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2016 highlights

<table>
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<tr>
<th>23,000</th>
<th>$3.6 bn</th>
<th>5</th>
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<tr>
<td>Full-time equivalent employees in the US, of which 7,000 are employed at our US-based R&amp;D sites</td>
<td>Invested in R&amp;D in the US, representing 40% of our global R&amp;D spend that totals $9 billion</td>
<td>FDA breakthrough therapy designations received by Novartis in 2016</td>
</tr>
<tr>
<td>90%</td>
<td>80,000</td>
<td>334,000</td>
</tr>
<tr>
<td>Of our payments to healthcare professionals are related to R&amp;D</td>
<td>Patients received support through our copay assistance program in 2016</td>
<td>Patients received free medication valued at approximately $3.4 billion through the Novartis Patient Assistance Foundation Inc. over the past five years</td>
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Foreword

At Novartis, our mission is to discover new ways to improve and extend people’s lives. We are passionate about what we do, and our medicines can have a dramatic impact on people’s lives: They can help patients live longer and in better health, and provide significant benefits to our society and economy.

We strive to harness the power of science to address some of society’s most challenging healthcare issues. Over the years, our company has delivered breakthrough innovations in complex fields such as transplantation, oncology and heart disease.

We understand, however, that some patients cannot afford the medicines they need. This is why we are working hard to ensure all patients who need our medicines have access to them. Our programs help patients get the medicines they need, when they need them, at prices they can afford.

Today’s innovative medicines are tomorrow’s generics and biosimilars. And, through our Sandoz Division, Novartis offers a broad portfolio of generic and biosimilar products with significant potential to help healthcare systems relieve budget pressure.

At the same time, we know we are at a critical juncture in the US. Companies like ours need to approach things differently, provide more transparency about our business practices, and take steps that will make our healthcare system sustainable over the long term.

The pharmaceutical industry cannot by itself address the issue of rising healthcare costs, but we at Novartis stand ready to work with stakeholders across the entire system to identify which interventions deliver the most value to patients.

We support a shift to a system where medicines are priced based on the benefits they deliver in four areas: clinical, patient, health system and societal. We believe such value-based pricing can help reduce waste and improve quality in the healthcare system. We also believe it is more transparent and focuses everyone on what matters most – better outcomes for patients. This shift will not happen overnight, but we must continue to drive it forward.

We know our stakeholders have important questions about our business practices, including our approach to price adjustments, patient assistance, investment in research and development, and marketing. We hope the information in this report will help answer those questions.

We welcome your feedback:

✉️ uscorporate.communications@novartis.com

Sincerely,

Thomas Kendris
President, Novartis Corporation, and US Country and Legal Head
Science and innovation

Novartis discovers new ways to improve and extend people’s lives. We harness the power of science to address some of society’s most challenging healthcare issues. We develop breakthrough treatments and deliver them to as many people as possible.

Our medicines can have a dramatic impact on patients’ lives. They can help people live longer and remain healthier, and they can provide significant benefits to our society and economy.

For more than 10 years, Novartis has been among the world’s top 20 R&D spenders across all industries. Novartis invests more than 18% of its global revenue in research and development (R&D). In 2016, our R&D investments reached $9 billion, exceeding our operating income ($8.3 billion). In the US, we invested $3.6 billion in R&D, representing 40% of our total global R&D spend.

In 2001, we introduced Gleevec, a life-changing medicine that has helped transform Philadelphia chromosome-positive chronic myeloid leukemia (CML) from a once fatal condition into a manageable disease. Today, nine out of 10 CML patients have a near normal lifespan.

Most recently, we introduced our medicine for chronic heart failure, Entresto, the first and only treatment to significantly reduce the rate of cardiovascular deaths and heart failure hospitalizations versus the ACE inhibitor enalapril.

Today our researchers are at the forefront of an entirely new approach to treating cancer where each dose is tailored to, and manufactured for, each patient using the patient’s own blood cells. This revolutionary immunocellular therapy offers hope to children and young adults with blood cancer.

Our collaborative approach to science

New R&D technologies are being developed in a variety of places, from university labs and biotech startups to multinational companies. Novartis is constantly seeking the best technological advances and partnerships. We currently work with an external network of more than 300 academic and 100 industry alliances. We believe scientific collaborations can boost efficiency and accelerate progress by facilitating access to ideas, capabilities and talent. By joining forces with external innovators to pursue shared scientific interests, we can increase the breadth and depth of the science that we cover.

