

NOVARTIS AG  
Form 6-K  
January 18, 2007

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

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THE SECURITIES EXCHANGE ACT OF 1934

Report on Form 6-K dated January 18, 2007

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**Novartis AG**

(Name of Registrant)

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**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):

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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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Enclosure:

Exforge® approved in Europe as powerful new blood pressure therapy combining two leading medications in a single pill (Basel, January 18, 2007)

Novartis receives US government contract to further develop a novel antigen technology that could extend vaccine supplies in a pandemic outbreak (Basel, January 17, 2007)

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**Investor Relations Release**

**Exforge®** approved in Europe as powerful new blood pressure therapy combining two leading medications in a single pill

- ***Exforge combines the actions of valsartan and amlodipine, two of the world's most prescribed branded antihypertensive medications***<sup>(1,2)</sup>
- ***Clinical data show Exforge delivers powerful blood pressure reductions, getting up to nine out of 10 patients to blood pressure goal***<sup>(3)</sup>
- ***EU approval based on clinical trials in more than 5,000 patients, showing better efficacy and less edema than with amlodipine alone***<sup>(3,4)</sup>

**Basel, January 18, 2007** Novartis announced today that the European Commission has granted approval for Exforge® as a new and highly effective single-pill treatment for patients with high blood pressure.

Exforge combines in one tablet the power of the two most commonly prescribed branded hypertension medicines Diovan® (valsartan) and Norvasc® <sup>(1)</sup> (amlodipine besylate). Exforge is indicated for the treatment of hypertension in patients whose blood pressure is not adequately controlled by amlodipine or valsartan alone<sup>(1,2)</sup>.

Exforge will be launched shortly in Germany followed by launches in most other European Union countries throughout the year, pending expiration of the patent protection for Norvasc. The EU decision, which applies in all 27 EU member states plus Iceland and Norway, follows recent tentative approval in the US and approval in Switzerland.

High blood pressure is a major health concern. If left uncontrolled, it can lead to heart attacks, strokes, heart and kidney failure and premature death, said Professor Rainer Düsing, internist at the Medizinische Universitäts-Poliklinik at the University of Bonn in Germany. The combination of these two well-known and powerful antihypertensive medications in one tablet will help patients reach and maintain their blood pressure goal with favorable tolerability.

Clinical trials involving over 5,000 patients demonstrated that Exforge helped up to nine out of 10 patients to reach their blood pressure goal (i.e. diastolic blood pressure under 90 mmHg or a more than 10 mmHg reduction from baseline) <sup>(3)</sup>. Exforge has been shown in trials to deliver reductions in blood pressure of 36mmHg and up to 43mmHg in some patient populations<sup>(5)</sup>.

Overall, clinical trials have demonstrated that Exforge is highly efficacious and well tolerated with an improved side effect profile over amlodipine alone<sup>(3)</sup>. In particular, Exforge has demonstrated a lower incidence of peripheral edema (or swelling) compared to amlodipine monotherapy<sup>(3)</sup>.

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<sup>(1)</sup>Norvasc is a registered trademark of Pfizer Inc.



Exforge promises to be an attractive therapy option for patients because it brings together two of the most powerful mechanisms of action in one pill, said James Shannon, MD, Global Head of Development at Novartis Pharma AG. Delivering two agents in a single pill is associated with better compliance<sup>(6)</sup>. Research has shown that improving compliance in patients being treated for high blood pressure leads to a reduction in medical costs, a reduced risk of hospitalisation<sup>(7)</sup> and reduced use of outpatient resources<sup>(8)</sup>.

#### **About high blood pressure**

High blood pressure and its consequences is the world's number one cause of death<sup>(9)</sup>. It causes damage to the arteries, burdening the heart, kidneys, brain and other vital organs<sup>(10)</sup>. If left uncontrolled, high blood pressure can lead to heart attacks, strokes, heart and kidney failure and premature death. At present, high blood pressure affects at least 25% of all adults and approximately one billion people suffer from the condition globally. It is predicted that this figure will rise to 1.56 billion by 2025<sup>(11)</sup>.

The treatment of high blood pressure continues to be a major problem. It is estimated that seven out of 10 people with high blood pressure do not have their condition controlled to recommended levels, and adequate control is achieved even less frequently in patients at particularly high risk, such as those with diabetes<sup>(12,13,14)</sup>. The majority of patients require two or more therapies in order to gain adequate control of their blood pressure<sup>(15)</sup>.

