NOVARTIS AG
Form 6-K
November 08, 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 November 8, 2012

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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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

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Novartis future growth prospects secured by industry-leading pipeline, with more than 139 projects with 73 new compounds

- ***Pharmaceuticals Division growth over the next 5 years expected to be driven by portfolio of recently launched products***
- *Division had 7 blockbusters in portfolio in 2011 and expects to achieve 14 or more blockbusters by 2017*

- ***Industry-leading Pharmaceuticals pipeline with 73 new compounds presented:***
- *9 key regulatory milestones achieved so far in 2012*
- *Over the next 12 months, data read out of 13 late-stage pipeline projects, 9 filings and up to 7 regulatory decisions expected*
- *Oncology pipeline, AIN457 and heart failure (LCZ696 and RLX030) expected to provide significant newsflow; filing of RLX030 planned to commence in early 2013 in US and EU*
- *LAMA/LABAs, including QVA149 have potential to become new standard of care for COPD*

- ***Oncology business aims to grow through* Glivec *patent expiry***
- *Robust late stage pipeline including 13 new chemical entities and 19 new indications*
- *Oncology late-stage pipeline products expected to contribute more than USD 1 billion in sales by 2017*
- Afinitor *now expected to contribute USD 2 billion sales in advanced breast cancer alone by 2017*
- *Start of broad scale clinical development program announced for leading PI3K inhibitor BKM120 across multiple indications (PRISM)*

Basel, November 8, 2012 Novartis today will provide an update on its leading Research and Development (R&D) pipeline and plans for turning these assets into commercial success to provide the basis for continued growth of the Group through 2017. Continuing R&D productivity in the Pharmaceuticals Division has fueled an industry-leading pipeline with 139 projects in clinical development with more than 73 New Molecular Entities (NMEs) across a multitude of disease areas. Highlights include RLX030 and LCZ696 in heart failure as well as AIN457 in

psoriasis and multiple sclerosis. In addition, the company will showcase a comprehensive early and late-stage pipeline of novel oncology compounds.

As a science-driven company, Novartis is focused on innovation to address unmet medical needs for patients around the world. said Joseph Jimenez, CEO of Novartis. As a result, our leading pipeline in all phases of development positions us well for continued future growth.

Leading pipeline positions Pharmaceuticals for sustained future growth

Novartis Group continues to lead the industry with 56 new approvals in the US, Europe, Japan and China since 2007. In 2012 alone, the Pharmaceuticals division has received 9 approvals or positive recommendations to date.

Novartis Pharmaceuticals has established a strong foundation for the company s ongoing growth based on currently marketed products. In addition for the next 12 months, Pharmaceuticals expects data read-out on 13 pivotal studies, 9 filings and 7 regulatory decisions. For the following 13 to 24 months, strong pipeline newsflow is expected to continue with a further 11 pivotal trials read-out, 11 filings and 10 regulatory decisions.

As evidenced by the recent launches of *Afinitor, Seebri Breezhaler*, *Jakavi* and *Signifor*, Novartis has a proven track record of bringing innovative products to market. With the current marketed portfolio, Pharmaceuticals is expected to grow from the second half of next year despite loss of exclusivity on mature brands like *Diovan*, *Zometa* and *Aclasta*.

Oncology aims for continued growth through *Glivec* patent expiry

The Novartis Oncology portfolio has delivered approvals for 6 indications including 2 new molecular entities so far this year and anticipates continued growth over the next five years. One of the major growth drivers, *Afinitor*, has five indications already approved and has the potential to exceed sales of USD 2 billion in breast cancer alone by 2017. In addition, launches of *Jakavi* and the planned launches of pipeline projects such as BKM120 for various tumors and LDK378 in lung cancer have the potential to contribute more than USD 1 billion in sales by 2017.

***Tasigna*: Path to Cure - a potential paradigm shift in CML treatment**

Novartis has transformed Ph+ chronic myeloid leukemia (CML) to a treatable, chronic condition and is again on the way to redefine what is possible in CML. The new goal is for patients to live free of drug therapy once they have achieved long-term response to treatment. *Tasigna*, a potent 2nd generation targeted therapy for CML, has demonstrated a reduced risk of progression and deeper and more sustained molecular response than *Glivec*. Based on these advances, as well as advances in molecular response monitoring, in 2013 the company plans to initiate *Tasigna* clinical trials to explore the goal of achieving sustained treatment-free remission in patients living with CML. If positive, this could lead to a major paradigm shift in CML treatment.

PRISM: a broad scale program for BKM120, a pan-PI3K inhibitor

Novartis has initiated a broad scale clinical development program named PRISM for its leading PI3K inhibitor BKM120 across multiple indications, both as a single agent and in combination with other therapeutic agents in various breast cancer settings, as well as other indications.

The company also plans to initiate pivotal studies of LDK378, an ALK inhibitor that has shown potent activity in patients with Alk+ non-small cell lung cancer (NSCLC) as well as activity on brain metastases, in December 2012. Additional trials planned for 2013 and regulatory filings expected to begin in 2014 if trials are successful.