Novartis generally seeks collaborations at the stage of idea generation and early discovery through

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1 www.strategyand.pwc.com/innovation1000/#/tab-2005
Ranked in the top 20 of the world’s largest R&D spenders across all industries
clinical proof-of-concept. We then invest in scaling up and completing the full development process, as well as in building the necessary manufacturing capacity. For example, we were the first major pharmaceutical company to advance an innovative new type of personalized cell therapy to fight cancer, known as CAR-T, through our collaboration with the University of Pennsylvania. Novartis has since invested substantially in clinical trials to demonstrate the therapy’s safety and effectiveness to health regulators, as well as in a facility that is able to prepare the treatment for each individual patient.

Developing safe and effective treatments

Clinical trials are research studies intended to answer scientific questions and find better ways to treat or prevent diseases. They are fundamental to the development of medicines and devices. Novartis conducts clinical trials globally for a range of diseases. In the US, as of December 2016, we had more than 130 pivotal trials1 across disease areas.

Novartis pivotal trials per disease area in the US

- Oncology
- Cardiometabolic
- Immunology/dermatology
- Neuroscience
- Ophthalmology
- Respiratory
- Biosimilars

Providing managed access programs for patients with limited treatment options

There are instances where a patient has a serious or life-threatening disease or condition for which all currently available treatment options have been exhausted and enrollment into a clinical trial is not possible. Novartis Managed Access addresses this need by making certain investigational or unapproved treatments available to eligible patients.

In the US, we currently have 25 managed access programs across disease areas.

Sharing clinical trial results

Novartis supports clinical trial data transparency. We believe providing access to information on clinical trials and their results serves study participants, researchers, patients and their healthcare providers, as well as the public at large.

Participants in clinical trials can gain access to new investigational therapies not yet available to the public, while helping advance medical innovation.

In 1999, Novartis began registering its clinical trials on www.clinicaltrials.gov, the public US clinical trial registry. We have registered more than 2,900 trials on the site since.

In 2005, before it became a legal requirement, Novartis was one of the first healthcare companies to publicly disclose clinical trial results from Phase IIb–IV1 patient trials for our approved and unapproved innovative medicines on our website, www.novartisclinicaltrials.com.

Public disclosure of clinical trial results was later expanded to include all Phase I and Phase IIa1 patient trial results for approved and unapproved innovative medicines.

The results of Novartis clinical trials are also posted on other online public databases (US, EU and German results websites), and significant results are published in peer-reviewed journals. In 2014, Novartis began providing access to anonymized data to qualified external researchers via www.clinicalstudydatarequest.com.

In 2016, Novartis committed to help inform patients about Phase I and IIa clinical trials they participated in by providing an easy-to-understand clinical trial summary. Our commitment is being expanded in 2017 to include Phase IIb and III1 trials. All patient summaries will be posted on the Novartis website: www.novartisclinicaltrials.com.

For more information: ➔ www.novartis.com/our-work/research-development

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1 Clinical trials generally proceed through the following phases: In Phase I, researchers test a new drug in 20 to 100 healthy volunteers or people with the disease to gather information on safety and dosage. In Phase II, the drug is tested in several hundred patients with the disease to assess efficacy and side effects. Phase III studies, also known as pivotal studies, involve 300-3,000 or more patients with the disease and aim to demonstrate efficacy and monitor for adverse reactions. Phase IV trials are usually done after product launch to further explore safety and efficacy in several thousand patients.
Driving the shift to value-based healthcare

In the US, it is estimated that 21% to 34% of health spending is wasted every year (i.e., between $558 billion and $910 billion).\(^1\) To make healthcare affordable, wasteful spending within the system needs to be urgently addressed. We believe a value-based healthcare system could help reduce some of the unnecessary spending and focus everyone on what matters most – better outcomes for patients.

