NOVARTIS AG
Form 6-K
August 11, 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 August 11, 2014

(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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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

Novartis to showcase heart failure leadership at ESC Congress 2014 with results on new first of its type medicine LCZ696

- *LCZ696 significantly reduced cardiovascular deaths in head to head study against enalapril, in addition to current best treatment, in patients with HF-REF*

- *PARADIGM-HF is the largest heart failure study ever conducted stopped early in March 2014 due to compelling efficacy(1),(2)*

- *LCZ696 recently granted FDA Fast Track status rolling submission expected to be complete by end of year*

Basel, August 11, 2014 New data revealing the reduction in cardiovascular (CV) deaths with Novartis LCZ696 in patients with heart failure with reduced ejection fraction (HF-REF) will be presented at the world s largest cardiology congress, the European Society of Cardiology (ESC) Congress 2014, on Sunday August 31st at 08.30 CET. The data will also be highlighted in the official ESC press conference on Saturday August 30th at 13.00 CET. The study met the primary endpoint showing LCZ696 reduced heart failure hospitalizations along with CV deaths.

The 8,442 patient study, PARADIGM-HF, was specifically designed to see if LCZ696 could increase survival over and above what can be achieved with ACE-inhibitor enalapril in addition to current best treatment in HF-REF patients(1). In March 2014 the Data Monitoring Committee overseeing the study confirmed those given LCZ696 were significantly less likely to die from CV causes, leading to the trial being closed early.

Over 26 million people worldwide live with heart failure, facing a high risk of death and poor quality of life, despite currently available medicines(3),(4),(5). As a serious condition with an urgent need for new treatments, the FDA has granted LCZ696 Fast Track designation, which can expedite the review of new medicines intended to treat serious or life-threatening conditions. Fast Track designation also allows for rolling submission in the US, which Novartis expects to complete by the end of 2014.

The scientific presentation at the ESC Congress 2014 will include safety data from the study showing LCZ696 was well-tolerated and side effects manageable. 10 further presentations throughout ESC Congress 2014 will provide a wider overview of Novartis s ongoing research in heart failure and other areas of cardiology.

Novartis presentations on LCZ696 at ESC include:

- 7 abstracts (2 oral presentations and 5 posters):

- Results of the Prospective comparison of ARNI with ACEI to Determine Impact on Global Mortality and morbidity in Heart Failure trial (PARADIGM-HF) (#881), M Packer - Hot Line: Cardiovascular disease: novel therapies Sunday August 31st, 08:30 - 10:20 (08:30-08:45)

- Results of the Prospective comparison of ARNI with ACEI to Determine Impact on Global Mortality and morbidity in Heart Failure trial

(PARADIGM-HF) (#1115), J McMurray, M Packer - Meet the Trialist I: PARADIGM-HF - Sunday August 31st, 10:10 - 10:50 (10:10)

- High prevalence of elevated high sensitivity troponin-T and reduction in levels by LCZ696 in heart failure with preserved ejection fraction in the PARAMOUNT trial (#P5847), P S Jhund - Moderated Posters: Defining prognosis in heart failure with preserved ejection fraction Tuesday September 2nd, 15:30 - 16:30 (15:55)

About LCZ696

LCZ696, an investigational twice a day tablet for heart failure, acts in a unique multimodal way to enhance the protective neurohormonal system of the heart (NP system) while simultaneously suppressing the harmful system (the RAAS) (2),(6),(7). Known as an ARNI (Angiotensin Receptor Neprilysin Inhibitor) LCZ696 is thought to reduce the strain on the failing heart, promoting the ability of the heart muscle to recover(2),(7).

About the PARADIGM-HF study

PARADIGM-HF is a randomized, double-blind, Phase III outcome study evaluating the efficacy and safety profile of LCZ696 versus enalapril (a widely used ACE inhibitor) in 8,442 patients with HF-REF(1),(2). It was specifically designed to see if LCZ696 could increase survival by at least 15% over and above what can be achieved with enalapril in addition to current best treatment in HF-REF patients. The primary outcome is a composite of time to first occurrence of either cardiovascular death or heart failure hospitalization, and is the largest heart failure study ever done. It was initiated in December 2009 and in March 2014 the Data Monitoring Committee confirmed those given LCZ696 were significantly less likely to die from CV causes, leading to the trial being stopped early.

About heart failure

Heart failure is a progressive, debilitating disease where the heart is unable to pump enough blood throughout the body. Symptoms such as breathlessness, fatigue and fluid retention can appear slowly and worsen over time, significantly impacting quality of life(4),(8). Approximately half of patients have the HF-REF form of the disease(9). It is a significant and growing public health concern and every year costs the world economy $45 billion, expected to double to $90 billion by 2030(3),(10),(11),(12),(13). As such, there is a high unmet need for new treatments that reduce cardiovascular mortality and the frequency of hospitalization.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as to showcase, expected, will, can, expects, investigational, growing, or similar terms, or by express or implied discussions regarding potential marketing approvals for LCZ696, or regarding potential future revenues from LCZ696. 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 LCZ696 will be approved for

sale in any market, or submitted for approval in any additional markets, or at any particular time. Neither can there be any guarantee that LCZ696 will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that LCZ696 will be commercially successful in the future. In particular, management s expectations regarding LCZ696 could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; 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, 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 135,000 full-time-equivalent associates and sell products in more than 150 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

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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 11, 2014	By:	/s/ MALCOLM B. CHEETHAM
		Name:	Malcolm B. Cheetham
		Title:	Head Group Financial Reporting and Accounting