#### **Disclaimer**

The foregoing release contains forward-looking statements which can be identified by the use of terminology such as, "pending expiration", "will help", "promises to be", or similar expressions, or by express or implied discussions regarding the potential regulatory approval of Exforge, or potential future revenue from Exforge. 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 Exforge will be approved for any other indications in the European Union, the United States or any other market or in any indications in currently non-approved markets, that Exforge will be brought to market in the EU, the US or in any other country, nor that Exforge will reach any particular sales levels. In particular, management's expectations regarding the approval and commercialization of Exforge could be affected by, among other things, additional analysis of clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; our 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 Novartis AG'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

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, cure 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. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics, human vaccines and leading self-medication OTC brands. Novartis is the only company with leadership positions in these four areas. In 2006, the Group's businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 101,000 associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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**Investor Relations Release**

**Novartis receives US government contract to further develop a novel antigen technology that could extend vaccine supplies in a pandemic outbreak**

- ***Latest contract, for USD 55 million, marks fourth award for Novartis from the US Department of Health and Human Services to support the government's pandemic preparedness efforts***
- ***MF59 adjuvant technology could extend vaccine supplies by allowing smaller amounts of viral antigens to be used in each dose compared to vaccines without this additive***

**Basel, January 17, 2007** Novartis announced that it has received a contract from the US Department of Health and Human Services (HHS) of approximately USD 55 million. The contract supports the company's efforts to bring the antigen-sparing capabilities of the MF59 adjuvant to the United States. An adjuvant is a substance added to a vaccine to enhance the body's immune response to the vaccine's active constituent, called the antigen.

Novartis is committed to the development and supply of vaccines to help protect against both seasonal influenza as well as the possible emergence of pandemic influenza. The use of our proprietary adjuvant MF59 with influenza vaccines has shown to be dose sparing and to provide additional immunogenicity against a broader range of potential pandemic influenza strains, while using lower amounts of viral antigen for the vaccine, said Dr. Jörg Reinhardt, CEO of Novartis Vaccines and Diagnostics.

This latest HHS contract supports development efforts in the US to evaluate the safety and effectiveness of the MF59 adjuvant in a cell cultured based pandemic influenza vaccine. The award will also support the design, equipment and validation for a US-based MF59 production facility in Holly Springs, North Carolina. In May 2006, Novartis received a contract from the HHS to develop a cell culture based influenza vaccine and to develop and design a manufacturing facility for such a vaccine in the US. Separately, in October 2005 and November 2006 Novartis was awarded contracts for a pre-pandemic vaccine by the HHS to contribute to the US National Strategic Stockpile, which is being built in accordance with the US Pandemic Preparedness Plan.

While normal seasonal influenza vaccines use 15 micrograms of antigen per influenza strain in each single dose of trivalent vaccine, current clinical data show that similar H5N1 pandemic vaccines may require up to 90 micrograms of antigen per dose, with two doses necessary to achieve the desired immunogenicity in people(1). However, several studies have found that the addition of the MF59 adjuvant from Novartis may reduce the amount of antigen necessary. In addition, the adjuvant holds the potential to provide cross-protection against drifted strains of an avian influenza virus.

- Clinical research published in the *Lancet* in 2001 showed that a MF59-adjuvanted vaccine induced antibodies against H5N1 influenza virus at levels believed to provide protection. The vaccine achieved these results with two immunizations containing 7.5 micrograms of antigen – half the



dose used to protect against a normal seasonal influenza strain. Overall, MF59 was well tolerated and adverse events were observed at similar frequency compared to the non-adjuvanted vaccine.

- In 2003, a small follow-up study published in the journal *Vaccine* explored the potential of longer-term protection following a booster dose of MF59-adjuvanted vaccine. The study demonstrated that a dose of the MF59-adjuvanted vaccine administered 16 months after the original study boosted antibodies back to putative protective levels.
- A study published in the *Journal of Infectious Diseases* in 2005 examined the breadth of the immune response generated by the vaccines in these earlier trials. The results showed that the MF59-adjuvanted vaccine induced broadly cross-reactive antibodies capable of neutralizing H5N1 strains isolated from a number of Southeast Asian countries between 1997 and 2004. Seroconversion rates were significantly higher than those achieved by non-adjuvanted vaccines, ranging from 43 percent up to 100 percent.
- Data from a clinical study supported by the NIH of an MF59-adjuvanted vaccine against an H9N2 avian influenza virus were published in *Clinical Infectious Diseases* in December 2006. In this study, the MF59-adjuvanted vaccine induced antibody levels expected to provide protection using 3.75 micrograms of antigen.

