

NOVARTIS AG  
Form 6-K  
October 02, 2003

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## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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### 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 September 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:

Form 20-F  Form 40-F

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  No

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  No

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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Enclosures:

1. Nutritional advance offers support for people with cancer (September 22, 2003)
2. Prexige® (lumiracoxib), a novel COX-2 selective inhibitor approved in the United Kingdom (September 16, 2003)
3. New data from Val-HeFT shows Diovan® reduced the incidence of atrial fibrillation by 35% in heart failure patients (September 2, 2003)
4. First results of three multicenter open-label clinical trials with Stalevo show improved symptomatic benefits and enhanced convenience for patients with Parkinson's disease (September 1, 2003)

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**Nutritional advance offers support for people with cancer**

Nyon, September 22, 2003 Cancer patients experiencing weight loss may now benefit from Resource® Support , a specialized nutritional product with a unique blend of key nutrients designed to help cancer patients gain weight in the form of muscle tissue and enhance immune function. Resource® Support , a high-protein, high-energy nutritional supplement developed by Novartis Medical Nutrition, was officially presented today in Cannes, France, to coincide with the annual meeting of the European Society for Parenteral and Enteral Nutrition (ESPEN). Resource® Support , is being progressively launched and has been available in the US since June 2003 and, with other countries following soon.

Resource® Support has been specifically designed to help improve patients' quality of life and improve their tolerance of cancer treatments such as surgery, radiotherapy and chemotherapy.

Data from the International Agency for Research on Cancer show that there were an estimated 2.6 million new cases of cancer in Europe in 1995, and around 1.6 million deaths from cancer. After adjusting for differing population age structures, overall incidence rates in men were highest in the Western European countries<sup>1</sup>. Lung cancer, with an estimated 377,000 cases, was the most common cancer in Europe in 1995. Together with cancers of colon and rectum (334,000), and female breast (321,000), the three cancers represented approximately 40% of new cases in Europe.

Data from the American Cancer Society suggest that 1.33 million new cases of cancer will be diagnosed in 2003. In men, cancers of the prostate, lung, colon and rectum, and urinary bladder will be diagnosed most often, whereas in women, cancers of the breast, lung, colon and rectum, and uterine will be diagnosed most often<sup>2</sup>.

Weight loss is common in patients with cancer, particularly those with solid tumors. Up to 20% of cancer patients are thought to die from the effects of malnutrition alone rather than from the direct effects of their disease<sup>3</sup>. Even minor weight loss as little as 5% can affect the patient's response to therapy, lowering their chance of survival compared to patients who have not lost weight<sup>4</sup>. Clearly, the sooner that cancer patients can be helped to maintain or regain a healthy weight, the better is their long-term outlook.

Weight loss may be the result of mechanical obstruction, treatment side-effects, pain or malabsorption, which are typically seen in patients with head and neck, esophageal and intestinal tumors. But it may also be the result of a complex range of metabolic abnormalities that result in cancer cachexia, a syndrome characterized by muscle loss and symptoms such as anorexia, asthenia, and weight loss, from both fat and lean tissue.

Patients begin to show changes in the mass and function of a variety of organs that result in symptoms and signs such as weakness and anemia, all of which contribute to a reduction in the quality and duration of the patient's life.

Early nutritional intervention can help prevent the development of malnutrition and weight loss. But while conventional nutritional supplements may help to increase overall dietary intake they cannot tackle the underlying metabolic disorders that lead to cachexia and its characteristic loss of muscle mass<sup>5</sup>.

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The formulation of Resource® Support is based on the latest understanding of these metabolic abnormalities. It is rich in omega-3 polyunsaturated fatty acids, particularly eicosapentaenoic acid (EPA). In addition, it contains a high level of proteins, essential amino acids and vitamin E.

These nutrients have been shown to improve rates of protein synthesis, while the carefully selected nutrient blend is known to limit the magnitude of cachectic metabolic abnormalities and to support immune responses.

Dr Carmen Gomez Candela, Head of Clinical Nutrition and Dietetics Department, la Paz Hospital, Madrid, Spain, said "Early and continued use of specialized nutrition such as Resource® Support will allow the oncology team to help patients gain weight, optimize nutritional support and tackle the detrimental effects of malnutrition on patients' responses to standard therapies and their well being."

She added that, "specialized nutritional support should be viewed as a cornerstone of weight management for patients with solid tumors who have cachexia or are at risk of developing it."

Delegates heard from Dr Mike Tisdale, Professor of Pharmacology, Ashton University, Birmingham, UK, how the use of EPA has been shown to modulate the metabolic response to cancer induced weight loss.

