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- ▶ Unleash the power of our people
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# **About this report**

The Novartis in Society Integrated Report 2022 provides an overview of our business, strategy and performance, and describes how we create value for stakeholders and society.

The Novartis in Society Integrated Report 2022 is intended for all Novartis stakeholders. It will be of interest primarily to shareholders, investors and environmental, social and governance (ESG) analysts.

The report has been prepared in alignment with the Integrated Reporting Framework, the Task Force on Climate-related Financial Disclosures (TCFD), the Sustainability Accounting Standards Board (SASB) and the latest non-financial standards issued by the Global Reporting Initiative (GRI).

The Novartis in Society Integrated Report 2022 is published in conjunction with our Annual Report filed with the SIX Swiss Exchange and our Form 20-F filed with the US Securities and Exchange Commission (SEC). All our annual reports can be found on our corporate website.

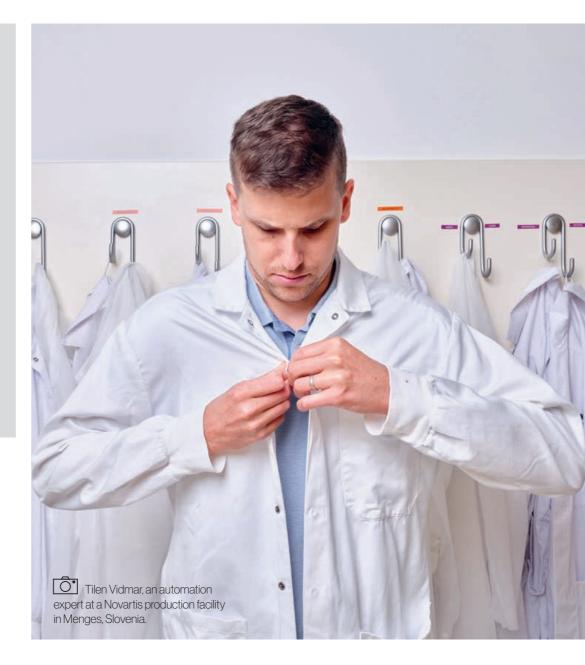
Unless otherwise stated, data in this report relates to our financial year, which runs from January 1 to December 31. Environmental data is based on nine-month actual data (January to September 2022) plus three-month estimates. This data will be restated with actual figures on our website during 2023.

The Novartis in Society Integrated Report 2022 comprises six main sections:

- Introduction including letters from our Board Chair and CEO
- Who we are providing details of our medicines, operations and organizational structure
- Business environment describing trends and issues currently affecting our operating environment
- Strategy and value creation including an overview of our corporate strategy and model for value creation
- Performance in 2022 providing details of performance against our strategy
- Governance describing our principal governance structures, risk management, internal policies and controls, and approach to Executive Committee compensation

KPMG has provided limited independent assurance on the performance indicators on pages 81-84.

Please note that all product names printed in italics in this report are trademarks owned by, or licensed to, the Novartis Group.



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# 2022 at a glance

10.0 bn

Invested in research & development

(USD)

(vs. USD 9.5 bn in 2021)

Approvals in the US, EU, China and Japan

for new medicines and new indications for existing medicines (vs. 21 in 2021)

**Ongoing Phase III** programs

Of employees

(vs. 98% in 2021)

trained and certified in the

Novartis Code of Ethics

16.7 bn

(vs. USD 16.6 bn in 2021)

(USD)

Core operating income

in our development pipeline (vs. 54 in 2021)

AA

Novartis was upgraded to AA in the MSCI ESG Ratings assessment in June.

Novartis was upgraded to A

in both CDP Climate Change

and CDP Water Security

**ESG** ratings

**Double A list** 

in December.

**MSCI ESG Ratings** 

4th

Novartis has ranked in the leadership group for more than 10 years.

access to medicine = Inpex **T** 

16.9

With an ESG Risk Rating score of 16.9. Novartis is assessed as Low Risk.

**SUSTAINALYTICS** 

4th

Novartis ranks fourth in the industry (as of the end of 2022). S&P Global

54.6 m

**Patients reached** 

through access programs, predominantly in low- and middle-income countries (LMICs) (vs. 56.2 m in 2021)

50.5 bn

(vs. USD 51.6 bn in 2021)

**Net sales** 

(USD)

49%

Reduction in greenhouse gas emissions

in our own operations (vs. 2016 baseline)

**Dividends** 

paid to shareholders (USD) (vs. USD 7.4 bn in 2021)

7.5 bn

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# **Chair's letter**

Medical progress and innovation are evolving with impressive speed even in a world of increasing volatility and uncertainty. In 2022, we initiated a major transformation of our organization to further improve our innovation capabilities and align with our growth strategy as a pure-play medicines company.

We expect these changes to simplify our business, enhance accountabilities and strengthen our commercial activities by enabling us to better focus on our in-market products and high-value pipeline assets. Overall, our efforts are set to support our long-term sales and profit growth and help us create sustainable shareholder value.

As part of this transformation, which includes our intention to spin off our Sandoz generics and biosimilars Division, we merged our Oncology and Pharmaceuticals commercial organizations and created a new Operations organization that combines our manufacturing and services activities. Besides substantial cost savings, we expect these steps to increase our operational agility and strengthen our business in key markets such as the United States and China.

The organizational changes, which we expect to finalize in 2023, complete the portfolio shift we started in 2014. Over this time, we have divested several non-core businesses and spun off our eye-care division Alcon. With a view to boosting our innovation power, we have also made substantial investments in cutting-edge technology platforms, including gene and cell therapy, radioligand therapy and RNA technology.

and while executing on our ongoing transformation, which entailed job reductions due to structural changes. This performance was supported by cost discipline and continued operational streamlining, as well as the strong uptake of recently launched medicines, such as multiple sclerosis treatment *Kesimpta*, and continued strong demand for our cardiovascular medicine *Entresto* and psoriasis treatment *Cosentyx*.

Last year also saw new leadership at the Novartis Institutes for BioMedical Research

Novartis delivered on its sales and operating

profit targets in 2022 despite the challenges

of a volatile macroeconomic environment

Last year also saw new leadership at the Novartis Institutes for BioMedical Research and our Global Drug Development organization, the research and development (R&D) engines of Novartis, and a renewed focus on improving governance and speeding up the transition between early drug discovery and clinical development. These measures should help further strengthen our portfolio of medicines, which we have consistently broadened in recent years with launches including cancer treatments *Pluvicto* and *Scemblix*.

We have also further intensified our efforts to integrate our environmental, social and governance (ESG) activities into our daily business, which we believe is vital for the success of Novartis. Among a variety of steps aimed at reaching as many patients as possible, we renewed our commitment to

continue our R&D efforts in neglected tropical diseases and to work further toward the elimination of malaria. In addition, we are partnering with the American Society of Hematology to deepen our efforts to fight against sickle cell disease in Africa.

The Board of Directors also remained vigilant in its governance oversight efforts by putting added emphasis on values such as integrity as Novartis pivots towards becoming a high-performance, pure-play medicines company. Likewise, the Executive Committee and the Board of Directors are keeping up the intensive dialogue with stakeholder groups and working towards achieving our vision to be the most valued and trusted medicines companies in the world.

I thank you for the confidence you have placed in our company and am pleased to be able to propose a dividend increase of 3.2% to CHF 3.20 at the next Annual General Meeting.

Sincerely,

J. Romberd L

Joerg Reinhardt
Chair of the Board of Directors



Novartis delivered on its sales and operating profit targets last year despite the challenges of a volatile macroeconomic environment and while executing on our ongoing transformation.

Joerg Reinhardt

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# **CEO's letter**

2022 was a year of transformation for Novartis. After more than USD 100 billion in acquisitions and divestures over the last several years, our structural transformation from a diversified healthcare conglomerate into a focused, innovative medicines company will be largely complete after the planned spin-off of Sandoz in 2023.

We also begin 2023 with a simplified organizational structure that will spur innovation and give us a stronger foundation for growth in a rapidly changing global business environment.

While Novartis has pursued bold portfolio change, core elements of our company remain the same. Our vision is to become the most trusted and valued medicines company in the world – valued not only for our business performance, but also for the difference our innovation makes for patients and society.

The world is counting on us to succeed. Fewer than 10% of diseases known to affect humans are currently treatable, and globally, people live an average of 10 years with a disease or disability. Yet new treatments broadly still reach only a fraction of eligible patients, and manageable conditions like heart disease cause millions of avoidable deaths each year.

Our performance in 2022 showed that we are making progress in addressing society's greatest disease burdens. Our focus on

cardiovascular disease, for example, gives countries and healthcare systems solutions to address the world's leading cause of death and disability. *Entresto*, our medicine for heart failure and hypertension, is estimated to be treating around 10 million patients worldwide, while our cholester-ol-lowering siRNA treatment *Leqvio* is now approved in 70 countries.

We saw robust growth momentum across our in-market medicines. This includes stronger-than-expected uptake in the US for *Pluvicto*, our novel radioligand therapy for advanced prostate cancer, highlighting our ability to turn the promise of next-generation medicines into a reality for patients.

Despite challenging macroeconomic conditions and an unstable geopolitical environment, we delivered a solid financial performance that underscores the progress we are making, with 4% growth in net sales in constant currencies (cc) and 8% growth (cc) in core operating income compared with the previous year. Looking ahead, we aim to generate sales growth of 4% CAGR over the next five years, and grow above peer median beyond 2027.

Our investments in R&D are key to achieving these ambitions. In 2022, we saw a positive Phase III readout for iptacopan, which was discovered at NIBR, in a rare and deadly blood disorder. We saw an important positive Phase III result for *Pluvicto* in earlier lines of prostate cancer. And we also



As we look to the future as a focused medicines company, our dedication to innovation and excellence will drive us forward.

Vas Narasimhan

reported positive Phase III results for *Cosentyx* in hidradenitis suppurativa, offering the potential to expand one of our most successful medicines and bring a new treatment option to patients with this painful skin disease.

As we continue innovating for patients, millions around the world are still without proper access to healthcare. Translating the latest science into lasting progress requires us to work with healthcare systems and other stakeholders to advance access for underserved patients in low- and middle-income countries, while also tackling access barriers in some of the wealthiest countries in the world.

In the US, for example, we expanded our 10-year Beacon of Hope initiative, which seeks to address racial disparities in healthcare, including by increasing diversity among clinical trial participants and investigators. We also pledged to invest USD 250 million in R&D for the treatment of malaria

and neglected tropical diseases, building on our decades-long commitment to global health priorities. We continue to make progress in other aspects of our ESG agenda, including reducing greenhouse gas emissions from our own operations by nearly half since 2016.

As we look to the future as a focused medicines company, our dedication to innovation and excellence will drive us forward. We have set clear growth ambitions and we are confident we will meet them. Through reshaping Novartis, we are set to reimagine medicine for decades to come.

Sincerely,

MM

Vas Narasimhan Chief Executive Officer

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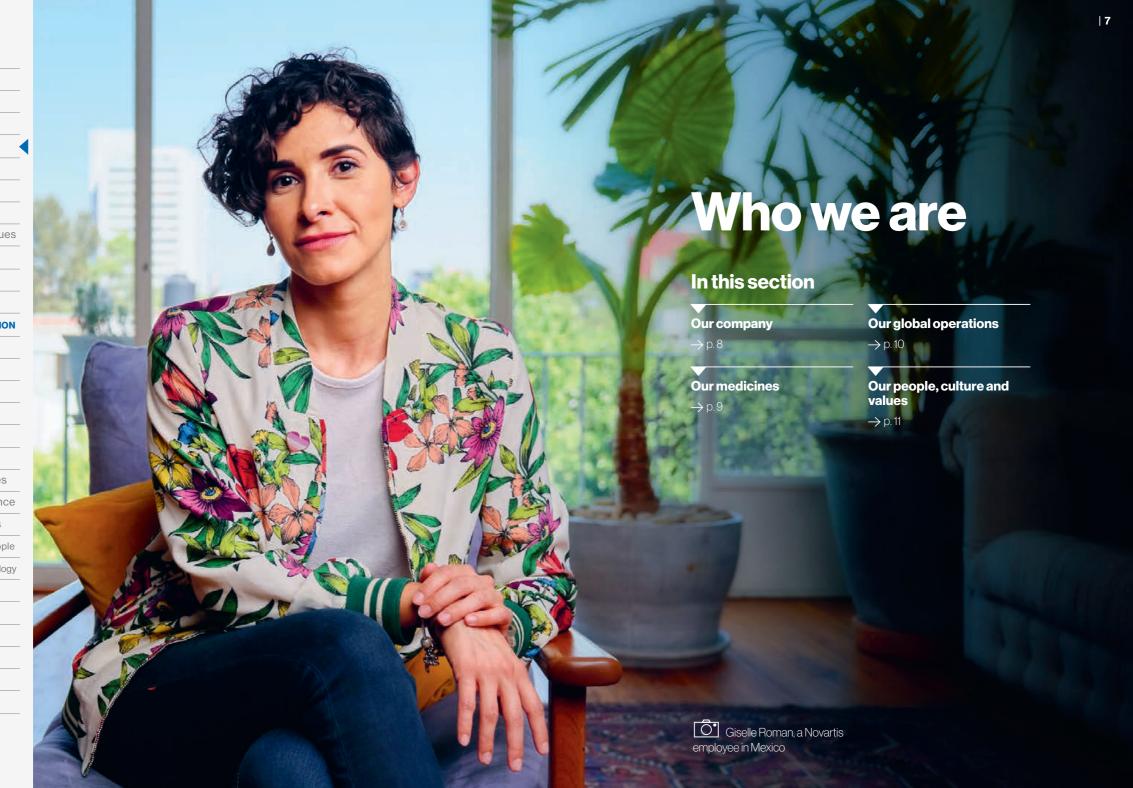
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# **Our company**

Novartis is one of the world's leading medicines companies. We use innovative science and technology to address some of society's most challenging healthcare issues. Worldwide, our medicines reached 743 million people in 2022.

### **Our purpose**

Our purpose is to reimagine medicine to improve and extend people's lives. We use innovative science and technology to address some of society's most challenging healthcare issues. We discover and develop breakthrough treatments and find new ways to deliver them to as many people as possible. We also aim to reward those who invest their money, time and ideas in our company.

# Operations Research & development Corporate functions Sandoz

### **Our company**

We have two operating divisions: **Innovative Medicines**, which specializes in patent-protected medicines, and **Sandoz**, which sells high-quality generics and biosimilars. Innovative Medicines is the larger of our two divisions in terms of consolidated net sales. These divisions are supported by our research and development (R&D) teams, our Operations organization and our corporate functions.

### **Our vision**

Our vision is to become the most valued and trusted medicines company in the world.

### **Innovative Medicines**

Innovative Medicines comprises two commercial units: Innovative Medicines US and Innovative Medicines International. These units were created in April 2022 as part of our new, integrated organizational structure. Our Innovative Medicines Division reached approximately 236 million patients in 2022.

### Sandoz

The Sandoz Division is a global leader in high-quality, affordable generics and biosimilars. Sandoz reached approximately 453 million patients in 2022.

### **Research and development**

At the heart of our company is research and development (R&D). Novartis consistently ranks among the world's top companies investing in R&D:

- The Novartis Institutes for BioMedical Research (NIBR) is our innovation engine, focused on discovering new medicines for diseases with unmet medical need.
- Our Global Drug Development (GDD) organization oversees the development of potential new medicines, running large clinical trials and steering the way to regulatory approval for general use in patients.

### **Operations and corporate functions**

**Operations** manufactures and delivers medicines to customers and takes care of IT and other support services across the organization. In 2022, our manufacturing facilities shipped approximately 72.5 billion treatments.

**Corporate functions** provide expertise in areas such as finance, human resources, legal, and communications, as well as ethics, risk and compliance. Our Strategy and Growth function combines corporate strategy, R&D portfolio strategy and business development.

We reached approximately 54 million patients in 2022 through our Global Health function, which focuses on transforming health in low- and middle-income countries.

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# **Our medicines**

Our medicines treat major diseases, from cancer and heart disease to rare genetic disorders, and are distributed in approximately 140 countries around the world.

We focus on five core therapeutic areas with high unmet patient needs:

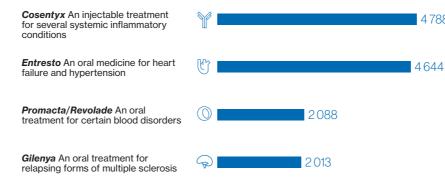
# Cardiovascular Immunology Neuroscience Solid Tumors Hematology

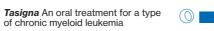
In addition, we have research and in-market programs in **Ophthalmology** and **Respiratory.** 

Through Sandoz, we also offer around 1000 generics and biosimilars in areas ranging from cardiovascular and respiratory illnesses to conditions affecting the central nervous system.

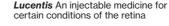
### Top 10 innovative medicines by sales

Brand / 2022 net sales (USD, millions)











# **Tafinlar + Mekinist** An oral combination therapy for certain types of skin, thyroid and lung cancers



**Jakavi** An oral therapy for certain rare blood disorders



**Zolgensma** A one-time intravenous gene therapy for spinal muscular atrophy in babies and young children



Xolair An injectable therapy for certain respiratory and immunological conditions, including severe allergic asthma





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# **Our global operations**

Novartis Group headquarters are in Basel, Switzerland. In addition, we have more than 380 operating sites around the world, including more than 50 production sites worldwide and R&D facilities in the US, Europe and Asia.

Select Novartis facilities (by size of site and/or number of employees)

### **Europe**

### **Switzerland**

### Basel

Global headquarters of Novartis; research and development

### **Stein**

Production of a range of medicines, including gene and cell therapies; production of active pharmaceutical ingredients

### Austria

### **Kundl and Schaftenau**

Production of biotechnological products, drug products and finished products, antiinfectives, active drug substances and nucleic acids; product development

### Germany

### Barleben

Production of a range of generics finished dosage forms

### Holzkirchen

Sandoz Division production of transdermal delivery systems, biosimilars development, and certain international and global service functions

### **Slovenia**

### Menges / Ljubljana

Production of drug substances, drug intermediates and finished product

### **France**

### Huningue

Production of drug substances for clinical and commercial supply

### **North America**

### **USA**

### East Hanover, NJ

Innovative Medicines Division US headquarters; research and development

### Cambridge, MA

Research and development

### Indianapolis, IN

Manufacture of our radioligand therapy *Pluvicto* (expected to be operational from 2023)

### **Durham, NC**

Manufacture of our gene therapy *Zolgensma* 

### Asia

### China

### Shanghai

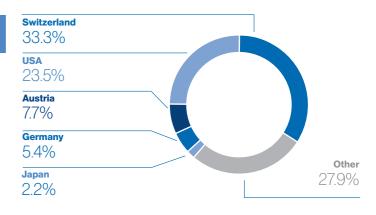
Research and development

### India

### Hyderabad

The largest of our six Novartis Corporate Centers providing services to all Novartis business units

### Our global supply chain (% of total supplier spend)



We work with thousands of external partners worldwide, from suppliers in our R&D organization to wholesalers and distributors who ensure our medicines reach patients. Where possible, we maintain multiple supply sources so that our business is not dependent on a single or limited number of suppliers.

Our suppliers are required to comply with applicable regulations, as well as Novartis standards for quality, ethical business practices and environmental sustainability. See page 43 for more information.

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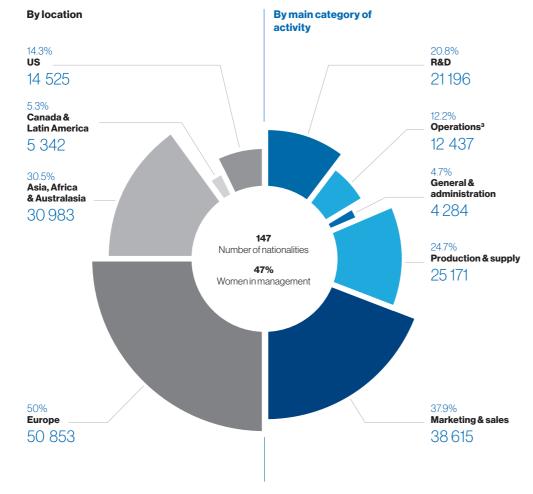
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# Our people, culture and values

The greatest strength of Novartis is our people, whose diversity, energy and creativity are crucial to our success. Around the world, we employ 105 533 people<sup>1</sup>. Approximately one-fifth of our employees work in R&D.

### Novartis employees<sup>2</sup>



<sup>1 101 703</sup> full-time equivalent positions (FTEs)

### Our Values and Behaviors underpin our culture

We encourage Novartis employees to be **inspired**, **curious** and **unbossed** and to act always with **integrity**.

### Inspired

Engage our people Strive for patients Live our purpose

### **Curious**

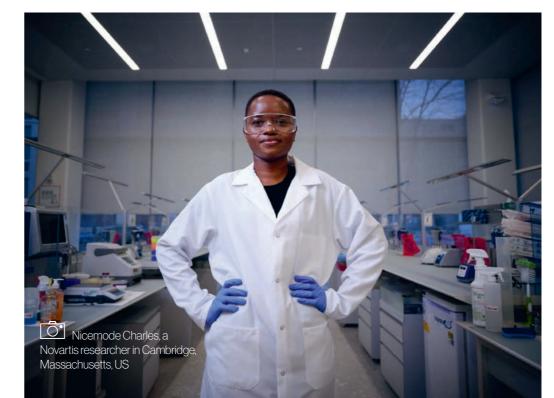
Learn
Be open
Be self-aware

### **Unbossed**

Create clarity
Serve others
Own your actions

### Integrity

Be honest Have courage Do what is right



<sup>&</sup>lt;sup>2</sup> Chart refers to FTE:

<sup>&</sup>lt;sup>3</sup> Relates to FTEs from our Operations unit, excluding production and supply FTEs which are shown separately

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# **Our business environment**

Medical technology continues to accelerate, as advanced new treatments emerge to meet the growing demand for high-quality healthcare. At the same time, aging populations are putting pressure on healthcare resources and access to healthcare remains a challenge around the world. Here are 10 major trends currently shaping our business environment.

### Spending on healthcare continues to grow

The need for high-quality healthcare is more critical than ever. Globally, people live for an average of 10 years with a disease or disability, and around 1.7 billion disability-adjusted life years are lost annually to ill-health and early death. Over the next five years, global spending on medicines is forecast to rise faster than GDP in many developed countries. The price of medicines remains a key issue as increased healthcare spending and a more uncertain economic outlook weigh on government budgets.

### Aging populations are fueling a rise in chronic illness

Increased longevity is one of the triumphs of modern medicine. By 2050, the UN expects there will be 1.5 billion people over the age of 65, double the current number. Aging and lifestyle changes are triggering an increase in non-communicable diseases (NCDs), such as cancer, heart disease and diabetes, causing millions of preventable deaths and putting further pressure on healthcare resources.

### Medical science continues to accelerate

Scientific innovation is advancing at an unprecedented rate. In recent years, new types of medicines have been approved, including RNA therapies, gene and cell therapies, and radioligand therapies, which offer targeted approaches to treating serious diseases. Because these medicines are complex, they require focused investment and expertise to bring them to reality for patients.

### Access to healthcare remains a formidable challenge

Worldwide, millions of patients struggle to access the medicines they need. This may be because of cost, inequity, or structural issues in healthcare systems. While access to medicines remains an acute issue in lower-income countries, it is a problem in developed countries too, where the pandemic highlighted that deep health inequities remain entrenched. As medical science advances so should access to medicines.

### Patients are moving to the center of healthcare

Patients are demanding more say over their treatment through patient representative groups and other means. In response, healthcare systems and pharmaceutical companies are moving toward a more integrated, end-to-end approach, with an increased focus on patient engagement in drug development and other areas. At the same time, patients are becoming more important as data owners - as personal data enables more targeted treatments and supports the development of new medicines.

# 3-6%

### Global healthcare spending

Over the next five years, spending on medicines globally is forecast to rise by 3–6%, growing faster than GDP in many developed countries. (IQVIA Institute, The Global Use of Medicines 2022)

76%

### Deaths from NCDs

Globally, NCDs accounted for 75.6% of all deaths in 2019, up from 60.8% in 2000. (World Health Organization, World Health Statistics 2022)

10-20

### US gene therapy approvals

By 2025, the US Food & Drug Administration (FDA) expects to be approving 10-20 gene and cell therapies annually. (FDA statement, 2019) 2bn

### People lacking access to essential medicines

Five billion people worldwide have access to medicines, leaving an estimated two billion without. (Access to Medicine Foundation, 2022) 78

### **Patient organizations**

Membership of the European Patients' Forum (EPF), an umbrella body of patient organizations across Europe, rose to 78 in 2022 from 13 in 2003. (EPF Annual Report 2020) CEO's letter

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### Our business environment (continued)

### Economic uncertainty is growing, post-pandemic

The global economy is facing considerable uncertainty, driven by concerns over rising prices and geopolitical instability. Forecasts suggest the current economic slowdown is likely to continue in 2023. In our own industry, COVID-19 put strain on supply chains and highlighted the importance of resilient supplies of active pharmaceutical ingredients (APIs) – the raw materials used to make finished medicines.

### Biopharma searches for more efficiency

At a time of growing economic uncertainty, investors are looking for sustainable growth in margins and earnings. To remain competitive, pharmaceutical companies are moving to more agile, efficient business models, particularly as they invest to build specialized capabilities in R&D and manufacturing. Meanwhile, rates of return on R&D are increasing for the first time in several years, largely because of emergency approvals during the COVID-19 crisis and faster innovation cycles.

### New technologies are reshaping our industry

The use of data science and technology is increasing across our industry in everything from R&D to manufacturing and marketing. While this has brought greater efficiency, it also requires new investment and skills. Importantly, new technologies are helping to close gaps between companies, healthcare systems and patients – for example, by providing insights into the social determinants of heart health, which are enabling the development of new prevention measures.

### Working practices are changing

Working practices are changing in many countries. Demand for new skills is increasing, especially in areas such as data science. Workforces are becoming more flexible and more diverse. This allows companies to tap into new talent pools, which is important at a time of skills shortages in many parts of the economy.

# Climate change is increasingly affecting human health

Extreme temperatures and poor air quality are changing patterns of both infectious diseases and NCDs, including malaria and respiratory illnesses. Ultimately, climate change could undermine decades of progress in improving human health at a time when antimicrobial resistance is also rising. At the same time, more governments are looking to decarbonize their economies over the long-term, while companies also face increased scrutiny over the sustainability of their operations and supply chains.

