

NOVARTIS AG  
Form 6-K  
November 19, 2003

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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 dated November 19, 2003  
(Commission File No. 1-15024)

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## Novartis AG

(Name of Registrant)

Lichtstrasse 35  
4056 Basel  
Switzerland

(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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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:  No:

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## Investor Relations Release

### Industry leading pipeline to bring novel treatments to patients and sustain above-market growth at Novartis

*New positive Phase II data on LAF237 (type-II diabetes), SPP100 (hypertension), AAE581 (osteoporosis) and QABI49 (asthma and chronic obstructive pulmonary disease)*

*Build-up of Novartis Institutes of BioMedical Research on track for completion in second quarter of 2004*

*Full pipeline includes 10 new medicines in late-stage development with peak sales potential in excess of USD 10 billion and 78 development projects in total*

New York / Basel, 19 November 2003 At its 2003 R&D Day in New York today Novartis unveils its pharmaceutical pipeline, which has been hailed as one of the strongest in the industry and is focused on attractive market segments and a broad range of unmet medical needs.

A total of 78 development projects fill the pipeline, of which 63 are in Phases II and III or in registration. They include 16 projects in cancer and nine in cardiovascular medicine, two of Novartis' key growth areas. In addition, Novartis has 47 development candidates in advanced pre-clinical testing that are expected to enter clinical trials in the next two years.

"Our strategic focus on innovation has delivered an exciting and competitive pipeline filled with many first-in-class potential therapies for cancer, diabetes, hypertension, bone disease and neuro-degeneration. These highly innovative compounds have the potential to better treat the rising number of patients suffering from these diseases. We will continue our efforts to attract the best talent and to utilize the most advanced technologies to further enhance our competitiveness in rapidly bringing continuously improved therapies to patients. The pipeline we are presenting today, combined with our clinical and commercial capabilities, gives us a robust platform for gaining segment share and further strengthening our leadership position," commented Dr. Daniel Vasella, Chairman and CEO, Novartis AG.

### Outpacing the competition with clinical and commercial excellence

The company's ability to complement strong organic research and development with successful partnership and in-licensing activities will continue to provide one of the most active launch schedules in the industry and a solid basis for capturing market share over the next five years.

Among its 63 late-stage development projects, Novartis highlighted ten major Phase II and III medicines (see below) that are estimated to generate total peak sales of more than USD 10 billion. The pipeline, together with current strong growth and the limited level of patent exposure of the product

portfolio currently on the market, confirm Novartis' expectation to grow above the market and to deliver profits above last year's performance, barring any unforeseen events.

### Top tier productivity in Research & Development

Productivity in Novartis Research and Development is best in class in terms of the number and speed of product approvals and in terms of commercial value. Novartis led the industry over the past four years with 11 novel compounds that won approval in the US, making Novartis the most innovative pharmaceutical company. In addition, over the past three years, Novartis has succeeded in reducing the average development time by approximately 25%. To further enhance the flow of drugs from the laboratory to the pharmacy, collaboration between Research and Development is being strengthened, with the proof of concept in man being established to ensure early selection of promising products. Development is also collaborating closely with Marketing to optimize and achieve the full potential of in-market products. At the same time, further speed and quality improvements are being achieved with novel technologies, such as electronic data capture to support the annual clinical program of 200 new trials, 20 000 active clinica sites, 2000,000 patients in trials, 1.2 million patient visits, and 60 million clinical data points.

## Development highlights

### Phase II/III:

#### 10 highly innovative compounds in advanced development for patients with high medical need

The number of promising projects in clinical development grew 44% between 2000 and 2003, with a significant increase in the mid-to late-stage clinical pipeline. Many of the leading compounds focus on diseases with increasing incidence and prevalence, like diabetes, and conditions that increase with age such as osteoporosis and cancer, taking advantage of the ongoing demographic change.

#### Cardiovascular/metabolic medicines

Novartis' cardiovascular research program spans a broad range of patient populations including high risk patients, those who are difficult to treat and those with co-morbidities. An estimated 70% of people with diabetes also have high blood pressure<sup>1</sup>. Two of Novartis' Phase III projects are expected to complement existing compounds and trial programs in this area, where there is a high unmet medical need:

**LAF237** (type 2 diabetes), an oral DPP4 inhibitor, is expected to be the **first in a highly attractive new class of compounds for diabetes** control. Type-2 diabetes is a growing medical problem and the fact that all current treatments have limitations underscores the huge medical need and the importance of LAF237, which is about **to move into Phase III**. LAF237 represents a novel therapeutic concept: it increases the amount of circulating active GLP-1, a peptide that increases insulin secretion in a glucose-dependent fashion, lowering blood glucose. Additional benefits include: slowing gastric emptying, decreasing appetite and potentially increasing the development of insulin producing beta-cells, which may modify the disease. LAF237 is now in Phase IIb, where most recent results have revealed a statistically significant dose dependent reduction in HbA1c, both as monotherapy and as an additive effect to metformin. In addition, the Phase II studies revealed an excellent safety and tolerability profile.

