NOVARTIS AG
Form 6-K
June 04, 2008

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 June 4, 2008

(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: x Form 40-F: o

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Yes: o **No**: x

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- Investor Relations Release -

Novartis presents full pipeline of novel vaccines addressing significant unmet needs

- *Late stage development pipeline with Menveo and MenB vaccines creating meningococcal vaccine franchise with strong growth potential*

- *Novartis leverages research excellence with first in class vaccines in early pipeline, preventing infections from Helicobacter pylori, Group B Streptococcus and other pathogens which pose significant public health challenges*

Cambridge, June 4, 2008 Novartis unveiled today a promising pipeline of novel vaccines, highlighting vaccine candidates that address significant unmet needs for prevention of fatal diseases such as meningococcal infections and other hospital and community acquired infections. Several vaccine candidates from the Novartis Vaccines research and development portfolio have the potential of being first of its kind.

Our emerging late and early stage pipeline underscores our commitment to prevention as a means to improve health and address public health challenges, said Dr. Joerg Reinhardt, CEO of Novartis Vaccines and Diagnostics. We are focusing on diseases such as meningococcal meningitis where current vaccines do not protect against all strains that cause this potentially fatal condition which affects up to 500,000 people a year.

Late stage pipeline: Prevention of meningococcal disease as leading targets

- *Novartis has two meningococcal vaccines in late stage development, Menveo® (ACWY-CRM conjugate vaccine) for infants and adolescents and MenB for multiple strains of the meningococcal serogroup B*

- *Novartis is the only company currently developing vaccines against all five meningococcal serogroups (A, B, C, W-135 and Y) in Phase III clinical trials*

Currently available vaccines do not provide adequate protection against all meningococcal disease serogroups, particularly in young children and adolescents who have the highest rate of disease. The disease is estimated to strike an estimated 500,000 people annually of whom an estimated 50,000 die and up to 20% suffer from serious long-term consequences such as deafness, neurological damage or limb loss.

Novartis is currently the only company developing vaccines against all five disease-causing meningococcal serogroups (A, B, C, W-135 and Y) with vaccine candidates being investigated in Phase III clinical trials. Menveo and MenB show promise in clinical trials completed to date and may form the basis of a new meningococcal vaccine franchise.

Meningococcal meningitis is a potentially vaccine-preventable disease and with new vaccines offering protection across age groups, other families may not have to suffer losing a child as I did to this devastating, yet preventable illness, said Lynn Bozof, Executive Director and one of the five founding members of The National Meningitis Association.

Recent Phase III trial data for Menveo (MenACWY-CRM) suggest that it has the potential to become the first meningococcal vaccine to protect all age groups from infancy to adulthood against the four vaccine preventable serogroups (A, C, W-135 and Y). A pivotal phase III study compared Menveo head to head with Menactra®*. The co-primary objectives were lot-to-lot consistency for three Menveo lots and seroresponse non-inferiority of Menveo as compared with Menactra for the 11 to 18 and 19 to 55 years of age groups, followed by a pre-defined superiority analysis after non-inferiority was first demonstrated. Menveo demonstrated statistically superior immune responses versus Menactra both on percentage of subjects protected and on the strength of the immune response. This was of special relevance for serogroup Y which causes about 39% of meningococcal infections in the US and where the use of Menveo in this study increased the rate of protection of previously non-immune individuals by 50% compared to Menactra. Novartis expects to file with regulatory authorities in the second half of 2008 for individuals 11-55 years of age in the US, Canada, EU and Australia. Submissions for infants and young children 2 months-10 years of age are planned for 2009. Menveo is expected to fit within standard childhood vaccination schedules.

The Novartis MenB vaccine is a recombinant vaccine that is designed to protect against a majority of global strains of serogroup B for which no vaccine is currently available. In Europe, North America and many other parts of the world the B strain is the most common meningococcal serogroup. In clinical trials completed to date, the Novartis MenB vaccine has shown excellent immunogenicity in infants and strong immunogenicity in adults in early clinical development. A Phase III trial in infants and children is currently ongoing as part of a comprehensive Phase III development effort for the vaccine. Regulatory submissions for the Novartis MenB vaccine for infants and children are planned for 2010.

Novartis has a strong position in prevention of meningococcal disease achieved via the distribution of more than 26 million doses of Menjugate® (MenC-CRM) and the production of MeNZB® against a strain of meningococcus B specific to an outbreak in New Zealand.

Exciting early stage pipeline of novel vaccines

- *Focusing on unmet needs such as prevention of Helicobacter pylori infections, a major cause of gastritis that can lead to gastric ulcers and gastric cancer*
- *Novel Group B Streptococcus vaccine candidate in Phase I clinical trials, with potential to protect against 85% of neonatal sepsis and meningitis*
- *Novartis, a leader in traditional and novel research approaches, will open vaccines research site in Cambridge later this year to focus on viral vaccine discovery*

It is estimated that more than 80% of adults in developing countries and 20-50% of adults in developed countries are infected with Helicobacter pylori (H pylori). H pylori causes gastritis, gastric ulcers and gastric cancer. The Novartis H pylori vaccine candidate is in Phase I and has been shown to be safe and immunogenic in early trials. A proof of concept trial is planned for the end of 2008.

Group B Streptococcus is a significant cause of mortality in early life and can lead to neonatal sepsis and meningitis, which together lead to an estimated 2,725 cases per year in the US alone. Novartis is in Phase I clinical trials with a Group B Streptococcus vaccine candidate that has the potential to significantly protect against the disease burden. Group B Streptococcus may also be responsible for up to 10% of all stillbirths, and is recognized as a cause of invasive disease in the elderly.

Vaccine research using both reverse vaccinology and conjugation technology aims to prevent infections from Group A Streptococcus (GAS), which causes phyaryngitis, rheumatic fever and necrotizing fascititis. GAS is a highly diverse pathogen with more than 150 strains described. The Novartis vaccine is currently in preclinical development and is expected to enter Phase I in 2010 as is a new pneumoccocus vaccine to cover increasingly new strains as well as those becoming drug resistant, which still are a major cause of death and hospitalization in children.

Building upon the expertise of reverse vaccinology, novel research programs are expected to drive sustained future growth. The company has established leadership in both traditional and novel research approaches and its scientists have unique skills in vaccine design, bacterial genomics, conjugation chemistry and antigen selection. A new research site with up to 250 scientists is expected to open in Cambridge, Massachusetts later in 2008, which will formalize the establishment of a center of excellence in viral vaccine discovery. In addition, the alliance with Intercell AG aims to develop first in class vaccines in further areas where unmet needs remain.

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 pipeline , development , potential , commitment , potentially , estimated , promise , suggest , exp expected , designed to , will , can , aims to or similar expressions, or by express or implied discussions regarding potential future filings or marketing approvals of existing vaccines or of vaccine candidates, or potential future revenues from existing vaccines or from vaccine candidates, or potential new indications for existing vaccines. 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 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that any of the products referred to in this release will be submitted or approved for sale in any market, or that any new indications or labeling will be approved for any existing products. Nor can there be any guarantee that any such products will achieve any particular levels of revenue in the future. In particular, management s expectations could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected 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 the additional factors discussed in Novartis AG 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 this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this document 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 preventative 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 include influenza, 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 provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on growth areas in healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines and 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 98,000 full-time associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

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**Menactra is a registered trademark of Sanofi Pasteur*

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: June 4, 2008

By: /s/ MALCOLM B. CHEETHAM

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