Next wave of promising pipeline newsflow

Strong data in heart failure

Recently presented data for RLX030 show that patients receiving a single infusion of RLX030 had both short-term and long-term benefits. In the short term, RLX030 treated patients had improved heart failure symptoms such as dyspnea (shortness of breath) and edema, in addition to having a shorter stay in the hospital. The long term benefits of RLX030 resulted in a statistically significant 37% reduction in cardiovascular mortality and all-cause mortality. Furthermore, fewer patients treated with RLX030 had worsening of heart failure as measured on day 5 and day 14 after treatment. Worsening of heart failure during hospitalization was defined as intensification of intravenous therapy or

mechanical ventilator or circulatory support. Based on these findings of the RELAX-AHF study, Novartis plans to initiate regulatory filings for RLX030 in early 2013 in the US and Europe.

Comprehensive clinical program in COPD

Novartis is also progressing its comprehensive clinical program in respiratory to meet the needs of patients with chronic obstructive pulmonary disease (COPD). QVA149 has the potential to establish a new standard of care for patients with COPD, preventing exacerbations and showing improvement in bronchodilation compared to placebo and current standard of care. Across numerous clinical studies, QVA149 enables the limited use of inhaled corticosteroids (ICS) as rescue medications as recommended by the GOLD treatment guidelines for COPD.

IL-17 as promising target in psoriasis and other indications

Clinical data for AIN457, a highly effective novel IL-17 inhibitor, across multiple disease areas including psoriasis, ankylosing spondylitis, rheumatoid arthritis and multiple sclerosis were presented. In Phase II clinical studies, AIN457 has shown rapid improvement of psoriasis signs and symptoms in patients with moderate to severe psoriasis. Phase III studies for AIN457 in this setting are ongoing with regulatory filings expected to start in late 2013. In addition, the company is investigating AIN457 across multiple indications including multiple sclerosis.

Innovative initiatives showcase how to accelerate development; managing more projects at stable cost level

The discovery process in the Novartis Institute of BioMedical Research (NIBR) focuses on disorders where there is unmet medical need and good mechanistic understanding. This approach has increased the success rate from pre-clinical through Phase 2 trials to more than 20%, three times the industry average. Companion diagnostics and biomarkers, especially in oncology, where most Phase I and II trials have patient selection markers included, have enabled early patient selection for clinical trials, reducing overall development timelines and costs. As a result, Novartis has shown greater than average pipeline return on investment achieving highest average annual peak sales of first launched products amongst industry.

In addition, Novartis is striving to increase efficiency and productivity to manage more projects while keeping costs at a stable level. Introducing novel technologies and methods reduce recruitment time and trial costs, while improving study quality and patient comfort and safety. These include mobile field monitoring, continuous manufacturing and Telehealth. In addition, through a research initiative with Walgreens in the US, clinical trials will provide more real-world evidence and lower access barriers for participants.

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 s continuing operations 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 127,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

Disclaimer

This press release contains forward-looking statements that can be identified by terminology such as future growth prospects, pipeline, expects, expected, planned, potential, aims, will, plans, recommendations, projected, promising, anticipates, could, goal, can, by express or implied discussions regarding potential new products, potential new indications for existing products, or regarding potential future revenues from any such products; or regarding potential future sales or earnings of the Novartis Group or any of its divisions; or by discussions of strategy, plans, expectations or intentions. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of the Group 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 any new products will be approved for sale in any market, or that any new indications will be approved for any existing products in any market, or that any approvals which are obtained will be obtained at any particular time, or that any such existing or potential new products will achieve any particular revenue levels, or at any particular time. Nor can there be any guarantee that the Group, or any of its divisions, will achieve any particular financial results. In particular, management s expectations could be affected by, among other things, the inherent difficulties and uncertainties involved in making predictions about events expected to take place in the medium- to long-term future; unexpected clinical trial results, including additional analyses of existing clinical data or unexpected new clinical data; unexpected regulatory actions or delays or government regulation generally; government, industry, and general public pricing pressures; uncertainties regarding future demand for our products; uncertainties involved in the development of new healthcare products; competition in general; the Group s ability to obtain or maintain patent or other proprietary intellectual property protection, including the ultimate extent of the impact on the Group of the loss of patent protection on key products which commenced last year and will continue this year; uncertainties regarding actual or potential legal proceedings, including, among others, actual or potential product liability litigation, litigation and investigations regarding sales and marketing practices, shareholder litigation, government investigations and intellectual property disputes; unexpected product manufacturing and quality issues, including the potential outcomes of the Warning Letter issued to us with respect to three Sandoz manufacturing facilities, and the potential outcome of efforts to restart production of products formerly produced at the Consumer Health manufacturing facility at Lincoln, Nebraska; uncertainties regarding the effects of the ongoing global financial and economic crisis, including the financial troubles in certain Eurozone countries; uncertainties regarding future global exchange rates; the impact that the foregoing factors could have on the values attributed to the 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 described herein as 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 as a result of new information, future events or otherwise.

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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:	November 8, 2012	By:	/s/ MALCOLM B. CHEETHAM
		Name:	Malcolm B. Cheetham
		Title:	Head Group Financial Reporting and Accounting