# 2.9%

### Expected global GDP growth

Global GDP growth is forecast to slow to 2.9% in 2023.
Growth in some of the world's most advanced economies is expected to be lower.
(International Monetary Fund—World Economic Outlook, 2022)

45%

### Increased spending on R&D

Spending on R&D by large pharmaceutical companies increased by nearly 45% between 2016 and 2021. (IQVIA, Global Trends in R&D 2022)

## 410 bn

### Added value in healthcare (USD)

Technology-driven innovation in healthcare could create up to USD 410 billion in added value every year by 2025. (McKinsey, The era of exponential improvement in healthcare, 2019)

76%

### Employees valuing diversity

76% of job seekers and employees believe that a diverse workforce is an important factor when evaluating job offers, and nearly a third (32%) would not apply to a company that lacks diversity. (Glassdoor, 2020)

250 000

### Additional deaths

and Health, 2021)

Between 2030 and 2050, climate change is expected to cause approximately 250 000 additional deaths per year due to malnutrition, malaria, diarrhea and heat stress.

(WHO, Climate Change

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# **Our material issues**

Through our materiality assessment, we identify issues where we have the most potential to create value for stakeholders and society.

Every four years, we conduct a detailed assessment to identify our material issues. Results from this assessment inform our strategy and ESG reporting. The assessment sits alongside our regular risk analysis (see page 68).

Our latest assessment, conducted in 2021, was based on a survey of more than 500 external and 12 000 internal stakeholders. Respondents were asked to rank the impact of Novartis across eight impact clusters. Follow-up interviews were conducted with 140 respondents. The results of this exercise can be seen in the chart on the right.

External stakeholders were drawn from our main stakeholder groups, including patients, customers, partners and shareholders. Internal stakeholders, including senior management, were drawn from across business divisions and functions.

Overall, these results were in line with the previous assessment carried out in 2017 and were consistent across stakeholder groups. Patient safety, access to healthcare, innovation and ethical business practices also ranked highly in our previous survey.

### **Ranking of impact clusters**

External / internal stakeholders



### Patient health and safety $\rightarrow p.43$

Patient health and safety is fundamental to our business. Our activities are focused on three key areas: product quality, pharmacovigilance and combating falsified medicines.

### 2 Access to healthcare $\rightarrow p.54$

Access to medicines is one of the world's greatest healthcare challenges. We have well-defined access principles, covering research and development, affordability and strengthening healthcare systems.

### 3 Innovation $\rightarrow$ p. 31

We are working to reduce the burden of disease for patients and society. We discover and develop new medicines, with a focus on unmet patient needs across five core therapeutic areas.

### 4 Ethical business practices $\rightarrow p.60$

Our stakeholders expect us to uphold high ethical standards throughout our business, from R&D and manufacturing to supply chain management and our commercial operations.

### **People and culture** $\rightarrow$ p. 48

We have a strong culture based on defined values and behaviors. This drives performance and innovation, and ensures we attract and retain the talent we need to deliver on our purpose.

### **Good governance** $\rightarrow$ p. 62

Good governance is about how we take decisions and allocate resources. It supports effective management of our business and forms the basis of trust in our company.

### Sustainable financial performance $\rightarrow p.25$

Maintaining our financial performance enables us to deliver returns to shareholders and invest in areas where we believe we can create the most value for stakeholders and society.

### 8 Environmental sustainability → p.44

Environmental sustainability is an essential part of our strategy and business model. We aim to limit our impact on the environment by reducing emissions, waste and consumption of natural resources, including water.

### For full details of our materiality assessment, please see

www.novartis.com/materiality

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# Strategy and value creation

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Marta Cortes-Cros, director of a radioligand therapy research site at Novartis headquarters in Basel, Switzerland.

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# **Our strategy**

Our strategy as a focused medicines company is to deliver high-value medicines that alleviate society's greatest disease burdens through technology leadership in R&D and novel access approaches.

We have made significant progress in transforming Novartis from a diversified healthcare conglomerate into a focused medicines company. In doing so, we have divested or spun off non-core businesses and made targeted acquisitions to focus on our core business: discovering and developing new medicines and finding new ways to deliver them to as many people as possible.

In 2022, we continued to execute on our strategy by putting in place a new organizational structure to support innovation, growth and productivity. We also updated our strategic priorities and announced our intention to spin off our Sandoz Division, which paves the way for Novartis to advance as a company focused fully on innovative medicines.

Our focus areas determine where we invest most of our time, energy and resources.

Our focus areas are supported by our **strategic priorities**, which determine how we implement our strategy.

Core therapeutic areas with high unmet patient needs: cardiovascular; immunology; neuroscience; solid tumors; and hematology.

**Technology platforms** where we have the depth and scale to discover, develop and commercialize new therapies: chemistry; biotherapeutics; RNA therapy; radioligand therapy; and gene and cell therapy.

Priority geographies that together account for the majority of expected growth in global healthcare spending: US, Germany, China and Japan. We aim to be a top-five player in the US by 2027. While these are our priority countries, we maintain a continued presence in other markets worldwide.



**Deliver high-value medicines** to accelerate growth



Embed operational excellence to deliver returns

### **Strengthen our foundations:**

Unleash the power of our people



- Scale data science and technology
- Build trust with society

### Our five-year targets

Through our strategy, we aim to deliver on our purpose and create value for our shareholders and society.

### **Innovation power**

Top three in bringing high-value medicines to market

### Growth

Sales growth of 4% CAGR

### Returns

Low 40s IM margin; industry top-quartile for total shareholder return (TSR)

### **ESG**

Sector leader in material ESG factors

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This page highlights how our strategic priorities address our material impact clusters and link to ESG targets. This ensures our strategy is closely aligned with our goal of long-term value creation.

### **Material impact** clusters

### **Relevant ESG targets**

### **Deliver high-value medicines**

Delivering new medicines is at the core of our purpose and value creation as a company. We focus on innovative medicines with the potential to transform the treatment of diseases across five core therapeutic areas. To do this, we seek to maximize the value of our key in-market and launch medicines, while finding new ways to deliver them to as many people as possible and investing in R&D to deliver the next generation of therapies for patients. As part of our efforts, we continue our longstanding commitment to reduce the burden of infectious and tropical diseases that predominantly affect underserved populations in LMICs.

### Innovation Access

- Invest USD 250m to advance R&D for NTDs and malaria (over 5 years from 2021-2025)
- · Implement a global access strategy for all new medicines launched



### **Embed operational excellence**

We aim to drive efficiency and free up resources to invest in innovation for patients. This also underpins our financial performance and makes us more agile - better able to take quick decisions and scale the use of new technologies - with effective cooperation across our business. In everything we do, we maintain high standards of product quality and patient safety, while also working to reduce our environmental footprint.

### **Patient health** and safety

Sustainable financial performance

Ethical business practices

**Environmental** sustainability

- Conduct risk assessments for all new eligible suppliers
- Become carbon neutral in our own operations (Scope 1 and 2) by 2025<sup>1</sup>
- Include environmental criteria in all supplier contracts by 2025
- Become carbon neutral (Scope 1, 2 and 3) by 2030 and achieve net zero carbon emissions across our value chain by 20402
- Reduce water consumption in our own operations by half by 2025<sup>3</sup>
- No water quality impacts from manufacturing effluents by 2025
- Become water neutral in our own operations by 2030<sup>4</sup>
- Enhance water quality wherever we operate by 2030
- Eliminate polyvinyl chloride (PVC) in packaging by 2025<sup>5</sup>
- Reduce the amount of waste sent for disposal by half by 2025<sup>3</sup>
- Become plastic neutral by 2030 <sup>6</sup>
- All new products meet sustainable design principles by 2030



### **Strengthen our foundations**

Unleash the power of our people: We continue to focus on culture as a key enabler of our strategy to drive innovation and long-term performance. For us, this is about building an agile, diverse workforce and making sure we attract and retain the right talent for the future.

Scale data science and technology: We are investing in data science and technology to increase efficiency, support innovation, better respond to the needs of patients and physicians, and ultimately improve the way we develop and deliver our medicines.

Build trust with society: We aim to increase access to our medicines for underserved populations around the world and follow high standards of ethical behavior wherever we operate.

### Access

People and culture

**Ethical business** practices

Good governance

- Implement a global access strategy for all new medicines launched
- Increase by at least 200% patients reached with strategic innovative medicines in LMICs7 by 2025 (compared with 2019)
- Increase by at least 50% the number of patients reached with Novartis global health flagship programs<sup>8</sup> in LMICs<sup>7</sup> by 2025 (compared with 2019)
- Close the gender pay gap by 2023
- Achieve gender balance in management by 2023
- Remove bias from the system by eliminating the use of historical salary data bv 2023
- Create pay transparency for employees by 2023

<sup>1</sup> Scope 1 and Scope 2 from energy

<sup>&</sup>lt;sup>2</sup> In accordance with SBTi net-zero standard

<sup>3</sup> Vs. 2016 baseline performance

<sup>4</sup> All Novartis sites to reduce water consumption in all areas and be water neutral in water-stressed regions by not depleting local water reserves. Water-stressed regions are determined using WWF water risk filter

<sup>&</sup>lt;sup>5</sup> From Novartis owned and operated sites. Defined as secondary and tertiary packaging; primary packaging when feasible

<sup>6</sup> Plastic neutral defined as weight of plastic packaging entering the environment for disposal is approximately the same as weight being recovered for recycling

<sup>&</sup>lt;sup>7</sup> Low- and middle-income countries as defined in sustainability-linked bond prospectus

<sup>8</sup> Malaria, leprosy, Chagas disease, sickle cell disease

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### Transforming and focusing our company

We have evolved from being a diversified healthcare conglomerate to a focused, innovative medicines company. Announced in April 2022, our new organizational structure aligns the way we operate with this strategy.

The changes – part of our Transforming for Growth initiative – are designed to power our next phase of innovation, growth and productivity. We aim to drive shareholder returns by sharpening our focus on our core business, becoming more agile and efficient, and creating the conditions for growth in our priority markets. The new structure became fully operational in January 2023. Please see page 42 for further details.

In August 2022, we also announced plans to spin off 100% of our Sandoz Division, which we expect to be complete by the second half of 2023. The spin-off will create Europe's leading producer of generics and a global leader in biosimilars and allow us to concentrate fully on our core business. Spinning off Sandoz is in the best interests of our shareholders as it would create two standalone companies focused on their respective growth strategies.

Completion of the transaction is subject to certain conditions, including consultation with works councils and employee representatives (as required), general market conditions, tax rulings and opinions, final Board of Directors endorsement and shareholder approval in line with Swiss corporate law. The transaction is expected to be tax neutral to Novartis.

2023

### Sandoz spin-off

We expect the planned spin-off to be completed by the second half of 2023.



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# How we create value

Through our core business, we improve and extend the lives of millions of people around the world, while creating value for our employees, shareholders and the communities in which we operate.



10.0 bn Invested in R&D (USD)

Core therapeutic areas (cardiovascular: immunology; neuroscience; solid tumors; hematology)

Key technology platforms (chemistry: biotherapeutics: RNA therapy; radioligand therapy; gene & cell therapy)

**Ongoing Phase** III programs

Approvals in the US, EU. Japan and China

Novartis is a focused medicines company. More than three quarters of our sales comes from innovative medicines.

We use innovative science to address some of society's most challenging healthcare issues.

We invest in advanced technology platforms, like radioligand therapy, which offer targeted approaches to fighting disease.

New medicines undergo clinical trials to prove they are safe and effective. Not all succeed. Those that do are submitted to regulators for approval.

# 54.6 m

Patients reached through access approaches

Priority geographies (US, Germany, Japan and China)

50.5 bn Net sales (USD)



Reduction in greenhouse gas emissions in our own operations compared with 2016 baseline

0.16 Lost-time injury and illness rate (Novartis employees)

72.5 bn 101703 **Employees** Treatments (FTEs) produced

Novartis has more than 380 sites worldwide.

including more than 50

manufacturing facilities

### **Access for patients**

Through our access strategies, we aim to bring our medicines to patients across the income pyramid.

We sell our medicines primarily to wholesale and retail distributors, hospitals, government agencies and managed healthcare providers.

Before launching new products, we engage with health systems, patients and other stakeholders to understand their needs.

We not only discover and develop new medicines, but also find new ways to deliver them to as many people as possible.

### Operations and supply chain

Across our business. we are streamlining and digitizing our operations to improve efficiency and We apply high quality standards to produce safe and effective medicines, while working to keep our people safe and reduce our environmental footprint.

accelerate growth.



Patients reached with Novartis medicines (236 m through Innovative Medicines, 453 m through Sandoz and 54 m through our Global Health function)

7.5 bn

Paid in dividends to shareholders (USD) 2.0 bn

Total income taxes paid (USD)

### Social, financial & economic value

Novartis medicines improve and extend the lives of millions of people around the world.

We generate financial returns for shareholders, provide salaries and other benefits for employees and create economic value through the taxes we pay and our relationships with suppliers and partners worldwide.

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# Stakeholder engagement

To implement our strategy, we work with individuals and groups who are important to our business. Engaging these stakeholders helps us to understand their needs and expectations, and work together toward common goals.

The table below shows a summary of why and how we engage with our main stakeholder groups and the main issues discussed.

	Patients and caregivers	Customers	Employees	Shareholders and investors	Partners	Policymakers and regulators
Objectives	Identify unmet patient needs; ensure the long-term safety of our medicines; recognize patient perspectives and embed them into our decision-making in a consistent and systematic way.	Explain the benefits and risks of our medicines; understand customer expectations and constraints on pricing and distribution; ensure a reliable supply of our medicines to patients.	Continue to attract, develop and retain employees; develop new skills across the company; promote a corporate culture based on our values and behaviors; ensure a safe and healthy working environment.	Explain our strategy, performance and governance to shareholders and potential investors; ensure continued access to international capital markets for Novartis.	Work with external researchers, partners and organizations to discover and develop new medicines; secure supplies we need for our business; improve access to medicines and support business growth.	Maintain constructive dialogue with regulators; provide data on patient out- comes; ensure our views and interests are represented on issues affecting our industry.
Approach	Dedicated patient engage- ment teams; partner with patient organizations to address unmet needs; co-design clinical trials.	Personalized contact with physicians through face-to-face visits and dedicated online platforms; scientific and medical congresses; discussions with healthcare systems on reimbursement and access to medicines.	Townhalls and events; quarterly surveys to measure engagement and other aspects of our culture; health and well-being offerings; regular evaluation, training, and feedback.	Meetings with portfolio managers, stewardship teams and analysts; quarterly updates; press releases and disclosures; roadshows and presenta- tions; continued focus on our largest 100 shareholders, who together represent 60% of our ownership.	Network of alliances with industry, academia and non-governmental organizations; regular third-party risk assessments; face-to-face meetings and industry conferences.	Dedicated public affairs teams; working with industry associations; meetings with regulators, governments, and other policymakers.
Main issues discussed	Elevating the voice of patients in healthcare systems; including patient perspectives in the lifecycle of our medicines to improve health outcomes.	Sharing results from our clinical trials; efforts to optimize disease management; innovative contract structures such as outcome-based agreements; collaborations to improve patient access.	Employee engagement; explaining our new organizational model; updates to our corporate strategy.	Financial and operational performance; updates on our strategy; R&D pipeline progress; the healthcare policy environment; ESG strategy and progress.	R&D partnering across our therapeutic areas and technology platforms; business development and licensing opportunities; standards on quality, ethics, environmental management and human rights in our supply chain.	Advocacy supporting value-based healthcare; measures to support innovation in the life sciences; constraints on healthcare spending; our therapeutic areas and expanding access to our medicines.

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### **Patient engagement**

Novartis has a longstanding commitment to respect and understand the perspective of patients throughout our business to ensure we meet their most critical needs.

Research shows that effective patient engagement leads to faster enrolment in clinical trials, increased patient retention and more efficient trial design – helping to streamline R&D and bring medicines to patients faster. Embedding patient insights into our commercial activities also leads to more successful launches and better patient adherence to treatments.

We have developed a five-point framework (see infographic below) to gather input – from early research through to post-launch – and we are making progress in consistently and systematically embedding patient insights into these key milestones. For example, in 2022 we obtained patient input in 87% of our early research programs and 37% of our clinical development programs (compared with 84% and 30%, respectively, in 2021).

The broader industry is also moving to a more patient-centric model of healthcare, as companies and healthcare systems recognize the benefits of patient engagement and patients demand a greater say in their treatment. Healthcare regulators in the US, Europe and other countries recently issued guidelines on patient engagement, including recommendations on co-designing clinical trial endpoints with patients. See page 37 for more information on our approach to clinical trials.

Of Novartis research programs include insights collected directly from patients and their representatives

O Diana Wong Ramos (right), a stroke survivor and patient advocate in Lisbon, Portugal, has her blood pressure checked during a regular rehabilitation session

### Five key milestones for patient engagement





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# **Measuring our impact**

Our business positively impacts society in various ways. By delivering high-value medicines, for example, we improve and extend people's lives. At the same time, our activities may have negative effects, which is why we strive to reduce our environmental footprint, uphold safety standards and protect human rights in our value chain.

Novartis supports the development of emerging methodologies and standards to measure the impact of companies on society and the environment. We focus on two areas: impact valuation and assessing our contribution to the UN Sustainable Development Goals (SDGs).

### **SDGs**

In 2022, we took part in a pilot project with the United Nations Environment Program Finance Initiative (UNEP FI) to assess our activities against social and environmental impact areas.

The analysis is based on our industry sector as well as information about our main countries by sales, production and supplier spend. It uses country-level proxy data to identify potential positive and negative impact areas that connect to the SDGs. We publish the results for information purposes only.

The results show a significant positive association with "health and sanitation" – which connects to SDG 3 – through the impact of our medicines on human health. UNEP FI defines a significant impact area

as one where there is a strong correlation with a company's business, its sector and the countries in which it operates. Please see page 34 for further information about our contribution to SDG3. The analysis also showed a moderate positive impact on employment and the economy due to wages, benefits and employee development.

As a company with a global manufacturing network and supply chain, we have a potential moderate negative impact on natural resources including climate, air and water. We also have a potential moderate negative impact on employment due to risks associated with occupational safety. Minimizing our impact on the environment and ensuring a safe working environment are key parts of our strategy and operating model. See pages 46 and 51 for more details.

### **Impact valuation**

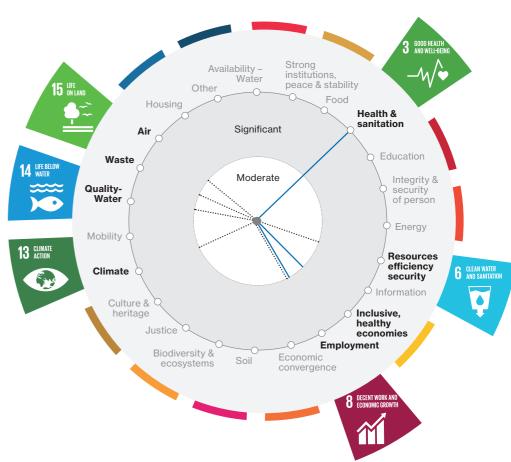
Novartis is a founding member of the Value Balancing Alliance (VBA), a non-profit organization that aims to create a standard for measuring the value companies provide to society.

Based on VBA methodology, we are pioneering an approach called social, environmental and economic (SEE) impact valuation, which aims to show the positive impact we bring to countries, health systems and individuals, balanced by the negative impact of our operations on the environment and other areas. Expressing these impacts in monetary terms makes them transparent and comparable. Please see our corporate website for more information.

### Our impact on the SDGs

Bold text in the infographic denotes areas of impact for Novartis. Our significant potential positive impact is on SDG 3 (good health and well-being). Note that impact areas and their connection to the SDGs are defined by UNEP FI.

Positive ······ Negative



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# Financial performance

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50.5 bn

Net sales (USD)

Compared with USD 51.6 billion in 2021

9.2 bn

Operating income (USD)

Compared with USD 11.7 billion in 2021

7.0 bn

Net income (USD)

Compared with USD 24.0 billion in 2021

16.7 bn

Core operating income (USD)

Compared with USD 16.6 billion in 2021



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### **Group performance**

Novartis maintained its growth momentum in 2022, with Group net sales increasing 4% in constant currencies from the prior year.

 $\rightarrow$  p. 26

### **Innovative Medicines**

The IM Division delivered net sales of USD 41.3 billion in 2022, an increase of 4% (cc) from the prior year.

 $\rightarrow$  p. 27

### Sandoz

Sandoz returned to growth with a 4% (cc) increase in net sales.

 $\rightarrow$  p. 29

Sadiq Walker-Baker, a student at the Morehouse School of Medicine in Atlanta, Goergia, US. Sadiq was one of 17 Beacon of Hope Summer Fellows at the Novartis Institutes for BioMedical Research in 2022. Fellows gain experience in drug discovery, data analytics and clinical research practices.

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### **Financial performance**

Novartis maintained its growth momentum in 2022, supported by increased sales of key products across our core therapeutic areas.

### **Group performance**

Novartis full-year net sales were USD 50.5 billion, up 4% from the prior year when measured in constant currencies (cc) to remove the impact of exchange rate movements, but down 2% when measured in US dollar terms.

Increased sales of key products across our core therapeutic areas continued to underpin our financial performance.

Sales of our heart failure medicine *Entresto* grew 37% (cc) to USD 4.6 billion, driven by sustained growth and increased patient share across all geographies. Sales of our cholesterol-lowering treatment *Leqvio* reached USD 112 million following launch in the US and other countries during 2022.

Cosentyx, our treatment for psoriasis and other autoimmune diseases, also continued to grow. Sales rose 5% (cc) from the prior year to USD 4.8 billion, driven primarily by continued volume growth across key markets.

Kesimpta, a treatment for relapsing multiple sclerosis, reached blockbuster status for the first time, with sales growth driven by launch momentum across all geographies. It registered sales of USD 1.1 billion, up 200% (cc) from the prior year.

Kisqali, a treatment for breast cancer, also reached blockbuster status for the first time with sales growth of 38% (cc) to USD 1.2 billion, driven by double-digit growth across all regions. *Jakavi*, a treatment for blood disorders and cancers, grew 9% (cc) to USD 1.6 billion.

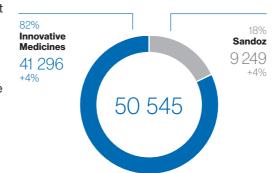
Kesimpta, a treatment for relapsing multiple sclerosis, reached blockbuster status for the first time

Sales of Sandoz biopharmaceuticals continued to perform strongly, with a 9% (cc) increase to USD 2.1 billion. Overall Sandoz Division net sales were USD 9.2 billion, up 4% (cc).

Novartis Group sales in Europe, our largest market, grew 2% (cc). Sales in the US grew by 5%. Sales in emerging growth markets grew 9% (cc), led by a 6% (cc) increase in China.

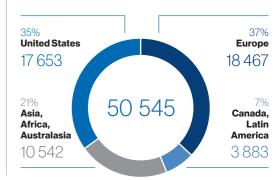
### 2022 net sales by division

(in USD millions, % growth in constant currencies, and divisional share of net sales)



### 2022 net sales by geographical region

(% of net sales and in USD millions)



			9/	6 Change
<b>Key figures</b> <sup>1</sup> (in USD millions, unless indicated otherwise)	2022	2021	USD	Constant currencies
Net sales to third parties	50 545	51 626	- 2	4
Operating income	9 197	11 689	- 21	- 13
% of net sales to third parties	18.2	22.6		
Net income	6 955	24 018	- 71	- 67
Basic earnings per share <sup>2</sup> (USD)	3.19	10.71	- 70	- 66
Core operating income	16 665	16 588	0	8
% of net sales to third parties	33.0	32.1		
Core net income	13 352	14 094	- 5	3
Core earnings per share <sup>2</sup> (USD)	6.12	6.29	- 3	6
Free cash flow	11 945	13 282	- 10	
Share information	2022	2021	% Change	
Share price at year-end (CHF)	83.59	80.28	4	
ADR price at year-end (USD)	90.72	87.47	4	
Dividend <sup>3</sup> (CHF)	3.20	3.10	3	

¹ This Novartis in Society Integrated Report 2022 includes non-IFRS financial measures such as core results, constant currencies and free cash flow. Novartis believes that investor understanding of the Group's performance is enhanced by disclosing these non-IFRS measures. A definition of non-IFRS measures used by Novartis, and further details, including reconciliation tables, can be found in "Item 5. Operating and Financial Review and Prospects" of the Novartis Annual Report 2022.

<sup>&</sup>lt;sup>2</sup> 2022 weighted average number of shares outstanding: 2 181 million (2021: 2 243 million)

<sup>3</sup> Dividend 2022: proposal to shareholders for approval at the Annual General Meeting on March 7, 2023

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Operating income was USD 9.2 billion, down 13% (cc) from the prior year, mainly due to higher restructuring costs related to the implementation of our new organizational model and higher impairments.

Net income was USD 7.0 billion, compared with USD 24.0 billion in the prior year, mainly due to the divestment of our stake in Roche in the prior year. Excluding the Roche impact, net income declined by 9% (cc), mainly due to lower operating income. Earnings per share were USD 3.19 compared with USD 10.71 in the prior year. Excluding the Roche impact, EPS declined by 7% (cc).

To help people understand our underlying performance, we also present our core results, which exclude the impact of amortization, restructurings, acquisitions and other significant items. Core operating income of USD 16.7 billion rose 8% (cc). Core net income of USD 13.4 billion rose 3% (cc). Core earnings per share were USD 6.12, up 6% (cc). Free cash flow of USD 11.9 billion was down 10%, mainly due to a decrease in net cash flows from operating activities and lower divestment proceeds, partly offset by lower purchases of property, plant and equipment.

### **Innovative Medicines**

Our Innovative Medicines Division focuses on our five core therapeutic areas, as well as other promoted brands (in the therapeutic areas of ophthalmology and respiratory) and established brands.

The IM Division delivered net sales of USD 41.3 billion in 2022, an increase of 4% (cc) from the prior year.

Six products with multibillion-dollar sales potential – Cosentyx, Entresto, Zolgensma, Kisqali, Kesimpta and Leqvio – contributed 32% of IM net sales in 2022, up from 26% in 2021

Six products with multibillion-dollar sales potential – *Cosentyx*, *Entresto*, *Zolgensma*, *Kisqali*, *Kesimpta* and *Leqvio* – contributed 32% of IM net sales in 2022, up from 26% in 2021. Core operating income for the IM Division was USD 15.2 billion, up 8% (cc).



### Innovative Medicines 2022 net sales

(in USD millions, % growth in constant currencies, and therapeutic area share of net sales)

76%	Promoted Brands	31 396   +12%	
	Cardiovascular	4 756   +40%	
	Immunology	7 287   +7%	
	Neuroscience	5 051   +5%	
	Solid Tumors	4 723   +21%	41 bn
	Hematology	6 452   +7%	41bn +4%
	Other Promoted Brands	3 127   -1%	
24%	Established Brands	9 900   -13%	

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### Cardiovascular

Sales were USD 4.8 billion, up 40% (cc). The performance was driven by continued strong growth for Entresto, which registered sales of USD 4.6 billion, up 37% (cc), with increased patient share across all geographies.

