its marketing strength as five products generated more than USD 1 billion in sales in 2004.

Looking to the future, Dr. Vasella highlighted the strength of the Novartis pipeline as the key driver of sustained growth. "A pharmaceuticals company must have a full pipeline to maintain attractive growth rates going forward," Dr. Vasella said. "With 75 projects in clinical development, including 43 new molecular entities, six of which have the potential to be first-in-class medicines, our research and development program is among the best in the industry."

Dr. Vasella also commented on the recently announced acquisition of Hexal AG and Eon Labs, a transformational merger that will create the world leader in the fast-growing generics industry. "In the future, generic medicines will play an increasing role in managing rising costs due to the aging of the population and the subsequent higher demand for drugs and healthcare services. With the successful completion of these transactions, Sandoz will become the world's largest manufacturer of generic medicines, with leading positions in a number of European markets, including Germany the largest

generics market in Europe and in the US. We will also strengthen our market position in Asia, especially in India, China and Japan. Our leading position in generics expands our pharmaceutical business portfolio and provides synergies not only in the manufacture of our branded and generic products, but also in negotiations with key customers such as government and major pharmacy chains."

Dr. Vasella said that Novartis will continue to focus on good corporate citizenship. "Overall, we provided USD 570 million worth of support to patients in need in 2004," Dr. Vasella said. "This commitment is not only an expression of our solidarity with patients, but also a recognition of the unique social expectations placed upon healthcare companies."

In closing, Dr. Vasella said he expects yet another strong performance in 2005. "Our outlook remains positive as we continue to focus our energies on expanding our medicines business," Dr. Vasella said. "Our chances for further increasing market share remain good and we expect high single digit sales growth and further improvement in profits, provided there are no unforeseen, negative events."

Fifth share buyback program approved, share capital reduced

The new share buyback program worth CHF 4 billion is further proof of the commitment to return surplus liquidity to shareholders. In addition, shareholders approved the annulment of 38 million shares acquired in 2004. Novartis also completed share buyback programs totaling CHF 4 billion each in 1999 and 2001 and a further buyback worth over CHF 3 billion in 2004.

Elections to the Board of Directors and terms in office

Dr. h.c. Birgit Breuel was re-elected to the Board for a further two-year term. Prof. Dr. Peter Burckhardt, Alexandre F. Jetzer, Pierre Landolt and Prof. Dr. Ulrich Lehner were each re-elected by Novartis shareholders for a three-year term in office. The Board of Directors will continue to consist of 12 members.

Disclaimer

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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 4, 2005

By: /s/ MALCOLM B. CHEETHAM

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

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