

NOVARTIS AG  
Form 6-K  
August 06, 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 August 6, 2012**

**(Commission File No. 1-15024)**

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**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:

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**Form 20-F:** ☒ **Form 40-F:** ☐

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: ☐ **No:** ☒

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes: ☐ **No:** ☒

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: ☐ **No:** ☒

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**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**

**Novartis and University of Pennsylvania form broad-based R&D alliance to advance novel T-cell immunotherapies to treat cancer**

- *Novartis and Penn enter into multi-year collaboration to study chimeric antigen receptor (CAR) technology for the treatment of cancer*
- *Parties establish joint Center for Advanced Cellular Therapies at Penn to develop and manufacture CARs*
- *Pilot trial of first CAR investigational therapy, CART-19, shows two patients with advanced chronic lymphocytic leukemia in remission after more than a year(1),(2)*
- *Novartis licenses worldwide rights to CART-19 from Penn and obtains worldwide commercial rights to products from the collaboration*

**Basel, August 6, 2012** Novartis and the University of Pennsylvania (Penn) announced today an exclusive global collaboration to research, develop and commercialize targeted chimeric antigen receptor (CAR) immunotherapies for the treatment of cancers. In addition, the parties will jointly establish a new research and development facility on the Penn campus, called the Center for Advanced Cellular Therapies (CACT).

By combining Penn's expertise on this pioneering technology with Novartis' strength in bringing innovative therapies to patients, we have the potential to transform the future of cancer treatment," said Hervé Hoppenot, President, Novartis Oncology.

In CAR immunotherapy, immune cells (T cells) are drawn from a patient's blood. Then, using CAR technology, the T cells are re-coded to identify and seek out cells that express proteins present on a patient's cancerous tumor. When the T cells are re-introduced into the patient's blood, they bind to the targeted cancer cells and destroy them.

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As part of the transaction, Novartis acquired exclusive rights from Penn to CART-19, a novel investigational CAR therapy, currently being studied by Penn in a pilot clinical trial. CART-19 targets a protein called CD19 that is associated with a number of B-cell malignancies such as chronic lymphocytic leukemia (CLL), B-cell acute lymphocytic leukemia and diffuse large B-cell lymphoma.

To accelerate the discovery and development of additional therapies using CAR immunotherapy, Novartis and Penn will build the Center for Advanced Cellular Therapies on the Penn campus in Philadelphia. This will be a first-of-its-kind research and development center established specifically to develop and manufacture adoptive T-cell immunotherapies under the research collaboration guided by scientists and clinicians from Novartis and Penn.

This collaboration underscores our commitment to working with partners that are at the forefront of science and medicine, said Mark Fishman, President of the Novartis Institutes for BioMedical Research. Immunotherapy is one of the exciting frontiers in

cancer research and the CAR technology developed by the team at Penn has shown early promise as a new way for treating cancer.

Early results from a clinical trial of CART-19, conducted by Penn, showed potent antileukemic effects in three patients with advanced CLL who had previously undergone multiple courses of chemotherapy and biological therapy. Two of the patients were still in complete remission more than a year into the CART-19 trial, and the third patient maintained partial remission for more than seven months. An immune deficiency known as hypogammaglobulinemia, an expected chronic toxic effect, was corrected with infusions of intravenous immune globulin. Patients were also treated for symptoms associated with tumor lysis syndrome, an effect of tumor breakdown<sup>(1),(2)</sup>. Novartis expects to initiate a Phase II clinical trial with CART-19 in collaboration with Penn during the fourth quarter of 2012.

Initial data provide proof that this CAR therapy can activate a patient's own immune system to fight cancerous tumors, said Carl June, MD, director of Translational Research and professor of Pathology and Laboratory Medicine in the University of Pennsylvania's Abramson Cancer Center and Perelman School of Medicine. In partnering with Novartis, we aim to develop CAR therapies into commercial agents in the battle against cancer.

Penn's intellectual resources combined with a pharmaceutical industry leader like Novartis offers a powerful symbiotic relationship in our mutual goal of finding more effective treatments for cancer, said J. Larry Jameson, MD, PhD, dean of the Perelman School of the Medicine at the University of Pennsylvania and executive vice president for the Health System. With our shared commitment to rapidly advancing new therapies and cures, this new alliance will provide the support for the essential clinical trials with engineered T cells, which may open doors for use of this promising treatment option for cancer patients who have reached the end of currently available treatments.

Under the terms of the agreement, Penn grants Novartis an exclusive worldwide license to CARs developed through the collaboration for all indications and CART-19. In addition Novartis will provide an up-front payment, research funding, funding for the establishment of the CACT and milestone payments for the achievement of certain clinical, regulatory and commercial milestones and royalty payments.

## Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as to advance, multi-year collaboration, to study, to develop and manufacture, will, expect, potential, to accelerate, commitment, promise, expects, aim, goal, may, expressions, or by express or implied discussions regarding the establishment of the research and development alliance with Penn and the CACT, regarding potential new therapies which might be developed using CAR technology or regarding potential future revenues from CAR technology. 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 with CAR technology to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that the research and development alliance with Penn, and the CACT will be successfully established or achieve any of their goals. Nor can there be any guarantee that any new therapies, including CART-19, will be developed or brought to market using CAR technology. Neither can there be any guarantee that CAR technology or any therapies developed based on such technology, including CART-19, will achieve any particular levels of revenue in the future. In particular, management's expectations regarding the research and development alliance with Penn, the CACT, any therapies which might be developed using CAR technology, including CART-19, and any financial impact from any such therapies could be affected by, among other things, the outcome of



a legal dispute, including two pending lawsuits, between Penn and St. Jude Children's Research Hospital concerning two agreements between the parties related to CAR technology; Novartis' and Penn's ability to obtain or maintain patent or other proprietary intellectual property protection for such technology and therapies developed based on the technology; unexpected research and development issues, including the uncertainties involved in the research and development of therapeutic technologies; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; unexpected issues with respect to the collaboration with Penn; competition in general; government, industry and general public pricing pressures; unexpected manufacturing issues; 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 2011, the Group 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 126,000 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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## References

- (1) Porter DL, Levine BL, Kalos M, et al. Chimeric antigen receptor-modified T cells in chronic lymphoid leukemia. *N Engl J Med*. 2011 Aug 25;365(8):725-33.
- (2) Kalos M, Levine BL, Porter DL, et al. T cells with chimeric antigen receptors have potent antitumor effects and can establish memory in patients with advanced leukemia. *Sci Transl Med*. 2011 Aug 10;3(95):95ra73.

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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 6, 2012

By: /s/ MALCOLM B. CHEETHAM

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