Legvio, our treatment for high cholesterol, registered sales of USD 112 million in its first year after launch. Legvio is the first and only small interfering RNA (siRNA) therapy to lower low-density lipoprotein cholesterol approved in the US. It is approved in 70 countries. Launch of the product is ongoing, with a focus on patient on-boarding, removing access hurdles and enhancing medical education.



### **Immunology**

Sales reached USD 7.3 billion, up 7% (cc) from the previous year. Cosentyx delivered USD 4.8 billion in sales, up 5% (cc) from the prior year, driven by continued volume growth across key geographies, partly offset by higher US revenue deductions. Since initial approval in 2015. Cosentvx has treated more than 960 000 patients worldwide.

Xolair registered sales of USD 1.4 billion, up 6% (cc). Sales of *llaris* were USD 1.1 billion. up 15 % (cc), with continued growth across all regions.



### **Neuroscience**

Sales were USD 5.1 billion, increasing by 5 % (cc), mainly driven by sales growth of Kesimpta, but partly offset by a decline in sales of Gilenya. Kesimpta showed strong sales growth, up 200 % (cc) to USD 1.1 billion, driven by launch momentum across all geographies. It is now approved in 80 countries with more than 36 000 patients treated. Sales of Zolgensma grew 5 % (cc) to USD 1.4 billion.

Gilenva sales were USD 2.0 billion, declining 24 % (cc) from the prior year, mainly due to generic pressure in the US and Europe.



### **Solid Tumors**

Sales were USD 4.7 billion, up 21% (cc) from the prior year. Tafinlar + Mekinist grew 11% (cc) to USD 1.8 billion, with growth across all geographies. The combination therapy remains the worldwide targeted therapy leader in BRAF+ melanoma.

Sales of *Kisgali* grew strongly across all geographies based on increasing recognition of its overall survival and quality of life benefits in HR+/ HFR2advanced breast cancer

Sales of Kisgali grew 38% (cc) to USD 1.2 billion, growing strongly across all geographies based on increasing recognition of its overall survival and quality of life benefits in HR+/ HER2- advanced breast cancer, the most common subtype of breast cancer. Pigray sales grew 14% (cc) to USD 373 million, with a strong performance in the US, benefiting from indication expansion into PIK-3CA-related overgrowth spectrum.

Sales of *Pluvicto* were USD 271 million as launch in the US in 2022 progressed well. Pluvicto is the first and only radioligand therapy approved by the FDA for the treatment of progressive, PSMA-positive metastatic castration-resistant prostate cancer.



### Hematology

Sales were USD 6.5 billion, up 7% (cc) from the prior year. *Promacta*, which is known as Revolade outside the US, grew 9% (cc) to USD 2.1 billion, driven by increased use in secondline persistent and chronic immune thrombocytopenia and as a first-line and/or second-line treatment for severe aplastic anemia.

Scemblix continued its strong launch uptake with sales of USD 149 million, demonstrating the high unmet need in chronic myeloid leukemia. Jakavi registered sales of USD 1.6 billion, up 9% (cc) from the previous year, driven by strong demand in the myelofibrosis and polycythemia vera indications.

Scemblix continued its strong launch uptake, demonstrating the high unmet need in chronic myeloid leukemia

### **Other Promoted Brands**

Sales were USD 3.1 billion, declining by 1% (cc) from the previous year due to competition for our respiratory and ophthalmology portfolios. Lucentis sales declined 4% (cc) to USD 1.9 billion, mainly in Japan and Europe, due to biosimilar launches, Xiidra sales were USD 487 million, up 4% (cc) from the prior year. Beovu sales grew 18% (cc) to USD 203 million.

Ultibro Group sales declined by 9% (cc) to USD 479 million, mainly in Europe and Emerging Growth Markets, due to competition. Ultibro Group consists of Ultibro Breezhaler, Seebri Breezhaler and Onbrez Breezhaler.

### **Established Brands**

Sales were USD 9.9 billion, down 13% (cc) from the previous year, as sales of established medicines such as Afinitor and Glivec declined due to generic competition.

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### Sandoz

The Sandoz Division is a global leader in generic pharmaceuticals and biosimilars, and sells products in well over 100 countries. The division has three global franchises: Retail Generics, Biopharmaceuticals and Anti-Infectives.

Sandoz returned to growth in 2022, with a 4% (cc) increase in net sales from the previous year to USD 9.2 billion.

# Sandoz returned to growth in 2022, with a 4% (cc) increase in net sales from the previous year

In Retail Generics, Sandoz develops, manufactures and markets finished dosage forms of small molecule pharmaceuticals for sale to third parties across a broad range of therapeutic areas, including finished dosage forms of anti-infectives sold to third parties. Sales in the franchise were USD 6.8 billion, up 4% (cc) from the prior year, growing across all regions apart from the US.

Sales in the Biopharmaceuticals franchise grew 9% (cc) to USD 2.1 billion, driven by growth across all geographies. Sandoz develops, manufactures and markets protein- and other biotechnology-based products, including biosimilars, and provides biotechnology manufacturing services to other companies.

# Sales in the Biopharmaceuticals franchise grew 9% (cc), driven by growth across all geographies

In Anti-Infectives, Sandoz manufactures and supplies active pharmaceutical ingredients and intermediates, mainly antibiotics, for use by the Retail Generics franchise and for sale to third-party customers. Total franchise sales to third parties were USD 380 million, a decrease of 5% (cc) from the prior year, mainly due to product discontinuations and supply challenges.



### Sandoz 2022 net sales by franchise

(in USD millions, % growth in constant currencies, and franchise share of net sales)

73%	Retail Generics	6776   +4%	
23%	Biopharmaceuticals	2 093   +9%	
4%	Anti-Infectives (contract manufacturing)	380   -5%	9.2 bn +4%

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# Deliver high-value medicines

### 2022 highlights

10.0 bn

Invested in R&D (USD)

comprising approximately 19.8% of our net sales

44

Ongoing Phase III programs

in our development pipeline

24

### **Submissions**

in the US, the EU, Japan and China for new treatments as well as new indications for existing treatments 23

### **Approvals**

in the US, the EU, Japan and China



### In this section

### Bringing our medicines to patients

We seek to maximize the value of our key in-market and launch medicines, while investing in R&D to deliver the next generation of therapies for patients.

 $\rightarrow$  p.31

### Research and development

From the inception of a potential therapeutic through to clinical development and launch, our teams collaborate in support of our purpose to improve and extend people's lives.

 $\rightarrow$  p. 35

### Our approach to clinical trials

Clinical trials help determine whether our investigational medicines are effective and safe before they are approved by regulatory authorities for general use in patients.

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### Key assets in our R&D pipeline

We provide an update on select R&D programs across our core therapeutic areas as well as select programs linked to our global health priorities.

 $\rightarrow$  p. 39

Van Lacour received a Novartis radioligand therapy, *Pluvicto*, for advanced prostate cancer as part of a managed access program in 2021. Today, he is living a fulfilling life in his hometown of Natchez, Louisiana, in the US, where he enjoys taking photographs and listening to his collection of old records.

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### **Deliver high-value medicines**

Millions of people around the world live with serious diseases that cause early death and disability and place an enormous burden on healthcare systems. At Novartis, we are dedicated to discovering and developing new treatments for diseases including cancer, heart disease and neurological conditions – and delivering them at scale to reach as many patients as possible.

Delivering new medicines is at the core of our purpose and value creation as a company: we are in the business of improving and extending people's lives and helping governments shape healthier societies.

Improving human health is more critical than ever. Globally, people live for an average of 10 years with a disease or disability. Chronic conditions make up an increasing share of the disease burden as populations age, with cardiovascular disease and cancer together responsible for 28 million deaths annually.

We use a variety of scientific tools to meet this challenge. Medical science is advancing at an unprecedented rate and new types of treatments are coming to the fore, including RNA therapies, gene and cell therapies, and radioligand therapies that offer targeted approaches to treating serious diseases.

In 2022, Novartis continued to deliver highvalue medicines to patients. We received 23 approvals in the US, EU, China and Japan, including a novel radioligand therapy for advanced prostate cancer in the US and EU. We advanced our focused pipeline of investigational medicines, with several clinical data readouts paving the way for further launches in 2023 and beyond.

However, we also had disappointments as some clinical trials of investigational compounds – including ACZ885 (canakinumab) for lung cancer and UNR844 for presbyopia – did not meet their primary goals.

### **Bringing our medicines to patients**

We focus on high-value innovative medicines with the potential to transform the treatment of diseases across our five core therapeutic areas where we have a leadership position and where there are high unmet patient needs.

To do this, we seek to maximize the value of our key in-market and launch medicines, while investing in R&D over the longer term to deliver the next generation of therapies for patients. We follow an integrated, end-to-end approach across the drug development continuum – from early research through development, launch and

patient access – with close collaboration between our R&D, manufacturing and commercial teams to broaden the reach and impact of our medicines.

We also focus our activities on key markets that represent the majority of the expected growth in healthcare spending over the next several years. Foremost among these is the US, the world's largest healthcare market, where we aim to be a top-five player by 2027.

Across our key products and markets, we pursue effective life-cycle management and launch excellence to maximize the commercial potential of our medicines and broaden access for patients in line with the Novartis Access Principles (see page 54). This involves investing earlier in pre-launch preparation and working systematically to

### Related links and disclosures

- → Novartis Pipeline
- → Position on Responsible Clinical Trials
- → Commitment to Patients and Caregivers
- → Commitment to Diversity in Clinical Trials
- → Clinical Study Transparency
- → Position on Post-Trial Access

meet the needs of healthcare professionals and patients, including by reducing time to diagnosis and working with healthcare systems to find solutions that improve the health of entire populations.

2

### Deliver high-value medicines performance indicators 1 2021 2022 2020 Projects entering development pipeline<sup>2</sup> 5 6 44 54 Ongoing Phase III programs<sup>3</sup> 44 3 2 US FDA breakthrough therapy designations 4 1 34 13 Major submissions (US, EU, JP, China) 5 24 23 21 26 Major approvals (US, EU, JP, China)

1 Includes Innovative Medicines and Sandoz biosimilars only

New molecular entity (NME) approvals 6

- <sup>2</sup> Includes projects having achieved first patient, first visit (FPFV) in confirmatory development (incl. projects entering confirmatory development from an acquisition or in-licensing). Figures shown for the year 2021 and 2020 consider projects applying the former methodology, i.e. projects entering confirmatory development from internal R&D activities. FPFV has occurred in post-proof-of-concept stage after NIBR.
- 3 Includes projects with FPFV in a Phase III study but not yet filed in the US, EU, Japan or China
- <sup>4</sup> Number of breakthrough therapy designations granted by the US Food and Drug Administration for therapies under development by Novartis
- <sup>5</sup> Includes small molecules or biologics; new fixed-dose combinations of existing APIs; and new target indications, defined as new disease or new line of treatment (e.g., first line vs. second line)
- <sup>6</sup> Includes NMEs such as small molecules, biologics; in the EU, new fixed-dose combinations of existing APIs

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In each of our core therapeutic areas, we have key products that together we expect to contribute more than two-thirds of our growth in the next five years.



### Cardiovascular

Key products: Entresto, Leqvio

Cardiovascular disease (CVD), which includes chronic conditions affecting the heart and blood vessels such as heart failure, heart attacks and strokes, is the world's leading cause of death and one of society's biggest health concerns. More people die every year from heart attacks and strokes than died from COVID-19 during the recent pandemic. Many of these deaths are preventable through management of risk factors including high cholesterol. The total global cost of CVD is set to rise to more than USD 1 trillion by 2030.

Our cardiovascular portfolio comprises therapies to treat heart failure and reduce low-density lipoprotein (LDL) cholesterol (also known as 'bad cholesterol'), a key contributor to the build-up of fat deposits in arteries (atherosclerosis). We are also working systematically to meet the needs of health systems and patients through innovative access approaches, such as population health agreements, that work in tandem with our medicines to reduce the impact of CVD equitably and at scale.

Our cholesterol-lowering treatment *Leqvio* has now been approved for use in 70 countries worldwide. *Leqvio* is a subcutaneous injection given by a healthcare provider every six months (after an initial dose and one at three months). In conjunction with a healthy diet and statins, *Leqvio* may help those who have difficulty sticking to medicines that are self-administered and have greater dosing frequency.

The launch of *Leqvio* in the US and other markets is ongoing, with a focus on patient on-boarding, removing access hurdles and enhancing medical education. In the US, we continue to see steady progress in expanding access to *Leqvio*. After securing coverage from key payers, the medicine is covered at or near label for 76% of patients around one year after launch. In addition, 67% of patients pay out-of-pocket expense of less than USD 10.

We are advancing our partnership with the National Health Service (NHS) in England focused on people who have had a cardiovascular event and have high LDL cholesterol. The aim is to help doctors to identify and treat 300 000 people over three years. In 2022, as part of our collaboration, we secured access for *Leqvio* in nearly all local care formularies, developed tools to more easily identify patients not being optimized, and helped the NHS improve overall cholesterol management in primary care.



### Addressing the factors behind heart disease in the US

Almost a quarter of deaths in the US are due to cardiovascular disease. Social factors such as living conditions, education and diet play a key role in determining a person's heart health. These risk factors are exacerbated by racial inequity: according to the American Heart Association, heart disease accounts for nearly 40% of the disparity in life expectancy between Black and white Americans.

Our three-year Closing the Gap initiative with Thomas Jefferson University and Jefferson Health focuses on addressing the social determinants of heart health in five vulnerable neighborhoods in Philadelphia with high rates of stroke and adverse outcomes related to heart disease. The aim is to reduce the impact of undertreated and untreated heart disease risk factors by creating systems of change in these communities that enable people to live healthier lives and experience better connections to health systems.

Closing the Gap enables us to take an upstream approach. Dedicated clinical personnel and community health workers conduct screenings and connect people with resources such as food, health, education or housing assistance. Assistance is also provided to help people reduce health risks related to diabetes and hypertension, and connect them to trusted sources of care.

### 40% CVD drives health disparities

According to the American Heart Association, heart disease accounts for nearly 40% of the disparity in life expectancy between Black and white Americans.

Nancy Porroa, a community health worker in Philadelphia, checks the blood pressure of a local resident

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We also continue to strengthen the position of *Entresto*, our medicine for heart failure and hypertension, which we estimate to be treating approximately 10 million patients worldwide. With the update of the 2022 guidelines issued by the American Heart Association, American College of Cardiology and Heart Failure Society of America, *Entresto* is now included as a treatment option for the majority of patients with heart failure and is recommended as a preferred drug in its class for the treatment of heart failure with reduced ejection fraction, a form of heart failure with high morbidity and mortality.



### **Immunology**

Key product: Cosentyx

Immunology covers a broad spectrum of conditions, including chronic skin diseases such as psoriasis. Immunological diseases affect an estimated 4.5% of the world's population, and their prevalence is increasing.

In 2022, we saw continued growth for *Cosentyx*, our treatment for several systemic inflammatory conditions, due to approvals for new indications in key markets and initiatives to expand patient access. Since initial approval in 2015, *Cosentyx* has treated more than 960 000 patients worldwide.

In the EU, *Cosentyx* received approval for active enthesitis-related arthritis (ERA) and active juvenile psoriatic arthritis (JPsA) in

children aged six years and over, following US approval in 2021. ERA and JPsA are subtypes of juvenile idiopathic arthritis that, if left untreated, can lead to high levels of pain and disability.

In China, Cosentyx maintained a strong growth trajectory as we continued to expand hospital access for continued patient uptake. Based on internal Novartis estimates, Cosentyx is now available in approximately 1900 hospitals in China and has been used to treat around 250 000 psoriasis and ankylosing spondylitis patients since approval in 2019.

We also reported Phase III results for *Cosentyx* in hidradenitis suppurativa (HS), a painful and recurrent skin disease that affects around one in 100 people. The data showed HS patients treated with *Cosentyx* experienced rapid and long-lasting symptom relief, with favorable safety consistent with the medicine's well-established profile. Data from these trials has been submitted to regulatory authorities in Europe and the US and other countries, with the goal of bringing *Cosentyx* as a new treatment option to patients as soon as possible.



### **Neuroscience**

Key products: Kesimpta, Zolgensma

Around 2 million people worldwide suffer from multiple sclerosis (MS), an autoimmune disease that is the most common cause of

neurological disability unrelated to trauma in people under 40 years of age.

Kesimpta, our treatment for relapsing forms of MS, which has been shown to reduce the risk of worsening disability from MS for up to four years, has now been approved in 80 countries with more than 36 000 patients treated. Kesimpta has seen strong launch uptake in the US, Japan and Europe. In Europe, it saw additional launches in Italy and Spain during 2022, and reached 10 000 active patients by the end of the year.

New data in 2022 showed that earlier treatment with *Kesimpta* is more effective in limiting the progression and impact of MS compared with treatment at a later stage – helping to reduce the burden of the disease for patients and healthcare systems. *Kesimpta* is a once-monthly injectable treatment that can be taken from home, which helps broaden access for patients who have difficulty visiting healthcare facilities.

Zolgensma, a one-time, intravenous gene replacement therapy for spinal muscular atrophy (SMA), has now launched in most major markets. SMA is a rare genetic neuromuscular disease that results in the progressive and irreversible loss of motor neurons, which causes muscle weakness and atrophy. Zolgensma has been approved for use in 45 countries. In 2022, South Korea and Poland agreed to reimburse patients for the therapy. So far, more than 2 500 patients have used Zolgensma across

clinical trials, access programs and in the commercial setting.

New data in 2022 also reinforced the transformational benefit of *Zolgensma*, demonstrating age-appropriate development when used pre-symptomatically, and maintenance of the ability to speak, swallow and meet nutritional needs when used symptomatically.



### **Solid Tumors**

Key products: Kisqali, Pluvicto

Cancer is the second leading cause of death worldwide, and is a growing health issue in LMICs. The WHO estimates there will be 50% more new cancer cases in 2040 than there are today.

Breast cancer is one of the most prevalent types of cancer. Kisqali, our medicine for HR+/HER2- advanced breast cancer, the most common subtype of breast cancer. has now been approved for use in more than 95 countries and has been used to treat more than 60 000 patients. Kisqali, which inhibits two enzymes involved in the control of cell cycle progression known as CDK4 and CDK6, continues to show strong growth due to the increasing recognition of its impact on overall survival and quality of life benefits in the advanced breast cancer setting. In early 2023, it was approved in China for premenopausal and perimenopausal women with advanced breast cancer.

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When faced with incurable disease, the hope for many patients is to live as long and as well as possible. In 2022, *Kisqali* data continued to demonstrate an overall survival benefit while maintaining or improving quality of life for people living with HR+/HER2- advanced breast cancer, which has now been observed across all three Phase III clinical trials. A Phase III study of *Kisqali* in early-stage breast cancer – the biggest-ever clinical study of a CDK4/6 inhibitor for this disease – is ongoing.

During the year, we also secured approval in the US, EU and other countries for *Pluvicto*, our radioligand therapy for progressive metastatic castration-resistant prostate cancer (mCRPC), an advanced form of prostate cancer that currently has few treatment options. Prostate cancer is among the most frequently diagnosed cancers in men and causes more than 30 000 deaths in the US every year. Since launch, we have been working to scale up production of *Pluvicto* to meet higher-than-expected demand.

In December, we announced positive early results from a second, pivotal Phase III study of *Pluvicto* in mCRPC patients prior to receiving a taxane-based chemotherapy. An additional Phase III trial in an earlier line of treatment for metastatic prostate cancer is ongoing, with a data readout anticipated in 2024.



### **Hematology**

Key product: Scemblix

Around 500 000 new cases of leukemia are recorded globally every year. Approximately 15% of all cases are chronic myeloid leukemia, or CML, most common in adults over 65. Significant advances in recent years have led to improved survival rates, enabling more patients to live with the disease. Even so, many patients remain at risk of disease progression, and are resistant to, or intolerant of, most available treatments.

# Our CML treatment Scemblix is now approved for use in 40 countries

In 2022, our CML treatment *Scemblix* received approval for use in the EU and Japan following US approval in 2021. It is now approved for use in 40 countries. New data for *Scemblix* also showed long-term efficacy for patients with Philadelphia chromosome–positive CML in chronic phase. *Scemblix* is also being studied for possible use in patients newly diagnosed with chronic CML.



# Working to eliminate malaria and neglected tropical diseases

UN Sustainable Development Goal 3 is about good health and well-being. At Novartis, we have been working for decades to find new treatments for some of the world's biggest healthcare challenges – from noncommunicable diseases like cancer and cardiovascular disease to infectious diseases such as malaria.

One of the targets to support SDG 3 is to end the epidemics of malaria and neglected tropical diseases (NTDs). Every year, NTDs trap millions of people in a cycle of poverty and illness.

In June, we endorsed the Kigali Declaration on Neglected Tropical Diseases and pledged USD 250 million over five years (2021-2025) to advance new treatments for NTDs and malaria. This commitment includes the development of next-generation antimalarials, including an optimized formulation for infants, as well as further research into Chagas disease, dengue, leishmaniasis and cryptosporidiosis, a parasitic infection that causes life-threatening diarrhea in malnourished children.



Target 3.3 reads: By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases.

Please see page 23 for more information on our impact on the SDGs



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### Research and development

As with our commercial strategy, we have clear priorities in R&D to maximize the value of our pipeline of investigational medicines.

From the inception of a potential therapeutic through to clinical development and launch, our teams collaborate in support of our purpose to improve and extend people's lives. Researchers at the Novartis Institutes for BioMedical Research (NIBR) work across several therapeutic areas to uncover biological insights into the origins and pathogenesis of disease to drive the discovery and development of the next generation of medicines. Our Global Drug Development (GDD) organization leads the advanced clinical development of potential new medicines, running large clinical trials and steering the way to regulatory approval and access for patients.

This work is powered by technology platforms that help us to discover, develop and commercialize new therapies across our therapeutic areas. We focus on two established platforms – chemistry and biotherapeutics – plus three advanced platforms – RNA, radioligand therapy, and gene and cell therapy – that offer targeted approaches to treating disease. We are investing to build our capabilities in these advanced platforms and expect them to play an increasingly important role in developing new medicines in the future.

Within this 'two plus three' approach, we focus our development resources on our priority assets to maximize high potential early programs and ensure flawless execution of late-stage pipeline programs, in addition to supporting lifecycle management by growing the evidence base for key in-market assets.

We continue to make significant investments to support our R&D strategy. In 2022, we invested USD 10.0 billion in R&D, compared with USD 9.5 billion in the prior year. Approximately 21 000 Novartis employees work in R&D – around one fifth of our total workforce.

Delivering high-value medicines requires a focus on productivity and prioritization to increase our returns on R&D investment – for example by moving quickly to expand projects with high potential and stop or out-license non-core programs. At the same time, we are using AI to optimize drug discovery and development, and reduce cycle times (see page 52).

While most of our research is conducted internally, we increase our chances of discovering new medicines by collaborating with outside researchers and biotech companies. Our network consists of more than 300 outside academics and 100 industry alliances working on joint research and drug discovery.

Significant pipeline advancements in 2022 include the approval of novel radioligand therapy *Pluvicto*, and further approvals and indication expansions for *Scemblix*, *Kymriah* and *Cosentyx*. We also presented several late-stage data readouts that pave the way for further launches in 2023 and beyond.

For example, our complement factor B inhibitor iptacopan (LNPO23) met its primary endpoints in two Phase III studies in patients with paroxysmal nocturnal hemoglobinuria (PNH), a rare and deadly blood disorder. Global regulatory submissions for iptacopan for the treatment of PNH are anticipated to be filed in 2023. If approved, iptacopan has the potential to become the first oral monotherapy for PNH.

Iptacopan was discovered at NIBR through research targeting the immune system's alternative complement pathway, of which complement factor B is a key part. When it's working properly, this pathway helps clear the body of pathogens and damaged cells. When it's not, it can cause the destruction of critical cells in the body, leading to a variety of debilitating diseases.

Iptacopan is also being studied for other indications such as kidney diseases and other rare blood disorders. Its potential as an oral treatment for several complement-mediated diseases was recognized early, prompting the design of a streamlined, parallel development plan in multiple patient populations.

### 'Two plus three'- our key technology platforms

### Chemistry

Chemistry is the discovery of low molecular weight synthetic molecules that can be optimized as medicines.

### **Biotherapeutics**

Biotherapeutics, or biologics, are medicines derived from the molecules of life, carefully engineered to treat specific diseases.

### RNA therapy

RNA therapies use various forms of ribonucleic acids (RNA) to modify biological pathways in the body to treat or cure specific illnesses.

### Radioligand therapy

Radioligand therapy delivers precision-targeted radiation to cancer cells in the body with the goal of limiting damage to surrounding tissue.

### Gene & cell therapy

Gene therapies modify part of a patient's genetic makeup to help treat genetic or inherited diseases. Cell therapies treat diseases by restoring or altering certain sets of cells or by using cells to carry a therapy through the body.

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### Creating new possibilities in cancer care

Cancer is a spectrum of diseases with diverse characteristics that share a common feature – abnormal cells that grow out of control. Novartis has developed a world-class portfolio of compounds and biotherapeutics that inhibit key pathways driving cell survival and growth in a number of cancers. While tremendous progress has been made, an urgent need for new and better treatments remains. We are pursuing technologies that hold the potential for more diverse, targeted therapeutics to treat additional forms of cancer.

Novartis scientists are working to make CAR-T therapy, a treatment for certain blood cancers that sits at the intersection of cell-, gene-, and immuno-based therapies, better and more effective. The technology, known as *T-Charge*, shortens the time it takes to genetically engineer T cells during the CAR-T manufacturing process, so they can be given back to patients faster. *T-Charge* also helps these cells persist in patients longer, with the goal of giving them a better chance to control cancer. We are studying *T-Charge* in clinical trials to gauge its potential efficacy.

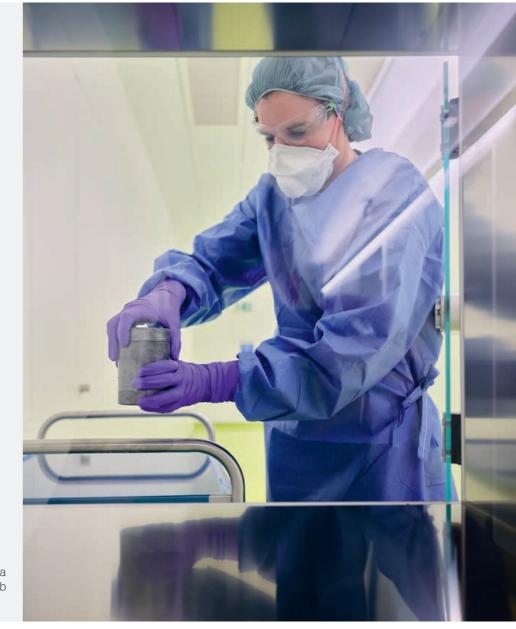
Radioligand therapy uses radiation to destroy cancer cells in a more targeted way than conventional radiotherapy. By using special molecules that carry a therapeutic radioisotope and circulate throughout the bloodstream, this technology can target cancer cells anywhere in the body while limiting damage to surrounding cells. Radioligand therapy is used for certain neuroendocrine tumors and advanced stages of prostate cancer. Novartis scientists are working to apply it to other cancer types.