<sup>1</sup>

Harris MI. Health care and health status and outcomes for patients with type 2 diabetes. Diabetes Care 200; 23 754-8

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**SPP100<sup>2</sup>** (hypertension) expected to be the **first oral renin inhibitor** and potentially the next generation of drugs for blood pressure and vascular disease control, may offer a new alternative for monotherapy and combination treatment of hypertension and other cardiovascular conditions. Having already shown a good safety profile, excellent tolerability and comparability to losartan in a Phase IIa study planned and conducted by Speedel in 200 patients, SPP100 has now demonstrated dose-dependent decreases in both diastolic and systolic blood pressure equivalent to irbestartan in a larger Phase IIb trial. At higher doses, SPP100 was significantly better than irbestartan at 150mg at lowering diastolic blood pressure. Preclinical results suggest that the new drug may also offer synergistic blood pressure lowering activity with *Diovan* in addition to protection against organ (kidney) damage resulting from hypertension. Novartis licensed SPP100 back from Speedel in 2002 and is solely responsible for the development and commercialization of the product, which is **about to advance into Phase III**.

#### Oncology

**PTK787** is a potent inhibitor of all vascular endothelial growth factor (VEGF) receptors, which play an important role in the formation of blood vessels (angiogenesis) that supply tumors. PTK787 is positioned to be the **first oral targeted angiogenesis inhibitor** and is a co-development, co-marketing project with Schering AG. With its proof of mechanism and tolerability confirmed in Phases I and II, PTK's effects on tumor vasculature have been correlated with improved early clinical outcomes in colorectal cancer with liver metastases. **Phase III** is progressing well with PTK being evaluated in first and second line treatment of colorectal cancer.

**ICL670** could bring a major improvement to the quality of life of patients with iron overload in transfusion-dependent anemias. With the advantage of being **an oral, once daily iron chelating agent**, ICL670 is expected to replace the current gold standard treatment, *Desferal*, which has to be administered via a daily subcutaneous infusion over 8 to 12 hours. In Phase II trials, ICL670 demonstrated comparability to *Desferal*, and multi-national **Phase III** trials are well underway both in adults and children with Beta thalassemia, MDS, sickle cell disease and other transfusion-dependent anemias.

### Transplantation

**FTY720**<sup>3</sup>, a new cornerstone in immune modulation, is currently in development for the prevention of acute rejection and graft loss in kidney transplant patients. In studies it has been shown to provide **a new mechanism of action that prevents rejection** but does not impair T-cell function, an important component in the immune system. Now in **Phase III**, FTY720 has shown very low acute rejection rates in combination with *Neoral*, and does not show an increase in infection rates.

### Bone and joint treatments

**Zoledronic acid** (postmenopausal osteoporosis and Paget's disease) is currently the most advanced of several new Novartis drugs for osteoporosis. Zoledronic acid, the most potent bisphosphonate, aims to provide 'bone protection' by increasing bone mineral density with a single annual dose. As such, it could become the gold standard in osteoporosis. Ongoing trials show that a single annual infusion achieves equivalent effects on bone density and turnover to those of the most widely prescribed frequently dosed oral bisphosphonate. With **Phase III** progressing well, the first filings, in Paget's disease, are planned for 2004.

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<sup>2</sup> licensed from Speedel Pharma AG

<sup>3</sup> licensed from Mitsubishi Pharma Corporation

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**AAE581** (osteoporosis), expected to be **the first in an innovative new class of drugs known as cathepsin K inhibitors**, is a once-a-day oral treatment that reduces collagen breakdown and bone resorption. In the Phase II program, a double blind study in 140 postmenopausal women showed a significant (p<0.001) difference in bone markers of resorption versus placebo, whilst other preliminary results suggest that AAE581 may also have a positive effect on bone formation. The product is now advancing through **Phase IIb** of clinical trials.

### Central nervous system

**TCH346** (Parkinson's disease and amyotrophic lateral sclerosis) with targeted neuro-protection is a GlycerAldehyde-3-Phosphatase dehydrogenase (**GAPDH**) **inhibitor** that promotes neuronal survival and has potential for treating Parkinson's Disease, Alzheimer's Disease and amyotrophic lateral sclerosis (ALS), where delaying or preventing disease progression is an urgent need. **Phase II** clinical trials for Parkinson's disease and ALS are in progress.

### Respiratory disease

**QAB149** (asthma and chronic obstructive pulmonary disease) is expected to be **the first long-acting Beta-2 agonist with a quick onset of action** offering 24-hour duration of lung function improvement with a once daily administration. **Phase II** clinical trials have shown clear efficacy and that QAB149 is safe and well tolerated.