Estimated wasteful spending on healthcare in the US\(^1\)

<table>
<thead>
<tr>
<th>Category</th>
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<tbody>
<tr>
<td>Failures of care delivery*</td>
<td>154</td>
</tr>
<tr>
<td>Unnecessary care**</td>
<td>226</td>
</tr>
<tr>
<td>Administrative complexities***</td>
<td>389</td>
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</table>

* Failures of care delivery, such as lack of widespread adoption of known best care processes, cost the system up to $154 billion.
** Subjecting patients to unnecessary care, such as overuse of antibiotics or surgeries where alternatives exist, causes waste of up to $226 billion.
*** Another estimated $389 billion is lost due to administrative complexities, e.g., when limited physician time is spent on needlessly complex billing procedures.

Novartis is committed to taking a leading role in helping the healthcare system transform the current “pay-for-service” approach to one that ties payment to outcomes delivered.

We believe medicines and healthcare services (e.g., diagnostic procedures, medical consultations and drug prescriptions) should be priced and paid for based on the outcomes they generate, namely:

- **Clinical outcomes**, such as shrinking a tumor, reducing blood sugar levels or prolonging survival
- **Patient outcomes**, such as improved quality of life
- **Health system outcomes**, such as reducing the rate or duration of hospitalizations or the intensity of care
- **Societal outcomes**, such as allowing patients or caregivers to return to work

In the pharmaceutical sector, Novartis is pioneering the shift to value-based pricing. We aim to focus our pricing approach on the value our medicines deliver with respect to clinical, patient, health system and societal outcomes. We also apply US-specific cost-effectiveness modeling to inform US prices and embed patient- and payer-relevant endpoints in our clinical trial programs.

When measured on the outcomes they deliver, innovative medicines can play a critical role in helping reduce waste in the system. For example, when used appropriately, Entresto could save more than 28 000 lives per year in the US alone, and over a two-year period it could save more than $27 million from reduced heart failure hospitalizations for every 100 000 patients treated.\(^2,3\) In the largest study ever conducted in heart failure patients with reduced ejection fraction (PARADIGM-HF), Entresto was shown to reduce cardiovascular deaths and heart failure hospitalizations by 20%, and all-cause mortality by 16%.

Our approach to pharmaceutical pricing in the US

1. We will pursue value-based pricing for our products
2. We will manage price adjustments responsibly for our branded medicines as well as our biosimilars and generic products
3. We will strive to ensure patient affordability

Value-based contracting

Novartis is one of the first companies to start entering into value-based contracting for our medicines. We are still at the early stages of this approach and are learning from our experience. We have multiple agreements in place where payments are linked to the outcomes our medicines deliver.

For example, we have value-based contracts in place for our innovative heart failure medicine, Entresto, where cost offsets from prevented hospitalizations determine part of the payment to insurers; for Tasigna, where some payments have been tied to our ability to halt disease progression in first-line patients with a form of chronic myeloid leukemia; and for Gilenya, where in some cases payments are based on our ability to decrease the annual relapse rate for relapsing-remitting multiple sclerosis patients.

However, even though many stakeholders agree with a value-based approach to pricing and contracting, the current US system includes many technical and regulatory barriers and is not yet set up to fully support this shift. For example, patients that use medications as stated in the product label may experience benefits that are not captured in the label. These benefits are of interest to the payers, providers and patients. However, due to current regulations, these benefits cannot be considered when developing value-based contracts. Removing such barriers and shaping the system is a long-term endeavor that will require concerted efforts and cooperation from all stakeholders in the healthcare system.
Managing price adjustments responsibly

Novartis is committed to managing price adjustments responsibly for all of our innovative and generic medicines. In the past few years, our annual price adjustments have gradually decreased.

### US product portfolio – % change vs. prior year

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<tr>
<td><strong>Total gross price change</strong>&lt;sup&gt;3&lt;/sup&gt;</td>
<td>9.9%</td>
<td>9.8%</td>
<td>9.9%</td>
<td>9.3%</td>
<td>6.2%</td>
</tr>
<tr>
<td><strong>Total net price change</strong>&lt;sup&gt;4&lt;/sup&gt;</td>
<td>5.2%</td>
<td>7.0%</td>
<td>5.3%</td>
<td>1.3%</td>
<td>-2.0%</td>
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1. US product portfolio for 2012 to 2016 includes all medicines sold by the US Innovative Medicines Division, including Alcon Ophthalmics products, and all generic medicines sold by the US Sandoz Division.
2. The company’s calculation of gross and net price changes was verified under agreed-upon procedures between Novartis and PricewaterhouseCoopers AG performed in accordance with International Standard on Related Services 4400. Our methodology may differ from the methodologies used by other companies. This pricing information should not be read in conjunction with the company’s filings with the Securities and Exchange Commission.
3. Represents the year-over-year change in the average list price of Innovative Medicines brands, combined with the year-over-year change in the average wholesale acquisition cost (WAC) of the Sandoz products that had an increase in gross price in the period. Individual gross price changes by brand or product are weighted by current year gross sales.
4. Represents the year-over-year change in the average net price. The net price is the total gross price less total rebates, discounts and deductions.