Finally, **targeted protein degradation** takes advantage of the proteasome, a cell's internal machinery for eliminating unwanted proteins. With this technology, scientists will potentially be able remove proteins from the cell, rather than just blocking their activity – opening the way to develop targeted therapies for cancer-causing proteins that have long eluded drug hunters.

50%

### More cancer cases

The WHO estimates there will be 50% more new cancer cases in 2040 than there are today.



A Novartis employee at a radioligand therapy research lab in Basel. Switzerland.

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# Progress against ESG targets Deliver high-value medicines



On track: progress in 2022 on R&D milestones for malaria and NTDs

**Progress** 

All new launches in 2022 had a global access strategy.

#### **Innovation for global health**

Invest USD 250m to advance R&D for NTDs.

Implement a global access strategy for all new

and malaria (over 5 years from 2021-2025)

**Target** 

medicines launched

In 2022, we also advanced our efforts to develop novel medicines for diseases that predominantly affect underserved patients in LMICs. For example, we announced we will progress ganaplacide/lumefantrine (KAF156) into Phase III development for the treatment of patients with acute uncomplicated malaria.

Ganaplacide is a novel agent with a new mechanism of action and is active against malaria parasites that are partially resistant to existing antimalarials. Combined with a once-daily formulation of lumefantrine, this combination has the potential not only to clear malaria infection, but also to block the transmission of the malaria parasite.

The Phase III trial is planned to start in 2023 and will include clinical sites in sub-Saharan Africa. Ganaplacide/lumefantrine is being developed with support from the Medicines for Malaria Venture and their partners.

# Our approach to clinical trials

Clinical trials play a critical role in delivering high-value medicines: they help determine whether our investigational medicines are effective and safe before they are approved by regulatory authorities for general use in patients.

For every clinical trial our primary responsibility is to protect the safety, well-being and legal rights of all participants and ensure adherence to the highest ethical standards for clinical research. For more information, see our position on responsible clinical trials.

As part of the Novartis Commitment to Patients and Caregivers, we are committed to seeking patient input into the design of our clinical trials, helping us to develop medicines that address patient needs. We are also committed to registering new medicines in every country where patients have taken part in clinical trials and to publishing the results. See page 22 for more information on patient engagement.

## **Diversity in clinical trials**

Diverse representation in clinical trials helps us understand how patient groups who are most likely to be treated for a disease will respond to a medicine - ultimately improving the quality of care for every patient, while also helping to address health inequities in society. In the US, for example, only 8% of participants across all clinical trials in the country in 2020 identified as Black or African American, despite this group having one of the lowest life expectancies and higher mortality from diseases such as CVD.

We include diversity and inclusion principles in all Phase III studies with US participation. For example, we consider epidemiology variances for race, ethnicity and gender for target disease indications during feasibility planning and trial recruitment. We plan to extend this approach to all studies worldwide.

To increase recruitment of under-represented groups in our trials, we are working with patient groups and through community partnerships - including with churches in Atlanta and with our partners in Beacon of Hope (see page 58 for details of this program). In one example, we leveraged these relationships to help enroll patients in a Phase III trial of Entresto for heart failure in the US. As a result, 50% of patients enrolled from these sites and 22% of patients overall in the trial were from under-represented groups.

To increase recruitment of underrepresented groups in our trials, we are working with patient groups and through community partnerships

In 2022, the FDA issued new guidance on diversity in clinical trials. In response, we are now updating our guidelines to incorporate the guidance into our priority programs from 2023.

# Clinical trials (phases I-V)

Phase I •OOO

The purpose of Phase I is to establish whether a drug is safe for use in humans. It usually involves a small group of healthy volunteers.

Phase II assesses the

Phase II ••OO

medicine's effectiveness and determines the right dosage. Trials involve larger groups of patients with the disease.

#### Approved for general use

Phase III determines whether the medicine is safe and effective for a wider variety of patients. This is the last phase before submission to regulators for approval.

Monitoring continues after approval. In some cases. Phase IV trials are carried out to collect data on potential long-term adverse effects.

Phase IV

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# Managed and post-trial access programs

Our managed access programs (MAPs) provide eligible patients – those with serious or life-threatening illnesses – with access to medicines not yet approved or available in their home countries. In 2022, we reviewed 7 730 MAP requests from physicians from 80 countries and across 55 compounds. We approved 94% of these. By the end of 2022, more than 9 700 patients were receiving treatment under Novartis MAPs.

We are the first pharmaceutical company to publish peer-reviewed research on our MAPs, spanning more than 30 000 patient requests from 110 countries over three years

We are the first pharmaceutical company to publish peer-reviewed research on our MAPs, spanning more than 30 000 patient requests from 110 countries over three years. Results showed an average approval rate of approximately 95%. Most programs (87%) took place in high-income countries, those with compassionate use regulations made available online (94%) and those with a high level of clinical trial activity (96%). This research is intended to inform discussions among policymakers, regulators and the industry on how to broaden access to patients through compassionate use.

Our post-trial access (PTA) policy, which applies to all confirmatory clinical trials and trials for serious and/or life-threatening conditions, ensures patients who have derived clinical benefit from an investigational treatment can continue to receive it, free of charge, until it is commercially available and accessible locally. Our PTA policy applies regardless of the severity of the disease, the availability of alternative therapies, or the location of the clinical trial. PTA plans were incorporated in all in-scope trials approved in 2022. See the Novartis Position on Post-Trial Access for more information.



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# Key assets in our R&D pipeline

The table below provides an update on select R&D programs across our core therapeutic areas as well as select programs linked to our global health priorities. Note that some assets are in development across multiple therapeutic areas. For information on our full R&D pipeline, please see the Novartis corporate website.

Product / compound name	Platform	Description	Potential indication(s)	Current phase
CARDIOVASCULA	R			
<b>Leqvio</b> inclisiran	RNA therapy	Lowers 'bad cholesterol' in conjunction with a healthy diet and statins. Approved in 70 countries worldwide. We are developing <i>Leqvio</i> for other potential indications.	Secondary prevention of cardiovascular events in patients with elevated levels of low-density lipoprotein cholesterol	•••0
LNP023	Chemistry	Investigational medicine targeting part of the immune system involved in triggering inflammation and fighting	IgA nephropathy	•••0
iptacopan		infection. Phase III studies are underway into potential use as a treatment for kidney diseases. Also being studied for a rare blood disorder (please see "Hematology" below)	C3 glomerulopathy	•••0
TQJ230 pelacarsen	RNA therapy	Potential, first-of-its-kind investigational treatment for cardiovascular events in patients with elevated levels of lipoprotein(a), an inherited risk factor that cannot be effectively addressed by diet or other lifestyle changes	Secondary prevention of cardiovascular events in patients with elevated levels of lipoprotein(a)	•••
<b>₩ IMMUNOLOGY</b>				
Cosentyx	Biotherapeutics	Treatment for various autoimmune and inflammatory diseases. Approved by the EU in 2022 for use against active	Giant cell arteritis	•••0
secukinumab		juvenile psoriatic arthritis and active enthesitis-related arthritis in children aged six years and over. Also in 2022, separate Phase III trial data showed positive results in treating HS.	Lupus nephritis	•••0
LOU064	Chemistry	Potential multi-indication investigational treatment for a variety of autoimmune and chronic inflammatory	Chronic spontaneous urticaria	•••
remibrutinib		diseases. Also being studied in multiple sclerosis (please see "Neuroscience" below)	Sjögren's syndrome	••00
VAY736	Biotherapeutics	Investigational therapy with unique, dual action being studied for treatment of autoimmune conditions. In	Autoimmune hepatitis	••00
ianalumab		2022, we reported positive data from a Phase II trial for Sjögren's syndrome, a disease of the immune system	Lupus nephritis	•••0
	affecting over two million people worldwide.		Sjögren's syndrome	•••0
NEUROSCIENCE				
OAV-101	Gene therapy	Investigational gene therapy for patients between 2 and 18 years of age with Type 2 spinal muscular atrophy (SMA). While disease progression is slower in patients with later-onset SMA, there are significant unmet needs. Potential to be first one-time treatment for this population	Spinal muscular atrophy (intrathecal formulation)	•••0
LOU064	Chemistry	Potential multi-indication investigational treatment for variety of autoimmune and chronic inflammatory	Multiple sclerosis	•••0



diseases (see also "Immunology" above).

remibrutinib

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# Key assets in our R&D pipeline (continued)

Product / compound name	Platform	Description	Potential indication(s)	Current phase
SOLID TUMOR				
<b>Kisqali</b> ribociclib	Chemistry	Ongoing Phase III clinical trials for early-stage breast cancer as an adjuvant therapy	Hormone receptor-positive (HR+)/ human epidermal growth factor receptor 2-negative (HER2-) early breast cancer (adjuvant)	•••
<b>Pluvicto</b> lutetium ( <sup>177</sup> Lu)	Radioligand therapy	Approved in 2022 for treatment of a progressive, deadly form of prostate cancer known as mCRPC.  Development is ongoing in several indications for certain other types of prostate cancer.	Metastatic castration-resistant prostate cancer, pre-taxane	•••0
vipivotide tetraxetan			Metastatic hormone-sensitive prostate cancer	•••0
JDQ443	Chemistry	Investigational oral therapy for KRAS-mutated tumors, which make up around 25% of all cancers. We reported positive data in 2022 from a Phase Ib study in advanced non-small cell lung cancer, showing that the compound is an anchor for combination strategies to improve outcomes for patients with specific KRAS-driven cancers	Non-small cell lung cancer	•••
NIS793	Biotherapeutics	Potential first-in-class therapy in development for pancreatic cancer and other solid tumor types. Designed to disrupt a pathway known to play an important role in the most common type of pancreatic cancer, which afflicts nearly half a million people worldwide	Pancreatic cancer	•••0
(1) HEMATOLOGY				
LNP023 iptacopan	Chemistry	Investigational oral medicine to prevent the destruction of red blood cells. Also being investigated for other blood disorders and complement-mediated kidney diseases. (please see "Cardiovascular" above)	Paroxysmal nocturnal hemoglobinuria	•••
<b>OPHTHALMOLOG</b>	Υ			
PPY988	Gene therapy	Acquired in 2022 as part of acquisition of Gyroscope Therapeutics. Experimental one-time gene therapy for treatment of geographic atrophy, an advanced form of age-related macular degeneration affecting more than five million people worldwide	Geographic atrophy	••00
GLOBAL HEALTH PRO	GRAMS			
<b>KAF156</b> ganaplacide/lumefantrine	Chemistry	Anti-malarial with novel mechanism of action to address threat of artemisinin resistance and potentially block disease transmission. In 2022, we announced our decision to move to Phase III trials.	Uncomplicated malaria	••00
LXE408	Chemistry	Entering Phase II trial for visceral leishmaniasis, a neglected tropical disease spread by sand flies that is typically fatal without treatment.	Visceral leishmaniasis	••00



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# **Embed operational excellence**

# 2022 highlights

72.5 bn

**Treatments supplied** 

through Novartis manufacturing sites 100%

**Regulatory inspections** 

of our facilities deemed acceptable

11 097

Suppliers risk assessed

through our third-party risk management process

49%

Reduction in greenhouse gas emissions

in our own operations, compared with our 2016 baseline



# In this section

# Focusing our organization

Changes to our operating model announced in 2022 are designed to power our next phase of innovation, growth and productivity.

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### **Excellence in manufacturing**

We are working to further increase efficiency across our manufacturing sites while also expanding capacity in strategic focus areas.

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### Supply chain management

We work with thousands of external partners worldwide, from suppliers in our R&D organization to wholesalers and distributors, who ensure our medicines reach patients.

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# Protecting patient health and safety

Patient health and safety is fundamental to our business. We cannot deliver on our purpose if we do not provide safe, high-quality medicines.

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### Environmental sustainability

We continue to make progress in reducing the environmental impact of our operations in line with our targets.

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Lara Potocnik, an employee at a Novartis production facility in Menges, Slovenia, adjusts an augmented reality headset

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# **Embed operational excellence**

In 2022, we introduced a new operating model to make our organization more agile and efficient in support of our strategy. We also took further steps to transform our manufacturing network, improve supply chain management and reduce our environmental footprint.

# **Focusing our organization**

In recent years, we have evolved from being a diversified healthcare conglomerate to a focused, innovative medicines company. Announced in April 2022, our new organizational structure aligns the way we operate with this strategy.

We integrated our former Novartis Pharmaceuticals and Oncology units under our Innovative Medicines Division with separate US and international commercial organizational units. We also integrated our manufacturing and business services teams into a single Operations organization and integrated our corporate functions.

These changes - part of our Transforming for Growth initiative - are designed to power our next phase of innovation, growth and productivity by sharpening our focus on our core business. Creating a simpler, more agile organization will enable us to take quicker decisions and scale the use of new technologies, while reducing duplications in

our marketing and sales activities and introducing more efficient end-to-end management across our research, development and commercial operations.

This new structure became fully operational in January 2023. We estimate these changes will result in cost savings of approximately USD 1.5 billion by 2024. freeing up resources for investment in research and development (R&D) and delivering returns to shareholders. In the short term, we expect the impact of these productivity gains to help offset moderately rising energy costs and inflationary pressures in our supply chain.

# **Excellence in manufacturing**

In 2022, we worked to further increase efficiency across our manufacturing sites. We introduced new innovative manufacturing techniques, such as continuous manu-

#### Savings of ~USD 1.5 bn to be fully embedded by 2024



facturing, based on an end-to-end, uninterrupted production line. We also automated more processes, such as packaging lines and inspection of prefilled syringes, and introduced 3D printing for spare parts. At the same time, we switched more of our production to cleaner energy and improved our environmental performance.

In recent years, we have been adapting our sites, consolidating production where possible, particularly in small molecules and generics where we face most competition. Since 2019, we have closed, exited or sold 17 manufacturing sites and have announced the closure, exit or sale of nine additional sites.

In parallel, we have been expanding capacity in strategic focus areas such as biopharmaceuticals and advanced technology platforms such as radioligand therapy. In 2022, we were given approval for a new 16 000m<sup>2</sup> facility in Durham, North Carolina, to produce Zolgensma, our gene therapy for spinal muscular atrophy. We also began operations at a new, state-of-the-art biopharmaceuticals plant in Austria that uses continuous and automated process technologies. In addition, we began siRNA drug substance production for our cholesterol drug Legvio in Switzerland, expanded radioligand therapy (RLT) production in the US and Europe, and continued work on our new RLT facility in Indiana, US, which is due to come into operation in 2023.

These changes mirror developments in our product mix and help us retain flexibility, so

#### Related links and disclosures

- → Novartis Third-Party Code
- → Quality Commitment
- → Environmental Sustainability Criteria for Suppliers
- → Pharmaceuticals in the Environment
- → Novartis Position on Falsified Medical **Products**
- → Environmental Sustainability Strategy

we maintain supplies and react quickly to fluctuations in demand. We increased production of Cosentyx and Tafinlar across various sites after the two medicines were added to China's national reimbursement list. Overall, we produced approximately 72.5 billion treatments in 2022, ensuring a continuous and reliable supply of our medicines to patients worldwide.

During the year, we also stepped up our contract manufacturing business, through which we leverage our manufacturing facilities and expertise, including in gene and cell therapy, to produce medicines for third-party customers alongside our own. Our sites in Singapore, the US and Europe are producing medicines and vaccines for other pharmaceutical companies. Contract manufacturing means we can increase capacity utilization at our sites while giving customers access to high-quality manufacturing expertise.

2021

12 064

85

912

37

2022

11 097

384

2020

8 448

35

521

120

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### Investing in early-stage technical development

In September, we announced a USD 300 million investment in early technical development capabilities for next-generation biotherapeutics at facilities in Switzerland. Slovenia and Austria. Biotherapeutics currently account for around half of all new drug approvals and have enormous potential to treat unmet patient needs across a range of diseases. Spanning both drug substance and drug product development, this investment is expected to lead to faster transition times from pre-clinical to first-in-human studies, helping to put Novartis at the forefront of biotherapeutic development.

# Supply chain management

We work with thousands of external partners worldwide, from suppliers in our R&D organization to wholesalers and distributors, who ensure our medicines reach patients. The diversity and geographic spread of our supply chain makes it highly resilient, even in times of pandemic or other economic shocks.

We contractually oblige third-party suppliers to abide by our standards on quality, ethics, and human rights. To support this approach,

we carry out regular risk assessments and audits in risk areas including health and safety, labor rights, information security and antibribery and corruption. We also work with suppliers to reduce their environmental impact (see section below).

In 2022, we extended our third-party risk assessments downstream to include wholesalers and distributors of our medicines, and updated our expectations for suppliers to carry out due diligence on human rights.

Over the past three years, we have assessed nearly 97% of our tier one suppliers in Operations that play a critical role in our supply chain. Of these, only around 1% were considered high-risk.

### Sustainability in our supply chain

Environmental sustainability criteria have been integrated in supply contracts covering more than a third of our Scope 3 supplier emissions. Our plan is to increase this to all suppliers by 2025. To support our approach, we are engaging with suppliers to develop sustainability roadmaps - part of our goal to achieve carbon neutrality across our value chain by 2030 and to be net zero by 2040.

# More than 90% of carbon emissions associated with our business are generated outside

our own operations.

**Actions taken** 

Suppliers audited

# Protecting patient health and safety

**Supply chain performance indicators** 

Number of suppliers risk-assessed by TPRM

Suppliers with remediation action agreed<sup>2</sup>

<sup>2</sup> Decreased due to fewer medium- and high-risk cases

Suppliers risk-assessed by Third-Party Risk Management (TPRM)

Supplier engagements stopped due to risk assessment outcomes

Figures do not include GxP audits (see "Patient health and safety performance indicators").

1 Assessment is done on new suppliers and new products, services or sites from existing suppliers. Not all suppliers trigger risk assessments.

Patient health and safety is fundamental to our business. We cannot deliver on our purpose if we do not provide safe, high-quality medicines. Our activities are focused on three areas: manufacturing safe medicines (product quality); ensuring these medicines remain safe and that we identify possible adverse events to minimize risks to patients (pharmacovigilance); and combating falsified medicines, which can pose a serious threat to human health.

# **Product quality**

All our facilities operate under strict regulations from regulatory health authorities. Health authorities regularly inspect our facilities to ensure we are complying with all relevant laws and standards. In 2022, health authorities, including the European Medicines Agency (EMA), Swissmedic and the US Food and Drug Administration (FDA),

carried out a total of 139 inspections. Of these, 100% were found to be acceptable. up from 99.2% in 2021. Novartis also routinely audits suppliers and other partners to ensure quality standards are maintained.

We carry out thorough investigations into safety issues with our products, and act quickly to address any concerns. For example, in May we suspended production of our Pluvicto radioligand therapy for prostate cancer at two sites in Italy and the US to address quality concerns in their manufacture. After remediating the issues, we restarted production in June and resumed delivery of doses to patients. These issues did not affect patient safety, and no risk to patients from the doses previously produced at these sites was identified.

During the year, we had 19 recalls - 7 for IM and 12 for Sandoz. None were related to Class I, where medicines in question could result in serious health problems. Recalls are carried out in agreement with the relevant health authorities.

# Progress against ESG targets Supply chain

## **Target**

#### Conduct risk assessments for all new eligible suppliers

# **Progress**

100% (conducted via TPRM process)

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### **Pharmacovigilance**

Effective pharmacovigilance relies on timely assessment and reporting of adverse events and is critical to ensuring patient safety. We maintain a high level of compliance to regulatory requirements for both individual case safety reports and periodic benefit-risk assessments.

Reports of adverse events from various sources, including clinical studies and spontaneous reports, are used to evaluate and optimize risk management actions for the proper use of our medicines. As an example, following two patient fatalities we updated the label for Zolgensma, in alignment with health authorities, to specify that fatal acute liver failure had been reported. While this is clinically important safety

information, it is not a new safety signal, and we firmly believe in the overall favorable risk-benefit profile of *Zolgensma*, which has been used to treat more than 2 500 patients worldwide. We notified health authorities in all markets where Zolgensma is used, and communicated to healthcare professionals as an additional step in markets where this action is supported by health authorities.

In 2022, we continued to support education programs for patients, providers and pharmacists. Our pharmacovigilance team also supported a program with the UK regulatory authority to provide early access to two cancer medicines - Scemblix and Pluvicto - for patients with clear unmet medical need before marketing approval was received later in the year.

#### Patient health and safety performance indicators 2022 2021 2020 **GxP** audits Total audits executed 1392 1 419 Internal 1 134 125 111 792 External<sup>2</sup> 1258 1 294 Regulatory authorities 139 126 126 Total inspections Inspections found to be acceptable (%) 100 99.2 99.2 Recalls Total recalls 19 27 Class I recalls 0 3 16 20 Class II recalls

# **Combating falsified medicines**

The illicit trade in falsified medicines is a threat to patient safety and an increasingly significant issue for health systems around the world. The Pharmaceutical Security Institute reported a 38% increase in pharmaceutical crime incidents between 2016 and 2021, leading to an all-time high in 2021.

Our strategy is focused on two areas: the quick authentication and reporting of falsified medicines, as well as collective action to address the issue. In 2022, we investigated 213 incidents in 48 countries and worked closely with law enforcement on 74 enforcement actions which led to the seizure of approximately 1.2 million units of falsified medicines. Since 2017, our efforts have prevented serious safety risks for an estimated 1.8 million patients.

We plan to roll out 250 Authentifield sensors in 75 countries in May 2023. These sensors enable our Innovative Medicines employees to rapidly authenticate (solid) drug products. which is vital in preventing falsified medicines reaching patients. Meanwhile, our MoVe internal mobile application, which enables employees to guickly verify the authenticity of secondary packaging of any Novartis product, is now active in 49 countries.

In 2022, Novartis also engaged over 8 100 key stakeholders across 27 countries on topics including public awareness, policy, and capacity-building. We voluntarily reported 100% of confirmed incidents to the WHO. 95% within the recommended 10-day timeframe.

# **Environmental sustainability**

We continue to reduce emissions, water consumption and waste sent for disposal in our own operations, in line with our 2025 targets. In 2022, we also introduced environmental sustainability criteria into suppliers' contracts and started engaging with them to define actions to reduce emissions in our supply chain.

Our environmental sustainability strategy and engagement activities are consistent with limiting global warming to below 1.5°C compared to pre-industrial levels in line with the goals of the Paris Agreement. We committed to the Science Based Targets Initiative (SBTi) to develop science-based targets in accordance with the SBTi Net

Zero standard. We also joined The Climate

Pledge which is working toward net-zero by

2040, in line with our own target.

To accelerate progress across the pharmaceutical sector and other industries, we work closely with organizations such as the AMR (antimicrobial resistance) Industry Alliance, Pharmaceutical Environmental Group, World Business Council for Sustainable Development and the Pharmaceutical Supply Chain Initiative.

See page 89 for our Task Force on Climate-related Financial Disclosures (TCFD) statement.

<sup>1</sup> Total number of audits performed on facilities owned by Novartis

<sup>&</sup>lt;sup>2</sup> Total number of audits performed on GxP suppliers to Novartis

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#### Climate

In 2022, we reduced our Scope 1 and 2 emissions by 23% from the prior year. representing a reduction of 49% compared with our 2016 baseline. We have been steadily reducing our emissions for several years, mainly through energy efficiency, increased use of renewables and new manufacturing technologies.

We are committed to using 100% renewable electricity across our operations by 2025. In 2022, we had renewable power purchase agreements in place to cover electricity consumption across our operations in Europe and North America.

Currently, 20 of our manufacturing sites are certified under ISO 14001 (Environmental Management) or the EU's Eco-Management and Audit Scheme - equivalent to about half of our total production by volume.

Our Scope 3 emissions increased by 20% from the prior year, driven primarily by purchased goods and services and, to a lesser extent, by increased business travel following the pandemic. The calculation of emissions from purchased goods and services is based on proxy (spending) data and statistical modelling. The resulting figure provides an approximate reflection of emissions based on industry averages. Over time, we plan to move to a calculation based on primary activity data, which we expect will give a more accurate representation of

our Scope 3 emissions and better highlight our efforts to engage with our suppliers on environmental sustainability.

#### Waste

In 2022, we continued efforts to reduce waste sent for disposal. We have introduced sustainable design guidelines for our products, devices and packaging. Where feasible. we are switching to recycled plastics, cutting back on the use of blister packs and increasing the use of reusable shipping boxes. Since 2016, we have reduced the amount of waste sent for disposal by 59%.

#### Water

We have continued to reduce our water consumption by using more recycled water (where local regulations allow) and adopting less water-intensive production techniques. Since 2016, our water use has reduced by 42%.

In 2022, we began to classify our facilities based on whether they are in areas affected by water scarcity. The initial results showed that 36 locations contributing approximately 11% of our water consumption are in areas of high risk or very high risk as defined by the WWF Water Risk Filter. During 2023 we plan to conduct operational water risk assessments at 15 priority locations with the highest water consumption to determine actions needed to ensure we become water neutral at these locations. We aim to be water neutral at all our locations by 2030.

# Progress against ESG targets Environmental sustainability



# **Target** Climate

- · Become carbon neutral in our own operations (Scope 1 and 2) by 20251
- Include environmental criteria in all supplier contracts by 2025
- Become carbon neutral (Scope 1, 2 and 3) by 2030 and achieve net zero carbon emissions across our value chain by 20402

#### **Progress**

On track: 49% reduction vs. 2016 baseline

On track: environmental criteria signed by priority top 500 suppliers

Progress made: Committed to set science-based targets; plan in place to strengthen data by collecting primary emissions data (vs spend proxy) from suppliers. Scope 3 emissions increased in 2022 due to the increase in our external spend vs. 2021.

