NOVARTIS AG
Form 6-K
August 29, 2018

UNITED STATES

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 29, 2018

(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:

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 announces voluntary global market withdrawal of *CyPass Micro-Stent* for surgical glaucoma

- Decision based on five-year data from COMPASS-XT long-term safety study
- *Alcon advises ophthalmic surgeons to cease further implantation*

Basel, August 29, 2018 — Reflecting its uncompromising commitment to patient safety, Alcon today announced an immediate, voluntary market withdrawal of the *CyPass Micro-Stent* from the global market. In addition, Alcon advises surgeons to immediately cease further implantation with the *CyPass Micro-Stent* and to return any unused devices to Alcon. This decision and corresponding recommendation is based on an analysis of five-year post-surgery data from the COMPASS-XT long- term safety study.

The US Food and Drug Administration (FDA) approved the *CyPass Micro-Stent* in July 2016 for use in conjunction with cataract surgery in adult patients with mild-to-moderate primary open-angle glaucoma based on the results of the landmark two-year COMPASS study. The COMPASS study demonstrated a statistically significant reduction in intraocular pressure at two years post-surgery in subjects implanted with the *CyPass Micro-Stent* at the time of cataract surgery, as compared to subjects undergoing cataract surgery alone. At two years post-surgery, there was little difference in endothelial cell loss between the *CyPass Micro-Stent* and cataract surgery-only groups, and results were consistent with peer-review literature benchmarks of cataract-related endothelial cell loss.[1, 2]

The COMPASS-XT study was designed to collect safety data on the subjects who participated in the COMPASS study for an additional three years, with analysis of the completed data set at five years post-surgery. At five years, the *CyPass Micro-Stent* group experienced statistically significant endothelial cell loss compared to the group who

underwent cataract surgery alone.

“We believe that withdrawing the *CyPass Micro-Stent* from the market is in patients’ best interest and is the right thing to do,” said Dr. Stephen Lane, Chief Medical Officer, Alcon. “Although we are removing the product from the market now out of an abundance of caution, we intend to partner with the FDA and other regulators to explore labeling changes that would support the reintroduction of the *CyPass Micro-Stent* in the future.”

This voluntary market withdrawal applies to all versions of the *CyPass Micro-Stent*. Alcon will be communicating directly with ophthalmic surgeons with recommendations for evaluating and managing those patients who have already received a *CyPass Micro-Stent* and instructions for returning unused devices.

Contact Information for U.S. Customers

Customer Services +1 800 862 5266 for assistance with product returns

Medical Information +1 800 757 9785 for medical information on the *CyPass Micro-Stent*

Medical Safety +1 800 757 9780 to report product complaints or adverse events

Customers located outside the U.S. should contact their local Alcon representative.

Disclaimer

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “advises,” “commitment,” “recommendation,” “believe,” “intend,” “would,” “will,” or similar terms, or by express or implied discussions regarding the potential outcome of the market withdrawal of CyPass Micro-Stent, including the potential financial or other impact of the market withdrawal on Novartis or Alcon, or regarding the potential reintroduction of the product in the future. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee as to the outcome of the market withdrawal of CyPass Micro-Stent. Nor can there be any guarantee as to the financial or other impact on Novartis or Alcon as a result of the market withdrawal. Neither can there be any guarantee that Alcon will be able to reintroduce the product to the market in the future. In particular, our expectations regarding such products could be affected by, among other things, regulatory actions or delays or government regulation generally; uncertainties relating to the market withdrawal process; unexpected inabilities to satisfy regulators’ requirements for the market withdrawal or for any potential reintroduction of the product to the market in the future; the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; safety, quality or manufacturing issues; the potential impact of the market withdrawal on the proposed spinoff of Alcon by Novartis; uncertainties involved in the development or adoption of potentially transformational technologies and business models; uncertainties regarding actual or potential legal proceedings, including, among others, actual or potential product liability litigation and government investigations generally, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. 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 is the global leader in eye care. As a division of Novartis, we offer the broadest portfolio of products to enhance sight and improve people's lives. Our products touch the lives of more than 260 million people each year living with conditions like cataracts, glaucoma, retinal diseases and refractive errors, and there are millions more who are waiting for solutions to meet their eye care needs. Our purpose is reimagining eye care, and we do this through innovative products, partnerships with eye care professionals and programs that enhance access to quality eye care. Learn more at 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, cost-saving generic and biosimilar pharmaceuticals and eye care. Novartis has leading positions globally in each of these areas. In 2017, the Group achieved net sales of USD 49.1 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 125,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit http://www.novartis.com.

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References

1 Reuschel, A., et al., Comparison of endothelial changes and power settings between torsional and longitudinal phacoemulsification. J Cataract Refract Surg, 2010. 36(11): p. 1855-61.

2 Buys, Y.M., et al., Prospective randomized comparison of one- versus two-site Phacotrabeculectomy two-year results. Ophthalmology, 2008. 115(7): p. 1130-1133 e1.

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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: August 29, 2018 By: /s/ PAUL PENEPENT
Name: Paul Penepent
Head Group Financial
Title: Reporting and
Accounting