NOVARTIS AG
Form 6-K
September 25, 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 September 25, 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:

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

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Yes: o **No**: x

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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

Results from Novartis Phase III study show that RLX030 reduced deaths in patients with acute heart failure

- *RELAX-AHF study met one of its two primary endpoints in reducing dyspnea or shortness of breath, and showed RLX030 (serelaxin) was well tolerated(1)*

- *Six-month study shows that investigational RLX030 reduced all-cause mortality in patients with acute heart failure (AHF)(1)*

- *Results of single Phase III clinical trial to be discussed with health authorities worldwide*

- *RELAX-AHF data will be presented at American Heart Association congress in November*

Basel, September 24, 2012 Phase III study results show that investigational RLX030 (serelaxin) reduced all-cause mortality in patients with acute heart failure (AHF)(1). The six-month RELAX-AHF study shows that RLX030 reduces the number of deaths in patients with this disease, which has a higher mortality rate than most other cardiovascular diseases(2).

The study had two primary endpoints using different scales to measure reduction in dyspnea, only one of which reached statistical significance(1). Dyspnea, or shortness of breath, is the most common symptom of AHF(3). RLX030 was well tolerated in the study(1).

RELAX-AHF was a Phase III clinical trial to investigate the efficacy and safety of RLX030 for the treatment of AHF. It was a randomized, double-blind, placebo-controlled study involving 1,161 patients in 11 countries(1). In the study, RLX030 was given on admission to the hospital in the form of an intravenous infusion for up to 48 hours in addition to loop diuretics and other medicines and was compared to placebo on top of standard of care treatment for AHF(4),(5).

The study will be presented at the American Heart Association (AHA) congress in Los Angeles in November, 2012. Novartis will initiate discussions of the results of this single Phase III study with health authorities worldwide shortly.

Heart failure is a disease in which the heart is unable to supply enough blood to meet the body s needs(6),(7)Around half of all patients die within five years of diagnosis(8), particularly as a result of acute episodes in which their symptoms suddenly become worse and urgent hospital treatment is needed(6). Acute heart failure (AHF) places an enormous burden on healthcare systems and accounts for around two million hospitalizations each year in the EU and US(9).

RLX030 is the first in a new class of medicines and is a recombinant form of the human hormone relaxin-2 which occurs naturally in both men and women(10). In women, levels of relaxin-2 rise to support important physiological changes during pregnancy(10). Serelaxin

acts by relaxing the blood vessels, leading to reduced stress on the heart and kidneys in both men and women(11).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as to be discussed, will, or similar expressions, or by express or implied discussions regarding potential marketing submissions or approvals for RLX030 or regarding potential future revenues from RLX030. 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 RLX030 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that RLX030 will be submitted or approved for sale in any market. Nor can there be any guarantee that RLX030 will achieve any particular levels of revenue in the future. In particular, management s expectations regarding RLX030 could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; competition in general; government, industry and general public pricing pressures; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; unexpected manufacturing difficulties; 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 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.

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(11) Conrad KP. Unveiling the vasodilatory actions and mechanisms of relaxin. Hypertension. 2010;56:2-9.

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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:	September 25, 2012	By:	/s/ MALCOLM B. CHEETHAM
		Name:	Malcolm B. Cheetham
		Title:	Head Group Financial Reporting and Accounting