#### Waste

- · Eliminate polyvinyl chloride (PVC) in packaging by 20253
- · Reduce the amount of waste sent for disposal by half by 2025 4
- Become plastic neutral by 2030 5
- · All new products meet sustainable design principles by 2030 6

#### On track: Nine out of ten sites in scope have eliminated PVC in packaging

Already met target: 59% reduction vs. 2016 baseline

On track: removed 100% of 17 types of single-use plastics in 132 workplaces

On track: 32% of new projects have environmental sustainability criteria included

#### Water

- Reduce water consumption in our own operations by half by 2025 4
- No water quality impacts from manufacturing effluents by 2025
- Become water neutral in our own operations by 20307
- · Enhance water quality wherever we operate by 2030

On track: 42% reduction vs. 2016 baseline

On track: More than 85% of Novartis manufacturing sites can demonstrate they meet internal water quality standards and 80% of high-risk suppliers have assessed their compliance

On track: Sites which must take action to become water neutral have been identified

On track: Plan in place to expand internal water quality standards to non-manufacturing sites and other suppliers

- 1 Scope 1 and Scope 2 from energy
- <sup>2</sup> In accordance with SBTi net-zero standard
- <sup>3</sup> From Novartis owned and operated sites. Defined as secondary and tertiary packaging; primary packaging when feasible
- 4 Vs. 2016 baseline performance
- <sup>5</sup> Plastic neutral defined as weight of plastic packaging entering the environment for disposal is approximately the same as weight being recovered for recycling
- <sup>6</sup> In-scope projects in development governed by the Innovation Management Board (IMB) at the end of 2022
- 7 All Novartis sites to reduce water consumption in all areas and be water neutral in water-stressed regions by not depleting local water reserves. Water-stressed regions are determined using WWF water risk filter

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#### Pharmaceuticals in the environment

We seek to minimize discharge of active pharmaceutical ingredients (APIs) into water systems and do not dispose of waste containing APIs in landfill. We regularly measure air and water quality to make sure we remain within safe limits. We also evaluate the potential impact of new medicines on human and environmental health during

the R&D process. See our position statement on pharmaceuticals in the environment for more information. In 2022, we engaged with more than 100 priority suppliers to assess their effluent load of active pharmaceutical ingredients in water streams against standards from the AMR Industry Alliance framework.

Environment performance indicators <sup>1</sup>	2022	2021	2020
Energy use – on site and purchased (million GJ)	9.9	9.8	10.9
Greenhouse gas (GHG) emissions (1 000 tCO <sub>2</sub> e)			
Total Scope 1 emissions	347.2	352.8	378.3
Total Scope 2 emissions (market based)	154.9	292.7	335.5
Total Scope 1 and Scope 2 (excluding offsets)	502.1	645.5	713.8
Total Scope 3 emissions <sup>2</sup>	8 770.0	7 290.4	7 268.8
Total Scope 1, Scope 2 and Scope 3 emissions	9 272.1	7 935.9	7 982.6
Water (million m³)			
Total water withdrawal <sup>3</sup>	52.1	47.6	54.7
Total water discharged <sup>4</sup>	49.6	46.6	54.5
Water consumption <sup>5</sup>	7.5	7.7	8.4
Operational waste (1 000 t)			
Total waste generated	97.0	103.6	130.6
Total waste diverted from disposal	69.5	73.4	88.6
Total waste directed to disposal	27.5	30.2	42.1

Other than where indicated, environmental data for the current year are based on actuals for January-September and estimates for October-December (to be updated with actuals in 2023 in our annual Novartis Environmental Sustainability datasheet). Any significant deviations are restated the following year in the Novartis in Society Integrated Report. Previous years' data reflect only actuals.



# Supporting global efforts to combat climate change

Healthcare contributes almost 5% to global greenhouse gas emissions<sup>1</sup>. But the effects of climate change cut both ways: rising temperatures and air pollution are also harming human health and, in some cases, changing disease patterns. Reducing greenhouse gases lies at the heart of the UN Sustainable Development Goals and the Paris Climate Agreement, which aims to achieve net-zero emissions by 2050.

Many countries around the world are decarbonizing their healthcare systems. So far, 50 have made the pledge, including Germany, the US, the UK and emerging markets such as Indonesia and Egypt. If we want retain our position in these markets, we must show progress with our own decarbonization program.

At Novartis, we aim to be net zero by 2040. Over the past two years, we have also started introducing environmental sustainability criteria into our supplier contracts, extending this to wholesalers and distributors in 2022.



UN SDG target 13.2 reads: Integrate climate change measures into national policies, strategies and planning.

Please see page 23 for more information on our impact on the SDGs

Diobel in Guinea-Bissau, increased flooding makes it

In the coastal village of

<sup>&</sup>lt;sup>2</sup> Scope 3 emissions are reported in accordance with the GHG Protocol. Only the Scope 3 categories which are assured are separately disclosed. The total scope 3 emissions figure includes all categories. Our Scope 3 emissions increased by 20% from the prior year, driven primarily by purchased goods and services and, to a smaller extent, by increased business travel following the pandemic

<sup>3</sup> Water withdrawals includes water used for cooling and returned to the environment without the need for additional treatment

<sup>4</sup> Water consumption and non-contact water withdrawn from the environment for cooling and returned directly to the environment after use

<sup>&</sup>lt;sup>5</sup> Water discharged via treatment and water lost

harder for residents to travel to Source: Decarbonising healthcare – a discussion paper (published in April 2022 jointly by The Health Policy Partnership and AstraZeneca). the nearest health center.

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# 2022 highlights

47%

Women in management compared with 46% in 2021

250 m Pledged (USD)

for research into new medicines for malaria and neglected tropical diseases 54.6 m

Patients reached

through access-tomedicine approaches 98%

**Employees trained** on our Code of Ethics



# In this section

### Unleash the power of our people

We continue to focus on culture as a key enabler of our strategy to drive innovation and long-term performance.

 $\rightarrow$  p. 48

#### Scale data science and technology

We are investing in data science and technology to improve the way we develop and deliver our medicines.

 $\rightarrow$  p. 52

#### **Build trust with society**

We aim to increase access to our medicines for underserved populations around the world and follow high standards of ethical behavior wherever we operate.

 $\rightarrow$  p. 54

Members of an indigenous community near Santa Cecilia, Colombia, where visceral leishmaniasis, a neglected tropical disease spread by sand flies, is endemic. With the nearest hospital hours away by car, access to healthcare is limited to irregular visits by a nurse from a nearby village.

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# Unleash the power of our people

Culture helps to drive innovation and long-term performance. In 2022, we moved to an integrated company structure to align with our focused strategy, while also putting in place measures to help employees manage through this significant change. We also continued to phase in new ways of working and advanced our efforts to increase workforce diversity.

# Changes to our organizational model

Executing on our strategy as a focused medicines company requires us to work differently. We reorganized our company to create a more agile and simpler organization that is aligned with our focused strategy and will support innovation, growth and productivity. Regrettably, our Transforming for Growth initiative also entails job losses as we reshape our company to focus on our core Innovative Medicines business.

We recognize that these changes cause considerable uncertainty for many of our employees. To manage the process, we put in place six basic principles:

- Fairness in decision-making: all decisions were taken in line with our Code of Ethics and Values and Behaviors.
- Balanced representation: where units were merged, we ensured proper balance in terms of both organizational structure and opportunities for leadership positions.
- Equal opportunities: throughout the process, we worked to ensure equal opportunities for all employees to maintain our commitment to diversity, equity and inclusion.
- Support and care: those affected by the changes had access to various support programs to help them transition to new roles, either within or outside Novartis.
- Social dialogue: during the process, we consulted with Works Councils and other employee representative bodies in accordance with local law and regulations.
- Simple approvals: we simplified approval processes so that key decisions could be taken as quickly as possible.

We appointed a dedicated transformation team, led by our Executive Committee, issued clear guidance to management, and set up targeted engagement plans for employees in critical roles or identified as top talent.

#### Related links and disclosures

- → Our Equal Pay International Coalition (EPIC) commitments
- → Global Guideline on P&O Principles and Labor Rights Practices
- → Health, Safety and Environment Policy
- → Global Non-Discrimination, Non-Harassment, Civility and Non-Retaliation Guideline
- → Global Parental Leave Guideline
- $\rightarrow$  Code of Ethics

With the new organization, we will see a reduction in our workforce over the next two years. In total, through Transforming for Growth we expect to reduce our workforce by up to 8 000 positions by the end of 2024. In 2022, employee turnover stood at 15%. Voluntary turnover was 9%, up from 8% in the previous year.

# **Investing in our culture**

We are investing in our culture to help drive our long-term performance as a focused medicines company. We encourage all Novartis employees to be inspired, curious and unbossed to unlock innovation and drive performance. For us, this is about building an agile, diverse workforce and making sure we attract and retain talent for the future.

People performance indicators	2022	2021	2020	
Headcount 1	105 533	108 514	110 738	
Full-time equivalent positions 1	101 703	104 323	105 794	
Percentage turnover: voluntary / overall	9/15	8.0 / 13.0	5.0 / 10.0	
Percentage of hires: internal / external	66/34	62/38	58 / 42	
Annual learning hours per employee <sup>2</sup>	42.4	52.1	53.2	
Representation of nationalities: overall / management <sup>3</sup>	147 / 118	143 / 115	142 / 113	
Employees represented by an employee representative body or covered by a collective bargaining agreement (%) 4	48	47	46	
Health and safety				
Lost-time injury and illness rate (per 200 000 hours worked): Novartis employees / Third-party personnel	0.16 / 0.20	0.14 / 0.05	0.12 / 0.20	
Total recordable case rate (per 200 000 hours worked) <sup>5</sup> : Novartis employees / Third-party personnel	0.31/0.28	0.25 / 0.13	0.23 / 0.30	
Fatalities: Novartis employees / Third-party personnel / Contractors	0/0/0	0/0/0	0/0/1	

<sup>&</sup>quot;Headcount" reflects the total number of employees in payroll systems. "Full-time equivalent positions" adjusts headcount for employees working

- <sup>2</sup> Since 2022, Novartis reports training hours for internal employees only
- <sup>3</sup> Management defined by Global Job Level Architecture and Novartis Top Leaders
- 4 Generally non-management employees
- <sup>5</sup> Data include all work-related injuries and illnesses, whether leading to lost time or not

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### Diversity, equity and inclusion (DEI)

We are focused on creating a work environment in which all employees feel they belong and can do their best work. We do this not only because it is right, but also because it helps generate new ideas, gives us access to a wider pool of talent and brings us closer to the diverse perspectives of customers, patients and other stakeholders. To support this approach, we embed DEI into objectives for managers and in internal policies and controls, including our Code of Ethics.

Gender equity is an important part of our DEI strategy. Women now make up 47% of our overall management, compared with 46% in 2021 and 42% five years ago.

As part of our public pledge to the UN's Equal Pay International Coalition (EPIC), we are also committed to further improving pay

equity and transparency. Based on the latest data available as of December 31. 2021. Novartis has a global mean pay gap of +3.1% and a global median pay gap of -3.0%, compared with +3.3% and -2.3%. respectively, in the prior year. While we acknowledge this percentage is influenced by worldwide workforce demographics, our global mean pay gap is significantly ahead of the Bloomberg benchmark of +19% mean for the same period.

Across the organization, we are also increasing pay transparency and systematically removing historical salary data when hiring to reduce the likelihood of perpetuating possible discrimination. At the end of 2022, 84% of our global hiring was taking place on this basis. Our aim is to complete preparations for full pay transparency for all employees by the end of 2023, in time for annual pay discussions in February 2024.

Diversity, equity and inclusion (DEI) performance indicators	2022	2021	2020
Gender representation (% female / % male) 1			
Overall headcount	51/49	51 / 49	50/50
Hires	52/48	52 / 47	52 / 48
Board of Directors	31/69	31 / 69	29 / 71
Executive Committee of Novartis	27/73	25 / 75	23 / 77
Novartis Top Leaders <sup>2</sup>	39/61	38 / 62	33 / 67
Senior management	41/59	39 / 61	39 / 61
Middle management	48/52	47 / 53	46 / 54
Overall management <sup>3</sup>	47/53	46 / 54	45 / 55

1 Fewer than 0.5% of employees have unknown classification. Some indicators do not add up to 100%.

<sup>2</sup> Novartis Top Leaders comprise the approximately 300 most senior managers at Novartis, including the Executive Committee of Novartis.

3 Management defined by Global Job Level Architecture and Novartis Top Leaders

Progress against ESG targets People		
Target	Progress	
Close the gender pay gap by 2023	On track: +3.1% mean pay gap as of Dec. 31, 2021	
Achieve gender balance in management by 2023	On track: increased to 47% women in management in 2022	
Remove bias from the system by eliminating the use of historical salary data by <b>2023</b>	On track: 84% of recruitment no longer using historical salary data	
Create pay transparency for employees by <b>2023</b>	On track: 47% of employees with pay transparency to external benchmarks	

We have more than 80 dedicated employee resource groups that connect employees with shared experiences or backgrounds. We also support the UN Standards of Conduct for Business to tackle discrimination against LGBTQI (lesbian, gay, bisexual, transgender, queer and intersex) employees and are members of the International Labor Organization's (ILO) Global Business and Disability Network. In 2022, we received the Stonewall Top Global Employer Silver Award and were included in the Bloomberg Gender Equality Index, a recognition of the progress we continue to make in providing a positive and inclusive work environment for all employees.

Through our parental leave program, introduced in 2019, all Novartis employees regardless of gender or sexual orientation

can benefit from a minimum period of 14 weeks paid parental leave following the birth or adoption of a child, ensuring equity and greater flexibility for birthing and non-birthing parents.

#### **New ways of working**

In recent years, working models have become more flexible - a logical step during the upheavals of the pandemic. In 2020, we took an experimental approach and launched a program called Choice with Responsibility to give employees more flexibility and maintain business continuity. while also emphasizing the importance of working together onsite on occasions to support innovation and strengthen teamwork and collective responsibility.

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As the pandemic has subsided in many countries, we have made the decision to further evolve our approach to hybrid working to increase our focus on collaboration and innovation. Our updated guidance was announced in 2022 and will be implemented in 2023 pending local consultations and country-specific requirements, including local health and safety regulations. We aim to provide flexibility where it makes sense, while also prioritizing time spent together, encouraging a team-first mindset, and giving greater clarity and accountability to our teams.

The diversity of roles across our organization allows for different levels of flexibility. As a result, we have provided specific guidance for our field force, office workers, lab workers and manufacturing workers.

# **Employee engagement**

We measure employee engagement every quarter. The engagement score decreased in the second half of 2022 to 73, two points below the global benchmark. Engagement favorability, which measures the percentage of "agree" or "strongly agree" survey responses, was 76% in the fourth quarter, compared with 85% a year earlier. This outcome was anticipated following the announcement of our Transforming for Growth initiative.

The engagement score is based on responses to two questions: "How happy are you at Novartis?" and "Would you recommend Novartis as a great place to work?".

The voluntary and anonymous survey, which

is sent to all Novartis employees, is carried out by an external consultant to ensure independence. In Q4 2022, 69% of Novartis employees took part in the survey. Results are used on an aggregated basis to identify potential risks and make improvements to working conditions, training and development, access to support programs and other areas where necessary.

# Learning, growth and leadership development

We want a future-ready workforce that can achieve our strategic objectives. To do this, we continue to promote curiosity, learning and growth, which helps us to adapt to our changing business environment and ensures we build strategic skills, particularly in areas such as R&D, data science, and launch excellence to drive performance.

Since 2019, we have made significant investments in learning and development through our 'Going Big on Learning' initiative, which has led to an approximately 50% increase in average employee learning hours since 2018. In 2022, employees dedicated an average of 42.4 hours to learning. While this was down from 52.1 hours in the previous year, largely due to the impact of organizational changes in our business, it was still ahead of pre-pandemic levels.

Although overall learning objectives and investments are being recalibrated in line with the broader organizational transformation at Novartis, we continue to prioritize

learning as a key part of our culture to drive innovation and performance. Alongside mandatory training in areas like ethics and health and safety, approximately 36 000 employees took courses through LinkedIn and Coursera on a range of topics including data science, digital skills and marketing.

In addition, more than 11 000 managers have taken part in our Unbossed Leadership Experience program since 2020, which gives them the skills to lead cultural change within the organization. We also provide dedicated training to first-time managers.

Match is our cross-company online platform that allows employees to take charge of their own learning and career development through a range of offerings, from jobs and mentoring opportunities to short-term project assignments and 'bite-sized' training modules. In 2022, we rolled out Match across the company. The number of users increased to over 33 000 – with more than 900 mentorships, over 350 project assignments and about 250 000 learning units on the platform completed.

# Performance management and career development

All Novartis employees receive support for performance management and career development through a flexible, continuous system of coaching, feedback and recognition by managers and colleagues. Teams and individuals create objectives that focus on both short- and longer-term impact. In

addition, managers and employees have regular discussions on topics including progress toward goals, development, feedback and well-being.

### Supporting mental health and well-being

Mental health is increasingly in the spotlight as the COVID-19 pandemic and other factors have taken a toll on people's mental, social and physical well-being. The effects of stress on daily life is the most frequently reported mental health issue globally, according to the Ipsos World Mental Health Day 2022 survey.

At Novartis, we have a dedicated well-being program for employees, known as Energized for Life. In 2022, we stepped up our employee assistance programs and e-training, as we recognized that Transforming for Growth would inevitably add to pressures for many employees.

In February, we launched a new version of "How are you feeling?", an online library of tools and resources, accessed by over 10 500 employees during the year. We also added a question on well-being to our regular employee engagement survey.

We measure employee attitudes before and after our well-being programs to ensure we are on the right track. Figures for 2022 show those participating in our programs had better work-life balance, communicated more with colleagues and were able to manage their time more effectively.

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# Wages and cost of living

Novartis is committed to paying employees a living wage that meets or exceeds the amount for basic living needs, in line with our UN Global Compact commitment.

The cost of living is understandably a concern for many of our employees as inflation remains high in many countries. While we continue to monitor macroeconomic conditions, we do not make changes to pay based solely on inflation – we also consider factors such as our competitive position, business needs and our EPIC and Living Wage commitments. Historically, our approach has led to salary increases in many countries above the local rate of inflation.

Our Employee Share Purchase Plan enables employees to voluntarily purchase Novartis shares at a discounted price. The plan currently covers employees in North America (the US, Puerto Rico and Canada), with rollout to employees in other countries and regions scheduled over the next several years. All permanent employees are eligible for the plan (with certain exceptions).

# **Engaging employees through volunteering**

Our Novartis Engagement & Volunteering Program empowers employees to make a difference through giving, community initiatives and skills-based volunteering with civil society partners in a chosen community. Over time, the program has evolved into a sustainable, skills-based model that generates impact for employees, Novartis, partners and society in areas that are aligned with our strategy and purpose.

We signed a new partnership with the UN High Commissioner for Refugees, while also providing support for those affected by the war in Ukraine

In 2022 we signed new partnerships with organizations such as the UN High Commissioner for Refugees, while also providing support for those affected by the war in Ukraine (see page 61). Our projects over the past year included mentoring health-tech entrepreneurs, supporting environmental sustainability in the supply chain, and working with the UN on projects for innovation.



# Providing a safe and secure working environment

Our commitment to occupational health and safety is built into our Code of Ethics. In addition, we have strict health and safety controls across our sites that go beyond legal requirements:

- At all our sites, we conduct regular audits to assess compliance with regulations and internal controls.
- We also carry out risk assessments to determine the necessary frequency of these audits, and have crisis management plans in place to deal with emergency situations.
- Both our own employees and outside contractors receive regular health and safety training

Health and safety standards are also incorporated into our supplier contracts and risk assessments. In addition, 18 of our sites have ISO 45001 certification, covering 35% of employees and third-party personnel working in manufacturing and supply.

Safety incident rates returned to pre-pandemic levels in 2022, consistent with industry benchmarks. However, over the longer term we continue to see improvement with the total recordable incident rate for employees and third-party personnel trending downwards, due in part to the implementation of new management systems.



UN SDG target 8.8 reads: Protect labor rights and promote safe and secure working environments for all workers, including migrant workers, in particular women migrants, and those in precarious employment.

Please see page 23 for more information on our impact on the SDGs

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# Scale data science and technology

We are investing in data science and technology to support innovation, increase efficiency, better respond to the needs of patients and healthcare professionals, and ultimately improve the way we develop and deliver our medicines.

To support our strategy, we use data science and technologies such as artificial intelligence (AI) across our company. Internally, we are investing to build a strong data, digital and IT foundation for our own systems and processes – spanning everything from R&D and operations to product management and commercial activities. We are also using data science and technology to better meet the needs of customers and patients. As part of our overall strategy, we focus on priority projects that can be scaled globally and have the highest impact.

# **Supporting innovation**

Our business produces enormous amounts of data, not only from research and development but also from production, distribution and marketing. We are taking advantage of this resource to improve productivity and spur innovation.

Our Generative Chemistry project, for example, helps scientists at the Novartis Institutes for Biomedical Research (NIBR) speed up the discovery of new high-value medicines. The process for researching and developing new medicines is complex, requiring the evaluation of hundreds of thousands of candidate compounds before a project reaches the clinical trial stage. We use machine learning algorithms to identify new patterns and suggest molecules to synthesize in the lab.

More than 250 specialist data scientists are embedded within NIBR project teams to help optimize and accelerate key aspects of our research

This is just one example of how data science has become a pillar of our drug discovery efforts. More than 250 specialist data scientists are embedded within NIBR project teams to help optimize and accelerate key aspects of our research - from target identification and dose modeling to refining predictive biomarkers. In pre-clinical and early clinical work, for instance, NIBR data scientists created a neural network model to assess brain penetration potential for several neurological drug candidates. Using biodistribution data, they also developed a method to accurately predict how doses of an investigational radioligand therapy would be absorbed by key radiosensitive organs.

In our drug development operations, our Nerve Live program collects data from dozens of domains to generate insights, drive efficiency and reduce risk – for example to keep clinical trials running smoothly or helping with oversight of drug safety operations for our portfolio. The program has been successfully scaled after launching five years ago, with thousands of employees now using Nerve Live's decision-support tools to help them in their daily work.

Andromeda, which was launched in 2020 and is now used by more than 10 000 employees, is a solution that covers the entire portfolio of Novartis, spanning research, development and our commercial operations. It uses advanced analytics and simulations to accelerate portfolio decision-making, helping to drive efficiency and contributing to the value of our pipeline.

Our data42 platform gives our data scientists and researchers access to 2 million patient years of data from thousands of clinical trials over more than two decades. Backed by robust privacy controls for patient data, it enables researchers to analyze millions of health records, genomic data, adverse events and other information to generate hypotheses and test them through statistical modeling. Today, this data analytics platform is being used by over 1100 Novartis data scientists and researchers.

#### Related links and disclosures:

- → Data Privacy Policy
- → Novartis Privacy Hub
- → Position on Regulatory Data Protection
- → Our Commitment to Ethical and Responsible Use of AI

# Building a data and digital backbone

We are making progress in modernizing our IT systems and connecting the large volumes of data created throughout our business.

In 2020, we launched a common platform for data and analytics aimed at maximizing the value of our data. Today, this platform is used at scale across the company to generate reliable data in a standard format and enable insights using AI and machine learning. Ultimately, this will speed up decision-making, increase efficiency and provide new insights.

Through our Lean Digital Core (LDC) program, we are replacing our legacy enterprise resource planning systems with a single system across our organization. This will simplify how we work and allow for easier and more cost-effective upgrades. We anticipate cost savings of approximately USD 500 million as a result.

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To support these changes, we are standardizing around 700 internal end-to-end processes used by our finance, procurement, manufacturing and commercial teams. We aim for initial deployment of LDC in two countries by the end of 2023 and expect the overall program to be completed by 2028.

Alongside LDC, we are investing in new technology for human capital management (HCM), built around Workday, a third-party software platform. This new approach will replace more than 15 global and local systems currently in use with just four global systems. With this change, we will be able to improve how we recruit, manage and develop our employees, as well as simplify and speed up our HR processes. In addition, both employees and managers will have access to new tools for training and career development. The project will be implemented in waves over the next two vears, with the first wave scheduled for the second half of 2023.

# **Engaging patients and healthcare professionals**

We are using data science and technologies to find new ways to support patients and engage healthcare professionals.

For example, a project called Leap uses technology and real-time data insights to make it easier and more efficient for

patients in the US to begin and remain on therapy as prescribed. We launched new web-enabled capabilities and a Novartis Patient Support Center (PSC) to help patients more easily access our medicines through financial and adherence support. In 2022, Leap was fully integrated into our US patient support activities for *Entresto*. We also began a scaled rollout to *Cosentyx* patients. We plan to cover the full Novartis product portfolio in the US by the end of 2024.

Leap uses technology and realtime data insights to make it easier and more efficient for patients to begin and remain on therapy as prescribed

At the same time, our Next Generation Engagement program uses a mix of data analysis, behavioral insights and communications technology to achieve the most effective mix of face-to-face and digital communications for healthcare professionals in key markets. For example, we personalized 36% of touchpoints with healthcare professionals for *Cosentyx* in the US. This personalized approach has led to increased customer engagement and supported sales growth.



# Using AI to tackle heart disease

In 2022, the Novartis Foundation launched the Al4HealthyCities Health Equity Network alongside Microsoft Al for Health and other partners. The aim is to use artificial intelligence to analyze health data and provide city authorities with insights into the main social determinants of heart disease so they can direct more resources to high-impact interventions. New York, US, and Lisbon, Portugal, are the first cities to take part in the program, with further major cities planned for 2023.

Insights from the program could increase understanding about heart disease and how heart health could be improved by tackling the underlying social, economic or environmental causes. These include everything from healthy diet and physical exercise to education, exposure to pollution and access to decent housing.

The Novartis Foundation seeks to improve the health of low-income populations around the world and reduce health inequity by using data and population health management.

For more information, see www.novartisfoundation.org

# 2 cities New York and Lisbon

are the first cities to take part in the Novartis Foundation's Al4HealthyCities program, with more planned for 2023.

Diana Wong Ramos, a stroke survivor and patient advocate, holds an information session for patients at a hospital in Lisbon, Portugal.

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# **Build trust with society**

We aim to increase access to our medicines for underserved populations around the world, and follow high standards of ethical behavior wherever we operate. In 2022, we pledged investment for research into new medicines for neglected tropical diseases while advancing partnerships to enhance cardiovascular and cancer care for patients across the world.

### Access to medicines

Despite recent medical advances, billions of people around the world still lack access to the medicines and healthcare services they need.

Many of the most acute issues are in low- and middle-income countries (LMICs). which face the dual burden of infectious and non-communicable diseases (NCDs). as well as fragile and under-resourced health systems. But the COVID-19 pandemic also exposed deep health inequities in higher-income countries, where barriers to access are often linked to structural health system issues as well as demographic, social and economic challenges.

At Novartis, we not only discover and develop new medicines, but also aim to make them available to as many people as possible. We have been committed to increasing access to medicines for decades. Over the years, we have moved from a donations-based approach to one that employs a combination of access models for more sustainable social impact. In 2022, our access programs and initiatives reached 54.6 million patients worldwide.

### **Our targets**

To reinforce our commitment to access, we have set key targets covering both our strategic innovative therapies and our global health priorities (see page 55).

In 2022, we achieved a 26% increase in patients reached with our strategic innovative therapies in LMICs compared with the previous year, representing an increase of 119% since 2019. Patients reached through our global health programs declined by 5% from the prior year, driven by increased availability of generic alternatives due to the easing of COVID-19-related supply disruptions in the wider industry. However, we remain on track to meet our target as the latest figure represents an increase of 107% from 2019.

