

NOVARTIS AG
Form 6-K
December 29, 2009

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 December 23, 2009

(Commission File No. 1-15024)

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: 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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- Investor Relations Release -

Novartis to acquire Corthera Inc., gaining worldwide rights to Phase III project relaxin for treatment of acute decompensated heart failure

- *Phase II results show relaxin has vasodilator (widens blood vessels) effects, improves breathlessness, reduces cardiovascular morbidity and days in hospital*
- *Acute decompensated heart failure (ADHF) remains a major clinical challenge with a high and increasing incidence and substantial morbidity and mortality*
- *Novartis to pay USD 120 million for acquisition; Corthera's current shareholders eligible for additional payments of up to USD 500 million contingent upon successful development and commercialization milestones*

Basel, December 23, 2009 Novartis will gain exclusive worldwide rights to relaxin, a recombinant version of a naturally occurring human peptide, through the acquisition of the privately held US biopharmaceutical company Corthera Inc. Relaxin is currently in Phase III clinical trials as a potential treatment option for patients with acute decompensated heart failure (ADHF).

Novartis will assume full responsibility for the development and commercialization of relaxin, with regulatory submissions in the US and Europe planned for 2013. The US Food and Drug Administration (FDA) has granted "Fast Track" designation to relaxin as part of its program to expedite the review of new drugs intended to treat serious or life-threatening conditions that can potentially address unmet medical needs.

Relaxin, which is administered to hospitalized patients via a 48-hour infusion, has been shown to cause an increase in cardiac output, systemic and renal vasodilation, which suggests potential benefits for patients with ADHF. In its natural form, this peptide is responsible for relaxing the female reproductive tract as well as mediating the cardiovascular and renal changes during pregnancy, leading to studies showing its potential applications in this cardiovascular disease.

Despite a range of current treatment options, acute decompensated heart failure is the leading cause of hospitalization in people over age 65 and remains a major clinical challenge with a high and increasing incidence and substantial morbidity and mortality, said Trevor Mundel, MD, Global Head of Development at Novartis AG. Relaxin will be an important addition to our expanding pipeline of novel development projects targeting cardiovascular disease.

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Acute decompensated heart failure estimated to affect millions of people in the US and in Europe is a condition often associated with chronic heart disease where patients typically suffer from severe shortness of breath (dyspnea) and the heart's ability to pump blood from the lungs is impaired. As a result, the lungs become overfilled with fluid, which reduces oxygen uptake. Diuretics and vasodilators are the current standard of care, but available agents from these

classes have been associated with renal impairment, low blood pressure (hypotension) and adverse outcomes.

We are extremely pleased to be entering into this transaction with Novartis, given their world-class capabilities and global leadership position in cardiovascular disease, said Stan Abel, President and Chief Executive Officer of Corthera. This transaction highlights relaxin's potential as an important treatment option for patients suffering from acute heart failure.

Relaxin is expected to further strengthen the position of Novartis and its extensive range of cardiovascular medicines and development portfolio:

- **Diovan (valsartan)** an angiotensin receptor blocker (ARB), is the number one selling hypertension medication worldwide(1), and is indicated in chronic heart failure (NHYA class II – IV). Diovan has been shown to significantly reduce hospitalizations for heart failure.(2)
- **Tekturna/Rasilez (aliskiren)** a first-in-class direct renin inhibitor approved for treatment of hypertension that is also currently in Phase III studies for use in chronic heart failure.
- **LCZ696** a single molecule dual-acting angiotensin receptor blocker / neprilysin inhibitor (ARNI) that entered Phase III development in late 2009 for systolic heart failure.
- **LCI699** a Phase II and first-in-class aldosterone synthase inhibitor (ASI) being explored as a potential treatment for heart failure.

Relaxin also further complements the Novartis strategy to expand in acute cardiology care that includes elinogrel, an anti-platelet agent in Phase II development with potential to reduce the risk of heart attack and stroke. Novartis has hospital-based specialty sales forces in place to maximize the commercial potential of this development portfolio.

Corthera successfully completed Phase II clinical trials in early 2009 before initiating Phase III trials in October. Pre-RELAX-AHF, a 234-patient Phase IIb, placebo-controlled clinical trial, explored the efficacy, tolerability and safety of intravenous relaxin in patients with ADHF who had normal to severe high blood pressure.(3)

Terms of Agreement

Under the terms of the transaction, Novartis will acquire all of the outstanding shares of Corthera's stock for USD 120 million. In addition, Corthera's current shareholders will be eligible to receive additional payments of up to USD 500 million that are contingent upon clinical milestones, regulatory approval of relaxin and the achievement of commercialization targets. This transaction, which is subject to customary regulatory approvals, is expected to be completed in the first quarter of 2010.

Corthera Inc. is a private biopharmaceutical company. Corthera's investors include Domain Associates, Kleiner Perkins Caufield & Byers, Caxton Advantage Life Science Fund, and Sears Capital Management Inc.

* Novartis will acquire the exclusive worldwide rights for relaxin in all countries except Australia and Canada

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as to acquire, to expand, to pay, eligible, contingent, will, potential, planned, Fast Track, potentially, pipeline, or similar expressions, or by express or implied discussions regarding potential regulatory approval for this proposed acquisition, the potential future development or marketing of relaxin or of the other products or new indications for existing

products described in this release, or regarding potential future revenues from such products or indications. 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 to be materially different from any future results, performance or achievements expressed or implied by such statements. In particular, there can be no guarantee that Novartis will receive the necessary regulatory approvals to proceed with this acquisition, or that the proposed acquisition will be completed in the expected form or within the expected time frame or at all. Nor can there be any guarantee that relaxin or the other products or new indications for existing products described in this release will be submitted or approved for sale in any market, or in accordance with any particular timeline. Neither can there be any guarantee that relaxin or any of these other products will achieve any particular levels of revenue in the future. Neither can there be any guarantee that Novartis will achieve any particular future financial results or future growth rates or that Novartis will be able to realize any of the potential strategic benefits or opportunities as a result of the proposed acquisition. In particular, management's expectations could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; unexpected regulatory actions or delays or government regulation generally; competition in general; government, industry and general public pricing pressures; 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 healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in each of these areas. In 2008, the Group's continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 99,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

References

- (1) IMS Midas Worldwide Sales Data, May 2009
- (2) Cohn JN et al. A randomized trial of the angiotensin-receptor blocker valsartan in chronic heart failure. *New England Journal of Medicine* 2001;345(23):1667-1675.
- (3) Teerlink JR, et al. Relaxin for the treatment of patients with acute heart failure (Pre-RELAX-AHF): a multicentre, randomized, placebo-controlled, parallel-group, dose-finding Phase IIb study. *Lancet* 2009;373:1429-1439

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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: December 23, 2009

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham
Title: Head Group Financial
Reporting and Accounting