### Infectious diseases

**LDT600**<sup>4</sup> Novartis believes that LDT600 (telbivudine) may take efficacy to a new level in the **treatment of hepatitis B**. In a recent study, 52-week data showed that LDT600 reduces serum hepatitis B (HBV) DNA levels significantly more than standard therapy, lamivudine, suggesting Novartis believes that it could become the best-in-class treatment. LDT600 is currently **Phase III**.

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<sup>4</sup> licensed from Idenix Pharmaceuticals Inc

**Planned Filings 2004-2007**

| 2004            | 2005              | 2006             | 2007             |                 |
|-----------------|-------------------|------------------|------------------|-----------------|
| Zelmac® (EU)    | ICL670            | LAF237           | QAB149           | EPO906          |
| IBS             | Iron overload     | Diabetes         | Asthma, COPD     | Cancer          |
| Xolair® (EU)    | SOM230            | PKC412           | NKS104           | LAQ824          |
|                 | Cancer            | AML              | Dyslipidemia     | Cancer          |
| Femara®         | FTY720            | Lucentis         | SAB378           | XAA296          |
| Extended adj.   | Transplantation   | AMD              | Chronic pain     | Cancer          |
| Focalin LA      | PTK787            | LDC300           | RGN303           | TCH346          |
|                 | Cancer            | Hepatitis B      | RA               | ALS, PD         |
| Lamisil® NOF    | LDT600            | Zelnorm®         | LIC477           | AAE581          |
|                 | Hepatitis B       | GERD             | Bipolar disorder | Osteoporosis    |
| Zoledronic acid | SPP100            | Visudyne® (US)   | Gimatecan        | LBM415          |
| Paget's Disease | Hypertension      | Occult AMD       | Solid tumors     | Antibacterial   |
| Diovan®         | Prexige® (US)     | RAD001           | RAD001           | Elidel® dry eye |
| VALUE           | OA, RA, Pain      | Solid tumors     | Rheum. arthritis | drops           |
|                 | Zelnorm®          | Exelon® TDS      | Zoledronic acid  | Lotrel®         |
|                 | Funct. dyspepsia  | Alzheimers       | Osteoporosis     | ACCOMPLISH      |
| NME             | Femara®           | Elidel® ointment | ASM981 oral      |                 |
| NME roll out    | Early adjuvant    |                  |                  |                 |
| LCM             | Sandostatin® LAR® |                  |                  |                 |
|                 | Diab. retinopathy |                  |                  |                 |

**Major pipeline projects in registration**

Several products highlighted at last year's R&D event have since gained important approvals while others have progressed to the registration phase in major markets. Among the projects currently in registration *Certican* and *Myfortic* (transplantation) are undergoing the European mutual recognition procedure and are both filed in the US, where *Certican* is approvable. *Enablex* (overactive bladder) and *Foradil*<sup>5</sup> multi-dose dry powder inhaler (asthma) are also approvable in the US, and are under review in Europe. New dosage strengths of *Lotrel* are also approvable in the US, where *Zelnorm* is under review for the new indication of chronic constipation. *Prexige* has received approval with a positive label in the UK. In the US, the FDA has requested a further study in osteoarthritis with a 200mg dose in addition to data from the ongoing TARGET trial. Closing data from this study are expected in mid 2004, when the European mutual recognition procedure is planned to start. Novartis is in discussion with the FDA regarding other trials which may be necessary.

**Accelerating productivity in drug discovery**

Through the growth of the Novartis Institutes for BioMedical Research (NIBR) and establishment of its new center in Cambridge, MA, Novartis is making a major investment in drug discovery. In combination with new scientific approaches, it will help to deliver a continuous flow of innovative new medicines.

NIBR's mission is to discover new medicines, reliably and predictably, that treat the cause rather than just the symptoms of disease. Its new global focus will increase successful discovery by concentrating on areas where both the understanding of the disease mechanism and the degree of unmet medical need are high. Using new genomic and chemistry tools, attrition in the pipeline will be shifted to earlier discovery stages, lowering the risk of compound discontinuation in clinical testing.

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under license from Yamanouchi and developed with SkyePharma

Although still in its first full year, the NIBR headquarters in Cambridge has succeeded in attracting top-level scientific talent. The global NIBR team has conducted a complete review of the current pipeline to maximize its potential, balancing the resources needed to optimize the

short-term pipeline and those needed to develop the future. They have also implemented a proof-of-concept model to ensure that compounds moving from discovery into clinical research are those with a maximal chance of success.

The first phase of NIBR's new, state-of-the art research facility at 100 Technology Square on the Massachusetts Institute of Technology campus in Cambridge was completed on-time. The building of the phase-two main facility is on-schedule for Spring 2004.

