

NOVARTIS AG
Form 6-K
January 22, 2013

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 22, 2013

(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
CH-4002 Basel
Switzerland

<http://www.novartis.com>

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis receives EU approval for Bexsero®, first vaccine to prevent the leading cause of life-threatening meningitis across Europe

- *Bexsero is indicated to help protect all age groups against meningococcal serogroup B (MenB) disease, including infants who are the most vulnerable(1)*
- *MenB disease is associated with a high human toll for families and communities, as it can be fatal or may cause serious, life-long disabilities in survivors(2),(3)*
- *Novartis is working with health authorities to provide access to Bexsero as soon as possible*

Basel, January 22, 2013 Novartis announced today that the European Commission has approved Bexsero® (Meningococcal Group B Vaccine [rDNA, component, adsorbed]) for use in individuals from 2 months of age and older. Novartis is committed to making Bexsero available as soon as possible.

This meningitis B vaccine is the most important medical breakthrough in the 30 years since I lost my son to the disease, said Meningitis UK Founder Steve Dayman MBE. It could save thousands of lives and prevent other parents suffering the same tragedy. The vaccine must be made widely available through the immunisation schedule as soon as possible – any delay could mean lives lost.

MenB disease is a bacterial infection and is the leading cause of meningitis across Europe(4), particularly in infants(1). Although rare, one reason this disease is so feared is that it affects healthy people rapidly and without warning(2),(3). Symptoms can often resemble the flu, making this disease easily misdiagnosed in its early stages(5). In many cases, doctors simply cannot treat infected patients soon enough to avoid serious outcomes. About one in ten of those who contract the disease will die despite appropriate treatment(3). Up to one in five survivors may suffer from devastating, life-long disabilities such as brain damage, hearing impairment or limb loss(3). Prevention through vaccination is therefore the best defense against this aggressive disease.

Each year, thousands of parents see their children die or left with severe disabilities as a result of this devastating disease. Through the combined efforts of many people over two decades, we are closer than ever to seeing an end to this suffering, said Andrin Oswald, Division Head, Novartis Vaccines and Diagnostics. Our vision is a world without meningitis, and our priority is to work with decision makers across Europe to ensure

there is broad and timely access to vaccination.

Following today's approval, EU member states will evaluate Bexsero for potential inclusion into national immunization programs and, where relevant, reimbursement schemes. Novartis is already engaging with governments interested in the early adoption of the vaccine.

Bexsero is the result of more than 20 years of pioneering vaccine research(6), and its tolerability profile and immunogenicity have been established through a comprehensive clinical program involving infants, children, adolescents and adults(7),(8),(9),(10),(11),(12). Starting at

two months of age, Bexsero offers several immunization schedule options that could fit with routine vaccination visits.

The approval of Bexsero underscores the unique leadership position of Novartis in the global fight against devastating meningococcal disease. Together, Bexsero and Menveo® help to protect against all five main serogroups of meningococcal bacteria (A, C, W-135, Y and now B) that cause the majority of cases around the world(13).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as as soon as possible, committed, could, vision, priority, will, potential, or similar expressions, or by express or implied discussions regarding the potential timing of the availability of Bexsero to the public, or regarding potential future revenues from Bexsero. 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 Bexsero to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Bexsero will be available to the public in any particular country at any particular time. Nor can there be any guarantee that Bexsero will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Bexsero could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally, including uncertainties as to whether Bexsero will be included in particular countries' national immunization programs; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; government, industry and general public pricing pressures; unexpected manufacturing issues; 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

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- (1) Rosenstein NE, et al. Meningococcal disease. *N Engl J Med* 2001;344:1378-88.
- (2) Thompson MJ, et al. Clinical recognition of meningococcal disease in children and adolescents. *Lancet* 2006;367:397-403.

- (3) World Health Organization. Meningococcal meningitis. Fact sheet #141. November 2012 update. Available at: <http://www.who.int/mediacentre/factsheets/fs141/en/>. Last accessed 15 Jan 2013.
- (4) World Health Organization. Meningococcal, staphylococcal and streptococcal infections. Available at: http://www.who.int/vaccine_research/documents/Meningo20091103.pdf. Last accessed 15 Jan 2013.
- (5) Mayo Foundation for Medical Education and Research. Meningitis. April 2011. Available at: <http://www.mayoclinic.com/health/meningitis/DS00118/DSECTION=symptoms>. Last accessed 15 Jan 2013.
- (6) Rappuoli R. Reverse vaccinology, a genome-based approach to vaccine development. *Vaccine* 2001;19:2688-91.
- (7) Santolaya ME, et al. Immunogenicity and tolerability of a multicomponent meningococcal serogroup B (4CMenB) vaccine in healthy adolescents in Chile. *Lancet* 2012;379:617-24.
- (8) Gossger N, et al. Immunogenicity and tolerability of recombinant meningococcal serogroup B vaccine administered with or without routine infant vaccinations according to different immunization schedules: A randomized controlled trial. *JAMA* 2012;307:573-82.
- (9) Vesikari T, et al. Immunogenicity and safety of an investigational multicomponent, recombinant, meningococcal serogroup B vaccine (4CMenB) administered concomitantly with routine infant and child vaccinations: results of two randomised trials. *Lancet* 2013 Jan 14. [Epub ahead of print].
- (10) Findlow J, et al. Multicenter, open-label, randomized phase II controlled trial of an investigational recombinant meningococcal serogroup B vaccine with and without outer membrane vesicles, administered in infancy. *Clin Infect Dis* 2010;51:1127-37.
- (11) Snape MD, et al. Immunogenicity of two investigational serogroup B meningococcal vaccines in the first year of life: a randomized comparative trial. *Pediatr Infect Dis J* 2010;29:e71-9.
- (12) Prymula R, et al. Catch-up vaccination of healthy toddlers with an investigational multicomponent meningococcal serogroup B vaccine (4CMenB) - exploration of a two-dose schedule. Presented at 29th ESPID Meeting, 7-11 June 2011; The Hague, The Netherlands.
- (13) World Health Organization. Meningococcal position paper. Weekly epidemiological record No. 44, 2002, 77, 329-40. Available at: http://www.who.int/immunization/wer7740meningococcal_Oct02_position_paper.pdf. Last accessed 15 Jan 2013.

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Novartis Media Relations

Central media line : +41 61 324 2200

Eric Althoff

Novartis Global Media Relations

+41 61 324 7999 (direct)

+41 79 593 4202 (mobile)

eric.althoff@novartis.com

e-mail: media.relations@novartis.com

Liz Power

Novartis Division Communications

+1 617 871 7985 (direct)

+1 617 583 3015 (mobile)

elizabeth.power@novartis.com

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Novartis Investor Relations

Central phone: +41 61 324 7944
Samir Shah +41 61 324 7944
Pierre-Michel Bringer +41 61 324 1065
Thomas Hungerbuehler +41 61 324 8425
Isabella Zinck +41 61 324 7188

e-mail: investor.relations@novartis.com

North America:
Helen Boudreau +1 212 830 2404
Stephen Rubino +1 862 778 83 01
Jill Pozarek +1 212 830 2445
Edwin Valeriano +1 212 830 2456

e-mail: investor.relations@novartis.com

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 22, 2013

By: /s/ MALCOLM B. CHEETHAM

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