# Our approach

To achieve our targets, we work to improve access for patients across the lifecycle of our medicines. We are guided by the Novartis Access Principles, which commit us to systematically integrate access strategies in how we research, develop and deliver our new medicines.

These strategies include innovative approaches to affordability, such as sustainable business models and value-based pricing, as well as efforts to adapt medicines for different patient groups or for diverse environments. While affordability and availability remain key issues, the ability of health systems to effectively use innovative medicines is another critical barrier to access.

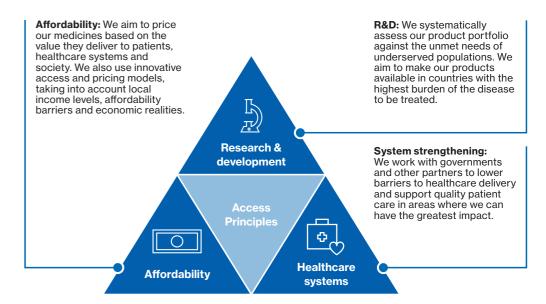
In 2022, we pledged additional funding for research into new medicines for neglected tropical diseases. We became the first pharmaceutical company to contribute an innovative medicine to the

#### Related links and disclosures:

- → Position on Access to Medicines
- → Position on Value-Based Healthcare
- $\rightarrow$  Code of Ethics
- → SpeakUp Guideline
- → Third Party Code
- → Anti-Bribery Report
- → Position on Collaborating with Patient **Organizations**

# **Novartis Access Principles**

We systematically integrate access strategies into how we research, develop and deliver our new medicines globally.



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ATOM Coalition to treat chronic myeloid leukemia (see page 56). We also expanded our 20-year collaboration with the Max Foundation to drive access to our innovative breast cancer treatment, in addition to chronic myeloid leukemia, and we launched key partnerships with health systems in both high-income countries and LMICs.

# **Novartis global health priorities**

Our work on global health is aligned with our overall efforts to expand access to our medicines. We follow an integrated approach for the elimination or control of four diseases where there has been market failure and little investment in research and development:

### Sickle cell disease (SCD)

Every day, an estimated 1 000 children are born in Africa with SCD. Of those, more than half die before their fifth birthday due to preventable complications from the illness. The Novartis Africa Sickle Cell Disease program is a holistic approach to diagnose, treat and manage the disease in sub-Saharan Africa (SSA). We are engaging with eight countries in SSA. This includes full partnership agreements with three countries, with more planned over the next several years. See page 59 for details of our integrated approach to tackling SCD.

#### Malaria

According to the WHO, there were an estimated 619 000 malaria deaths globally in 2021, despite it being a preventable and treatable disease. Novartis has been involved in the fight against malaria for decades. Since 1999, we have delivered more than one billion treatments of artemisinin-based combination therapy (ACT) to endemic countries, of which over 90% were supplied on a zero-profit basis. We are developing a new optimized dose of ACT for use in infants

Access to healthcare performance indicators	2022	2021	2020
Overall patients reached (millions)			
Patients reached through access approaches <sup>1</sup>	54.6	56.2	66.4
Sustainability-linked bond (September 23, 2020 – September 23, 2028)			
Patients reached with strategic innovative therapies	1 197 352	947 699	695 669
Patients reached through flagship programs	31 157 087	32 695 224	43 912 152

Includes patients reached with medicines through Novartis Global Health, as well as patients reached through support programs, emerging market brands and donations

of less than five kilograms. In 2022, we announced our decision to proceed to Phase III clinical trials in 2023 for our lead malaria pipeline program (see page 37).

#### Chagas disease

Chagas disease causes around 12 000 deaths a year. The disease is endemic in 21 countries, mostly in Latin America. Fewer than 1% of the six million people infected receive proper antiparasitic treatment. Starting as a parasitic disease, Chagas disease can lead to chronic heart disorders in up to 30% of patients. We are conducting a Phase IV study in patients with the cardiac form of Chagas disease in collaboration with the Brazilian Clinical Research Institute, and working to strengthen health care systems in Brazil, Mexico, and Bolivia. Novartis is also a member of the Global Chagas Disease Coalition.

## Leprosy

Currently, an estimated 2-3 million people live with leprosy. Over the past 30 years, great strides have been made in treating the disease through multidrug therapy (MDT).

Since 2000, Novartis donations of MDT packs have treated over 7.5 million people. In 2020, we renewed our pledge to continue donations for another five years. We are also working with the WHO on a process to reliably replenish the stocks of medicines used to treat leprosy.

# **Research and development**

We assess our R&D work against the needs of underserved populations and integrate access considerations and evidence needs for LMICs early into the development process. We begin anticipating potential access barriers and enablers for our investigational medicines at the end of Phase II development. To further improve access, we do not file or enforce patents in low-income countries.

In 2022, we pledged to invest USD 250 million for research into new medicines for malaria and neglected tropical diseases such as Chagas disease and leishmaniasis (see page 34).

# Progress against ESG targets Access and global health

larget	Progress
Implement a global access strategy for all new medicines launched	All new launches in 2022 had a global access strategy.
Increase by at least 200% patients reached with strategic innovative medicines in LMICs¹ by <b>2025</b> (compared with 2019)	On track: 1.2 million patients reached in 2022 (up 119% since 2019)
Increase by at least 50% the number of patients reached with Novartis global health flagship programs <sup>2</sup> in LMICs <sup>1</sup> by <b>2025</b> (compared with 2019)	On track: 31.2 million patients reached in 2022 (up 107% since 2019)

<sup>&</sup>lt;sup>1</sup> Low- and middle-income countries as defined in sustainability-linked bond prospectus

<sup>&</sup>lt;sup>2</sup> Malaria, leprosy, Chagas disease, sickle cell disease

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Beyond our investigational therapies, we also adapt existing medicines for different patient groups or for diverse environments. In 2022, we launched a pediatric friendly formulation of hydroxyurea, a treatment for sickle cell disease, in Ghana, with plans to expand to Kenya, Tanzania and Uganda.

# Affordability and availability

We use a combination of approaches to make our medicines affordable for patients across the income pyramid.

In high-income and upper-middle income countries, we seek to price our medicines based on the value they deliver to patients, health systems and society. We believe this approach incentivizes health systems to focus on interventions that deliver the most effective, efficient and sustainable outcomes. For more information on our position on value-based pricing, please see our corporate website.

In LMICs, we implement tiered pricing for launches of our strategic innovative therapies, taking income levels, local affordability barriers and economic realities into consideration. This approach supports governments in responding to unmet medical needs in a way that is sustainable for our business. All our medicine launches in 2022 included a tiered pricing strategy for LMICs.

Additionally, we have support programs to help patients facing financial hardship or other barriers to access, as well as to support education on disease awareness and adherence to medication. These include Novartis Patient Assistance in the US and Novartis Oncology Access for patients across Asia and the Middle East. Overall, we have around 800 active patient support programs in 80 countries.

To drive access in SSA, we launched a dedicated unit in 2019 to focus on reaching more patients in the region across several therapeutic areas through sustainable business models. We deliver our portfolio of medicines across the income pyramid in SSA and have established an ecosystem of local partners to drive impact and reach more patients across income levels.

Our Novartis Access program, an innovative business model to increase access to on- and off-patent medicines for noncommunicable diseases (NCDs) in countries across Africa, Latin America and Asia. evolved in 2022. The aim of this was to address the complexity of health system barriers that, along with a lack of access to high-quality and affordable medicines. contribute to poor health outcomes. To further drive impact and integrate the approach into our core business, we increased the flexibility of the product offering, broadened distribution to additional channels, and took steps to address health system needs that may inhibit access to these medicines.



# Breaking new ground in access to innovative cancer medicines

Novartis is a founding member of the Access to Oncology Medicines (ATOM) Coalition, a public-private partnership that aims to build a new sustainable access model for cancer medicines. Novartis is the first pharmaceutical company to contribute an innovative medicine to ATOM. We granted a "freedom to operate" license ahead of patent expiry in multiple LMICs for nilotinib¹, which was developed to treat chronic myeloid leukemia.

The agreement allows the Medicines Patent Pool, a United Nations-backed public health organization, to sub-license nilotnib to generic manufacturers who will be able to manufacture and commercialize the medicine in those markets. The approach has been tested successfully with communicable diseases like HIV and COVID-19, but never in cancer. We hope this will provide a new model for the sector to increase access to life-changing medicines for non-communicable diseases.

We know that making medicines available is only one part of the journey to improve access. Collaboration with our ATOM Coalition partners in diagnostics, training and delivery will also be critical to help meet our collective goal of bringing the most appropriate medical interventions to everyone who needs them.

# 1st

#### Novartis is the first

pharmaceutical company to contribute an innovative medicine to the ATOM coalition, a public-private partnership aimed at building a new sustainable model for access to cancer medicines.

Isabel Nango at her home in Djobel, Guinea-Bissau. Cancer is a growing health issue in LMICs

<sup>&</sup>lt;sup>1</sup> Marketed by Novartis under the brand name Tasigna

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At the same time, we continued to expand our emerging market brands (EMB) program, adding 29 new EMBs including for Legvio, Pigray and Kesimpta. We also continue to narrow or eliminate the time lag between launches in Europe and in other countries. For instance, during 2022 we launched an EMB of our lung cancer treatment Tabrecta in Malaysia two months before the first EU launch in Germany.

Through our donation programs, we help broaden access to patients in LMICs with serious or life-threatening illnesses and those affected by natural disasters and extreme poverty. In 2022, we expanded our 20-year collaboration with the Max Foundation to include donations of our Kisgali and Femara medicines for breast cancer a leading cause of cancer-related deaths among women in LMICs. The expanded program, known as CancerPathtoCare™, will also continue to support patients with chronic myeloid leukemia and other rare cancers through donations of our Glivec. Tasigna and Scemblix medicines.

We expanded our 20-year collaboration with the Max Foundation to include donations of our Kisgali and Femara medicines for breast cancer

For over 30 years, Novartis has been working with partners around the world to eliminate leprosv. Since 2000, through the WHO. Novartis has donated more than 70 million blister packs of multidrug therapy (MDT) valued at approximately USD 124 million, helping to treat more than 7.5 million leprosy patients worldwide. Our agreement with the WHO also covers donations of triclabendazole for the treatment of fascioliasis, a disease caused by parasites known as liver fluke. Novartis has been donating the medicine to the WHO since 2005.

# **Health system strengthening**

Barriers to access are complex: while affordability and availability remain key issues, the ability of health systems to effectively use innovative medicines is another barrier. We work closely with governments and civil society to strengthen health systems and lower barriers to healthcare delivery.

We follow a systematic, enterprise-wide approach. Health system strengthening (HSS) is being integrated throughout our core business planning processes, and all Novartis launches have a global HSS strategy for local adaptation.

Current projects include reducing delays in breast cancer diagnosis due to COVID-19 backlogs through clinic optimization in

Portugal and helping to establish heart failure clinics in 14 LMICs to reduce the high re-admission rates many patients face following heart failure. Our Avoidable Blindness program executed partnerships across four countries in Sub-Saharan Africa, focusing on strengthening policy, primary care integration and referral networks - all critical elements of equitable access to eye health services.

We supported key partnerships during the year. These included the Collaborative on Strategic Public Private Partnerships for Cardiovascular Health with Harvard University and the World Economic Forum to strengthen the capacity of health systems to detect, treat and ultimately prevent atherosclerotic cardiovascular disease (ASCVD).

which accounts for over 85% of all cardiovascular disease deaths. In the US, we expanded our Beacon of Hope program, which funds research at historically Black medical colleges into how to tackle disparities endemic in the US health system (see page 58).

The data table below covers HSS activities in LMICs managed by the Novartis Global Health organization. In 2022, we increased the number of people reached despite fewer points of service provision and standalone awareness events, due primarily to our focus on maximizing the efficiency of these activities. The ongoing impact of the COVID-19 pandemic in some countries also limited the number of community engagements during the year.

# **Novartis Global Health**

Health system strengthening performance indicators <sup>1</sup>	2022	2021	2020
Health educators trained	4 477	2 827	671
Healthcare providers trained	12 035	10 719	12 648
Points of service provision <sup>2</sup>	1 313	4 365	5 902
People reached at points of service provision	979 755	360 356	486 642
Awareness events held	297 700	412 872	424 878
People reached at awareness events	12 960 922	9 678 360	8 048 360

<sup>&</sup>lt;sup>1</sup> Data reflect the full scope of access approaches managed by the Novartis Global Health organization. <sup>2</sup> Points of service provision include facilities and health camps where healthcare services are provided

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#### **Act4Biosimilars**

In May, our Sandoz division founded and sponsored a new global initiative called Act4Biosimilars to increase access to biologics. Bringing together patient advocates, healthcare professionals and industry leaders, Act4Biosimilars is aimed at increasing global adoption of biosimilars by at least 30% in more than 30 countries by 2030. Biosimilars tend to cost much less than branded medicines, which makes them more affordable for those on low incomes. Sandoz already systematically considers access when pricing generics and biosimilars, typically entering a market at below the reference price. Sandoz medicines reached approximately 450 million patients worldwide in 2022.

# Fighting antimicrobial resistance

The WHO has declared antimicrobial resistance (AMR) – when antibiotics and other antimicrobial medicines become ineffective and infections become increasingly difficult or impossible to treat – a major public health threat. AMR causes nearly 1.3 million deaths a year, as many as HIV and malaria combined, according to the Global Research on Antimicrobial Resistance report published in 2022.

Novartis supports the global scientific consensus that overuse, underuse and misuse of antimicrobial medicines all contribute to the spread of AMR, and that a balanced approach is needed. Our approach to tackling AMR focuses on four areas:

- Prevention responsible manufacturing to prevent antibiotics entering the environment
- Access strengthening access to high-quality, affordable antibiotics
- Responsible use ensuring prescription of the right antibiotic at the right dose for the right duration
- Innovation investing in the development of new, more effective antibiotics through the AMR Action Fund

In 2022, Sandoz announced an additional EUR 50 million investment to support increased manufacturing capacity for finished dosage form penicillin at the Kundl, Austria, manufacturing site. Sandoz also extended its collaboration agreement with Ares Genetics to develop a digital platform for development and life-cycle management of antibiotics until 2025. In addition, Novartis is part of the AMR Action Fund, which plans to invest more than USD 1 billion in the clinical development of new antibiotics.

Sandoz announced an additional EUR 50 million investment to support increased manufacturing capacity for finished dosage form penicillin

Novartis is partnering with the Ecumenical Pharmaceutical Network (EPN) to support faith-based organizations in SSA combat AMR through prevention, education and awareness. See our corporate website for more information about our work on AMR.



# Taking action on health equity in the US

In 2022, we committed an additional USD 17.7 million to our Beacon of Hope initiative in the US to tackle racial health disparities, bringing total funding to more than USD 50 million over ten years. Beacon of Hope aims to address factors that disproportionately affect health in underserved communities by increasing diversity in clinical trials, reversing bias in data standards, and enabling the next generation of African American, Black and Hispanic healthcare leaders.

The additional funds are being used to create Clinical Trial Centers of Excellence at three historically Black medical colleges and universities (HBCUs) – Howard University College of Medicine, Meharry Medical College and Charles R. Drew University of Medicine and Science – in addition to the centers at the Morehouse School of Medicine, which were announced in 2021.

As part of the initiative, NIBR is offering a 10-week paid summer fellowship program for students at HBCUs to learn drug discovery, data analytics and clinical research practices, with the goal of training up to 250 scientific leaders over 10 years.

Beacon of Hope brings together Novartis, the Novartis US Foundation, the Morehouse School of Medicine, the Thurgood Marshall College Fund, Coursera, the National Medical Association, and 26 HBCUs in the US. In addition, two other global pharmaceutical companies joined the collaboration in 2022.

For more information, see our corporate website

# 50 m Funding (USD)

Total funding for our Beacon of Hope initiative stands at more than USD 50 million over ten years

KeAndreya Morrison, a student at Meharry Medical College, who was one of 17 Beacon of Hope Summer Fellows in 2022 CEO's letter

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### Integrated access in action: sickle cell disease (SCD) in Africa

The Novartis Africa Sickle Cell program provides a blueprint for how to address access barriers across the continuum of care. Launched in 2019, the program takes an end-to-end approach to tackling the disease in sub-Saharan Africa (SSA), from research into new medicines to efforts to break down barriers to diagnosis and treatment.

- R&D: While the genetic cause of SCD has been known for decades, it's only recently that the medical world has gained the tools to potentially fix the errant gene that causes the disease. Together with the Bill & Melinda Gates Foundation, we are exploring the possibility of a novel in vivo gene therapy for SCD, offering hope of a cure for the disease. We envision developing an accessible therapy that could potentially be administered directly to the patient through a single injection. This contrasts with complex procedures associated with ex vivo gene therapies that require cells to be extracted from the body and are individually manufactured before treatment.
- · Availability of existing treatments: We continue to roll out hydroxyurea across the continent. The medicine has been shown to improve health outcomes among those living with SCD. In 2022, we launched a pediatric-friendly formulation of hydroxyurea in Ghana, with plans to expand to Kenya, Tanzania and Uganda in 2023. Building on that, we are assessing the opportunity to introduce innovative therapies for SCD.
- Health system strengthening: We are working to strengthen early intervention in SCD treatment, particularly among young children. Our new partnership with the American Society of Hematology, agreed in 2022, will improve screening and diagnosis at health institutions in seven SSA countries.

80%

# **SCD** patients

An estimated 80% of people with SCD live in sub-Saharan Africa. The Novartis Africa Sickle Cell Program works with governments to tackle the disease.



A nurse takes a blood sample from a baby as part of a newborn screening program for sickle cell disease in Ghana.



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# **Maintaining high ethical standards**

Our industry faces ethical questions and decisions every day on issues such as patient care, data use, and access to medicines. To guide us in these decisions, we have a comprehensive Code of Ethics – developed together with our employees and experts in behavioral science – that applies to all employees, as well as a suite of internal policies and controls. We also provide online tools, such as the Ethical Decision Explorer, to help employees navigate ethical dilemmas, in addition to training on ethics to employees at all levels of the company. In 2022, 98% of employees completed training on our Code of Ethics.

In addition, our ethical standards are built into our relations with business partners via our Third Party Code and we have programs in place to combat falsified medicines and monitor potential adverse effects of our medicines (see page 44).

We also work through industry codes, including PhRMA's Code on Interactions with Health Care Professionals and the IFPMA's Code on Pharmaceutical Marketing Practices, as well through as regional and local industry associations. The UN Convention Against Corruption and the OECD's Convention on Combating Bribery of Foreign Public Officers inform our policies and programs. We are a signatory to the UN Global Compact and we are working to implement the UN Guiding Principles on

Business and Human Rights. You can read more about our approach to ethics, risk and compliance on pages 68-75.

#### **Encouraging employees to speak up**

The Novartis SpeakUp Office, our grievance mechanism, enables employees and external parties to raise concerns about potential misconduct while being protected against retaliation.

In 2022, a total of 2 569 complaints of alleged misconduct, resulting in 2 400 cases with 2 871 allegations, were received and handled. Of the total cases, 385 (16%) were classified as central matters (higher-risk cases) warranting further investigation. Lower-risk matters are addressed or investigated locally. The investigated central matter allegations resulted in 116 dismissals or resignations, and in 62 written warnings. Other remedial actions such as training, coaching and implementing new controls were also used when deemed appropriate.

The increase in cases from the prior year was primarily due to matters related to data security as a result of enhanced protective measures and monitoring systems the company put in place. These measures included a campaign on data loss prevention to support regular mandatory trainings on information management, data privacy and data use. The increase in reported cases indicates that our SpeakUp program and related awareness activities are having an

impact in encouraging people to raise their concerns.

### **Measuring our ethical climate**

In 2022, we conducted our second global ethics survey to gather data on ethical behavior and the ethical climate across our company. We received more than 33 000 responses. We use insights from the survey to drive conversations at the global and

local levels and take action where needed. For example, in 2022 we further clarified our commitment to protect employees who speak up from disciplinary action in a new standalone policy on non-retaliation, which was created in consultation with our human rights and employee relations teams. We intend to continue running the global ethics survey in 2023.

Ethical business practices performance indicators	2022	2021	2020
Code of Ethics			
Employees trained and certified (%) <sup>1</sup>	98	98	98
Grievance indicators: SpeakUp Office – central matters <sup>2,3</sup>			
Misconduct cases reported	385	174	157
Total allegations <sup>4</sup>	544	296	284
Allegations substantiated 5	257	137	118
Dismissals and resignations related to misconduct	116	62	101

- <sup>1</sup> Active Novartis employees with an email address, trained via e-learning.
- <sup>2</sup> A central matter applies to issues where a senior leader or manager is involved, or issues which may have a potentially disruptive reputational impact. Also, central matters can involve sexual harassment, discrimination, retaliation and issues with significant financial impact.
- <sup>3</sup> The number of misconduct cases, allegations reported/substantiated, and dismissals/resignations may change year-on-year as matters may be reassessed in the course of the case life cycle. As a result, we may restate data from previous years.
- <sup>4</sup> The number of allegations is higher than the actual number of cases as a case can have more than one allegation.
- <sup>5</sup> "Allegations substantiated" and "total allegations substantiated per category" may include allegations from previous years. Whereas "misconduct cases reported" and "total allegations" refer to allegations reported within each calendar year.

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### Helping those affected by the war in Ukraine

We provided support to refugees and those displaced by the war in Ukraine. We also provided essential medical supplies and continued to deliver our medicines to patients who need them.

- Since the start of the war, we have provided 21 million doses of medicine to those in Ukraine and to refugees in border areas, worth more than USD 33 million.
- We donated USD 3 million to organizations working with refugees and displaced people, including Save the Children, the International Rescue Committee and the Red Cross, and allocated a further USD 1 million to patient organizations supporting displaced refugees.
- Novartis employees donated more than USD 2.2 million to non-profit organizations through employee giving. Beyond donations, our employees also volunteered their time and skills and opened their homes to host refugees.

To protect employees, we suspended our operations in Ukraine in March. After studying safety protocols in the country, we resumed business operations remotely in June to help the country restore some basic critical business processes. We continue to review and adapt our activities to the prevailing security and safety situation. Protecting employees remains our priority.

In Russia, we took measures to freeze capital investment, advertising and other promotional activities. We also stopped new clinical trials and suspended enrollments in existing trials. We continue, however, to supply vital medicines to patients in Russia. We will keep measures affecting both Ukraine and Russia under review.

21 m Doses of medicine provided to people in Ukraine and refugees in border areas



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# **Corporate governance**

Strong corporate governance is vital for the effective management of our business and is the cornerstone of trust in Novartis. Our system of governance – along with our internal policies and controls – is aimed at ensuring we comply with applicable laws and regulations and meet high ethical standards. In doing so, it supports long-term value creation for shareholders, patients, employees and other stakeholders. For more detailed information on corporate governance at Novartis, please refer to our 2022 Annual Report.

# Our system of corporate governance

Our corporate governance is based on an effective system of checks and balances. We have a three-tier governance structure, which comprises the Annual General Meeting (AGM) of shareholders, our Board of Directors and the Executive Committee of Novartis (ECN):

- Shareholders approve dividend payments, compensation for members of the Board and ECN, as well as financial statements and other disclosures. They also elect the Board Chair, members of the Board of Directors, members of the Board's Compensation Committee, the Independent Proxy and external auditor. Shareholders meet at least once a year, usually in February or March.
- Our Board of Directors has ultimate decision-making authority (for those decisions not reserved for shareholders).
   The Board operates through five permanent committees: Audit and Compliance;
   Compensation; Governance, Sustainability and Nomination; Risk; and Science and Technology. The Board represents the interests of all stakeholders and oversees the work of the ECN.

The ECN is led by the Chief Executive
 Officer (CEO) and is responsible for operational management, including financial performance and fulfilment of the company's purpose, strategic priorities and targets. The ECN has 11 members, including the CEO and Chief Financial Officer, as well as the leaders of our commercial divisions, research and development organizations, Operations and other functions (see page 67).

In addition, our external auditor provides regular opinions to management and shareholders on the company's compliance with applicable standards, laws and reporting regulations.

# **Composition of the Board**

All Board members are independent and non-executive, as defined under our Board regulations. Members are elected for one year only; they may serve a maximum of 12 years<sup>1</sup>.

When choosing new members, the Board aims for a balance of skills, expertise and experience. Almost all current Board members have experience in leadership and management. Six have experience in

### **Governance bodies**

#### **GENERAL MEETING OF SHAREHOLDERS**

Approves operating and financial review, Novartis Group consolidated financial statements, and financial statements of Novartis AG; decides appropriation of available earnings and dividend; approves compensation of Board and Executive Committee; elects Board members, Board Chair, Compensation Committee members, Independent Proxy and external auditor; adopts and modifies Articles of Incorporation

#### **BOARD OF DIRECTORS**

AUDIT AND COMPENSATION COMPLIANCE COMMITTEE

GOVERNANCE, SUSTAINABILITY AND NOMINATION COMMITTEE

RISK COMMITTEE SCIENCE & TECHNOLOGY COMMITTEE

Sets strategic direction of Novartis, appoints and oversees key executives, approves major transactions and investments, adopts and modifies Board Regulations

#### **EXECUTIVE COMMITTEE**

Responsible for operational management of Novartis

#### **EXTERNAL AUDITOR**

Provides opinion on compliance of Novartis Group consolidated financial statements and the financial statements of Novartis AG with applicable standards and Swiss law, on compliance of the Compensation Report with applicable law, and on effectiveness of internal controls over financial reporting and limited assurance on selected performance indicators in the Novartis in Society Integrated Report

<sup>&</sup>lt;sup>1</sup> An exception to this rule was made in 2021 for Andreas von Planta. To ensure an orderly transition, Mr. von Planta was granted an exception to the 12-year limit on Board membership, introduced in 2020.

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pharmaceuticals, healthcare or medical research. We also aim to have a diverse Board in terms of gender, age, nationality, ethnicity and viewpoints, able to reflect the views of stakeholders and society.

