

NOVARTIS AG
Form 6-K
January 16, 2009

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 January 15, 2009

(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:

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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: ☒

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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: ☒

Novartis International AG

Novartis Global Communications

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- Investor Relations Release -

US Department of Health and Human Services awards Novartis USD 486 million contract to build manufacturing facility for pandemic flu vaccine

- *Holly Springs, North Carolina site will have capacity to provide 150 million doses of pandemic vaccine within six months of declaration of influenza pandemic*
- *Novartis novel cell-based manufacturing technology vital alternative to traditional egg-based vaccines production*
- *Commercial production of pre-pandemic and seasonal flu vaccines planned after completion in 2012*
- *Plant to provide 300 highly skilled jobs at opening*

Basel, January 15, 2009 Novartis announced today that the US Department of Health and Human Services, Biomedical Advanced Research and Development Authority (HHS, BARDA) has awarded Novartis Vaccines a contract for up to USD 486 million over eight years to support the design, construction, validation, and licensing of U.S. cell-based influenza vaccine manufacturing facilities in Holly Springs, North Carolina, to provide a pre-pandemic supply of influenza vaccine and to provide the capacity to manufacture 150 million doses of pandemic vaccine within six months of declaration of an influenza pandemic.

I am delighted that Novartis Vaccines' facilities in Holly Springs will be able to support the US Government's ability to respond quickly to a potential pandemic, as well as contribute to America's vaccine infrastructure for seasonal flu," said Dr. Joerg Reinhardt, Chief Operating Officer of Novartis. "We believe that this contract award underscores the US Government's commitment to ensure pandemic vaccine supply, and reflects their confidence in Novartis."

A major advantage of Holly Springs' future influenza cell culture production is that it will not rely on the availability of eggs. Avian influenza virus is currently considered the most likely source of the next pandemic – and it is lethal to both chickens and their eggs. Without eggs, traditional influenza manufacturing techniques cannot produce vaccines, so the Holly Springs flu cell culture production capabilities would be a vital alternative.

This HHS contract builds on the strategic investment made by Novartis in vaccines innovation, and reinforces the significant financial and technology investments we have already committed to Holly Springs, added Dr. Andrin Oswald, CEO of Novartis Vaccines and Diagnostics.

We currently anticipate that by 2012 the site will provide jobs for more than 300 highly skilled people with the capability to produce cell-based seasonal flu vaccine, pre-pandemic vaccine and 150 million doses of pandemic vaccine within six months of the declaration of an influenza pandemic.

Under the contract, Novartis is responsible for, among other things, pre-construction document development, land use and zoning, construction, commissioning, validation and licensing of the facilities (which are already under construction in Holly Springs, North Carolina), with the goals of

regulatory licensure, manufacture and release of seasonal and pre-pandemic vaccine, as well as provision for pandemic vaccine supply in the event of a pandemic. The contract also requires Novartis to provide two commercial-scale annual lots of pre-pandemic vaccine for a minimum of three years. In addition, HHS has the right to exercise options to purchase additional influenza vaccine over 17 years.

About influenza

Influenza is a contagious, potentially serious respiratory illness caused by influenza viruses that attack the upper respiratory tract. It can cause mild to severe illness, and can lead to death. Influenza viruses easily spread from person to person in respiratory droplets created by coughing and sneezing. According to the World Health Organization (WHO), every year an estimated 3 to 5 million people worldwide become seriously ill from influenza, and as many as 500,000 primarily children and the elderly die from ensuing complications⁽¹⁾. A recent study conducted by researchers at the Centers for Disease Control and Prevention (CDC) concluded that, in the US alone, the total economic burden (including direct medical costs, lost wages and impacts on productivity) imposed by such epidemics averages somewhere in the neighborhood of USD 87 billion every year⁽²⁾.

About pandemic influenza

Pandemic influenza occurs when a new influenza virus emerges that causes serious illness and is easily transmitted among humans. In this situation, the virus can result in a worldwide outbreak of disease, or pandemic. Pandemic influenza occurred three times in the last century. Avian influenza, or bird flu, does not normally infect humans, but recent outbreaks of H5N1 avian influenza have resulted in hundreds of human cases, with a mortality rate of more than 50%. Billions of birds have been destroyed in an effort to contain the virus, which is now considered endemic in parts of Asia.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as will, planned, potential, believe, commitment, strategic, anticipate, would, can, or similar expressions, or by express or implied discussions regarding the potential completion of construction of the production facility at Holly Springs, the potential commencement of and continued successful production of vaccines at Holly Springs, regarding the amounts to be paid by the government under the agreement described in this release, or regarding potential future revenues from vaccines produced at Holly Springs. You should not place undue reliance on these statements. 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 at the Holly Springs facility to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that we will complete construction at Holly Springs, commence production there, or successfully continue production of vaccines there. Nor can there be any guarantee that we will be paid the full amount referred to in this release. Neither can there be any guarantee that vaccines produced at Holly Springs will achieve any particular levels of revenue in the future. In particular, management's expectations regarding the Holly Springs production facility and vaccines produced there could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected construction difficulties or delays; unexpected production difficulties or delays, including difficulties or delays relating to the novel cell-culture production technique to be employed there; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; 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; the impact that the foregoing factors could have on the values attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet, 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 provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2007, the Group's continuing operations (excluding divestments in 2007) achieved net sales of USD 38.1 billion and net income of USD 6.5 billion. Approximately USD 6.4 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 97,000 full-time associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

References

- (1) WHO Fact Sheet No. 211. March 2003
- (2) Molinari, A., et al. *Vaccine*. 28 June 2007; 25 (27): 5086-5096

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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: January 15, 2009

By: /s/ MALCOLM B. CHEETHAM

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