#### **More about MF59 adjuvant**

The Novartis MF59-adjuvanted seasonal vaccine Flud® was designed to address the poorer antibody response of elderly persons to influenza vaccine, a problem attributed to the general phenomenon of immunosenescence, or aging of the immune system. Data presented at the Second International Conference on Influenza Vaccines for the World (IVW 2006) in Vienna, Austria, reconfirmed that the MF59 adjuvant augmented the antibody response to vaccination. These data were from a clinical trial comparing an MF59-adjuvanted seasonal influenza vaccine to a non-adjuvanted vaccine. Moreover, antibodies in recipients of the adjuvanted vaccine were produced to higher levels against antigenically drifted circulating influenza strains that were not included in the vaccine (heterovariants)(2).

MF59 has demonstrated to be an immune enhancing and well tolerated adjuvant used in a seasonal influenza vaccine. Flud is currently licensed in Europe where it is indicated for the prevention of seasonal influenza for persons 65 years and older. Numerous studies have demonstrated that Flud increased the antibody responses in elderly subjects above those seen with an unadjuvanted vaccine. Flud is well tolerated and the principal adverse event associated with the vaccine compared to an unadjuvanted vaccine is a higher incidence of pain at the injection site. Other local and systemic adverse events have occurred at similar rates. To date, more than 27 million doses of Flud MF59-adjuvanted influenza vaccine have been distributed, and post-marketing surveillance data have disclosed no unexpected serious adverse events(3).

### **More about the Novartis influenza vaccine program**

Novartis has developed a new production process utilizing the established principles of cell culture to produce influenza vaccine. The process, uses cell cultures rather than chicken eggs as the medium for viral growth. Viruses harvested from the cells are inactivated and processed to produce the vaccine's purified viral antigens. The new technology has the potential to reduce the vaccine's production time and could help meet demands of influenza outbreaks. In addition, production in cell cultures will not be impeded by strains of the virus, including avian influenza strains which are difficult or impossible to grow in eggs. The addition of an adjuvant would allow for a greater supply, as less antigen would be needed per dose. An application for marketing authorization of a seasonal cell culture-based influenza vaccine was submitted to the EMEA in June 2006. The seasonal cell culture-based vaccine is currently under study in clinical trials in the United States and elsewhere.

### **About pandemic influenza**

A pandemic influenza occurred three times in the last century; the 1918 outbreak killed at least 40 million people worldwide, with a mortality rate of approximately 2.5 percent in the United States<sup>(4)</sup>. Pandemic influenza occurs when a new influenza virus emerges that is easily transmitted among humans. Pandemic influenza strains can cause widespread illness as the global population has had no previous exposure to the virus and thus no immune resistance<sup>(5)</sup>.

Avian influenza, or "bird flu," does not normally infect humans, but there have been several examples in recent years of transmission to people, leading to concerns that a strain could emerge with the potential to result in a pandemic. The current outbreak of H5N1 avian influenza has resulted in more than 261 laboratory-confirmed human cases since 2003<sup>(6)</sup>. Should the H5N1 avian influenza virus become transmissible between humans, its consequences could be severe as currently more than 50% of reported cases resulted in the death of the infected person. The World Health Organization (WHO) classifies the current global situation as a level 3 pandemic alert (on a 1-6 scale where 6 is pandemic)<sup>(7)</sup>.

### **Disclaimer**

This release contains certain forward-looking statements, relating to the Novartis Group's business, which can be identified by the use of forward-looking terminology such as "may allow," "may provide," "may reduce," "hold the potential," or similar expressions, or by express or implied discussions regarding potential marketing approvals or future sales of candidate vaccines. Such statements reflect current views with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that vaccine candidates will be approved for any indications in any market or that they will reach any particular sales levels or that final approvals for Fluvad or any MF59 adjuvanted influenza vaccine will be obtained as expected. In particular, management's expectations regarding commercialization of cell culture-derived influenza vaccines and particular vaccine candidates could be affected by, among other things, additional analysis of clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the ability of Novartis 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 Novartis AG'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**

Novartis Vaccines and Diagnostics is a new division of Novartis focused on the development of preventive treatments. The division has two businesses: Novartis Vaccines and Chiron. Novartis Vaccines is the world's fifth-largest vaccines manufacturer and second-largest supplier of flu vaccines in the US. The division's products also include meningococcal, pediatric and travel vaccines. Chiron, the blood testing and

molecular diagnostics business, is dedicated to preventing the spread of infectious diseases through the development of novel blood-screening tools that protect the world's blood supply.

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, human vaccines 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 99,000 people and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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## Media materials

For images and video related to the development of Novartis flu cell cultures, please visit [www.thenewsmarket.com/novartisvaccines](http://www.thenewsmarket.com/novartisvaccines). Journalists may register and download print-quality images and broadcast-standard video from this site at no charge.

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10

**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: January 18, 2007

By: /s/

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