Dr Robert Wolfe, Professor of Clinical Research, University of Texas, US, said "Certain amino acids are important in both normal metabolism and cachexia. In particular, essential amino acids such as leucine appear to be critical to stimulating protein synthesis."

Patients will find that Resource® Support is convenient and easy to use, offering a nutritionally complete medical food prepared as a ready-to-use beverage designed to deliver calories, proteins and other specific nutrients quickly and efficiently.

#### **Disclaimer**

This 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 "may now benefit" and "can help prevent," or similar expressions, or by express or implied discussions regarding the potential development and commercialization of new products or regarding potential future sales from any such products. Such statements reflect the current views of the Company with respect to future events and are subject to certain risks, uncertainties and assumptions. Many factors could cause the actual results to be materially different from any future results, performances or achievements that may be expressed or implied by such forward-looking statements. There can be no guarantee that the transactions that are the subject of this release will reach any particular sales levels. Any such sales can be affected by, among other things, 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, 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 Medical Nutrition offers a complete range of enteral (tube feeding) and oral nutrition products and devices tailored to the varying needs of patients and healthcare professionals. The product range encompasses supplements, which are taken orally, as well as other products administered through tube feeds and specific medical devices.

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Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of USD 20.9 billion and a net income of USD 4.7 billion. The Group invested approximately USD 2.8 billion in R&D. Headquartered in Basel,

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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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### Investor Relations Release

#### **Prexige® (lumiracoxib), a novel COX-2 selective inhibitor approved in the United Kingdom**

Basel, 16 September 2003 Novartis announced today that Prexige® (lumiracoxib), a novel COX-2 selective inhibitor, has been approved by the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom. Prexige® was approved for the symptomatic relief of osteoarthritis (OA) at 100-200mg daily. In addition, Prexige® 400mg daily has been approved for the short-term relief of moderate to severe acute pain associated with primary dysmenorrhea, dental surgery and orthopaedic surgery.

This decision by the UK's MHRA, which will act as the reference member state in the mutual recognition procedure in Europe, marks the first European approval for Prexige® (lumiracoxib). It was based on applications for regulatory approval including more than 13,000 adult patients across the world and a total of 50 clinical and clinical pharmacology trials, making it the largest regulatory file in its therapeutic class.

Prexige will be launched in Europe once regulatory procedures are completed.

"Based on the data from our large-scale clinical trial program, we believe Prexige will be an important therapeutic option for OA patients and those suffering from acute pain to treat their condition," said Dr Jörg Reinhardt, Head of Development, Novartis Pharma AG.

OA is the most common form of arthritis and is a significant burden for patients around the world. It is characterized by the breakdown of cartilage in joints, causing affected bones to rub against each other and leading to inflammation, pain and loss of movement. It is estimated that more than 25 million Europeans and 20.7 million Americans are affected by OA. Globally, it accounts for half of all chronic conditions in those age 65 and older.

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The foregoing press release contains forward-looking statements that can be identified by the use of forward-looking terminology such as "will act", "will be launched", "will be an important therapeutic option" or similar expressions, or by express or implied statements regarding the potential for regulatory approvals to market Prexige in countries other than the United Kingdom or regarding potential future revenues from Prexige. 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 aforementioned regulatory approval will result in the commercialisation of Prexige in any market outside of the United Kingdom, or that Prexige will achieve any particular level of revenues. Any such results can be affected by, amongst other things, uncertainties relating to product development, including the results of the TARGET clinical trial and other such trials, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection, increased government pricing pressures and competition in general, as well as factors discussed in Novartis AG's Form 20-F filed with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of USD 20.9 billion and a net income of USD 4.7 billion. The Group invested approximately 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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**Investor Relations Release**

**New data from Val-HeFT shows Diovan® reduced the incidence of atrial fibrillation by 35% in heart failure patients**

*Study also shows heart failure patients with atrial fibrillation are at significantly higher risk for death<sup>1</sup>*

Vienna, 2 September 2003 Data from the landmark trial Val-HeFT showed Diovan® (valsartan) reduced new cases of atrial fibrillation by 35% versus placebo in heart failure patients who also took usual heart failure treatments.<sup>1</sup> Atrial fibrillation is the irregular beating of the heart. The new data, presented today at the European Society of Cardiology (ESC) Congress 2003, also showed that atrial fibrillation is an independent contributor to all cause mortality in heart failure patients.

