NOVARTIS AG
Form 6-K
November 21, 2012

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, 2012

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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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: x Form 40-F: o

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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: o **No**: x

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis receives FDA approval for Flucelvax®, the first cell-culture vaccine in US to help protect against seasonal influenza

- *Cell-culture technology, an alternative to traditional egg-based production, is the most significant advancement in influenza vaccine manufacturing in more than 40 years(1)*

- *Flucelvax is the only influenza vaccine of its kind in the US and does not contain any preservatives, such as thimerosal, or antibiotics(2)*

- *Approval demonstrates Novartis leadership in advancing novel influenza vaccine research and manufacturing technologies*

Basel, November 20, 2012 Novartis announced today that the US Food and Drug Administration (FDA) approved the use of Flucelvax® (Influenza Virus Vaccine), the first cell-culture-derived vaccine, for individuals 18 years of age and older(3).

Flucelvax utilizes full-scale cell-culture manufacturing technology, an alternative production method to traditional egg-based production(1). Cell-culture technology utilizes a well-characterized mammalian cell line rather than chicken eggs to grow virus strains(2). The production occurs in a closed, sterile, controlled environment, which significantly reduces the risk of potential impurities. Flucelvax does not contain any preservatives, such as thimerosal, or antibiotics(2).

Cell-culture technology enables rapid response to urgent public health needs such as a pandemic within weeks(1). Traditional influenza vaccine production depends on a large number of fertilized chicken eggs to grow virus strains and requires many months for organization of egg supplies, virus incubation and actual production before the vaccine is delivered to physicians or pharmacies(4). Cell-culture technology is successfully used to manufacture other vaccines, including those distributed during the H1N1 pandemic, as well as vaccines for polio, rubella and hepatitis A(5),(6).

The approval of Flucelvax is an important milestone for our influenza franchise and brings an innovative vaccine to the US, said Andrin Oswald, Division Head, Novartis Vaccines and Diagnostics. Modern cell-culture technology will likely become the new standard for influenza vaccine production and we are proud to lead the way.

Novartis has partnered with the US Department of Health and Human Services, Biomedical Advanced Research and Development Authority (HHS, BARDA) for the development of the cell-culture manufacturing technology, as well as for construction of the state-of-the-art facility in Holly Springs, N.C. Total public/private investment in the technology development and facility is more than $1 billion(1). Flucelvax will be produced in Holly Springs once the facility is ready for full-scale commercial production. The facility is the first of its kind in the US and also allows for enhanced domestic pandemic preparedness(1).

The availability of a cell-culture vaccine is an important step to ensuring our readiness for seasonal influenza, as well as a potential pandemic, said Dr. William Schaffner,

professor of medicine and chairman of preventive medicine at Vanderbilt University, Nashville, Tennessee. Annual influenza vaccination is an important public health measure that helps protect thousands of people from illness and death each year.

About influenza

Influenza is a highly infectious and potentially deadly disease of the respiratory tract, which spreads easily through transfer of respiratory droplets typically by coughing or sneezing(7). In any given season, influenza may cause between 3,000 and 49,000 deaths and can hospitalize more than 200,000 people in the US alone(7),(8). The Centers for Disease Control and Prevention (CDC) recommends that everyone 6 months of age and older get vaccinated for seasonal influenza every year(7).

About Flucelvax

The basis for approval included data from clinical trials that found Flucelvax to be well tolerated, with an efficacy of 83.8 percent against antigenically-matched strains compared to placebo(3). A multinational, randomized, observer-blinded, placebo-controlled trial was performed to assess clinical efficacy and safety of Flucelvax during the 2007-2008 influenza season in adults aged 18 to 49 years in the US, Finland and Poland(3). A total of 11,404 subjects received Flucelvax (N=3828), seasonal influenza vaccine Agriflu® (N=3676) or placebo (N=3900) in a 1:1:1 ratio(3). In a separate study in adults aged 65 years and older Flucelvax demonstrated comparable immunogenicity to Agriflu for all three strains post-vaccination(3).

