

NOVARTIS AG  
Form 6-K  
March 16, 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 March 16, 2012**

**(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:

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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:** ☒

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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**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**

**Alcon gains exclusive ex-US rights for ocriplasmin, potential first pharmacological treatment for symptomatic vitreomacular adhesion**

- *Symptomatic vitreomacular adhesion (VMA) is a progressive, debilitating eye disease, there is currently no pharmacological treatment available*
- *Phase III clinical data demonstrate resolution of symptomatic VMA following a single administration of ocriplasmin(1)*
- *More than 300,000 patients(2) in Europe alone could potentially benefit from this new therapy*
- *Alcon to make upfront payment to ThromboGenics, additional payments based on milestones and royalties on future sales*

**Basel, March 16, 2012** Alcon, the global leader in eye care and a division of Novartis, announced today that it has gained exclusive rights to commercialize ocriplasmin outside the United States for the treatment of symptomatic vitreomacular adhesion (VMA). If approved, it will be the first pharmacological treatment for patients with symptomatic VMA, including macular hole. Symptomatic VMA is a progressive, debilitating eye disease that may lead to visual distortion, loss in visual acuity and central blindness(3).

Alcon is licensing ocriplasmin from ThromboGenics, a bio-pharmaceutical company based in Belgium. The agreement grants Alcon exclusive commercial rights outside the United States. Under the terms of the agreement, Alcon will make an upfront payment of 75 million (approx. USD 100 million) to ThromboGenics with additional potential payments based on milestones, as well as royalties on sales of ocriplasmin, if approved.

There are thousands of symptomatic vitreomacular adhesion patients who currently do not have an available treatment option. The clinical results(1) for ocriplasmin show improved visual function and that earlier intervention may limit the progression of the disease, said Kevin Buehler, Division Head Alcon. Ocriplasmin is a strategic fit for Alcon and is expected to further enhance our portfolio of innovative treatments for the eye.

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Ocriplasmin is currently under review with the European Medicines Agency (EMA) as the first pharmacological treatment for symptomatic VMA, including macular hole. The drug was accepted for review by the EMA in October 2011. ThromboGenics retains the rights to commercialize ocriplasmin in the United States and a decision on approval is expected from the US Food and Drug Administration (FDA) in the second half of 2012.

Symptomatic VMA primarily involves the interface between the retina's highly sensitive macular area, which is responsible for detailed, central vision, and the posterior vitreous membrane, which separates the clear, jelly-like substance in the center of the eye, called vitreous, from the retina.

With symptomatic VMA patients, the vitreous adheres in an abnormally strong way to the retina, which can lead to traction ( pulling ) on the retina, causing symptoms including impaired vision. Further unresolved traction may lead to the development of macular holes and central blindness(3).

For many symptomatic VMA patients, there is no recommended treatment available. More than 300,000(2) symptomatic VMA patients in Europe alone could potentially benefit from this new treatment, if approved. The standard of care for patients advancing to late stage VMA is surgical vitrectomy.

Ocriplasmin is a recombinant truncated form of human protein (plasmin) administered through a one time intra-vitreous injection. Clinical data(1) demonstrate that ocriplasmin resolves symptomatic vitreomacular adhesion (VMA), on average within seven days, reducing the number of patients advancing to surgery.

The ocriplasmin in-licensing agreement confirms Alcon's commitment to bringing innovative eye care treatments to patients with unmet medical needs. With the company's extensive commercial capabilities, geographic footprint and strong relationships with retinal specialists and ophthalmologists around the globe, Alcon is well positioned to bring this innovative treatment to patients around the world.

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as to make, potentially, will, potential, expected, expects, commitment, or similar expressions, or by express or implied discussions regarding potential marketing approvals for ocriplasmin and the timing of any such approvals, or regarding potential future revenues from ocriplasmin. 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 ocriplasmin to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that ocriplasmin will be approved for sale in any market, or at any particular time. Neither can there be any guarantee that ocriplasmin will achieve any particular levels of revenue in the future. In particular, management's expectations regarding ocriplasmin could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally, both with regard to the completion of the license agreement, and with regard to the approval to market ocriplasmin; 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; government, industry and general public pricing pressures; unexpected manufacturing issues; competition in general; 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 Alcon**

Alcon, the global leader in eye care, provides innovative products that enhance quality of life by helping people worldwide see better. The three Alcon businesses - Surgical, Pharmaceutical and Vision Care - offer the widest spectrum of eye care products in the world. Alcon is the second largest division of the Novartis Group with pro-forma sales of USD 10 billion in 2011. Headquartered in Fort Worth, Texas, USA, Alcon has

23,000

employees worldwide, operations in 75 countries and products available in 180 markets. For more information, visit [www.alcon.com](http://www.alcon.com).

## 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 124,000 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>.

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## References

- (1) Thrombogenics. MIVI-TRUST Phase III Clinical Data.
- (2) Alcon internal estimates.
- (3) Trese M, Kaiser P, Dugel P, Brown D, & Humayun M (2011). Symptomatic Vitreomacular Adhesion (VMA): Diagnosis, Pathologic Implications, and Management. Retina Today, July/August (Supplement).

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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: March 16, 2012

By: /s/ MALCOLM B. CHEETHAM

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