"Because of its size, Val-HeFT offered an extraordinary opportunity to study both the onset and consequences of atrial fibrillation in a large population of heart failure patients," said Professor Aldo Maggioni, the Val-HeFT investigator who presented the findings and is from the GISSI Group, coordinated by the Italian Association of Hospital Cardiologists (ANMCO) and the Istituto di Ricerche Farmacologie, Mario Negri, Milan, Italy. "The data clearly shows valsartan works independently to prevent atrial fibrillation in heart failure patients already receiving the best, currently recommended heart failure treatment."

The new data was based on a sub-analysis of Val-HeFT (the Valsartan Hearth Failure Trial). It showed that atrial fibrillation developed in only 5.27% (n = 132/2506) of those who took Diovan compared to 7.86% (n = 196/2494) of those who took placebo with their usual heart failure treatments, representing a 35% reduction by Diovan in the onset of this dangerous risk factor ( $p = 0.0002$ ). The data also confirm atrial fibrillation as an independent risk factor for death in heart failure patients. In fact, after 23 months, all-cause mortality was 30.2% in patients with new onset atrial fibrillation versus 18.8% in those in whom this condition did not develop (RR Cox 1.36, 95% CI 1.08 1.70).

The study was one of several new abstracts from Val-HeFT presented at the ESC 2003. One of the largest studies ever conducted in the treatment of heart failure, Val-HeFT was sponsored by Novartis Pharma AG, the makers of Diovan. Diovan has proven to have combined mortality and morbidity benefits in heart failure and is indicated in more than 30 countries for the treatment of heart failure in patients also taking usual heart failure therapy such as diuretics, digitalis and either an ACE (angiotensin-converting-enzyme) inhibitor or a beta blocker, but not both. In the US, Diovan is the only drug in its class approved for the treatment of heart failure in patients who cannot tolerate ACE inhibitors. The fastest growing antihypertensive drug on the market today, Diovan is also approved for first-line treatment of high blood pressure in more than 80 countries.

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"Val-HeFT continues to yield a wealth of new data to advance the care of patients with heart failure," said Joerg Reinhardt, Global Head Pharma Development, Novartis Pharma AG. "The new data also strengthen our commitment to develop the full potential of Diovan as a cardio protective agent. We look forward to the results of VALIANT, another Diovan mega trial that will report later this year. VALIANT is studying Diovan in post-myocardial infarction (MI or heart attack), a different point on the cardiovascular disease continuum. Like Val-HeFT, VALIANT is designed to serve as a reference trial for the future treatment of the disease it is studying."

#### **About Val-HeFT**

Val-HeFT was a study of 5 010 patients in 302 centers in 16 countries that compared the effects of Diovan versus placebo in heart failure patients who also took usual treatments individually prescribed by their doctors including ACE inhibitors, beta blockers, diuretics, or digitalis. The overall findings, reported three years ago at the American Heart Association Scientific Sessions 2000 and published in the *New England Journal of Medicine*, showed Diovan significantly reduced combined heart failure mortality and morbidity by 13.2% ( $p = 0.009$ )<sup>2</sup> and reduced hospitalization for heart failure by 27.5% ( $p < 0.001$ )<sup>5</sup> versus placebo in patients also taking their individually prescribed heart failure drugs. In patients who were not prescribed ACE inhibitors (n = 366), Diovan significantly reduced mortality by 33% ( $p < 0.017$ )<sup>5</sup>.

In addition to demonstrating a reduced incidence of atrial fibrillation, other previously reported findings from Val-HeFT showed that:

Diovan improved the signs and symptoms of heart failure (e.g., dyspnoea, rales, fatigue)

Diovan improved patients' New York Heart Association (NYHA) functional class (a measure of disease progression)

Diovan positively affected several prognostic markers for poor outcomes, including brain natriuretic peptide (BNP), norepinephrine, and aldosterone.<sup>5</sup>

### About atrial fibrillation and heart failure

Atrial fibrillation is an abnormally fast irregular rhythm in which the two atria (upper chambers of the heart) contract irregularly, leading to an irregular ventricular rhythm, which in turn leads to an irregular pulse. Fast, irregular heart beats allow blood to pool in the atria and potentially clot, increasing the risk of a stroke or pulmonary embolus due to the passage of a clot from the heart to the brain or lungs. Atrial fibrillation may also decrease the heart's pumping ability by 20-30%, which can both cause and exacerbate existing heart failure. A common disorder, an estimated 1 in 20 (5%) of all persons worldwide age 70 or over have atrial fibrillation.<sup>4</sup> People with atrial fibrillation are 5 to 7 times more likely to suffer a stroke than the general population.