Solicited adverse reactions are similar to those observed with administration of other seasonal influenza vaccines. Overall, in clinical studies, the most common (≥10 %) solicited adverse reactions occurring in adults 18 to 64 years within seven days of vaccination with Flucelvax were pain at the injection site, erythema (redness) at the injection site, headache, fatigue, myalgia and malaise. The most common (≥10 %) solicited adverse reactions occurring in adults 65 years of age or older within 7 days of vaccination were erythema at the injection site, fatigue, headache and malaise(3).

Novartis Vaccines partnership with US Department of Health and Human Services

Development of cell-culture technology has been funded in part with Federal funds from the Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. HHSO100200600012C.

Construction of the Holly Springs facility was funded in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. HHSO100200900101C.

Indication and Important Safety Information

FLUCELVAX® is an inactivated vaccine indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUCELVAX is approved for use in persons 18 years of age and older.

Do not administer FLUCELVAX to anyone with a history of severe allergic reaction (e.g. anaphylaxis) to any component of the vaccine.

If GBS has occurred within 6 weeks of receipt of a prior influenza vaccine, the decision to give FLUCELVAX should be based on careful consideration of the potential benefits and risks.

The tip caps of the pre-filled syringes may contain natural rubber latex which may cause allergic reactions in latex-sensitive individuals.

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

After vaccination with FLUCELVAX, immunocompromised individuals, including those receiving immunosuppressive therapy, may have a reduced immune response.

Vaccination with FLUCELVAX may not protect all vaccine recipients against influenza disease.

Please see full Prescribing Information for Flucelvax.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as will, potential, potentially, or similar expressions, or by express or implied discussions regarding potential future revenues from Flucelvax. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Flucelvax to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Flucelvax will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Flucelvax could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; competition in general; government, industry and general public pricing pressures; unexpected manufacturing issues; unexpected regulatory actions or delays or government regulation generally; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; 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 provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2011, the Group s continuing operations achieved net sales of USD 58.6 billion, while approximately USD 9.6 billion (USD 9.2 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 127,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis.

References

(1). U.S. Department of Health and Human Services. HHS Awards Contracts Totaling More Than $1 Billion to Develop Cell-Based Influenza Vaccine. 2006 Available at: http://archive.hhs.gov/news/press/2006pres/20060504.html.

(2). Ambrozaitis, Arvydas et al. A novel mammalian cell-culture technique for consistent production of a well-tolerated and immunogenic trivalent subunit influenza vaccine. *Vaccine*. Vol 27. Issue 43. October 9,

2009: 6022 6029. Available at: http://www.sciencedirect.com/science/article/pii/S0264410X09011177. Accessed on October 3, 2012.

(3). Flucelvax Package Insert. 2012.

(4). Gerdil, Catherine. The Annual Production Cycle for Influenza Vaccine. *Vaccine* 21 (2003): 1776-1779.

(5). World Health Organization. Production and Availability of Pandemic (H1N1) 2009 Vaccines. 2009. Available at: http://www.who.int/csr/disease/swineflu/frequently_asked_questions/vaccine_preparedness/production_availability/en/index.html. Accessed October 2012.

(6). U.S. Food and Drug Administration. Guidance for Industry: Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications. 2010. Available at: http://www.fda.gov/downloads/biologicsbloodvaccines/ guidancecomplianceregulatoryinformation/guidances/vaccines/ucm202439.pdf. Accessed October 2, 2012.

(7). Centers for Disease Control and Prevention. Key Facts About Influenza and Flu Vaccine. 2012. Available at: http://www.cdc.gov/flu/keyfacts.htm. Accessed July 2012.

(8). Centers for Disease Control and Prevention. Seasonal Influenza-Associated Hospitalizations in the United States. 2011. Available at: http://www.cdc.gov/flu/about/qa/hospital.htm.

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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 20, 2012	By:	/s/ MALCOLM B. CHEETHAM
		Name:	Malcolm B. Cheetham
		Title:	Head Group Financial Reporting and Accounting