NOVARTIS AG
Form 6-K
February 13, 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 February 12, 2009

(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

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: o **No**: x

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Yes: o **No**: x

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 gains worldwide rights to elinogrel, a Phase II anti-clotting compound with potential to reduce risk of heart attack and stroke

- *Exclusive rights licensed from Portola Pharmaceuticals Inc. for elinogrel (PRT060128), further strengthening Novartis cardiovascular portfolio*

- *Elinogrel offers oral and intravenous formulations, has shown a fast onset of action and could offer physicians a rapid way to reverse its anti-clotting action if needed*

- *Novartis has responsibility for Phase III trials, manufacturing and commercialization, while collaborating with Portola on ongoing Phase II trials*

- *Novartis to make USD 75 million upfront payment, Portola eligible for milestones and royalties on future sales*

Basel, February 12, 2009 Novartis has gained the exclusive worldwide rights to elinogrel, a promising anti-clotting agent in Phase II clinical trials that has shown potential to offer clinical improvements over current anti-clotting medications in helping patients avoid heart attacks and strokes.

As part of the agreement with the US biotechnology company Portola Pharmaceuticals, Inc., Novartis will have responsibility for the Phase III development, manufacturing and commercialization of elinogrel.

Elinogrel belongs to a class of cardiovascular medicines that seek to prevent blood platelets circulating in the arterial system from sticking together and forming potentially dangerous clots. These clots can limit or stop the flow of blood to the heart or brain, leading to heart attacks or strokes.

More than 13 million people die every year from complications related to blood clots, which underscores the ongoing and significant unmet need, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. Elinogrel is a novel compound with attributes that have the potential to offer clinical benefits over currently approved antiplatelet therapies. Elinogrel will further diversify our cardiovascular pipeline and we hope it will prove to be a strong addition to our portfolio.

Elinogrel is being developed as oral and intravenous formulations. It has an instant onset of action that could quickly provide protection from clotting. Elinogrel s effect is also reversible, which may offer physicians a way to rapidly reverse its anti-clotting actions when necessary. Data from Portola s Phase I and Phase IIa trials showed elinogrel was well tolerated and had predictable, dose-dependent platelet inhibition(1).

INNOVATE-PCI, an 800-patient Phase IIb clinical trial, was initiated in December 2008 involving the intravenous and oral forms of elinogrel to explore the compound s clinical efficacy, biological activity, tolerability and safety. This trial includes a broad group of patients undergoing non-urgent surgery to repair a damaged blood vessel or to unblock a coronary artery (percutaneous coronary intervention). The trial involves a head-to-head assessment of elinogrel s intravenous and oral formulations against clopidogrel (Plavix®), considered the leading antiplatelet agent.

Clinical trials are planned for elinogrel in patients with acute coronary syndromes and more broadly in patients with a prior heart attack or stroke, and those with peripheral vascular disease.

Novartis is focused on improving the lives of the hundreds of millions of people with cardiovascular and metabolic diseases. As a global leader in cardiovascular and metabolic health for nearly 50 years, Novartis provides innovative therapies and support programs to treat high blood pressure and diabetes both major public health issues. The portfolio includes the world s most-prescribed angiotensin receptor blocker, the first and only approved direct renin inhibitor, a single pill combining two leading high blood pressure medicines, and a novel DPP-4 inhibitor. Novartis is dedicated to helping physicians and patients through effective medicines, programs and an ongoing commitment to research.

Terms of the agreement

Novartis will make an upfront payment of USD 75 million to Portola for the exclusive worldwide rights to elinogrel. Novartis will share with Portola the costs of the ongoing Phase II trial, but will have responsibility for Phase III clinical development, manufacturing and commercialization. Portola will also be eligible for additional payments based on achieving defined development and commercialization milestones and is also eligible to receive royalties on future sales. In addition, Portola has an option to co-promote elinogrel in the US limited to hospitals and specialty markets and an option to co-fund Phase III clinical trials and other development activities in return for additional royalties. This transaction is subject to customary regulatory approvals.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, potentially, will, seek, can, hope, could, may, to explore, planned, future sales, dedicated, commitment, or similar expressions, or by express or implied discuss regarding potential regulatory approval for the elinogrel license agreement, potential regulatory submissions or approvals to market elinogrel, or regarding potential future revenues from elinogrel. 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. There can be no guarantee that the agreement between Portola Pharmaceuticals and Novartis to license elinogrel will be approved by the necessary regulatory authorities. Neither can there be any guarantee that elinogrel will be submitted or approved for sale in any market. Nor can there be any guarantee that elinogrel will achieve any particular levels of revenue in the future. In particular, management s expectations regarding elinogrel could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; 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; 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 AG 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, preventive vaccines, diagnostic tools, cost-saving generic pharmaceuticals, and consumer health products. Novartis is the only company with leading positions in 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 96,700 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) Gretler DD, Conley PB, Andre P, Jurek M, Pandey A, Ronanko K, Leese PT, Hutchaleelaha A, Phillips DR First in human experience with PRT060128, a new direct-acting, reversible, P2Y12 inhibitor for IV and oral use. J Am Coll Cardiol. 2007;9(Suppl 2):326A.

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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: February 12, 2009

By: /s/ MALCOLM B. CHEETHAM

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