Sandoz

Our Sandoz Division is a global leader in generic pharmaceuticals and biosimilars and sells products in more than 150 countries. In the first half of 2017, Sandoz achieved consolidated net sales of USD 4.9 billion. Sandoz develops and markets finished dosage form medicines as well as intermediary products including active pharmaceutical ingredients.

Sandoz products reached well over 500 million patients worldwide in 2016 and its divisional strategy is to further increase patient access by driving sustainable and profitable growth. Sandoz executes on its strategy by focusing on key priorities, including investing in key markets and therapeutic areas, increasing the performance of its small-molecule Development and Regulatory organization and maximizing opportunities in biosimilars. Sandoz focuses on products that add more value for patients, payors and healthcare professionals than standard generics.

Examples of marketed generic products in the Sandoz portfolio include leading antibiotic amoxicillin-clavulanic acid, multiple sclerosis treatment Glatopa (glatiramer acetate injection) 20mg/mL, and pain medication fentanyl, which is delivered using a transdermal patch.

Sandoz has a strong and continued strategic focus on biosimilars, which it began developing in 1996 and today sells in more than 60 countries. As of July 2017, Sandoz has five marketed biosimilars in Europe – more than any other company. Omnitrope, a human growth hormone, was first marketed in 2006, followed by Binocrit, an erythropoiesis-stimulating agent used to treat anemia, and oncology support agent filgrastim, under the brand names Zarzio outside the US and Zarxio in the US.

Most recently, Rixathon was approved and launched in some countries in Europe to treat blood cancers and immunological diseases, and Erelzi was approved and launched in some countries in Europe to treat multiple inflammatory diseases. The FDA has also approved biosimilar Erelzi (etanercept-szsz) to treat multiple inflammatory diseases. A confirmatory clinical safety and efficacy study demonstrated that Erelzi is equivalent to reference product Enbrel®. The biosimilar launch in the US is pending litigation with Amgen, the manufacturer of Enbrel®.

In May 2017, the EMA accepted our regulatory filings for biosimilar adalimumab and infliximab and we plan to file for both products in the US in the course of 2017. Following separate requests from the FDA and EMA, we plan to submit additional data for our biosimilar pegfilgrastim by end 2017 and 2019, respectively.

According to IMS Health, Sandoz holds the global number one position in sales of biosimilars, as well as for generic anti-infectives, oncology and ophthalmics. In addition, Sandoz holds leading global positions in key therapeutic areas including generic dermatology, respiratory, cardiovascular, metabolism, central nervous system, pain and gastrointestinal.

Following an internal reorganization announced on January 27, 2016, nineteen mature products were transferred from our Innovative Medicines Division (formerly named the Pharmaceuticals Division) to the Retail Generics franchise of Sandoz.

Effective as of April 1, 2016, operational control for the Novartis Malaria Initiative was transferred from our Innovative Medicines Division to Sandoz. In addition, Sandoz has assumed operational responsibility for Novartis Access, launched in September 2015, which comprises an initial portfolio of 15 medicines to treat chronic diseases in low and middle income countries. The portfolio, the majority of which are Sandoz medicines, addresses cardiovascular diseases, diabetes, respiratory illnesses and breast cancer, and is offered to governments, non-governmental organizations (NGOs) and other public-sector health providers for one US dollar per treatment, per month. The existing Sandoz tuberculosis business, as well as Novartis Social Business, which includes the Arogya Parivar “Healthy
Family” initiative, is also operationally managed by the same unit, under the Sandoz Global Commercial Operations function.

Key product launches in 2016

In 2016, key product launches in the US included amphetamine salts extended release (Shire’s Adderall XR®), linezolid solution for infusion/injection (Pfizer’s Zyvox®), mometasone furoate (Merck & Co. Inc.’s Nasonex® nasal spray), and oxiconazole nitrate (Fougera’s Oxsita®).

In 2016, key product launches in various European countries included ACC solution for injection, buprenorphine 4 and 7 day transdermal therapeutic system, matrix patch (Mundipharma’s BuTrans®, Norspan®), calcipotriol bethametasone ointment (Leo Pharma’s Dovobet®), fluticasone salmeterol powder dose inhaler (GSK’s Seretide®), imatinib mesylate (Gleevec/Glivec®), and linezolid film coated tablet (Pfizer’s Zyvox®).

Businesses

Sandoz is organized globally in three franchises: Retail Generics, Anti-Infecives, and Biopharmaceuticals.

Retail Generics

In Retail Generics, Sandoz develops, manufactures and markets active ingredients and finished dosage forms of pharmaceuticals to third parties. Retail Generics includes the areas of oncology, dermatology, respiratory and ophthalmics, as well as cardiovascular, metabolism, central nervous system, pain, gastrointestinal, and hormonal therapies. Finished dosage form anti-infectives sold to third parties are also a part of Retail Generics.

Anti-Infecives

In Anti-Infecives, Sandoz manufactures active pharmaceutical ingredients and intermediates – mainly antibiotics – for internal use by Retail Generics and for sale to third-party customers.

Biopharmaceuticals

In Biopharmaceuticals, Sandoz develops, manufactures and markets protein – or other biotechnology-based products, including biosimilars, and provides biotechnology manufacturing services to other companies.

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Pharmaceuticals and Oncology business units to form the Innovative Medicines Division, the creation of the Global Drug Development organization and Novartis Operations (including Novartis Technical Operations and Novartis Business Services), the transfer of the Ophthalmic Pharmaceuticals products of our Alcon Division to the Innovative Medicines Division, the transfer of selected mature, non-promoted pharmaceutical products from the Innovative Medicines Division to the Sandoz Division, and the transactions with GSK, Lilly and CSL. Neither can there be any guarantee that shareholders will achieve any particular level of shareholder returns. Nor can there be any guarantee that the Group, or any of its divisions, will be commercially successful in the future, or achieve any particular credit rating or financial results. In particular, our expectations could be affected by, among other things: regulatory actions or delays or government regulation generally; the potential that the strategic benefits, synergies or opportunities expected from the significant reorganizations of recent years, including the creation of the Pharmaceuticals and Oncology business units to form the Innovative Medicines Division, the creation of the Global Drug Development organization and Novartis Operations (including Novartis Technical Operations and Novartis Business Services), the transfer of the Ophthalmic Pharmaceuticals products of our Alcon Division to the Innovative Medicines Division, the transfer of selected mature, non-promoted pharmaceutical products from the Innovative Medicines Division to the Sandoz Division, and the transactions with GSK, Lilly and CSL may not be realized or may take longer to realize than expected; the inherent uncertainties involved in predicting shareholder returns or credit ratings; the uncertainties inherent in the research and development of new healthcare products, including clinical trial results and additional analysis of existing clinical data; our ability to obtain or maintain proprietary intellectual property protection, including the ultimate extent of the impact on Novartis of the loss of patent protection and exclusivity on key products which commenced in prior years and will continue this year; safety, quality or manufacturing issues; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; the particular prescribing preferences of physicians and patients; uncertainties regarding actual or potential legal proceedings, including, among others, actual or potential product liability litigation, litigation and investigations regarding sales and marketing practices, intellectual property disputes and government investigations generally; general economic and industry conditions, including uncertainties regarding the effects of the persistently weak economic and financial environment in many countries; uncertainties regarding future global exchange rates; uncertainties regarding future demand for our products; and uncertainties regarding potential significant breaches of data security or data privacy, or disruptions of our information technology systems; 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 presentation 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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