NOVARTIS AG
Form 6-K
March 29, 2006

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

PURSUANT TO RULE 13a-16 or 15d-16 OF

THE SECURITIES EXCHANGE ACT OF 1934

Report on Form 6-K dated March 29, 2006

(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:

Novartis announces in-licensing of valopicitabine (NM283), a novel first-in-class treatment for hepatitis C that expands infectious diseases portfolio (Basel, Switzerland, March 29, 2006)

Novartis and Servier sign licensing agreement for a novel treatment of Major Depressive Disorder

Basel, Switzerland, March 29, 2006

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- Investor Relations Release -

Novartis announces in-licensing of valopicitabine (NM283), a novel first-in-class treatment for hepatitis C that expands infectious diseases portfolio

Novartis strengthens infectious disease portfolio and range of hepatitis compounds

Valopicitabine (NM283) the most advanced oral, direct antiviral compound in development for treatment of hepatitis C

More than 170 million patients worldwide chronically infected by hepatitis C virus(1)

Basel, Switzerland, March 29, 2006 Novartis announced today that it has exercised its option from Idenix Pharmaceuticals to in-license the late-stage development compound valopicitabine (NM283) for the treatment of hepatitis C, a condition estimated to affect more than 170 million people worldwide and a major cause of liver disease.

Under the terms of the agreement, Idenix and Novartis will co-promote this compound in the United States and the five major European markets (United Kingdom, Spain, France, Italy and Germany); Novartis will have exclusive rights to market and promote it in the rest of the world. Novartis may pay up to USD 70 million in license fees to Idenix, of which USD 25 million were paid at the time of exercising the option. Further payments may be payable based upon regulatory milestones.

Novartis is committed to achieving leadership in infectious diseases, building a strong portfolio of innovative compounds with complementary mechanisms of action, said Thomas Ebeling, Chief Executive Officer of Novartis Pharma AG. Valopicitabine complements our current hepatitis pipeline and represents an important step forward in our mission to bring more effective and safer drugs to patients suffering from hepatitis C .

In addition to valopicitabine, Novartis is developing two compounds for chronic hepatitis B in collaboration with Idenix: telbivudine, an oral antiviral potential best-in-class treatment in Phase III, and valtorcitabine, a Phase II oral antiviral. Novartis is also developing with partner Anadys the first-in-class ANA975, a novel Toll-like receptor 7 agonist for the treatment of both hepatitis C and hepatitis B. ANA975 is potentially synergistic with valopicitabine, and this

combination could become the first oral combination therapy available for the treatment of chronic hepatitis C.

About valopicitabine (NM283)

Valopicitabine, a once-daily oral treatment, is intended to block hepatitis C virus (HCV) replication by specifically inhibiting the HCV RNA polymerase. Initial clinical trials have shown that valopicitabine is active in patients infected with the genotype 1 strain of HCV. Preliminary results from clinical trials to date have demonstrated that the antiviral effects of this compound are enhanced when this agent is used in combination with pegylated interferon. Ongoing clinical trials are evaluating the combination of valopicitabine and pegylated interferon in hepatitis C patients who previously failed to respond to antiviral treatment, as well as in patients who have not yet been treated.

About Hepatitis C

Hepatitis C is a liver infection caused by the hepatitis C virus (HCV) which infects and inflames the liver, causing progressive liver damage that can lead to cirrhosis (scarring), liver cancer and death. Hepatitis C is a severe and progressive disease, with 70-85% of patients infected with HCV developing chronic infection, and of whom 20-30% develop cirrhosis.

A major unmet medical need exists in the treatment of chronic HCV since the current standard of care is associated with a high incidence of side effects and has limited efficacy in the most prevalent form (genotype 1), curing only about half the number of patients treated.

Novartis/Idenix collaboration

Idenix is developing its hepatitis B compound telbivudine and valtorcitabine in collaboration with Novartis Pharma AG under a development and commercialization arrangement established in May 2003. This collaboration agreement also granted Novartis an option to in-license valopicitabine, which it is now exercising. The collaboration arrangement further provides that Novartis and Idenix will co-promote in the United States, France, Germany, Italy, Spain and the UK those product candidates that are approved for marketing that Novartis has licensed, which now include telbivudine and valtorcitabine for the treatment of hepatitis B and valopicitabine for the treatment of hepatitis C. Novartis holds the exclusive license to these product candidates in the rest of the world.

About Novartis

Novartis (NYSE: NVS) is a world leader in offering medicines to protect health, treat disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. Novartis is the only company with leadership positions in both patented and generic pharmaceuticals. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics and leading self-medication OTC brands. In 2005, the Group s businesses achieved net sales of USD 32.2 billion and net income of USD 6.1 billion. Approximately USD 4.8 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 91,000 people and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

This release contains certain forward-looking statements , relating to the Group s business, which can be identified by the use of forward-looking terminology such as may , is potentially , could , intend , will , or similar expressions, or by express or implied discussions regarding the potent approval of telbivudine, valtorcitabine or valopicitabine by regulatory authorities, or regarding potential future sales of telbivudine, valtorcitabine or valopicitabine. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with telbivudine, valtorcitabine or valopicitabine to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that telbivudine, valtocitabine or valopicitabine will be approved for sale in any market, or that they will reach any particular level of revenue. Management s expectations regarding telbivudine, valtorcitabine or valopicitabine could be affected by, among other things, uncertainties relating to clinical trials, including new clinical data and additional analysis of existing 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 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.

