NOVARTIS AG
Form 6-K
April 19, 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 April 19, 2013**

**(Commission File No. 1-15024)**

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# Novartis AG

(Name of Registrant)

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**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:** x Form 40-F: o

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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: o **No**: x

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

**Alcon announces FDA approval of Simbrinza Suspension, a new beta blocker-free, fixed-combination therapy for glaucoma patients**

- *Simbrinza offers a wide range of treatment possibilities due to its strong efficacy, providing sustained control and a 21%-35% reduction in intraocular pressure*(1),(2),(3)

- *Combines Brinzolamide 1.0% and Brimonidine Tartrate 0.2% into one multi-dose bottle(1),(4)*

- *Alcon provides a broad spectrum of pharmaceutical and surgical glaucoma treatment solutions to address patient needs at all stages of the disease*

**Basel, April 19, 2013** Alcon, the global leader in eye care and a division of Novartis, announces US FDA approval for Simbrinza Suspension, indicated for the reduction of elevated intraocular pressure (IOP) in patients with primary open-angle glaucoma or ocular hypertension.(4) Elevated IOP is the only modifiable risk factor for glaucoma. Glaucoma is a group of eye diseases that lead to progressive damage of the optic nerve(5) and can result in gradual, irreversible loss of vision, and eventually blindness, if left untreated.(6) Glaucoma affects more than 2.2 million Americans(7) and is the second-leading cause of preventable blindness worldwide.(8)

Simbrinza is a fixed-dose combination medication that offers a wide range of treatment possibilities due to its strong efficacy and ability to decrease elevated IOP by 21- 35%.(1),(2),(3) In addition, it is the only available, fixed-dose combination therapy for glaucoma in the US without a beta blocker.(1),(2)

Alcon is the global leader in providing both pharmaceutical and surgical options for patients living with glaucoma, said Robert Warner, Area President, US and Canada for Alcon. The introduction of Simbrinza further expands our ability to provide effective treatments for patients with elevated IOP. Given its excellent efficacy, established safety profile, and the fact that it is the only available, fixed-dose combination without a beta blocker approved in the US, Simbrinza has the potential to re-shape the treatment paradigm for glaucoma.

The new ophthalmic suspension is a fixed-dose combination of a carbonic anhydrase inhibitor (Brinzolamide 1.0%) and an alpha 2 adrenergic receptor agonist (Brimonidine Tartrate 0.2%).(1),(4) It combines the two drugs into one multi-dose bottle, helping to reduce the medication

burden for glaucoma patients.(9) Patients are to administer one drop of Simbrinza into the affected eye(s), three times per day.

Simbrinza represents an important new option for treating glaucoma patients with elevated IOP, said Gregory Katz, MD, Glaucoma Service, St. Joseph Mercy Medical Center, Ann Arbor, Michigan. Glaucoma must be treated over the course of one s life, and elevated eye pressure must be managed every day. It s exciting to now have a product available that combines two effective compounds into one multi-dose combination, offering sustained control.

The FDA approval of Simbrinza is based on data from two pivotal Phase III clinical trials with approximately 1,300 patients.(1),(2) The studies evaluated the safety and efficacy of a fixed-dose combination of Brinzolamide 1.0% and Brimonidine 0.2%, administered three times daily, compared to separate three-times-per-day dosing of one or the other component.(1),(2) Both studies met their primary endpoint and demonstrated that Simbrinza is statistically superior compared to either component regarding mean IOP at Month 3 for all time points.(1),(2) In both studies, Simbrinza achieved a 5mm Hg to 9mm Hg reduction from baseline to Month 3. Patients mean IOP at baseline was 22mm Hg to 36mm Hg.(1),(2),(3)

In the two, three-month clinical trials, the most frequently reported adverse reactions in patients treated with Simbrinza (occurring in approximately 3-5% of patients in descending order of incidence) were blurred vision, eye irritation, dysgeusia (bad taste), dry mouth and eye allergy. Treatment discontinuation mainly due to adverse reaction was reported in 11% of Simbrinza patients.(4) The safety profile of the combination agent (Simbrinza) is comparable to each of the individual components.(1),(2) Additionally, there were no significant cardiovascular or pulmonary events found with Simbrinza in either clinical study conducted.(1),(3)

**About Glaucoma**

More than 67 million people worldwide have glaucoma, which is the second-leading cause of preventable blindness(8) and a disease that many know little about.(10) Glaucoma is a group of eye diseases that lead to progressive damage of the optic nerve.(5) Because the optic nerve transmits information from the eye to the brain,(11) glaucoma can result in a gradual, irreversible loss of vision and eventually blindness, if left untreated.(6) Elevated eye pressure is often present and is considered a risk factor for glaucoma.(11) However, in rare cases, even patients with a normal range of IOP can develop the disease.(6) The exact cause of glaucoma is unknown.

**Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, or similar expressions, or by express or implied discussions regarding potential additional marketing approvals for Simbrinza or regarding potential future revenues from Simbrinza. 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 Simbrinza to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Simbrinza will be submitted or approved for sale in any additional markets, or at any particular time. Nor can there be any guarantee that Simbrinza will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Simbrinza 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; government, industry and general public pricing pressures; competition in general; unexpected manufacturing issues; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; and 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 10.2 billion in 2012. Headquartered in Fort Worth, Texas, U.S.A., Alcon has more than 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 2012, the Group achieved net sales of USD 56.7 billion, while R&D throughout the Group amounted to approximately USD 9.3 billion (USD 9.1 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 128,000 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**

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(2) Nguyen QH, McMenemy MG, Realini T. Phase 3 randomized 3-month trial with an ongoing 3-month safety extension of fixed-combination Brinzolamide 1%/Brimonidine 0.2%. *J Ocul Pharmacol Ther*.

(3) Data on file, 2013

(4) Simbrinza Suspension Package Insert

(5) American Optometric Association. *Glaucoma* http://www.aoa.org/Glaucoma.xml

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(9) Curr Hypertens Rep. 2007 Jun;9(3):184-9 *Compliance and Fixed-dose Combination Therapy* http://www.ncbi.nlm.nih.gov/pubmed/17519122

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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**

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| Date: | April 19, 2013 | By: | /s/ MALCOLM B. CHEETHAM |
| | | Name: | Malcolm B. Cheetham |
| | | Title: | Head Group Financial Reporting and Accounting |