In 2016, the gross price increase across our portfolio was 6.2%. However, our net price over the same period decreased by 2.0%. Gross price (also called list price or wholesale acquisition cost) is the starting price set by the pharmaceutical company. Net price reflects the final amount received by the company. The difference between gross and net price is largely the result of many negotiations that take place between the pharmaceutical company and other stakeholders in the supply chain – such as government payers, insurers, pharmacy benefit managers, wholesalers, retailers and hospitals – that typically result in discounts and rebates to the gross price.

These discounts and rebates are not necessarily passed on to the patient, meaning net prices may differ from the final costs absorbed by payers and patients. Further, stakeholders in the supply chain may apply additional charges, increasing drug prices above the discounted amount charged by the manufacturer.

### Total US rebates and discounts<sup>1,2</sup>

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<tr>
<td><strong>Total US rebates and discounts</strong>&lt;sup&gt;1,2&lt;/sup&gt;</td>
<td>-37.6%</td>
<td>-39.8%</td>
<td>-43.3%</td>
<td>-45.8%</td>
<td>-47.7%</td>
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</table>

1. Total US rebates, discounts and deductions calculated as a percentage of total gross sales.
2. The company’s calculation of the total rebates and discounts was verified under agreed-upon procedures between Novartis and PricewaterhouseCoopers AG performed in accordance with International Standard on Related Services 4400.

In the US, the total annual rebates and discounts on Novartis products (both innovative medicines and Sandoz generics) increased from 38% in 2012 to 48% in 2016.

Novartis publishes key financial information annually in its Form 20-F and Annual Report, including total rebates, research and development costs, and gross and net sales.

Key corporate publications:

→ www.novartis.com/news/publications
Patient access

Making our medicines accessible and affordable

Novartis works to develop new ways to deliver its medicines to as many people as possible. Globally, we offer an array of approaches, including patient access programs, patient assistance programs and product donations. Our generics division, Sandoz, also helps make affordable, high-quality medicines available to more people.

In the US, we offer access-to-medicine programs that aim to make sure that patients' out-of-pocket costs are not a barrier to access. We work with stakeholders such as insurers and governments, with the goal of ensuring no patient is left behind.

**Commercially insured patients**

For US patients with commercial insurance, we offer copay assistance programs so eligible patients pay no more than $30 for a 30-day prescription (i.e., $1 per day) through retail or mail order for the vast majority of our branded and biosimilar products. This includes our cancer portfolio. All our branded products without generic alternatives and our biosimilar products will be available under this program by January 2018, subject to any limits imposed by a patient’s individual health plan and where allowed by law.

In 2016, Novartis copay assistance programs provided assistance to nearly 80 000 patients.

**Government-insured patients**

Due to current regulations, we are unable to offer copay assistance to patients covered by government healthcare programs (e.g., Medicare and Medicaid). While Medicaid patients already have the benefit of low out-of-pocket costs for their medicines, we believe regulations should be changed so that Medicare beneficiaries can also be provided the financial assistance available to commercially insured patients to help reduce their out-of-pocket costs for medicines.

Assisting patients with out-of-pocket costs can help reduce the level of unfilled or abandoned prescriptions and support their ability to adhere to their medicines as prescribed. This could ultimately impact longer-term health outcomes and reduce overall costs for the US healthcare system.

**Uninsured and underinsured patients**

Through the Novartis Patient Assistance Foundation Inc., we are providing medicines at no cost to eligible US patients experiencing financial hardship who have limited or no prescription drug coverage. We have increased the income eligibility limits for all branded products. For example, individual patients earning less than $75 000 per year and families of four with an income below $150 000 per year may be eligible for the program. We will continue to adjust income eligibility limits in accordance with changes to the federal poverty level and other external factors.

