

NOVARTIS AG
Form 6-K
August 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 August 15, 2012

(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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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

Phase III results published in NEJM show ocriplasmin could be first pharmacological eye treatment for vitreomacular adhesion patients

- *Vitreomacular adhesion is an age-related progressive, debilitating eye disease, often leading to blindness; standard of care is watchful waiting or surgery*
- *Phase III results show that ocriplasmin significantly ($p < 0.001$) resolved vitreomacular traction and closed macular holes compared to placebo*
- *For the majority of patients with resolution of vitreomacular adhesion after ocriplasmin administration, the resolution was achieved within seven days*
- *Alcon, the eye care division of Novartis, acquired the commercialization rights to ocriplasmin outside the United States from ThromboGenics*

Basel, August 15, 2012 Novartis announced today, that the New England Journal of Medicine (NEJM) published the results of two Phase III studies of the investigational eye treatment ocriplasmin. The studies including 652 patients found that ocriplasmin, significantly resolved vitreomacular traction and closed macular holes compared to placebo in patients with vitreomacular adhesion(1). Vitreomacular adhesion (VMA), including vitreomacular traction (VMT) and macular holes, is an age-related progressive, debilitating eye disease that may lead to visual distortion, loss in visual acuity and central blindness. More than 300,000 patients suffer from this disease in Europe alone(2).

Results from the Phase III program with ocriplasmin are significant as they demonstrate the potential for using an enzymatic approach to resolve vitreomacular adhesion. This represents a real advance for patients living with vitreomacular adhesion who currently only have the option of surgery at a later stage of the disease, said Prof. Dr. Peter Stalmans, Department of Ophthalmology, University Hospitals, Leuven, Belgium. The majority of patients who achieved resolution of their vitreomacular adhesion after a single intravitreal injection of ocriplasmin showed this positive outcome within the first seven days.

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The results of these Phase III trials, which both met their primary endpoints, demonstrate the efficacy of ocriplasmin which, if approved, could be the first pharmaceutical therapy to treat patients with vitreomacular adhesion. The ocriplasmin Phase III program was conducted by Alcon's partner ThromboGenics, NV.

In patients with VMA, the vitreous (jelly-like substance in the center of the eye that is surrounded by a membrane) adheres in an abnormally strong way to the retina (light-sensitive layer of tissue at the back of the eye), 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). The only treatment option for progressed VMT and macular holes is a surgical procedure called vitrectomy (removal of the vitreous from the eyeball). In cases where VMT and macular holes are not severe enough to require surgery, the standard of care is watchful waiting (4).

Ocriplasmin, a recombinant, truncated form of human protein (plasmin), works by dissolving the proteins that link the vitreous to the macula (center of the retina), relieving the traction and resulting in posterior detachment of the vitreous from the retina.

Alcon, a division of Novartis, acquired the commercialization rights to ocriplasmin outside the United States from the Belgian biopharmaceutical company ThromboGenics, who retains the rights to commercialize the drug in the US. As the global leader in eye care, Alcon is dedicated to bringing innovative eye treatments to patients with unmet medical needs.

The data from these studies provide a basis for worldwide regulatory filings, said Kevin Buehler, Division Head, Alcon. With Alcon's extensive commercial capabilities, geographic footprint and strong relationships with retinal specialists and ophthalmologists, we are well positioned to bring this innovative treatment to patients outside the United States, once it is approved.

Ocriplasmin is currently under review with the European Medicines Agency (EMA) and was accepted for review by the EMA in October 2011. In July 2012, the US Food and Drug Administration (FDA) Dermatologic and Ophthalmic Drugs Advisory Committee issued a positive recommendation supporting approval of ocriplasmin in the United States.

About the Studies

Study 006 and Study 007 are two multicenter, randomized, double-blind, placebo-controlled Phase III studies to test the efficacy and safety of a single intravitreal injection of ocriplasmin in patients with VMT and macular holes. One half and one third of the patients enrolled in Study 006 and Study 007, respectively, received placebo; all other patients received a single intravitreal injection of ocriplasmin (125 microgram). The primary endpoint for the studies was the percentage of eyes with nonsurgical resolution of vitreomacular adhesion at day 28, determined by optical coherence tomography (OCT) imaging.

After 28 days, following a single administration of ocriplasmin, resolution of vitreomacular adhesion was observed in 26.5% of patients compared to 10.1% in the placebo group, ($p < 0.001$). This statistically significant difference was maintained through six months of observation. For those patients with resolution of vitreomacular adhesion after ocriplasmin administration, resolution was achieved in the majority of patients within seven days. By the end of the six months observation period, fewer patients required a vitrectomy in the ocriplasmin treated group, compared to placebo (17.7% vs. 26.6% respectively, $p = 0.02$).

In the ocriplasmin group, ocular adverse events occurring in the studied eye were transient and mild in severity, the most common adverse event being self-reported vitreous floaters (in 68.4% of patients compared to 53.5% in the placebo group). In the group treated with ocriplasmin, the incidence of any serious ocular adverse event was 7.7%, compared to 10.7% in the placebo group, ($p = 0.26$).

Disclaimer

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The foregoing release contains forward-looking statements that can be identified by terminology such as could, potential, dedicated, or similar expressions, or by express or implied discussions regarding potential marketing submissions or approvals for ocriplasmin 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 submitted or approved for sale in any market, or at any particular time. Nor 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; 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; competition in general; government, industry and general public pricing pressures; unexpected manufacturing issues; 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 24,000 employees worldwide, operations in 75 countries and products available in 180 markets. For more information, visit 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 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 126,000 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) Stalmans P, Benz MS, Gandorfer A, et al. Enzymatic Vitreolysis with Ocriplasmin for Vitreomacular Traction and Macular Holes. *N Engl J Med*. 2012;367:606-615.
- (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).
- (4) Stalmans P. Management and Intervention Strategies for Symptomatic Vitreomacular Adhesions. *Retinal Physician*. May 2011.

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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)

beth.calitri@novartis.com

Heidi De Wit

Alcon Global Media Relations

+1 817 615 2976 (direct)

+1 972 955 7073 (mobile)

heidi.dewit@alconlabs.com

Julie Masow

Novartis US Media Relations

+1 212 830 2465 (direct)

+1 862 579 8456 (mobile)

julie.masow@novartis.com

e-mail: media.relations@novartis.com

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For questions about the site or required registration, please contact: journalisthelp@thenewsmarket.com.

Novartis Investor Relations

Central phone:	+41 61 324 7944		
Susanne Schaffert	+41 61 324 7944	North America:	
Pierre-Michel Bringer	+41 61 324 1065	Helen Boudreau	+1 212 830 2404
Thomas Hungerbuehler	+41 61 324 8425	Jill Pozarek	+1 212 830 2445
Isabella Zinck	+41 61 324 7188	Edwin Valeriano	+1 212 830 2456
e-mail: investor.relations@novartis.com		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: August 15, 2012

By: /s/ MALCOLM B. CHEETHAM

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