### **Projects supporting innovative in-market products and potential new indications**

To realize the full therapeutic and commercial potential of its key success drivers, Novartis has a strong clinical R&D (Phase IV) program, including some of the largest trials ever conducted in their respective areas. The following are main examples:

***Diovan*** (hypertension), one of the company's flagship products, has become the world's leading angiotensin II receptor blocker (ARB) and the fastest-growing branded treatment for high blood pressure on the strength of the most comprehensive clinical program conducted with this category of drug. This series of mega-trials (including more than 50 000 patients) continues to demonstrate *Diovan's* antihypertensive efficacy, cardiovascular protection profile and tolerability and compliance benefits. Most recently, the VALIANT trial has shown *Diovan* to be a potentially life-saving treatment after a heart attack, that could save 30 000 lives each year. Novartis will apply for registration of a further indication early in 2004, or sooner if possible, based on these results. The other major ongoing Phase IV trials are evaluating long-term use in patients with at least one additional risk factor for cardiovascular events (VALUE), and blood pressure control in diabetes and impaired glucose tolerance outcomes (NAVIGATOR). Based on the extensive data from multiple clinical trials, *Diovan* is on track to become the new gold standard across the cardiovascular continuum.

***Lotrel***, the leading combination treatment for hypertension in the US, continues to generate new supporting clinical data. The ACCOMPLISH mega-trial, with over 12 000 patients at more than 650 sites worldwide, is now in progress to compare *Lotrel* with a combination of an ACE inhibitor and a diuretic to determine the best combination therapy for the treatment of hypertension.

***Elidel***, the number-one branded non-steroid prescription treatment for eczema, is also the subject of intense clinical programs examining new indications and uses, such as in severe and chronic eczema, with an emphasis on showing relief from symptoms and prevention of flares. Novartis is also developing new formulations, including an ointment and a higher strength cream, for improved convenience and compliance.

***Zelnorm/Zelmac*** (irritable bowel syndrome with constipation) is gaining further acceptance in the US, thanks to science-based programs to increase disease awareness. Clinical trials are underway to support European approval and to explore new indications, including functional dyspepsia and gastro-esophageal reflux disease, which in addition to the recently filed chronic constipation indication will further drive *Zelnorm's* market penetration.

***Femara*** (breast cancer) has consistently demonstrated superiority across multiple breast cancer settings. Recently published findings in the landmark MA-17 Phase III study revealed that *Femara* almost halved the risk of breast cancer recurrence in post-menopausal women following five years of tamoxifen, offering a new possibility for patients where previously there was no therapy.

***Gleevec/Glivec*** continues to change the standard of care in leukemia and gastrointestinal stromal tumors (GIST), where it has altered the natural course of the disease and dramatically impacted patients' lives. A number of projects in Phase II are investigating the use of *Gleevec/Glivec* in a variety

of settings including: adjuvant treatment in GIST, treatment of polycythemia vera, and combination therapy in prostate cancer, breast cancer, AML and glioma.

### **Conclusion**

Summarizing the event, Dr. Vasella concluded: "Our pipeline reflects our passion for exploring new pathways and bringing new and better treatments to patients. Pharmaceuticals remains an attractive market for top innovators and we will leverage our commercial successes and strengths to increase the number of blockbuster products in our portfolio. I am confident that, with our high potential late-stage pipeline and commitment to a top scientific team driving discovery, we can sustain our leadership and continue to gain market share."

This press release contains certain forward-looking statements relating to the Company's business, which can be identified by the use of forward-looking terminology, such as "to bring .... and sustain", "potential", "forecast", "will", "estimate to generate", "promising", "expected",

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"potentially", "may offer", "could bring", or similar expressions or by express or implied discussions of the potential for pipeline drugs under development to be approved for sale in any country, of the potential that existing drugs may be approved for additional indications, or of potential revenues which Novartis might earn from existing drugs, from new indications for existing drugs or from such pipeline drugs in the future. Such statements reflect the current views of the Company with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that any pipeline drug or potential new indications for existing drug products will be commercialized in any market. Nor can there be any guarantee that Novartis will earn any particular levels of revenue from existing drugs or from potential pipeline drugs. Many factors could cause the actual results, performance or achievements of the Company to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. These factors include, among other things, unexpected regulatory delays, uncertainties relating to clinical trials and product development, the introduction of competing products, increased government pricing pressures, and the Company's ability to obtain or maintain patent and other proprietary intellectual property protection as well as other 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 expressly disavows any obligation to update the information presented in this release.

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of CHF 32.4 billion (USD 20.9 billion) and a net income of CHF 7.3 billion (USD 4.7 billion). The Group invested approximately CHF 4.3 billion (USD 2.8 billion) in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 78 200 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>

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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 19, 2003

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham

Title: *Head Group Financial Reporting and Accounting*

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