The Board is subject to an annual self-assessment. Every third year, this process is carried out by an external consultant. Board members also receive regular briefings and trainings; in 2022, these training sessions focused on:

- Health, Safety and Environment Policy
- 'Fit to Commit', focusing on anti-bribery, insider trading and procurement
- ESG educational session held by an external expert on holistic value creation
- Third Party Risk Management

# Board highlights in 2022

- Oversaw the company's strategy to become a fully focused medicines company
- Reviewed the set-up and functioning of the ECN in the context of the company's new organizational structure
- Reviewed the geopolitical situation in Europe
- Monitored the Transformation for Growth project to ensure successful implementation
- Received an update on the US, including priorities to accelerate growth in Innovative Medicines to become a top-five player
- Received an update on the German market and our strategic ambition to become the market leader
- Reviewed and discussed strategic considerations around mergers and acquisitions,

- and our larger strategic moves to drive sustainable growth
- Discussed in detail the strategic review of Sandoz. Decided to separate Sandoz through a 100% spin-off to offer the best value proposition to investors (subject to shareholder approval)
- Discussed the company's ESG strategy, plans and developments
- Discussed the upcoming non-financial disclosure regulations and Novartis non-financial reporting governance
- Discussed longer-term Board succession planning and required profiles, proposing one new Board member candidate to be elected at the 2023 AGM
- Discussed the amendment of the Articles of Incorporation of Novartis AG as part of the Swiss Corporate Law Reform
- Discussed and reviewed the annual Board self-evaluation

# **Novartis shares**

Novartis AG, the Group's holding company, is a corporation organized under Swiss law, with its registered office in Basel. Our shares are listed on the SIX Swiss Exchange (symbol: NOVN) and on the New York Stock Exchange (symbol: NVS). The latter are in the form of American depositary receipts, representing Novartis depositary shares. Shareholder rights are guaranteed under Swiss law and our Articles of Incorporation. All shares have equal voting rights and carry an equal entitlement to dividends.

Shareholders may vote themselves or nominate another shareholder or the Inde-

pendent Proxy to vote on their behalf. Our next AGM is scheduled to take place on March 7, 2023. It will be the first physical meeting since 2020 because of previous COVID-19 restrictions.

# Changes to the ECN

In 2022, we made changes to the ECN, partly to reflect the company's new organizational structure.

Four new members were appointed:

- Shreeram Aradhye as President, Global Drug Development and Chief Medical Officer
- Victor Bulto as President, Innovative Medicines US
- Aharon (Ronny) Gal as Chief Strategy and Growth Officer
- Fiona Marshall as President, Novartis Institutes for BioMedical Research

In addition, Marie-France Tschudin was named President, Innovative Medicines International and Chief Commercial Officer. Steffen Lang became President, Operations. Both were already ECN members.

Four former ECN members left Novartis:

- Susanne Schaffert (formerly President, Novartis Oncology)
- John Tsai (formerly Head of Global Drug Development and Chief Medical Officer)
- Robert Weltevreden (formerly President, Customer and Technology Solutions)
- Jay Bradner (formerly President, NIBR)

In addition, Richard Saynor (CEO of Sandoz) stepped down from the ECN following his appointment as CEO designate of the Sandoz standalone company expected to be created in the second half of 2023.

#### Website information

Share capital	o Articles of Incorporation of Novartis AG $ o$ Novartis key share data
Shareholder rights	ightarrow Articles of Incorporation of Novartis AG
Annual General Meeting of Shareholders	ightarrow Annual General Meeting of Shareholders
Board Regulations	ightarrow Board Regulations
Novartis code for senior financial officers	ightarrow Ethical Conduct Requirements for CEO, ECN and Senior Financial Officers of Novartis
Novartis financial data	ightarrow Novartis financial data
Press releases	ightarrow Press releases $ ightarrow$ Email service

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# **ESG** and material topic governance

At Board level, the Governance, Sustainability and Nomination Committee (GSNC) oversees performance regarding governance and ESG matters, including access to medicines, global health, environmental sustainability, and human capital management. The GSNC also discusses emerging trends and regularly advises the Board on ESG matters.

The ECN oversees operational management of ESG issues. The ECN-level ESG Committee, chaired by the CEO, meets every two months to review ESG performance and strategy.

The Board-level Science & Technology Committee is responsible for oversight and evaluation of the performance of the company's scientific, technological and R&D activities. At the management level, the Innovation Management Board (IMB) is responsible for strategic aspects of our development portfolio, including the endorsement of development project

priorities and decisions on project discontinuations. Our CEO chairs the IMB. Other representatives from Novartis senior management are among its core and extended membership.

Our Sustainability & ESG Office, part of our Global Health and Sustainability organization, is responsible for embedding ESG management across our business. ESG issues are integrated into our Enterprise Risk Management approach. In addition, we have internal policies and controls to minimize risk in areas such as human rights, health and safety, anti-bribery and corruption. Stakeholder engagement also plays an important role in helping us identify possible ESG risks and opportunities (see page 21). For example, we have an independent Bioethics Advisory Committee, which advises management on ethical issues related to our research, drug development and access programs.

The table on this page provides an overview of the governance of our four most material topics, identified as part of our materiality assessment (see page 15).

# Primary governance and oversight of our four most material topics

Topic	Board committee(s)	ECN/management
Patient health and safety	Audit and Compliance Committee	President, Operations     President, GDD
Innovation	Science & Technology     Committee	President, NIBR President, GDD Innovation Management Board
Access	Governance, Sustainability and Nomination Committee	President, Innovative Medicines US President, Innovative Medicines International President, Global Health & Sustainability ESG Committee
Ethical business practices	Audit and Compliance     Committee     Risk Committee	Chief Ethics, Risk & Compliance Officer ESG Committee

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# **Our Board of Directors**



Joerg Reinhardt, Ph.D. Board Chair

Nationality: German Year of birth: 1956 Board member since: 2013 Committees: 6



Simon Moroney, D.Phil Vice-Chair

**Bridgette Heller** 

Year of birth: 1961

Nationality: American

Committees: 123

Board member since: 2020

Nationality: German/New Zealander Year of birth: 1959 Board member since: 2020 Committees: 2 6



**Patrice Bula** Lead Independent Director

**Nationality: Swiss** Year of birth: 1956 Board member since: 2019 Committees: 23



Nancy C. Andrews, M.D., Ph.D.

Nationality: American/Swiss Year of birth: 1958 Board member since: 2015 Committees: 4 5



**Ton Buechner** 

Nationality: Dutch/Swiss Year of birth: 1965 Board member since: 2016 Committees: 1 4



Andreas von Planta, Ph.D.

**Nationality: Swiss** Year of birth: 1955 Board member since: 2006 Committees: 3 4



**Daniel Hochstrasser** 

**Nationality:** Swiss Year of birth: 1960 Board member since: 20221 Committees: 102

Frans van Houten

**Nationality:** Dutch Year of birth: 1960 Board member since: 2017 Committees: 10



#### **Committees**

- 1 Audit and Compliance Committee
- 2 Compensation Committee
- 3 Governance, Sustainability and Nomination Committee
- 4 Risk Committee
- 5 Science & Technology Committee



Average tenure (years) (end-2022)

**Profile of our Board** 

**Female representation** 

of Directors

**Members** 

31%

Average age

(end-2022)

For CVs of our Board members see www.novartis.com/ about/board-directors

Elizabeth (Liz) Doherty

Nationality: British / Irish Year of birth: 1957 Board member since: 2016

Committees: 1 4



Ana de Pro Gonzalo

Nationality: Spanish Year of birth: 1967 Board member since: 2022 Committees: 104



Charles L. Sawvers, M.D.

Nationality: American Year of birth: 1959 Board member since: 2013 Committees: 3 5



William T. Winters

Nationality: British/American Year of birth: 1961 Board member since: 2013 Committees: 23

<sup>1</sup> Ana de Pro Gonzalo and Daniel Hochstrasser were both elected to the Board in March 2022. They succeed Enrico Vanni and Ann Fudge, who did not stand for re-election at the 2022 AGM.

<sup>&</sup>lt;sup>2</sup> Since January 1, 2023

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# **Our Executive Committee**



**Vasant (Vas) Narasimhan, M.D.** Chief Executive Officer

Nationality: American Year of birth: 1976



Shreeram Aradhye, M.D.
President, Global Drug Development
& Chief Medical Officer

Nationality American Year of birth: 1962



Victor Bulto

President, Innovative Medicines US

Nationality: Spanish Year of birth: 1978



**Aharon (Ronny) Gal, Ph.D.** Chief Strategy & Growth Officer

Nationality: Israeli/American Year of birth: 1966



Karen L. Hale Chief Legal Officer

Nationality: American Year of birth: 1968



Harry Kirsch Chief Financial Officer

Nationality: German/Swiss Year of birth: 1965

Rob Kowalski Chief People & Organization Officer

Nationality: American Year of birth: 1968



**Steffen Lang, Ph.D.**President. Operations

Nationality: German/Swiss Year of birth: 1967



**Fiona Marshall, Ph.D.**President. Novartis Institutes

Nationality: British

Year of birth: 1964

for BioMedical Research



Klaus Moosmayer, Ph.D. Chief Ethics, Risk &

Compliance Officer

Nationality: German Year of birth: 1968

# Profile of Executive Committee members

11 Members

Members

27%

Female representation

Female representation

53.5

Average age (end-2022)

2.45

Average tenure (years) (end-2022)

For CVs or our ECN members and other members of senior management see www.novartis.com/ecn



Marie-France Tschudin

President, Innovative Medicines International & Chief Commercial Officer

Nationality: Swiss Year of birth: 1971

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# Ethics, risk and compliance

To meet the expectations society has of our industry, we strive to maintain high ethical standards, manage risk effectively and ensure we comply with applicable laws and regulations. In addition, we work to uphold human rights and reduce social and environmental risk throughout our value chain. To support our approach, we encourage employees to take personal accountability for their decisions.

#### **Our Code of Ethics**

The healthcare industry deals with ethical questions every day – for example on affordability and access to medicines, or how to protect patients' sensitive personal data. Many of these issues go to the heart of our strategy as a focused medicines company.

Our approach to managing ethical decisions is based on our Code of Ethics, which applies to all Novartis employees. This Code sets out commitments in 23 areas that are applicable across our business, codifying who we are, what we stand for and the principles to which we hold ourselves accountable. We conduct an annual global ethics survey to measure our progress in embedding our Code across our organization (see page 60).

# Managing risk

Our strategy as a focused medicines company creates both opportunities and risks for our business. Many of these risks relate to our business environment, such as the uncertainty inherent in research and development or increasing societal expectations of our industry. Effectively managing these risks is critical to achieving our strategic goals and creating value for our stakeholders and society.

Our Enterprise Risk Management (ERM) framework is designed to generate a holistic view of risks for the company and drive a culture of smart risk-taking. It ensures that effective risk management is integrated into our significant activities and helps us better understand our risk exposure by providing increased transparency for leaders on how our key threats and opportunities are evolving throughout the year.

Our annual ERM process results in the Novartis Risk Compass, which helps our

Board of Directors and senior management focus on key risks and align strategy with risk exposure.

Risks are grouped into three categories: strategic, operational and emerging. Risks are rated on a four-point scale – very high, high, medium, low – based on their likelihood and potential impact, using the 'most-probable worst-case' scenario for each risk as a reference point. Once key risks are identified, mitigation plans are created.

#### Related links and disclosures

- → Code of Ethics
- ightarrow Third Party Code
- → Anti-Bribery Policy
- → Professional Practices Policy (P3)
- → Novartis Position on Animal Research
- $\rightarrow$  Human Rights Commitment Statement

#### **Novartis Risk Compass**

# Strategic risks

are the most consequential to our ability to execute our strategy or achieve our business objectives.

# **Emerging risks**

require close monitoring and have the potential to become strategic or operational risks.



# Operational risks

relate to internal processes or systems, employee errors or external events.

# Awareness topics

are longer-term trending topics that have the potential to become new risks.

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In addition to the three categories described above, we identify separate "awareness topics" that we believe may become new risks over time. Awareness topics are not rated. We regularly monitor risks and revise our assessments, if necessary.

#### **Risk governance**

The effectiveness of risk management depends on its integration into the governance of the organization, including strategy-setting and decision-making. This requires involvement and support from management and governance bodies at different levels of the company:

- The Risk Committee of the Board of Directors oversees the risk management system and processes within Novartis.
   Together with senior management, this body revises the prioritization of risks, the risk portfolio and actions implemented by management, and performs ad hoc reviews of key risk areas.
- The ECN regularly assesses risks and fosters a culture of risk awareness, in line with the Novartis Values and Behaviors and the Novartis Code of Ethics. The overall ERM process is the responsibility of the Chief Ethics, Risk & Compliance Officer. The CEO reviews and validates the annual Novartis risk portfolio, while members of the ECN are appointed as risk owners for relevant strategic risks.

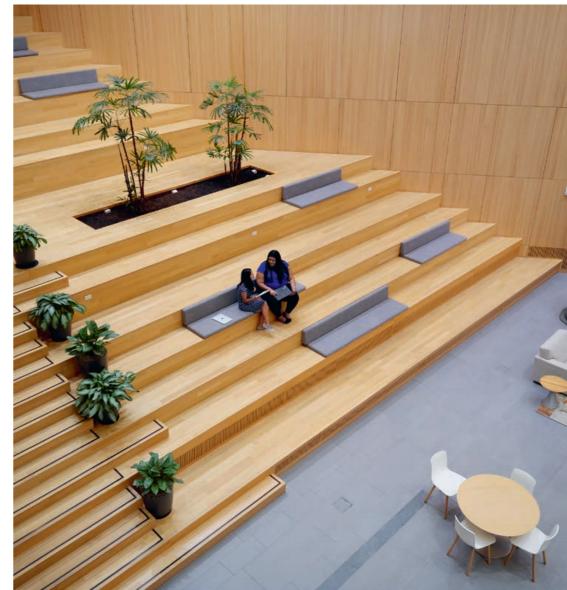
 These bodies are supported by the Risk & Resilience organization, which is part of the Ethics, Risk & Compliance (ERC) function and manages the ERM process, as well as risk leaders from key markets and functions.

### **Risks in 2022**

Our risk portfolio in 2022 comprises 16 risks. Of these, six are categorized as strategic, seven as operational and the remaining three as emerging. In addition, we have identified two awareness topics.

# Changes in our external environment have exacerbated some risks and given rise to new ones

While the majority of risks remain the same as in 2021, changes in our external environment over the past year – such as the war in Ukraine and an increasingly negative global macroeconomic outlook – have exacerbated some risks and given rise to new ones. In addition, the decisions to spin off our Sandoz Division and transform our organizational structure have influenced our risk portfolio due to the significant nature of these changes.



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### **Novartis 2022 risk portfolio**

The table below sets out our full risk portfolio for 2022. Please see the following page for more details on our six strategic risks.

#### Strategic risks

- Key products and commercial priorities Failure to deliver key commercial priorities and successfully launch new products
- Research and development Failure to successfully prioritize, integrate and execute our research and development programs for new products or new indications for existing products, given our focus on innovative medicines
- Pricing, reimbursement and access Pricing and reimbursement pressure, including pricing transparency and access to healthcare
- Alliances, acquisitions and divestments Failure to identify, execute, and/or realize the expected benefits from our external business opportunities
- Strategic transformations Failure to meet organizational transformation programs objectives and/or unintended adverse impacts on our business
- Environmental, social and governance matters

Failure to meet environmental, social and governance expectations

# **Operational risks**

- Cybersecurity and IT systems
  - Cybersecurity breaches, data loss, and catastrophic loss of IT systems
- Fragmented IT landscape and strategic technology programs implementation

Failure to address fragmented business processes, unclear data ownership, and IT applications and infrastructure nearing their end-of-life may disrupt our core business processes.

 Talent management Inability to attract, retain and motivate qualified individuals in key roles and markets

#### Third-party management

Failure to maintain adequate governance and oversight over third party relationships, and failure of third parties to meet their contractual, regulatory or other obligations

Legal, ethics and compliance

Challenges posed by evolving legal and regulatory requirements and societal expectations regarding ethical behavior

- Manufacturing and product quality Inability to ensure proper controls in product development and product manufacturing, and failure to comply with applicable regulations and standards
- Supply chain Inability to maintain continuity of product supply

# **Emerging risks**

- Geopolitical developments Impact of geo- and socio-political threats
- Macroeconomic developments Impact of macroeconomic developments
- Climate change Impact of climate change and increased risk of major natural disasters

# **Awareness topics**

### **Antimicrobial resistance and pandemics**

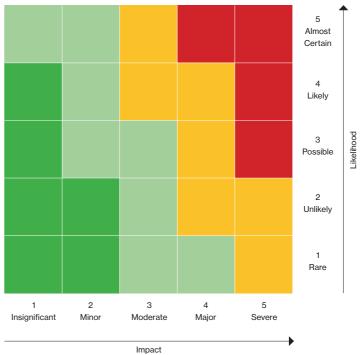
Rise of antimicrobial resistance could potentially create future pandemics and impact the performance of certain Novartis products (e.g., oncology)

#### **Falsified medicines**

Impact of falsified medicines on patient safety, and reputational and financial harm to Novartis and our products



# **Novartis risk ratings**



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### Strategic risks in focus

The table below provides an overview of our six strategic risks. Further information on our risk portfolio can also be found in the Novartis Annual Report.

Risk rating: 

Very high High Medium Lo

Risk Context Actions

#### **Deliver high-value medicines**

Key products and commercial priorities

Failure to deliver key commercial priorities and successfully launch new products

Our ability to grow our business depends on the commercial success of key products. Their success could be impacted by a number of factors, including pressure from new or existing competitive products; changes in the prescribing habits of healthcare professionals; unexpected side effects or safety signals; supply chain issues or other product shortages; pricing pressures; regulatory proceedings; changes in labeling; loss of intellectual property protection; and global pandemics.

- We are focusing our commercial strategy on eight priority brands / launch assets across five core therapeutic areas, as well as four priority geographies (US, Germany, China, Japan).
- We also continue to evolve our customer engagement model to combine traditional face-to-face visits with virtual engagements with healthcare professionals. We are similarly changing our approach to partnering with healthcare systems, payers and other healthcare providers.

Research and development

Failure to successfully prioritize, integrate and execute our research and development programs to develop new products or new indications for existing products, given our focus on innovative medicines

We engage in costly, lengthy and uncertain R&D activities, both independently and in collaboration with third parties, to identify and develop new products and new indications for existing products. Failure can occur at any point, including after substantial investment. New products must undergo intensive preclinical and clinical testing. Further, regulatory authorities continue to establish new and increasingly rigorous requirements for approval and reimbursement. The post-approval regulatory burden has also increased.

- As with our commercial strategy, we have clear priorities in R&D. We focus
  on five technology platforms: two established platforms (chemistry and
  chemical biology; biotherapeutics) plus three advanced platforms (RNA
  therapy; radioligand therapy; gene and cell therapy).
- We seek to enter into agreements with other pharmaceutical and biotechnology companies and with academic and other institutions to develop new medicines.
- We are also accelerating the use of data science and digital technology to make the drug discovery and development process more efficient and effective.

# **Embed operational excellence**

Alliances, acquisitions and divestments

Failure to identify, execute, and/or realize the expected benefits from our external business opportunities

As part of our strategy, we acquire and divest products or entire businesses, and enter into strategic alliances and collaborations. This strategy depends in part on our ability to identify strategic opportunities, value them appropriately and competitively and close transactions with third parties. Efforts to develop and market acquired products, to integrate acquired businesses or to achieve expected synergies may fail or may not fully meet expectations. Also, our strategic alliances and collaborations with third parties may not achieve their intended goals and objectives.

- We established a new Strategy and Growth function to help drive our growth strategy end-to-end, including establishing an enterprise-level business development and M&A strategy to help identify external opportunities that align with our strategy.
- We are also enhancing our due diligence approach, for example by strengthening risk assessments in areas such as advanced therapies.

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### Strategic risks in focus (continued)

Risk Context Actions

#### **Embed operational excellence**



#### Strategic transformations

Failure to meet organizational transformation programs objectives and/or unintended adverse impacts on our business

In 2022, we announced a new organizational structure and operating model designed to support our innovation, growth, and productivity ambitions as a focused medicines company (Transforming for Growth). We also announced our intention to separate our Sandoz Division into a new publicly traded standalone company, by way of a 100% spin-off in order to maximize shareholder value. The significant nature of these organizational changes, and the additional workload and complexity for our employees in some areas, could potentially result in instability within the organization that may lead to failure to achieve the desired benefits.

- We established a dedicated transformation team for Transforming for Growth, which reports to our Executive Committee, while also putting in place measures to help employees and leaders manage through this significant reorganization of our business.
- Ahead of the proposed Sandoz spin-off, we are working to strengthen Sandoz's capabilities in functions that are currently shared and begin the separation of function- country- or site-level dynamics. Sandoz is also considering plans to strengthen its development and manufacturing capabilities.

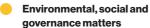
### Strengthen our foundations



# Pricing, reimbursement and access

Pricing and reimbursement pressure, including pricing transparency and access to healthcare We experience increasing pressure on our ability to obtain and maintain satisfactory rates of reimbursement from governments, insurers and other payers. These pressures have many sources, including rising healthcare costs (exacerbated by the COVID-19 pandemic); funding restrictions and policy changes; and public controversies, debate, investigations and legal proceedings around pharmaceutical pricing. Such pressures may impact product pricing and market access. We also face price controls and other measures imposed by governments and other payers. In addition, our Sandoz Division faces continued price erosion in the generics and biosimilars segment.

- We are increasing efforts to enable patient access through innovative pricing and access initiatives in the US, Europe and other markets, including contract structures such as pay-over-time and outcome-based agreements.
- We also continue to execute against access-to-medicine and global health targets. These targets are backed by a sustainability-linked bond, which embeds them into the core of our business operations.



Failure to meet environmental social and governance expectations

An inability to successfully perform on ESG matters may have negative effects on our recruitment and retention of employees, as well as on our operations, financial results, reputation, and/or share price. Examples include failing to meet our access-to-medicines commitments or ensuring that third parties in our value chain comply with ESG requirements. We may also fail to meet evolving ESG due diligence and reporting regulations.

 We regularly review our ESG strategic roadmap to ensure commitments are on track and latest developments are incorporated. We also monitor ESG regulatory changes and set up internal governance and processes to be compliant with regulatory requirements.

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## Third-party risk assessments

We established a third-party risk management (TPRM) framework in 2019 to help identify and manage risks when interacting with third parties. In 2022, we extended our TPRM program to perform risk assessments on wholesalers and distributors in addition to vendors and suppliers.

Our TPRM framework is supported by our Third Party Code, which we recently updated to specify human rights due diligence and environmental sustainability expectations from third parties. We have also introduced guides to help procurement teams buy more of our supplies from certified sources.

Novartis is a member of the Pharmaceutical Supply Chain Initiative (PSCI). Our Third Party Code is consistent with the PSCI's principles for responsible supply chain management.

## Complying with laws, regulations and controls

We operate in a highly regulated industry. Making sure we comply with laws and regulations is important to secure the trust of both regulators and the wider public.

We have a comprehensive compliance management system, developed in line with external standards (e.g., those issued by the OECD), which that helps us to prevent, detect and correct systemic misconduct.

The aim of this system is to ensure compliance not only with laws and regulations, but also with own internal policies and controls. In 2022, we conducted a review of our Compliance Evaluation Program, supported by an external non-profit organization focused on governance and anti-corruption.

We conducted a review of our Compliance Evaluation Program, supported by an external nonprofit organization focused on governance and anti-corruption

We work to detect and prevent misconduct. Where evidence of misconduct is found, we take swift and appropriate action. Our programs are supported by our SpeakUp Office, which allows employees and external parties to raise concerns about potential misconduct in confidence (see page 60).

## **Anti-bribery policies and practices**

Novartis does not tolerate any form of bribery and/or corruption. Our Anti-Bribery Policy, Professional Practices Policy and Conflict of Interest Policy outline our expectations for all employees. We also clearly set out our standards in our Code of Ethics. Bribery risks in our supply chain are addressed by our Third Party Code and Anti-Bribery Third Party Guideline. The

Third Party Code is an integral part of every supplier contract.

Working with Norges Bank Investment
Management (NBIM), we helped develop a
reporting standard on anti-bribery for the
pharmaceuticals industry. The resulting
expectation document issued by NBIM,
which is based on principles such as the
United Nations (UN) Global Compact and the
OECD Guidelines for Multinational Enterprises, formed the basis of our first dedicated anti-bribery report published in early
2022. We plan to report on a regular basis.

#### Internal Audit

Internal Audit assists the Board of Directors and the ECN by providing independent assurance and advice on the effectiveness. efficiency and adequacy of processes and controls that support Novartis in achieving its strategy, managing major risks, and ensuring compliance with applicable policies, laws and regulations. To ensure its independence, our Internal Audit sits outside the ERC function; it works according to an audit plan approved by the Board's Audit and Compliance Committee. During 2022, Internal Audit carried out 63 audits, reviews and advisories relating to both our own operations and our suppliers. These audits include the review of ethical standards.

## **Product quality and patient safety**

We have extensive policies, systems and controls in place to protect patient safety. These relate primarily to two areas: product quality and pharmacovigilance.

To ensure product quality, we maintain a robust quality management system for our medicines in full compliance with requirements from health authorities and other regulators. We have manufacturing licenses and relevant ISO and Good Manufacturing Practice (GMP) certificates for all our manufacturing, medical devices, supply and distribution operations, issued after inspections by regulators such as the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), the Japanese Pharmaceuticals and Medical Devices Agency (PMDA), the World Health Organization (WHO) and Swissmedic.

We conduct thorough investigations whenever there is any evidence of deviation from these standards, or if we detect failures in our manufacturing processes. We conduct comprehensive quality and safety training for employees and third parties. We require all employees involved in manufacturing, supply and distribution to attend at least two annual training sessions on quality standards. All third parties providing services or goods manufactured to good practice standards are required to have

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their own quality assurance and formal training process. Furthermore, we are regularly audited on our training procedures, and training is also included in our audits for third parties.

Following regulatory guidance (including FDA and EMA recommendations) we monitor chemical and biological medicines for impurities, including those classified as "probable human carcinogens" (e.g., nitrosamines). Any product identified with a potential risk undergoes further evaluation and risk management, with results submitted to the relevant health authorities as required.

Pharmacovigilance involves monitoring the safety of our drugs both during development and in the commercial setting. This enables us to detect any adverse effects that may emerge at any stage of the drug's lifecycle. In accordance with international regulations, we share periodic safety reports with the relevant health authorities and maintain current benefit-risk analyses for our medicines.

We also support education programs for patients, providers and pharmacists, and provide regular training to employees in adverse event reporting. For some medicines, post-approval studies may be conducted to collect more data on possible long-term or adverse effects.

### **Health, safety & environment (HSE)**

We work to maintain a safe and healthy environment at all our facilities. To achieve this, we have an integrated HSE management system. Every year, we carry out a comprehensive assessment to ensure compliance with all relevant laws, regulations and internal standards. We also have extensive health and safety programs that cover a broad spectrum of work related hazards.

To monitor progress, we set annual HSE targets, investigate all safety incidents, including "near-misses" and encourage employees to report all incidents. Novartis sites are subject to inspection by health, safety and environmental regulators. In addition, we require sites to carry out regular self-assessments; a dedicated team conducts more focused audits on a 3- to 5-year cycle.

We are also committed to protecting contractors' safety: we assess outside contractors and make sure they have the right resources and procedures in place to be working at our sites. Supplier contracts include specific occupational health and safety criteria.