Heart failure results from the progressive weakening of the heart muscle until it no longer pumps blood effectively. In addition to atrial fibrillation, major risk factors for heart failure include a history of high blood pressure and MI. Because more people are surviving heart attacks than ever before, more people are developing heart failure, making it the fastest growing cardiovascular disease in the world and the most common reason why the elderly are hospitalized.<sup>5</sup> An estimated 20 million people worldwide suffer from this devastating disease.

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### Mega trial program involves more than 45 000 patients

Diovan is supported by one of the world's largest clinical trial programs with an ARB, which involves more than 45 000 patients, including 8 000 patients with diabetes. Besides Val-HeFT, several mega trials are investigating new applications for Diovan across the spectrum of cardiovascular and renal (kidney) disease. Later in 2003, results are expected from VALIANT, a study of 14 703 post-MI patients. In 2004, results are expected from VALUE, a study of 15 314 patients with high blood pressure and at least one additional cardiovascular risk factor (e.g., high cholesterol, diabetes, stroke, and left ventricular hypertrophy, among others). Another major ongoing Diovan trial is NAVIGATOR, which will be the largest study ever conducted in patients with impaired glucose tolerance, or pre-diabetes, at high risk for cardiovascular events.

The foregoing release contains forward-looking statements that can be identified by terminology such as "develop", "potential", "investigating", "new applications", or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Diovan, or regarding potential future revenue from Diovan. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Diovan to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Diovan will be approved for any additional indications or labeling in any market or regarding potential future revenue from Diovan. In particular, management's ability to ensure satisfaction of the health authorities' further requirements is not guaranteed and management's expectations regarding commercialization of Diovan could be affected by, among other things, additional analysis of Diovan 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 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.

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**MEDIA RELEASE    COMMUNIQUE AUX MEDIAS    MEDIENMITTEILUNG**

**First results of three multicenter open-label clinical trials with Stalevo show improved symptomatic benefits and enhanced convenience for patients with Parkinson's disease.**

Basel, 1 September 2003 Results from new clinical studies with Stalevo presented today at the Congress of the European Federation of Neurological Societies in Helsinki, Finland confirm clear patient benefits. Data from these first-ever studies in patients with Parkinson's disease (PD) taking Stalevo the new levodopa combination product containing levodopa, carbidopa and entacapone show enhanced symptomatic benefits resulting in greater control of PD symptoms, as well as convenience of administration compared to traditional levodopa therapy.

While levodopa therapy remains the cornerstone of PD treatment, its long term utility is limited by the occurrence of motor complications. Stalevo was therefore developed to optimize the pharmacokinetic profile of levodopa and enhance its clinical benefits.

The individual components of Stalevo have a well-established efficacy record supported by numerous clinical trials<sup>1,2,3,4,5,6</sup>, which provided the basis for regulatory agency approval of Stalevo<sup>7</sup>. These first-ever clinical studies provide valuable data regarding dosing, tolerability and efficacy of Stalevo.

Commenting on the clinical relevance of the TC-INIT study<sup>8</sup>, one of the lead investigators, Professor David Brooks, of the Medical Research Council Clinical Sciences Centre and Imperial College London, UK said: "These interim data show that levodopa treated PD patients may be switched to Stalevo and experience enhanced benefits of their levodopa therapy. In addition, this real-life experience is significant as it demonstrates that the switch can be achieved easily and conveniently".

The TC-INIT study compares the switch from traditional levodopa/dopa decarboxylase inhibitor (DDCI) therapy to either Stalevo or levodopa/DDCI plus entacapone (Comtess/Comtan) tablets taken separately in 200 PD patients experiencing wearing-off symptoms. Interim results of 111 patients show that patients taking

Stalevo experience improved symptom control comparable to levodopa/DDCI plus entacapone taken separately. At the end of week two, a majority of patients saw their condition improve when their levodopa therapy was optimized. When switched to Stalevo, 82% (investigator assessment) and 81% (patient assessment) of patients reported improved symptom control versus 76% (investigator assessment) and 73% (patient assessment) when switched to levodopa/DDCI plus entacapone taken separately.

In addition, treatment with Stalevo as a single tablet was easy to initiate and provided simplicity and convenience of administration for patients.

