NOVARTIS AG
Form 6-K
December 20, 2011

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 20, 2011

(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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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

Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland
http://www.novartis.com

- Investor Relations Release -

Novartis announces termination of ALTITUDE study with Rasilez®/ Tekturna® in high-risk patients with diabetes and renal impairment

- *ALTITUDE study involved patients with type 2 diabetes and renal impairment who are at high risk of cardiovascular and renal events*

- *Committee overseeing study identified higher adverse events when Rasilez/Tekturna was added to an ACE or ARB drug in this patient population*

- *Patient safety is the highest priority and Novartis is in dialogue with health authorities worldwide. Patients should contact their health care provider if they have any concerns*

- *Assessment of results of the ALTITUDE study and the potential implications for Rasilez/Tekturna-based products* is ongoing*

Basel, December 20, 2011 Novartis announced that following the seventh interim review of data from the ALTITUDE study with Rasilez®/Tekturna® (aliskiren), a decision to terminate the trial has been taken on the recommendation of the independent Data Monitoring Committee (DMC) overseeing the trial.

The DMC concluded that patients were unlikely to benefit from treatment added on top of standard anti-hypertensives, and identified higher adverse events in patients receiving Rasilez/Tekturna in addition to standard of care in the trial. Specifically, in the trial arm in which Rasilez/Tekturna was added to the standard of care there was an increased incidence after 18-24 months of non-fatal stroke, renal complications, hyperkalemia and hypotension in this high-risk study population.

The placebo-controlled Phase III ALTITUDE study is the first trial to investigate Rasilez/Tekturna for more than one year in a specific population of patients with type 2 diabetes and renal impairment. These patients are known to be at high risk of cardiovascular and renal events. In the study, Rasilez/Tekturna was given in addition to optimal cardiovascular treatment including an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB).

Novartis is in ongoing discussions with health authorities worldwide about the implications of the findings from ALTITUDE for patients. As a precautionary measure Novartis will cease promotion of Rasilez/Tekturna-based products for use in combination with an ACE-inhibitor or ARB.

Patient safety is the highest priority for Novartis, and we are in a dialogue with health authorities worldwide, said David Epstein, Division Head of Novartis Pharmaceuticals.

Novartis is recommending that ALTITUDE investigators remove Rasilez/Tekturna-based products from their patients treatment regimen and review their high blood pressure medication. Novartis is also reviewing the findings with DMCs of other clinical studies involving Rasilez/Tekturna-based products and combination therapies.

Patients in ALTITUDE should contact their study site for guidance on medication and should not stop treatment until they have seen their physician in view of the importance of controlling high blood pressure. Any patients using Rasilez/Tekturna or other aliskiren combination products who may have questions about their medication should consult their healthcare provider. For more information visit www.novartis.com.

Total sales of Rasilez/Tekturna-based products for the first nine months of 2011 were USD 449 million (1% of Novartis Group sales) and are likely to be negatively impacted by the study results going forward. Product profitability in 2011 was negative. A further update of the actual financial implications will be communicated when the regulatory dialogue has been concluded.

About Aliskiren

Aliskiren was approved in 2007 in the EU and US under the brand-names Rasilez and Tekturna respectively, for the treatment of hypertension (high blood pressure) either as monotherapy or in combination with other medications. The efficacy and safety of Rasilez/Tekturna have been investigated in more than 57,000 patients who have been treated with this medicine in clinical studies.

Rasilez/Tekturna-based products include:

- Rasilez®/Tekturna®
- Rasilez HCT®/Tekturna HCT®, a single-pill combination of Rasilez/Tekturna and hydrochlorothiazide (HCT)
- Valturna®, a single-pill combination of Rasilez/Tekturna and valsartan, available in the US only
- Rasilamlo®/Tekamlo®, a single-pill combination of Rasilez/Tekturna and amlodipine
- Rasitrio®/Amturnide®, a triple combination of Rasilez/Tekturna, amlodipine and hydrochlorothiazide (HCT)

About ALTITUDE

ALTITUDE was a multinational study in 8,606 patients from 36 countries evaluating the potential benefits of Rasilez/Tekturna to reduce the risk of cardiovascular and renal events in this patient population.

ALTITUDE was the first randomized, double-blind, placebo-controlled study to investigate Rasilez/Tekturna for more than one year in a specific population of patients with type 2 diabetes and renal impairment. These patients are known to be at high risk of cardiovascular and renal events. In the study, Rasilez/Tekturna was given in addition to optimal cardiovascular treatment including an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, ongoing, will, likely, or similar expressions, or by express or implied discussions regarding the potential impact of our dialogue with worldwide health authorities on the future of Rasilez/Tekturna-based products; regarding potential future revenues from Rasilez/Tekturna-based products; or regarding the potential financial impact on Novartis of the matters described in this release. 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 as to the outcome of our dialogue with worldwide health authorities on the future of Rasilez/Tekturna-based products. Nor can there be any guarantee regarding the levels of revenue or profitability that Rasilez/Tekturna-based products might achieve in the future. Neither can there be any guarantee as to the ultimate financial impact on Novartis of the matters described in this release. In particular, management s expectations regarding these matters could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected additional analysis of the existing ALTITUDE clinical data and unexpected new clinical data; 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 2010, the Group s continuing operations achieved net sales of USD 50.6 billion, while approximately USD 9.1 billion (USD 8.1 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 121,000 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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Novartis Media Relations

Central media line : +41 61 324 2200
Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

John Taylor
Novartis Pharma Communications
+41 61 324 6715 (direct)
+41 79 593 4279 (mobile)
john.taylor@novartis.com

Novartis Investor Relations

Central phone:	+41 61 324 7944		
Susanne Schaffert	+41 61 324 7944	**North America:**	
Pierre-Michel Bringer	+41 61 324 1065	Richard Jarvis	+1 212 830 2433
Thomas Hungerbuehler	+41 61 324 8425	Jill Pozarek	+1 212 830 2445
Isabella Zinck	+41 61 324 7188	Edwin Valeriano	+1 212 830 2456

e-mail: investor.relations@novartis.com

e-mail: investor.relations@novartis.com

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 20, 2011	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting