

NOVARTIS AG  
Form 6-K  
June 18, 2014

# 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 June 18, 2014**

**(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):

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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:  No:

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**Novartis emphasizes new focused portfolio at its first Meet Novartis Management investor day**

- **New Novartis focused on three leading businesses with innovation power and global scale**
- Pharmaceuticals building business depth in Dermatology, Heart Failure, Respiratory and Cell Therapy, complementing already strong Oncology business
- Alcon is positioned well for continued growth in all three of its franchises: Surgical, Ophthalmic Pharmaceuticals and Vision Care
- Sandoz expected to extend its global leadership position in complex, differentiated generics and biosimilars, benefiting from in-house science-based innovation engine
- **Innovation remains a strategic priority and differentiator across the portfolio**
- Approximately three-quarters of new drug candidates in the Novartis industry-leading Phase III clinical pipeline were generated from NIBR
- Particularly strong in targeted therapies for oncology, Novartis is pioneering the development of CART immunotherapies and developing a suite of immune checkpoint antibodies
- **New Novartis expected to improve core operating income margin**

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- With more focused portfolio, 2013 core operating income margin would have been 250 basis points higher than the announced 24.7% on a pro forma basis
- Synergies through shared services organization Novartis Business Services (NBS) expected to improve margin over time

**Basel, June 18, 2014** For its first Meet Novartis Management investor day, Novartis gathered more than 20 of its top executives, drawn from the leadership of Pharmaceuticals, Alcon, Sandoz and NIBR, to meet with approximately 100 investors and analysts in Basel.

In the first few months of 2014, we have delivered on a number of commitments made at our last investor event in November to actively manage our portfolio, achieve greater synergies between divisions, and lay the foundation for superior returns to shareholders, said Novartis CEO Joseph Jimenez.

The conclusion of the portfolio review announced in April would create a new and more focused Novartis.<sup>(1)</sup> Each of the three remaining businesses have both the innovation power to produce breakthroughs in areas of unmet medical need and the global scale to achieve growth across geographies which is critical to winning in the changing healthcare landscape.

The new Novartis is expected to be more profitable. Under the announced new structure, the Group's core operating income margin in 2013 would have been 27.2%, 250 basis points higher than the announced 24.7% on a pro forma basis. Through the creation of Novartis Business Services (NBS), Novartis is taking steps to improve profitability by generating synergies across businesses by harmonizing services across Group and divisions. The scope of NBS covers over USD 6 billion in expenses, and complements other ongoing productivity initiatives, including manufacturing footprint.

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*(1) Subject to the completion of the transactions with GSK and Eli Lilly announced on April 22, 2014. The transactions with GSK are inter-conditional and are subject to approval by GSK shareholders and subject to customary closing conditions including regulatory approvals; these are expected to close in H1 2015. The transaction with Eli Lilly is subject to customary regulatory approvals; it is expected to close in Q1 2015.*

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Looking ahead, the Group's strategic priorities of innovation, growth and productivity remain unchanged.

### **Pharmaceuticals**

Pharmaceuticals is preparing for a new growth phase, driven by greater depth in five business areas – Oncology, Dermatology, Heart Failure, Respiratory and Cell Therapy – to make a real difference in patients' lives, while at the same time delivering significant returns on investment and contributing to margin expansion over time, said David Epstein, Pharmaceuticals Division Head.

The Novartis Oncology business ranks number two in sales worldwide, and its pipeline is among the broadest in the industry. Particularly strong in targeted therapies, the business is well-positioned for novel combinations, and is working to become a leader in bringing CARTs (autologous patient T-cells reprogrammed to kill cancer cells) to market.

The Phase III trial on LEE011 (a highly selective CDK4/6 inhibitor) in first line hormone receptor positive advanced breast cancer is progressing well, with the goal to complete accrual by the end of the year.

Pivotal data for *Jakavi* was recently presented at ASCO for the treatment of polycythemia vera (PV). If approved, the PV indication could allow *Jakavi*, currently indicated for myelofibrosis, to exceed USD 1 billion in peak sales, making it one of the 14 or more blockbusters the Pharmaceuticals Division is projecting by 2018.

In Dermatology, Pharmaceuticals has developed AIN457 (secukinumab), the first and only fully human antibody targeting IL-17A, which is expecting first regulatory decisions at the end of 2014 and early 2015. Biologic psoriasis products sales are currently USD 4.8 billion and are expected to grow at a compound annual growth rate (CAGR) of 10% over the next five years.

Dermatology also now includes the investigational compound LDE225 (sonidegib, hedgehog inhibitor) in basal cell carcinoma, the most common form of skin cancer. A pivotal Phase II study of LDE225, also presented at ASCO, met its primary endpoint in both treatment arms and demonstrated a positive benefit-risk profile. LDE225 was submitted in the EU in the second quarter of 2014, and additional worldwide submissions are underway.

In Heart Failure – a significant and growing public health concern with more than 20 million people living with the disease across Europe and the US alone – Novartis has the potential to change treatment paradigms with LCZ696 in chronic heart failure and RLX030 (serelaxin) in acute heart failure.

The LCZ696 PARADIGM-HF study in heart failure with reduced ejection fraction (HF-rEF) was stopped early, based on the unanimous recommendation of the study's Data Monitoring Committee, due to compelling efficacy data. The baseline characteristics of patients in the study, recently published in the *European Journal of Heart Failure*, showed that – compared to recent heart failure trials – PARADIGM-HF patients were particularly well-treated with beta-blockers (over 90%) and mineralocorticoid receptor antagonist (60%). Full data will be presented at the upcoming European Society of Cardiology meeting on August 31 in Barcelona. Submission for the HF-rEF indication is expected in the US by

the end of 2014 and in the EU in the first quarter of 2015.

Meanwhile, for the RLX030 submission we await the results of the ongoing RELAX-AHF-2 trial, expected to complete in the second half of 2016, with an interim analysis anticipated in the second half of 2015. RELAX-HF-2 has cardiovascular mortality as the primary endpoint.

In Respiratory, the roll-out of *Ultibro Breezhaler* is building momentum with recent data from the LANTERN and QUANTIFY studies reinforcing its strong competitive profile. LANTERN, in particular, demonstrated superiority in lung function (122ml p<0.001) compared to Seretide® in patients with chronic obstructive pulmonary disease (COPD), importantly with or without exacerbations in the previous year.

Through its newly created Cell and Gene Therapy unit, Pharmaceuticals is committed to advancing its novel cell therapy portfolio, with programs such as Facilitating Cell Therapy Platform (FCRx) and CART. Through multiple CART programs, Novartis is pursuing personalized cellular immuno-oncology (IO) therapies for both hematological and solid tumors.

These five business areas aim to build on the Division's strong growth platform of blockbuster products with exclusivity until 2018 and beyond, including *Lucentis* and *Gilenya*. Novartis recently expanded this platform with the acquisition of exclusive rights to *Fovista*, a novel anti-PDGF therapy in wet age-related macular degeneration (wet AMD), confirming our commitment in this space. In addition, new data on *Gilenya* confirmed its efficacy on four key measures of multiple sclerosis, consolidating its position as the treatment of choice for first efficacy switch.

Pharmaceuticals is also aiming to further enhance the allocation of resources and the use of new technologies to improve productivity in R&D and SG&A productivity. Pharmaceuticals aims to create shareholder value through a systematic approach to resource allocation and productivity supporting growth and innovation, said Epstein. Our resource allocation is expected to be a key enabler of margin expansion.

### **Alcon**

As the number one player in eye care globally, Alcon is positioned well for continued growth in all three of its franchises: Surgical, Ophthalmic Pharmaceuticals and Vision Care.

Our strong innovation pipeline, productivity and quality, as well as performance-driven people and culture, are key components of our future success, emphasized Jeff George, Alcon Division Head. Building on our best-in-class positioning in eye care, strong brand and customer loyalty, Alcon is poised to accelerate highly profitable top-line growth.

In Surgical, the launches of new cataract surgery platforms are expected to drive growth. These include the *Centurion* Vision System, Alcon's next generation phacoemulsification technology and the full Cataract Refractive Suite by Alcon including, the *Verion* Image Guided System, which is designed to provide greater accuracy and efficiency during the surgical process. By shifting the paradigm to refractive outcomes, Alcon expects to increase penetration of advanced technology intraocular lenses (AT-IOLs). Additionally, phacoemulsification development presents a significant opportunity to address unmet patient needs in key emerging markets such as China, Brazil, India, and Russia, where surgical capacity and patient access present future growth potential.

In Ophthalmic Pharmaceuticals, the glaucoma market is undergoing a significant change, with fixed-dose combination products gaining momentum. *Simbrinza*, the Division's beta-blocker-free/timolol-free fixed-dose combination, is expected to be a growth driver for Alcon by providing additional treatment possibilities for patients who cannot tolerate beta-blockers. It was approved in the US in April 2013 and received a positive CHMP opinion in the EU in May 2014.

Alcon also has a strong pipeline of pharmaceuticals for retinal treatments, including RTH258 and LFG316, which target wet and dry age-related macular degeneration (AMD). RTH258, formerly known as ESBA 1008, is a compound in development for the treatment of neovascular AMD and has potential for additional indications. LFG316 is in development for geographic atrophy, an advanced form of dry AMD.

In Vision Care, global expansion of *Dailies Total1* continues to drive strong growth, capturing significant market share in the daily disposables premium silicone hydrogel segment in launched markets.

**Sandoz**

Sandoz, the second largest generics player in the world, outperformed the market in all regions in 2013, including both developed and emerging markets. The share of emerging markets in total Sandoz generic sales reached 28%, twice as high as the equivalent figure for its closest global competitor further reinforcing the company's leading role in addressing access and healthcare system demands around the world.

Overall, Sandoz continues to strengthen its leadership in complex, differentiated generics and biosimilars. Future patent expiries remain strong, said Richard Francis, Sandoz Division Head, but there is a shift to complex products, validating the Sandoz strategy, which is deeply rooted in innovation. From 2007 to 2012, the global sales of products set to lose patent protection in the following year amounted to USD 198 billion, with 30% from differentiated products. From 2013 to 2018, that number is expected to rise to USD 215 billion, with 50% from differentiated products.

In line with that trend, Sandoz has grown its differentiated portfolio strongly, from 32% to 45% of total sales from 2008 to 2013, at a CAGR of nearly 12%. One example is *AirFluSal Forspiro*, a respiratory



inhaler for asthma and COPD patients, which offers the proven combination of salmeterol (a long-acting inhaled  $\beta_2$ -agonist) and fluticasone (an inhaled corticosteroid) in an innovative new inhalation device. *AirFluSal Forspiro* has received European approvals in eight countries following the successful completion of EU decentralized procedures. Sandoz is also number one in generic injectables, with more than USD 2 billion of sales in 2013, up by a CAGR of 17% over the last five years, as well as in generic ophthalmics and dermatology.

In biosimilars, Sandoz is the world leader, with 54% of the global biosimilars market (2) and over USD 400 million of sales in 2013. Sandoz has three biosimilar products on the market, each of which is number one in its respective category, and six molecules in Phase III clinical trials or registration preparation phase. Sandoz has long been the industry pioneer in the biosimilars space, and with our well-advanced pipeline, we are extending that competitive edge, said Vas Narasimhan, Head Biopharmaceuticals & Oncology Injectables.

Productivity is a key element of performance for Sandoz. As of 2013, Sandoz had reduced annual costs by more than USD 500 million through a broad operating improvement program known as Project Compete, which has been running from 2009 to 2013. Over those five years, Project Compete generated over USD 2.5 billion in cost savings. We're continuing to find ways to become more efficient and improve our margins, said Francis.

## **NIBR**

The core driver of our science-based innovation strategy is our global drug discovery organization, the Novartis Institutes for BioMedical Research (NIBR). Approximately three-quarters of new drug candidates in the Group's industry-leading Phase III clinical pipeline were generated from NIBR, and NIBR's success rate of compounds from pre-clinical to Phase II is approximately three times the industry average (according to data from analytics firm KMR).

Our drug discovery efforts are driven by patient need and guided by sound science, said Mark Fishman, NIBR President. We are focused on discovering new medicines that we believe will have a major impact. NIBR has delivered to development new drugs for a spectrum of diseases, ranging from common (e.g., LCZ696 for heart failure, AIN457 for psoriasis, KAE609 for malaria, QAW039 for asthma) to rare diseases (e.g., LCQ908 for familial chylomicronemia, and LCI699 for Cushing's disease). In oncology, NIBR has focused on targeted therapies and now has drug candidates for more than ten pathways in late-stage clinical trials or registration, and so is well positioned for the future of oncology therapy, which is anticipated to rely in many cases upon combination therapy.

NIBR is pioneering the development of CART immunotherapies with the University of Pennsylvania (Penn), with 90% response to CTL019 in early clinical trials for acute lymphoblastic leukemia and near 50% for chronic lymphocytic leukemia. Through the collaboration with Penn, NIBR is expanding the CART pipeline to include additional hematological malignancies and solid tumors. The second component of NIBR's immunotherapy portfolio is a suite of immune checkpoint antibodies: PD-L1, PD-1, LAG-3, and TIM-3.

Scientists and clinicians at NIBR are also pursuing new directions in aging and regenerative medicine to combat diseases such as hearing loss, AMD and muscle wasting. Patients are currently being recruited for Proof of Concept clinical trials for CGF166, a novel gene therapy for sensorineural hearing loss, and Phase II clinical trials are underway for LFG316 as a potential therapy for geographic atrophy, an advanced form of dry AMD. To combat muscle-wasting disorders, BYM338 (bimagrumab) is in a pivotal clinical study for sporadic inclusion body myositis (sIBM) and is also being tested for sarcopenia and cachexia associated with chronic obstructive pulmonary disease.

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It is an exciting time to be working in research, said Fishman. I believe that we have the commitment, tools and teams in place to discover new medicines that will change the practice of medicine.

### **The New Novartis**

With Pharmaceuticals, Alcon and Sandoz, as well as NIBR, we have shaped Novartis to win in a future world in which innovation and scale are expected to be critical to meet demand, said Jimenez, in closing. Following the expected completion of the portfolio transformation transactions, the new Novartis will be more focused, more profitable, with the potential to grow faster.

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(2) Includes products approved in North America, Europe, Japan and Australia

**For background slides please refer to the following link:** <http://www.novartis.com/investors/event-calendar/index.shtml>

#### **Disclaimer**

This release contains forward-looking statements that can be identified by words such as *expected, to build, laying the foundation, would, taking steps, ongoing, priorities, expect, confident, will, preparing, well-positioned, working, goal, could, expecting, underway, anticipated, momentum, committed, pursuing, aim, commitment, aiming, aims, poised, expects, opportunity, positive CH, focused, believe, or similar terms*, or by express or implied discussions regarding potential new products, potential new indications for existing products, or regarding potential future revenues from any such products; regarding the potential completion of the announced transactions with GSK and Eli Lilly, and regarding any potential strategic benefits, synergies or opportunities as a result of the announced transactions; or by discussions of strategy, plans, expectations or intentions. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking 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 products will achieve any particular revenue levels. Nor can there be any guarantee that the proposed transactions will be completed in the expected form or within the expected time frame or at all. Neither can there be any guarantee that Novartis will be able to realize any of the potential strategic benefits, synergies or opportunities as a result of the transactions. Neither can there be any guarantee that Novartis or any of its businesses will achieve any particular financial results in the future. In particular, management's expectations could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; the potential that the expected strategic benefits, synergies or opportunities may not be realized or may take longer to realize than expected; the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; the Company's ability to obtain or maintain proprietary intellectual property protection; unexpected manufacturing or quality issues; global trends toward health care cost containment, including ongoing pricing pressures; general economic and industry conditions; ; uncertainties regarding future demand for our products; uncertainties involved in the development of new healthcare products; and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. 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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#### **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, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2013, the Group achieved net sales of USD 57.9 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 135,000 full-time-equivalent associates and sell products in more than 150 countries around the world. For more information, please visit <http://www.novartis.com>.

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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: June 18, 2014

By: /s/ MALCOLM B. CHEETHAM

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