Interim data from a second study (SELECT-TC) assessing the switch to Stalevo in 160 PD patients currently being treated with levodopa/carbidopa and experiencing wearing-off symptoms, indicate that the majority of patients can easily be transferred to Stalevo with few, or no levodopa dose adjustments.<sup>9</sup>

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"These data show that dose modifications are rarely needed when switching from levodopa treatment to Stalevo and can be accomplished with ease and convenience, and most importantly with the patient's acceptance. There are a number of complicated regimens that currently exist in PD treatment. Many patients often have to take medications for other co-existing conditions. Stalevo clearly has everyday practical benefits for patients and for physicians prescribing the treatment by combining three medicines in one", added Professor David Brooks.

In a third, four-week completed study (SIMCOM) more than two-thirds of the patients preferred taking Stalevo to levodopa/DDCI and entacapone taken separately. Furthermore, the vast majority of patients reported that Stalevo was easier to dose, use, handle and swallow.<sup>10</sup>

In all studies, Stalevo was generally well tolerated. The most common side effects were dopaminergic in nature (e.g. dyskinesia or involuntary movements, nausea). These side effects are mild and moderate in nature, and when they occur, they can usually be managed with dose modifications. Side effects seldom lead to treatment discontinuation. In addition, the components of Stalevo have a well-established safety and tolerability profile supported by numerous clinical trials<sup>1,2,3,4,5,6</sup> and over 300 000 patient years of experience with levodopa/DDCI plus entacapone.<sup>11</sup>

Novartis and Orion Pharma received US Food and Drug Administration (FDA) approval for Stalevo in June 2003 and have recently [26 June 2003] received a positive opinion from the European Committee for Proprietary Medicinal Products (CPMP).

This 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 "first-ever studies" or similar expressions, or by express or implied discussions regarding potential future sales of Stalevo. 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 actual results with Stalevo to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that the aforementioned clinical trials will result in the commercialization of Stalevo in any market. Any such commercialization can be affected, among other things, uncertainties relating to unexpected regulatory delays, further clinical trial results, the ability to obtain or maintain patent or other proprietary intellectual property protection, government regulation or competition in general, increased government pricing pressures, 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.

#### ***About Orion Pharma***

Orion Pharma is a research and development-orientated pharmaceutical division of the Orion Group (HEX:ORIA, ORIB), which is one of the leading companies in the healthcare sector in the Nordic area of Europe. Pharmaceutical R&D at Orion Pharma focuses on three core therapy areas: CNS therapies, cardiology and critical care, and hormonal therapies. Entacapone, a COMT enzyme inhibitor used in the treatment of Parkinson's disease, is one of Orion Pharma's patented molecule discoveries. It is available globally as Comtess® and Comtan®. It is also one of the three active compounds in Orion's novel levodopa treatment, Stalevo, which is already approved in the US and awaiting European marketing approval. For further information please consult <http://www.orionpharma.com/>.

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#### **About Novartis**

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#### **Notes to Editor:**

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Parkinson's disease (PD) is a chronic and progressive neurological condition. The overall prevalence of Parkinson's disease in the world is estimated to be 6.3 million. It affects 1 per 100 persons over the age of 60 years and 1 per 50 people over the age of 80 years<sup>12</sup>.

The cornerstone of PD treatment is levodopa. It can provide benefit throughout the whole course of the disease and is the only medication that has been shown to have an effect on quality of life and significantly prolongs life expectancy in PD patients.<sup>13</sup> However, when standard levodopa therapies are used over the long term, patients may begin to experience a wearing-off of its clinical effects, with changes in mobility, mood and sensation, and treatment may need to be adjusted periodically.

Stalevo is the first new levodopa treatment in many years and combines levodopa, carbidopa and entacapone. Whilst carbidopa reduces the side effects of levodopa, entacapone enhances its benefits, offering smoother and more consistent plasma levels of levodopa. This optimized pharmacokinetic profile translates into significant improvement in the PD patient's ability to perform everyday tasks and alleviates motor complications associated with long-term therapy.

Randomized, single-dose, four-way crossover studies investigating the pharmacokinetics of Stalevo in healthy subjects showed that Stalevo was bioequivalent to levodopa/carbidopa and entacapone administered separately without requiring dose modification.<sup>7</sup> The studies evaluated the bioequivalence of Stalevo 50mg, 100mg and 150mg with corresponding doses of levodopa/carbidopa and entacapone and served as the basis for approval by regulatory agencies.

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1. Larsen JP, Worm-Petersen J, Siden A, Gordin A, Reinikainen K, Leinonen M and the NOMESAFE Study Group. The Tolerability and Efficacy of Entacapone Over Three Years in Patients with Parkinson's Disease. *Eur J Neurol* 2003; 10: 137-146.
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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: October 1, 2003

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham

Title: *Head Group Financial Reporting and Accounting*

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