In 2016, the Novartis Patient Assistance Foundation Inc. provided more than $1 billion in free medicines to more than 45 000 patients in the US. Over the past five years, free medication valued at roughly $3.4 billion has been provided to around 334 000 patients.

**Patient support services**

Getting access to medications can be difficult, confusing, and at times stressful for patients. Novartis offers tools and support designed to help make that process easier. We offer a range of services to support patients with all aspects of access, from insurance verification to financial assistance to a supportive call center.

Find out more about our programs:

Novartis patient assistance programs
→ [www.patientassistancenow.com](http://www.patientassistancenow.com)

Novartis Oncology Universal Co-Pay Program
→ [www.copay.novartisoncology.com](http://www.copay.novartisoncology.com)
Today’s innovative medicines are tomorrow’s generics and biosimilars

Novartis is a global leader in the generics sector through our Sandoz Division, which offers biosimilars and high-quality generic medicines.

Novartis launched the first biosimilar under the Biologics Price Competition and Innovation Act of 2009 in the US. Our biosimilar pipeline includes plans for five major US launches by 2020.

According to the Association for Accessible Medicines, generics account for 89% of prescriptions dispensed in the US, but for only 26% of spending on prescription medicine. In 2016, savings to the US healthcare system from generic drugs totaled $253 billion, while generic drugs saved Medicare and Medicaid $77 billion and $37.9 billion, respectively.¹

In 2016, Sandoz medicines reached an estimated 535 million patients globally, and 264 million prescriptions were dispensed for Sandoz products in the US. We estimate that our generics helped save the US healthcare system around $13.4 billion in 2016 and $87.1 billion in the last decade. By 2020, we are projected to contribute $69.2 billion in savings to the US healthcare system.

Savings from generic drugs to the US healthcare system¹

$1.67 tn over the past 10 years

Estimated savings from biosimilars to the US healthcare system²

$44 bn over 10 years

¹ Generic Drug Access & Savings in the US, 2017, Association for Accessible Medicines
² www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf
Responsible business practices

At Novartis, our vision is to be a trusted leader in changing the practice of medicine, and we must do all we can to build and nurture that trust. We continually challenge ourselves to meet the highest standards of compliance, integrity and performance in all that we do. This helps ensure a sustainable future of innovation for the benefit of patients, as well as society at large and Novartis.

Marketing practices

When promoting our products, we have an ethical responsibility to provide accurate, balanced and updated information to healthcare professionals, patients and consumers.

In addition to complying with the PhRMA Code on Interactions with Healthcare Professionals in the US, our marketing practices are guided by our Comprehensive Compliance Program.

The fundamental principles that guide our actions are disclosed on our website at:

→ www.pharma.us.novartis.com/corporate-responsibility/business-conduct

We continually evolve our marketing practices and approach to customer interactions with the aim of maintaining high ethical standards and staying in step with society’s increasing expectations. For example:

• We have changed how we incentivize our sales force. We no longer incentivize purely on performance, but also on how the work is done and whether this aligns with our Values and Behaviors.
• We are also changing how we engage with doctors by developing, with their input, a variety of educational options. These include new digital communications tools, as well as impactful changes to traditional in-person events to provide even more doctors with information on the safety and efficacy of our products.

Learn more about our marketing practices:


Payments to healthcare professionals

Novartis collaborates with physicians and healthcare organizations such as teaching hospitals to advance patient care. It is a relationship that has helped deliver numerous innovative medicines and change the way many diseases impact the lives of patients.

Our work together includes a range of activities, from clinical research to sharing best clinical practices. For many products, clinical development activities also continue after the product is made available on the market. As an industry, we make payments and other “transfers of value” to physicians and healthcare organizations to compensate them for their time spent working with us.

Almost 90% of Novartis payments or “transfers of value” in the US are related to R&D.

Novartis discloses payments and other transfers of value made to healthcare professionals and organizations in the US in line with the Physician Payments Sunshine Act. The vast majority of these transfers of value are related to our research and development efforts, which have yielded one of the most robust pipelines in the industry. Novartis engages physicians in our research efforts as clinical trial investigators and works with hospitals to conduct clinical research studies. As part of this,
we also supply the medicines used in these clinical trials and include the value of these medicines when we report payments and transfers of value under the requirements of the law.