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(1) World Health Organization. Hepatitis B Fact Sheet Number 204 Available at ww.who.int/mediacentre/factsheets/fs204/en/print.html Accessed 12/8/05

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- Investor Relations Release -

Novartis and Servier sign licensing agreement for a novel treatment of Major Depressive Disorder

Once-daily treatment in Phase III with a novel mechanism of action as potential innovation for the pharmacological treatment of depression

Novartis acquires exclusive development and marketing rights to the US and several other countries

Basel, Switzerland, March 29, 2006 Novartis and Servier announced today the signing of a licensing agreement for agomelatine, a Phase III investigational drug for the treatment of major depressive disorder, a condition estimated to affect one in ten adults in the US alone.

Under development as a once-daily treatment, agomelatine is a novel melatonergic antidepressant that acts as an agonist at MT1 and MT2 receptors with additional 5-HT2c antagonist properties. Due to its unique receptor profile, agomelatine represents a potential innovation for the pharmacological treatment of depression.

Under the terms of the agreement, which requires antitrust approval in the United States, Novartis has acquired the exclusive rights to further develop and market agomelatine in the US and several other countries. Servier retained the rights to develop and market the product in the rest of the world. Financial terms of this agreement were not disclosed.

This collaboration shows our commitment to invest in promising and innovative compounds like agomelatine to further strengthen our portfolio, said James Shannon, Head of Development, Novartis Pharma AG. With the initiation of a clinical development program for agomelatine in the US, Novartis will be able to build on its leadership position in neurology and potentially become a key player in the field of psychiatric disorders such as depression.

Approximately one out of 10 adults in the US will suffer from a depressive illness in a given year(1). Depression is the leading cause of disability in the US, resulting in more days of disability than other chronic medical conditions like heart disease, hypertension, diabetes and lower back pain and is the principal cause of suicide in the US(2). Despite the growing awareness of depression in the general population, it is estimated that only about half of patients with depression are diagnosed(3) and only 22% are

adequately treated with an antidepressant(4). Of those patients treated, discontinuation and/or switching of current medication often occurs due to either efficacy or tolerability concerns.

The efficacy, tolerability and safety of agomelatine has been assessed in several double-blind, randomized, placebo- and active-controlled Phase III studies conducted by Servier, mainly in Europe, Canada and Australia. In the active-controlled studies, which utilized a commonly prescribed product for the treatment of major depression, the effect of agomelatine was similar to that of the active-control.

In general, the number of adverse events experienced in patients treated with agomelatine during these studies was comparable to placebo. The main adverse events were dizziness, headache and nausea(8)

Additionally, the tolerability and safety profile of agomelatine includes a lack of clinically significant weight gain, no apparent effects on sexual function (particularly as compared with the active-control), a low incidence of gastro-intestinal adverse events as well as absence of discontinuation symptoms upon withdrawal(5),(6),(7),(8). These side effects, often observed with current therapies, contribute to non-adherence or discontinuation of therapy(6),(8).

Disturbances of circadian rhythms, especially alterations of the sleep-wake rhythm, are strongly associated with depressive states. Sleep disturbances are among the most frequent complaints and can be observed in up to 80% of depressive patients(9). Agomelatine restores restful sleep and improves daytime alertness(10) by normalizing the timing and continuity of sleep in depressive patients.

About Major Depression

Essential features of a major depression are depressed mood, loss of interest in daily life activities, weight loss (or gain), decrease of appetite, sleep disturbances, feeling of worthlessness and/or of guilt, presence of suicidal ideation or behavior(11). The average age of onset of symptoms peaks between ages 30 - 45, but diagnosis is often not made until some years later. Depression is often chronic and recurrent, as 55-70% of individuals with a single episode can be expected to have a second episode and over 80% of individuals who experience a second episode have a third within three years without treatment(12).

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 goal is , potentially become , will be able , will suffer , or similar expressions, or by express or implied discussions regarding potential indications for agomelatine, the potential that agomelatine will be approved for marketing, or regarding potential future revenue from agomelatine. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with agomelatine to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that agomelatine will be approved for any indications in any market or regarding potential future revenue from agomelatine. In particular, management s expectations regarding commercialization of agomelatine could be affected by, among other things, additional analysis of agomelatine clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays in 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 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

Novartis has been a leader in the neuroscience area for more than 50 years, having pioneered early breakthrough treatments for Alzheimer s disease, Parkinson s disease, attention deficit/hyperactivity disorder, epilepsy, schizophrenia and migraine. Novartis continues to be active in the research and development of new compounds, is committed to addressing unmet medical needs and to supporting patients and their families affected by these disorders.

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, treat disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. Novartis is the only company with leadership positions in both patented and generic pharmaceuticals. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics and leading self-medication OTC brands. In 2005, the Group s businesses achieved net sales of USD 32.2 billion and net income of USD 6.1 billion.

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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: March 29, 2006

By: /s/ MALCOLM B. CHEETHAM

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