NOVARTIS AG
Form 6-K
March 28, 2014

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 27, 2014

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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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:

Form 20-F: x Form 40-F: o

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Yes: o **No**: x

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis to work with FDA on path forward for RLX030 for acute heart failure following Advisory Committee outcome

- *Advisory Committee members voted against RLX030 for the treatment of acute heart failure (AHF)(1)*

- *Novartis believes RLX030 has the potential to be an important treatment for AHF, a disease with lower survival rates than many advanced cancers or a heart attack*

- *Second phase III study RELAX-AHF-2 started enrolment in September 2013 using mortality as primary endpoint*

- *Over 1 million people in the US are hospitalized for AHF each year,(2) every episode results in a downward spiral of worsening health and poorer prognosis(3)*

Basel, March 27, 2014 Novartis announced today that the US Food and Drug Administration (FDA) Cardiovascular and Renal Drugs Advisory Committee (CRDAC) voted against approval for RLX030 (serelaxin) for the treatment of acute heart failure (AHF).(1)

Data presented at today s Advisory Committee meeting included phase II and III efficacy and safety data from the RLX030 clinical development program, including the pivotal phase III RELAX-AHF study. In this study RLX030 improved the symptoms of acute heart failure (AHF) through reducing the rate of worsening heart failure, a measure of symptom deterioration that requires intensification of therapy.(4)

Recognizing the urgent patient need, today we presented what we believe to be a persuasive picture of the evidence for RLX030 so far compelling results from our Phase II and III trials with no significant safety concerns, said Tim Wright, Global Head of Development, Novartis Pharmaceuticals. The discussion provided important information that we will address with the FDA as it completes its review. In the meantime we ll continue to drive our robust clinical trial program and build upon the already established body of evidence.

RLX030 is under review to improve the symptoms of AHF through reduction of the rate of worsening of heart failure. Its proposed administration is in addition to conventional therapies, as a 48-hour infusion in the hospital during an AHF episode.(5) The recommendation of

the Advisory Committee will be considered by the FDA in its review of the Biologics License Application (BLA) for RLX030, but the FDA is not bound to follow them. The FDA makes the final decision on approvals of new treatments.

About RLX030

RLX030, a relaxin receptor agonist,(6) is a recombinant form of a naturally occurring hormone (human relaxin 2) present in both men and women which rises in women during pregnancy to help the body cope with the additional cardiovascular demands.(7),(8) RLX030 has multiple effects including relaxing the blood vessels and reducing fluid buildup. Some evidence also suggests it can reduce damage to heart and vital organs, which may be of

particular importance when considering the cascade of damage that occurs during an AHF episode.(5),(9),(10)

RLX030 was granted Breakthrough Therapy (BT) designation status by the FDA in June 2013(11) for the ongoing development program. The BT designation is independent of the BLA currently under review and its corresponding FDA action date. The ongoing development program includes RELAX-AHF-2, a global, phase III outcomes study of more than 6,300 patients, of which approximately 1,000 will be from the US. The study began recruiting in 2013; results are expected in 2016 and will add to the current body of evidence for RLX030.

About acute heart failure (AHF)

Heart failure (HF), when the heart is unable to pump enough blood throughout the body, is a significant and growing public health concern, substantially impacting quality of life for an estimated 5.1 million Americans.(2) AHF can occur in people who have never had HF before or when patients with chronic HF suffer critical episodes where symptoms become worse and urgent hospital treatment is required.(3),(12) As an AHF episode approaches, patients become increasingly more breathless, incapacitated, and may rapidly gain weight due to fluid build-up in the body, which is often compared to the sensation of drowning due to fluid in the lungs.(13) Every episode results in a downward spiral of worsening health and a cascade of damage to vital organs, such as the heart, kidneys and liver, which decreases the chance of the patient surviving another episode.(3)

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as to work, path forward, potential, goal, will, under review, recommendation, suggests, ongoing, expected, or similar terms, or by express or implied discussions regarding potential marketing approvals for RLX030, or regarding potential future revenues from RLX030. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management 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 that RLX030 will be approved for sale in any market, or at any particular time. Nor can there be any guarantee that RLX030 will be commercially successful in the future. In particular, management s expectations regarding RLX030 could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; the company s ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected manufacturing issues, 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 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 2013, the Group achieved net sales of USD 57.9 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment

and amortization charges). Novartis Group companies employ approximately 136,000 full-time-equivalent associates and operate in more than 140 countries around the world.

For more information, please visit http://www.novartis.com.

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Accessed October 17, 2012.

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 27, 2014	By:	/s/ MALCOLM B. CHEETHAM
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