We believe that disclosing payments and transfers of value related to these already well-regulated relationships builds understanding of these collaborations and addresses public concerns about interactions between the medical community and the pharmaceutical industry. Altogether, this reinforces our commitment to high ethical business standards.

We stand by this commitment to transparency and have established rigorous data collection and reporting processes. We also recognize what a complex undertaking it is to track and report this volume of data, and we are committed to ongoing collaboration with the federal government’s Centers for Medicare & Medicaid Services (CMS), physicians and teaching hospitals to help ensure we report the information requested.

The relevant reports for healthcare professionals and healthcare organizations are available on our website. For more information, please visit:

→ www.pharma.us.novartis.com/corporate-responsibility/payments-healthcare-professionals
→ www.pharma.us.novartis.com/corporate-responsibility/payments-healthcare-organizations

Patient group funding

Novartis works with many organizations that advocate for patients around the world, and we disclose the payments we make as part of these relationships. These organizations play a crucial role by informing and supporting patients, as well as working to safeguard the rights of patients and caregivers. Further, patient organizations provide healthcare companies with important advice from their own perspective. Interacting with patient organizations enables Novartis to learn about and understand unmet patient needs as well as barriers to treatment success. This information can guide us in developing therapies and solutions that effectively address these needs.

Novartis discloses the funding provided to patient organizations in the US and other countries by March 31 every year.

Find out more:


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1 R&D costs include all the expenditures linked to bringing a new drug to market (or adapting an existing drug), from drug discovery through clinical trials to market approval.
2 General payments include: compensation, consultancy fees or honoraria; travel; meals; charitable contributions; educational materials and items for physician use; in-kind services such as educational grants or disease management programs, etc.
Political contributions and lobbying

Novartis strives to engage in constructive dialogue with policymakers and other external stakeholders. Representing our perspective in the policymaking process and providing policymakers with data and insights enables informed decision-making conducive to improving patient outcomes.

In the US, pharmaceutical companies are required to report the sum of our federal lobbying activities on a quarterly basis to the clerk of the House of Representatives and to the secretary of the Senate. Included in the amount disclosed is the value of the labor hours spent on lobbying activities by all relevant company officials. Registered state lobbyists comply with all reporting requirements as defined by each state. In 2016, Novartis spent a total of $6 643 000 on federal lobbying-related activities.

Novartis makes financial contributions to support political dialogue on issues of relevance to our industry. Novartis only makes financial political contributions in countries where such contributions by corporations are legal and considered appropriate (the amount of these contributions is published in the corporate governance section of the 2016 Novartis Annual Report). In the US, such contributions are only made at the state level in select states where use of corporate funds is permissible by state law. In 2016, Novartis made political contributions totaling approximately $250 000 in the US.

The Novartis political action committee (PAC) makes contributions to federal candidates, federal party committees and some state candidates. The PAC uses funds received from Novartis employees (but not from the company) to make political contributions. These contributions are reported monthly to the Federal Election Commission and twice a year to the clerk of the House of Representatives and to the secretary of the Senate. In 2016, Novartis PAC contributions amounted to approximately $240 000.

The reports disclosing the sum of federal lobbying expenses and PAC contributions are all available for public access and can be found on the website of the Federal Election Commission and the US House of Representatives’ Office of the Clerk.

Find out more:

→ www.fec.gov/data
→ disclosures.house.gov/ld/ldsearch.aspx
About Novartis Corporation

At Novartis, we discover and develop breakthrough treatments and find new ways to deliver them to as many people as possible. Our business model reflects this: We aim to create value for patients, healthcare systems and society based on our innovation capability.

We are a global company with strong roots in the US, where we have more than 23,000 full-time equivalent employees in skilled positions across 24 locations. We have four main campuses: East Hanover, New Jersey; Princeton, New Jersey; Fort Worth, Texas; and Cambridge, Massachusetts.

Corporate responsibility at Novartis

Novartis has a strong history of corporate responsibility (CR) activities, and transparent reporting is a central part of our commitment. We have reported on CR since 2000 through our Annual Report and several online and printed materials.

The CR Performance Report consolidates the company’s CR reporting and details our progress against our targets. It is based on the Global Reporting Initiative G4 guidelines, with disclosure at “comprehensive” level.

View our 2016 CR Performance Report:
