

NOVARTIS AG  
Form 6-K  
May 28, 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 May 26, 2009**

**(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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**Novartis International AG**

Novartis Global Communications

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**- Investor Relations Release -**

**Novartis to enter Japan vaccines market through agreement for Haemophilus Influenzae Type B (Hib) vaccine**

- *Marketing and distribution agreement with Takeda Pharmaceuticals for Vaxem-Hib® is another step in Novartis global vaccines expansion strategy.*
- *Takeda will become the exclusive partner for Vaxem-Hib in Japan and pay Novartis 100 million Yen and milestone and royalty payments.*
- *Hib infection is responsible for an estimated 386,000 deaths per year worldwide.*

**Basel, May 26, 2009** Novartis announced today that it has entered an agreement with the Takeda Pharmaceutical Company in Japan for the distribution of the Novartis Vaxem-Hib® vaccine for the prevention of infection caused by Haemophilus influenzae type B (Hib). Through this agreement, Novartis will manufacture the vaccine and supply it to Takeda, which will obtain exclusive rights to license, market and distribute the vaccine in Japan.

The WHO estimates that Hib is responsible for some three million serious illnesses and an estimated 386,000 deaths per year world wide, chiefly through meningitis and pneumonia(1). Every year in Japan, 7.5 per 100,000, or more than 450 children, under the age of five are affected by Hib meningitis(2). Almost all victims are children under the age of five(1).

Novartis is committed to bringing Vaxem-Hib® to Japan as soon as possible to help protect Japanese children from Meningitis and other Hib induced infectious diseases through this strategic partnership with Takeda, said Dr. Andrin Oswald, CEO of Novartis Vaccines and Diagnostics. Vaxem-Hib® is the first of many vaccines that Novartis hopes to bring to Japan to help improve public health and address unmet medical needs.

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Vaxem-Hib® will mark Novartis entrance into the Japan vaccines market and is part of Novartis Vaccines global expansion strategy. Japan is the world's third largest vaccine market valued at USD 640 million and is expected to grow further.

With this agreement Takeda will become the exclusive partner for Vaxem-Hib in Japan, and will be responsible for conducting clinical trials and submitting a New Drug Application (NDA). Following approval, Takeda will label the product and sell the vaccine under the Novartis brand name. Under the terms of the deal, Takeda will pay Novartis 100 million Yen upfront and will be responsible for paying milestones and royalties in accordance with development and sales of the product.

### **About Haemophilus Influenzae Type B**

Hib is a severe bacterial infection, occurring primarily in infants and children under 5 years(3). It is commonly found in the noses and throats of healthy individuals living in regions where vaccination is not carried out(2). Hib disease is spread through the air by coughing, sneezing, and even breathing. If the bacteria spread to the lungs or bloodstream, the child can get meningitis (inflammation of the covering of the brain), pneumonia, epiglottitis (inflammation in the throat), arthritis, or other problems. A child who is infected can spread the disease to others for as long as the bacteria remain in the body(3).

Symptoms of Hib are meningitis, pneumonia, sepsis, epiglottitis (a severe throat infection), skin infections, and arthritis. Complications of the disease can lead to Hib meningitis (death in one out of 20 children, and permanent brain damage in 10% - 30% of the survivors)(3).

### **About Vaxem-Hib**

Vaxem-Hib is a vaccine indicated for vaccination against Haemophilus Influenzae Type B in children less than five years of age.

### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as to enter, strategy, will, committed, hopes, expected, can, or similar expressions, or by express or implied discussions regarding potential Japanese marketing approvals for Vaxem-Hib, potential future agreements to sell additional Novartis vaccines in Japan or regarding potential future revenues from Vaxem-Hib or other Novartis vaccines in Japan. 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 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Vaxem-Hib will be approved for sale in Japan. Nor can there be any guarantee that Novartis will reach agreements to market any other vaccines in Japan. Neither can there be any guarantee that Vaxem-Hib or any such other vaccines will achieve any particular levels of revenue in the future. In particular, management's expectations could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; 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; 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 Vaccines and Diagnostics is a 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.

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 2008, the Group's continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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## References

- (1) World Health Organization. Haemophilus influenzae type B (HiB). <http://www.who.int/mediacentre/factsheets/fs294/en/>. Accessed May 12, 2009
- (2) Kato et al. Japan Medical Journal, No.4370, p77
- (3) Centers for Disease Control and Prevention. Parents Guide to Childhood Immunizations (Hib). [http://www.cdc.gov/vaccines/vpd-vac/hib/downloads/pg\\_why\\_vacc\\_hib-508.pdf](http://www.cdc.gov/vaccines/vpd-vac/hib/downloads/pg_why_vacc_hib-508.pdf). Accessed May 14, 2009.

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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: May 26, 2009

By: /s/ MALCOLM B. CHEETHAM

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