## **Cybersecurity**

As reflected in our Code of Ethics, we are committed to the responsible use of information in our business processes, including personal information, and we adhere to appropriate standards to achieve this purpose. We have robust governance, processes

and policies in place to ensure the security of our data and IT systems. All Novartis employees participate in annual mandatory training in information management.

To prevent IT system interruptions, Novartis has risk-based services continuity and systems recovery plans in place, which are tested periodically. We also conduct ongoing internal vulnerability analyses (including simulated hacking) as well as external testing via a third-party to ensure the effectiveness of our cybersecurity controls. We require employees to report IT security incidents to a Cyber Security Operations Center that operates 24 hours a day. Novartis has not experienced any material cybersecurity incidents in the three years through 2022.

#### **Animal welfare**

Animal research lies behind many recent medical advances, including cancer treatments, vaccines and drugs to treat neurological diseases such as epilepsy, schizophrenia and depression. It is a currently unavoidable part of medical science. Animal studies are also often required by health regulators to prove that medicines are safe and effective for humans.

Our animal research is governed by our Animal Welfare Policy, updated in 2022. This policy applies to all Novartis-sponsored studies, whether internal or external. As part of the policy, we are committed to applying the 3 R's rule – to reduce the number of

animals needed in our studies, to refine study methods to minimize animals' distress or pain and to replace animal studies with alternative options where possible. See page 84 for our 2022 animal research performance indicators.

In 2022, we recognized several award-winning projects that significantly advanced the 3Rs at Novartis, including one that replaced mice in rheumatoid arthritis studies with a novel human cell based in-vitro assay. We also launched a grant program to prospectively fund research projects to validate new alternatives to animal research, reduce animal numbers and improve the animals' experience.

## **Transparency and disclosure**

We attach great importance to being transparent about our activities and performance. In addition to our Annual Report and this Novartis in Society Integrated Report, we publish many of our internal policies, codes and guidelines, and provide quarterly updates on our financial and ESG performance. We also disclose our progress against the UN Global Compact principles, as well as our payments to healthcare professionals and patient organizations, our political contributions and the results from our clinical trials. For more information, see our corporate website.

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## Upholding our commitment to human rights

Over the years, we have worked to embed human rights in our business. In our Code of Ethics, we pledge to conduct our business in a manner that respects the rights and dignity of all people. In 2022, we updated our Human Rights Commitment Statement.

To ensure we live up to our commitments, we have a human rights management program, based on three pillars, aligned with the UN Guiding Principles on Business and Human Rights:

## **Due diligence**

We conduct ongoing human rights due diligence across our business. We also make sure we have policies and management systems in place to support our commitments. Our suppliers and partners are regularly assessed and monitored against our Third Party Code and we collaborate with industry partners like the Pharmaceutical Supply Chain Initiative on topic-specific supply chain projects such as conflict minerals and child labor.

In 2022, we carried out an assessment of our global health program to assess compliance with international human rights standards. This assessment applied to specific functions within our global health program and was based on the Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, issued in 2008 by the UN Special Rapporteur on the right to health. In addition, our human rights team worked with our pharmaceutical export business to conduct human rights risk assessments covering high-risk countries.

## **Empowerment**

We work to provide access to effective grievance mechanisms for those who may have been affected by human rights abuses, primarily through our SpeakUp office. In 2023, we plan to update our SpeakUp reporting tool to make the process of reporting a human rights grievance more accessible to third parties. We provide targeted training for employees in high-risk functions or locations – and raise awareness throughout the Group regarding the importance of respecting human rights.

## **Engagement**

We engage with stakeholders to listen to their concerns, take collective action where it makes sense and regularly report our performance on human rights. We share actions taken to address the potential risk of conflict minerals, forced labor, child labor and other salient risks in our global supply chain through our annual UK and Australia Joint Modern Slavery Statement and other public disclosures.

## Our human rights priorities

In 2022, we updated and streamlined our Human Rights Commitment Statement to focus on four priority areas, each aligned with the Novartis Code of Ethics. Below, we provide links to key policies and commitments relevant to each focus area.

## Right to health

#### Key topics

Access to medicine; clinical trials; product quality; falsified medicines

- Novartis Access Principles
- · Commitment to Diversity in Clinical Trials
- Quality Commitment
- Position on Falsified Medical Products

## **Labor rights**

#### **Key topics**

Freedom of association and collective bargaining; non-discrimination and equal treatment in employment; occupational health and safety; living wages; child labor; modern slavery including forced labor and human trafficking

- Global Guideline on P&O Principles and Labor Rights Practices
- Equal Pay International Coalition (EPIC) Commitments
- · Third Party Code
- UK and Australia Joint Modern Slavery Statement 2021
- · Health, Safety & Environment Policy

## **Human rights & the environment**

#### Key topics

Environmental impact of our operations and products over their lifecycle

Environmental Sustainability Strategy

## **Technology & human rights**

#### Key topics

Responsible use of personal information; ethical use of artificial intelligence (AI)

- Global Privacy Policy
- Commitment to Ethical and Responsible Use of AI

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## **Compensation Report**

In 2022, we continued to make progress in transforming Novartis into a focused medicines company. Feedback received prior to our last Annual General Meeting (AGM) indicated that shareholders agreed our compensation system is aligned with our purpose, strategy and culture.

## 2022 performance highlights

2022 was a year of solid financial performance, with growth in constant currencies across sales, core profits and core margins. The performance was driven by key in-market and launch products, including *Entresto*, *Kesimpta*, *Kisqali*, *Cosentyx*, and *Pluvicto*.

In April 2022, we announced the introduction of a new organizational model designed to support our next phase of innovation, growth, and productivity as a focused medicines company. The restructuring is expected to deliver USD 1.5 billion in savings by 2024.

There was nonetheless an immediate impact on Operating Income that, along with unfavorable fair value adjustments on financial assets, impacted operating income growth.

We continued to deliver high value medicines to patients with 23 approvals, including a novel radioligand therapy, *Pluvicto*, and 24 submissions across our priority geographies. We also had several important clinical data readouts, for example, iptacopan for the treatment of paroxysmal nocturnal

hemoglobinuria. However, we also had disappointments as some clinical trials of experimental compounds did not meet their primary endpoints, including ACZ885 (canakinumab) in lung cancer, and UNR844 in presbyopia.

Novartis also continued to deliver on its commitments to broaden access to medicines and tackle major global health challenges. We pledged further investment for research into malaria and neglected tropical diseases, increased access to our innovative medicines in low- and middle-income countries (LMICs) and formed new collaborations to strengthen healthcare systems.

Performance against incentive targets, combined with base salary and other benefits and pension, resulted in 2022 total realized compensation for the CEO of CHF 8 452 176. This is a reduction of 24.7% compared with 2021, driven mainly by lower payout of the Long-Term Performance Plan (LTPP). More details on CEO performance and compensation are available in the Compensation Report of our 2022 Annual Report.

# Changes to Executive Committee compensation system and disclosures

During the year, we reviewed our Executive Committee compensation system, with the aim of simplification and increased transparency.

Effective the 2022-2024 cycle of the LTPP, we strengthened the assessment of research and early development performance under the Innovation metrics, to ensure that targets are focused more directly on activities that create long-term value. From this cycle, the Science & Technology Committee sets targets that take into account the expected Net Present Value (eNPV) of programs transitioning to latestage clinical development.

Effective from performance year 2023, we will remove "Share of Peers" as a financial performance measure for the Annual Incentive plan. The weighting of the three remaining financial measures, Group Net Sales, Group Operating Income and Group Free Cash Flow, will be 40%, 30% and 30%, respectively. In addition, we will fold division specific financial targets, where applicable, into individual strategic objectives (40% weighting) of the related Executive Commit-

tee member. All Executive Committee members will be evaluated, with a 60% weighting, against the performance of Group financial measures mentioned above.

During the year, we announced our intention to separate our Sandoz generics and biosimilars Division into a new publicly traded standalone company, by way of a 100% spin-off, subject to approval of the Novartis AG Board of Directors and shareholders. Based on the planned completion of the spin-off in 2023, the Compensation Committee made some initial decisions on the 2023 compensation elements related to the spin-off.

## Alignment with company strategy

In 2022 we refocused our strategy to deliver high-value medicines that alleviate society's greatest disease burdens through technology leadership in research and development, and novel access approaches. In line with this refocused strategy, we updated our strategic priorities to target innovation power, sales growth, delivering both margin and total shareholder returns, and sector leadership in material ESG factors.

This resulted in some enhancements to the Annual Incentive plan and LTPP plans as explained earlier.

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Shareholder votes on compensation at the 2023 AGM

In line with our Articles of Incorporation, at the 2023 AGM, shareholders will be asked to approve the maximum aggregate amount of compensation for the members of the Executive Committee of CHF 90 000 000. This is lower than the prior term, primarily due to the stepping down of the CEO, Sandoz from the Executive Committee. For the

Board of Directors, the maximum aggregate amount proposed to shareholders is CHF 8 750 000, which is slightly higher than the prior term, due to change in committee memberships. Full details on compensation for the CEO, other Executive Committee members and Board members can be found in the Compensation Report of our 2022 Annual Report, and in the compensation votes at the 2023 AGM.

## 2022 Executive Committee compensation system

	2022 fixed pay and benefits		Performance-related variable pay		
	Annual base salary	Pension and other benefits	2022 Annual Incentive	Long-Term Incentive awards cycle 2022-2024LTPP¹	
Purpose	Reflects responsibil- ities, experience and skill sets	Provide retirement and risk insurances (tailored to local market practices/ regulations)	Rewards for perfor- mance against short- term financial and strategic objectives, and Values and Behaviors	Rewards long-term shareholder value cre- ation and innovation in line with our strategy	
Form of payment	Cash	Country/individual- specific and aligned with other employees	50% cash 50% equity <sup>2</sup> deferred for three years <sup>3</sup>	Equity, vesting following a three-year performance period	
Performance measures	-	-	Balanced scorecard comprising: • Financial measures <sup>4</sup> (60%) • Strategic objectives <sup>5</sup> (40%)	Net sales growth CAGR (25%)     Core operating income CAGR (25%)     Innovation (25%)     Relative TSR (25%)	

#### <sup>1</sup> LTPP = Long-Term Performance Plan

## **Executive Committee compensation governance**

A summary of the compensation decision authorization levels within the parameters set by the AGM is shown below, along with an overview of the risk management principles.

#### **Decision on**

Compensation of CEO

Compensation of other Executive Committee members

## **Decision-making authority**

Board of Directors

Compensation Committee

## **Executive Committee compensation risk management principles**

- Rigorous performance management process, with approval of targets and evaluation of performance for the CEO by the Board of Directors
- Balanced mix of short-term and long-term variable compensation elements
- Values and Behaviors are a key component of the Annual Incentive and are embedded in our culture
- Performance-based Long-Term Incentives, with three-year cycles
- All variable compensation is capped at 200% of target
- Contractual notice period of 12 months
- Post-contractual non-compete period is limited to a maximum of 12 months from the end of employment. Resulting compensation, if applicable, will not exceed the average annual compensation (annual base salary plus Annual Incentive) of the previous three financial years

- Good and bad leaver provisions apply to the variable compensation of leavers
- No severance payments or change-of-control clauses
- Clawback and malus principles apply to all elements of variable compensation
- Share ownership requirements; no hedging or pledging of Novartis share ownership
- No loans granted to current or former members of the Executive Committee and the Board of Directors or to "persons closely linked" to them

<sup>&</sup>lt;sup>2</sup> Executive Committee members may elect to receive more of their Annual Incentive in equity instead of cash

<sup>&</sup>lt;sup>3</sup> The Annual Incentive deferred in equity is granted under the Deferred Share Bonus Plan (DSBP)

Financial Measures are Group Net Sales (30%), Group Operating Income (30%), Group Free Cash Flow as a % of sales (cc) (20%) and Share of peers (20%)
Strategic objectives are aligned with our transformation to become a pure-play Innovative Medicines company: Strategy, Growth / Launches, Innovation, Operational excellence, Build trust with society

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## 2022 CEO pay for performance – outcomes

Measure	Target	Achievement versus target				
2022 Annual Incentive						
Financial measures – 60% of total Annual Incentive, comprising:						
Group net sales (cc) (30%)	USD 54 360 million	Met				
Group operating income (cc) (30%)	USD 11 630 million	Met*				
Group free cash flow as a % of sales (cc) (20%)	24.8%	Below				
Share of peers for Novartis Group (USD) (20%)	7.3%	Met				
Overall assessment of Group financial targets in cons	stant currencies	Met				

<sup>\*</sup> The Board concluded that the achievement for Group operating income versus target was "Met" after approving adjustments mainly to exclude restructuring costs arising from the implementation of the new organizational model announced to investors on April 4, 2022 (and were not available at the time of target setting in January 2022), and costs related to the planned Sandoz spin-off, to transform Novartis into a focused medicines company.

## Strategic objectives – 40% of total Annual Incentive, comprising:

Strategy (15%)	Met
Growth / Launches (15%)	Met
Innovation (15%)	Met
Operational excellence (15%)	Met
Build trust with society (40%)	Above
Overall assessment of strategic objectives	Met

Overall assessment of CEO balanced scorecard	Met
--	-----

TOTAL Annual Incentive:	100% of target (payout range 0% – 200%)
-------------------------	---

#### 2020-2022 Long-Term Incentives

Long-Term Performance Plan (LTPP)	Long-Term Performance Plan (LTPP)		
Net sales CAGR (25%)	5.7%		
Core operating income CAGR (25%)	10.6%		

Core operating income CAGR (25%)	10.6%	Below
Innovation (25%)		Below
Relative TSR (25%)		Below threshold

TOTAL LTPP:	57% of target (payout range 0% - 200%

## 2022 total realized compensation for the CEO

The 2022 total realized compensation for the CEO was CHF 8 452 176. It includes payouts of the Annual Incentive and LTPP based on actual performance assessed for cycles concluding in 2022.

	Fixed pay	and benefits	Variable p performance-	•	
CHF	Annual base salary	Pension and other benefits	2021 Annual Incentive	LTPP 2020-2022 <sup>1</sup>	Total realized compensation
Vasant Narasimhan	1786 500	673 933	2 684 321	3 307 422	8 452 176

¹ The shown amount represents the underlying share value of the total number of shares vested (including dividend equivalents of CHF 317 316) to the CEO for the 2020-2022 LTPP performance cycle.

## 2022 Board of Directors compensation

Below

All fees to Board members are delivered at least 50% in equity and the remainder in cash. Board members receive no variable or performance-based compensation, no share options, and no additional fees for attending meetings. Board members do not receive any company pension or insurance benefits.

CHF 000	2022-2023 AGM, annual fee
Compensation of Chair	3 800
Board membership	280
Vice-Chair	50
Lead Independent Director	20
Chair of the Audit and Compliance Committee	130
Chair of the Compensation Committee	90
Chair of the following committees: Governance, Sustainability and Nomination Committee Science & Technology Committee Risk Committee	70
Membership of the Audit and Compliance Committee	70
Membership of the following committees:	40

Total actual compensation earned by Board members in the 2022 financial year was CHF 3 803 670 for the Board Chair and CHF 4 702 585 for the other members of the Board.

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## Our approach to reporting

The Novartis in Society Integrated Report is published annually. Its purpose is to provide an overview of our business, strategy and performance. Our full annual reporting suite, including our Annual Report and Form 20-F regulatory disclosures, can be found on our corporate website.

## **Reporting principles**

The Novartis in Society Integrated Report is intended for all Novartis stakeholders, but is primarily aimed at shareholders, investors and ESG analysts.

The report has been prepared in alignment with the Integrated Reporting Framework, the Sustainability Accounting Standards Board (SASB) and the latest standards issued by the Global Reporting Initiative (GRI). It also contains our main disclosures against the Recommendations from the Task Force for Climate-related Financial Disclosures (TCFD) and the UN Sustainable Development Goals. In compiling this report, we also considered "Section Six: Transparency on Non-Financial Matters" under the Swiss Code of Obligations.

## Scope

This report covers all business and consolidated entities (in line with the Novartis Annual Report and 20-F). Annual performance data relates to the Group's financial year (from January to December). Environmental data is based on January to September data, plus estimates for October to December. This data will be restated using twelve-month figures on our corporate website during 2023. All information in this report reflects the continuing operations of Novartis Group, including various changes to the Group's portfolio of activities in prior years.

#### **Content**

- Selection of content was based primarily on our corporate strategy and results from our materiality assessment.
- All content was subject to approval by the Novartis Board of Directors prior to publication.
- An overview of definitions and methodologies for ESG performance indicators in the Novartis in Society Integrated Report 2022 is available here.
- Novartis financial data has been taken from our Annual Report, prepared in accordance with International Financial Reporting Standards (IFRS), as issued by the International Accounting Standards Board (IASB). Novartis financial data is presented in US dollars (USD).
- Some figures have been rounded. Some percentages have also been calculated using rounded numbers.
- Any material corrections or restatements are included in the text of this report.
- A list of abbreviations can be found on page 95.

#### **External assurance**

KPMG provided limited assurance in accordance with ISAE 3000 on the performance indicators on pages 81-84. See the Independent Assurance Report on page 93 for more details.



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## **Performance indicators**

2022	2021	2020
5	7	6
44	54	44
1	3	2
24	34	13
23	21	26
1	2	4
	5 44 1 24	5 7 44 54 1 3 24 34 23 21

Patient health and safety performance indicators	2022	2021	2020
GxP audits			
Total audits executed	1392	1 419	903
Internal <sup>7</sup>	134	125	111
External <sup>8</sup>	1258	1 294	792
Regulatory authorities			
Total inspections	139	126	126
Inspections found to be acceptable (%)	100	99.2	99.2
US FDA			
FDA inspections	10	10	6
FDA warning letters	0	0	0
FDA Form 483	7	5	1
US FDA sponsor inspections			
Inspections related to clinical trial management and pharmacovigilance	1	3	1
Number of FDA VAI (voluntary action indicated) classifications	0	0	0
Number of FDA OAI (official action indicated) classifications	0	0	0
Recalls			
Total recalls	19	27	27
Class I recalls	0	3	1
Class II recalls	16	20	21
US FDA			
FDA recalls	1	1	0

Supply chain performance indicators	2022	2021	2020
Suppliers risk-assessed by Third-Party Risk Management (TPRM) 9			
Number of suppliers risk-assessed by TPRM	11 097	12 064	8 448
Suppliers assessed by risk area 10			
Anti-bribery	1 553	2 303	2 014
Animal welfare 11	18	9	10
Health, safety and environment	296	477	315
Information security and data privacy	6 694	5 668	3 174
Labor rights	5 379	6 755	4 635
Quality GmP <sup>12</sup>	594	848	561
Actions taken			
Suppliers audited	86	85	35
Suppliers with remediation action agreed <sup>13</sup>	384	912	521
Supplier engagements stopped due to risk assessment outcomes	17	37	120

<sup>&</sup>lt;sup>1</sup> Includes Innovative Medicines and Sandoz biosimilars only

<sup>&</sup>lt;sup>2</sup> Includes projects having achieved first patient, first visit (FPFV) in confirmatory development (incl. projects entering confirmatory development from an acquisition or in-licensing). Figures shown for the year 2021 and 2020 consider projects applying the former methodology, i.e. projects entering confirmatory development from internal R&D activities. FPFV has occurred in post-proof-of-concept stage after NIBR.

<sup>3</sup> Includes projects with FPFV in a Phase III study but not yet filed in the US, EU, Japan or China

<sup>&</sup>lt;sup>4</sup> Number of breakthrough therapy designations granted by the US Food and Drug Administration for therapies under development by Novartis Includes small molecules or biologics; new fixed-dose combinations of existing APIs; and new target indications, defined as new disease or new line of treatment (e.g., first line vs. second line)

<sup>6</sup> Includes NMEs such as small molecules, biologics; in the EU, new fixed-dose combinations of existing APIs

<sup>&</sup>lt;sup>7</sup> Total number of audits performed on facilities owned by Novartis

<sup>8</sup> Total number of audits performed on GxP suppliers to Novartis

<sup>9</sup> Assessment is done on new suppliers and new products, services or sites from existing suppliers. Not all suppliers trigger risk assessments. Figures do not include GxP audits (see "Patient health and safety performance indicators").

<sup>10</sup> Reflects risk assessments conducted on suppliers. One supplier can trigger more than one assessment depending on the risk areas involved.

<sup>&</sup>quot;Increased primarily due to re-assessments and rescheduled assessments following the COVID-19 pandemic

<sup>&</sup>lt;sup>12</sup> Risk area "Quality GmP" de-scoped from November 2022 onwards

<sup>13</sup> Decreased due to fewer medium- and high-risk cases

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Environment performance indicators 1	2022	2021	2020
Energy use – on site and purchased (million GJ)	9.9	9.8	10.9
Greenhouse gas (GHG) emissions (1 000 tCO <sub>2</sub> e)			
Total Scope 1 emissions	347.2	352.8	378.3
Combustion and process	256.4	264.1	287.0
Vehicles	90.8	88.7	91.3
Total Scope 2 emissions (market based)	154.9	292.7	335.5
Total Scope 2 emissions (location based) <sup>2</sup>	399.2	439.4	487.2
Total Scope 1 and Scope 2 (excluding offsets)	502.1	645.5	713.8
Total Scope 3 emissions <sup>3</sup>	8 770.0	7 290.4	7 268.8
Purchased goods and services	7 350.6	5 958.4	5 754.0
Capital goods	301.2	303.8	278.7
Business travel <sup>4</sup>	93.0	36.2	68.3
Use of sold products <sup>5</sup>	260.1	199.2	163.9
Total Scope 1, Scope 2 and Scope 3 emissions	9 272.1	7 935.9	7 982.6
Carbon offsets <sup>6</sup>	30.7	- 34.7	33.6
GHG emissions intensity (tCO <sub>2</sub> e)			
Scope 1 and Scope 2 per million USD sales	9.9	12.3	14.4
Scope 1 and Scope 2 per FTE	4.9	6.1	6.6
VOCs (t)			
Halogenated volatile organic compounds	0.8	0.8	11.6
Non-halogenated volatile organic compounds	313.1	304.7	443.0
Water (million m³)			
Total water withdrawal <sup>7</sup>	52.1	47.6	54.7
Surface water	7.9	6.5	7.1
Groundwater	36.8	35.3	41.7
Third-party water	7.4	5.8	5.9
Total water discharged 8	49.6	46.6	54.5
Water consumption <sup>9</sup>	7.5	7.7	8.4

Environment performance indicators <sup>1</sup>		2021	2020
Operational waste (1 000 t)			
Total waste generated	97.0	103.6	130.6
Total non-hazardous waste	63.6	66.7	68.7
Total hazardous waste	33.4	36.9	61.9
Total waste diverted from disposal	69.5	73.4	88.6
Non-hazardous waste recycled	53.4	56.0	59.9
Hazardous waste recycled	16.1	17.4	28.7
Total waste directed to disposal	27.5	30.2	42.1
Non-hazardous waste not recycled	10.2	10.7	8.8
Hazardous waste not recycled	17.3	19.5	33.3

Other than where indicated, environmental data for the current year are based on actuals for January-September and estimates for October-December (to be updated with actuals in 2023 in our annual Novartis Environmental Sustainability datasheet). Any significant deviations are restated the following year in the Novartis in Society Integrated Report. Previous years' data reflect only actuals.

<sup>&</sup>lt;sup>2</sup> Using location based emission factors published in 2014 or 2015 depending on geography and data source. We plan to update the emission factors in the future reporting periods with the latest available ones.

<sup>&</sup>lt;sup>3</sup> Scope 3 emissions are reported in accordance with the GHG Protocol. Only the Scope 3 categories which are assured are separately disclosed. The total scope 3 emissions figure includes all categories. Our Scope 3 emissions increased by 20% from the prior year, driven primarily by purchased goods and services and, to a smaller extent, by increased business travel following the pandemic

<sup>&</sup>lt;sup>4</sup> Data includes indirect emissions from air travel, train travel, car rentals and hotel stays. The indicator is calculated using 12-month actual data.
<sup>5</sup> For all disclosed years, the calculation for our inhalers is based on the IPCC 2015 GHG emission factor and assumes all hydrofluorocarbon (HFC) gas used in the production process is released upon use of the inhalers. We are in the process of determining if a portion of this gas is released during manufacturing and whether a portion also remains in the inhaler after its use, which would therefore need to be excluded from

our calculation of Scope 3 use of sold products emissions.

<sup>6</sup> Carbon offsets are based on data provided by third parties. For further details, please see our Reporting Criteria document.

<sup>7</sup> Water withdrawals includes water used for cooling and returned to the environment without the need for additional treatment

<sup>8</sup> Water consumption and non-contact water withdrawn from the environment for cooling and returned directly to the environment after use.

<sup>9</sup> Water discharged via treatment and water lost

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People performance indicators	2022	2021	2020
Headcount <sup>1</sup>	105 533	108 514	110 738
Full-time equivalent positions 1	101 703	104 323	105 794
Percentage turnover: voluntary / overall	9/15	8/13	5/10
Percentage of hires: internal / external	66/34	62/38	58 / 42
Annual learning hours per employee 2	42.4	52.1	53.2
Representation of nationalities: overall / management <sup>3</sup>	147/118	143 / 115	142/113
Employees represented by an employee representative body or covered by a collective bargaining agreement (%) 4	48	47	46
Health and safety			
Lost-time injury and illness rate (per 200 000 hours worked): Novartis employees / Third-party personnel	0.16 / 0.20	0.14/0.05	0.12 / 0.20
Total recordable case rate (per 200 000 hours worked) <sup>5</sup> : Novartis employees / Third-party personnel	0.31/0.28	0.25 / 0.13	0.23 / 0.30
Fatalities: Novartis employees / Third-party personnel / Contractors	0/0/0	0/0/0	0/0/1
Gender representation (% female / % male) <sup>6</sup>			
Overall headcount	51/49	51 / 49	50 / 50
Hires	52/48	52 / 47	52 / 48
Promotions	53 / 47	55 / 45	52 / 48
Overall turnover	49/51	50/50	49 / 51
Voluntary turnover	51/49	51 / 49	52 / 48
Board of Directors	31/69	31/69	29 / 71
Executive Committee of Novartis	27/73	25 / 75	23 / 77
Novartis Top Leaders 7	39/61	38/62	33 / 67
Senior management	41/59	39/61	39 / 61
Middle management	48/52	47 / 53	46 / 54
Overall management <sup>3</sup>	47/53	46 / 54	45 / 55
Entry-level positions	52/48	52 / 48	52 / 48
Revenue-producing roles <sup>8</sup>	51/49	51 / 49	50 / 50
STEM roles <sup>9</sup>	46/54	46 / 54	46 / 54

People performance indicators	2022	2021	2020
Gender representation by contract type (female / n	nale)		
Permanent	52 311 / 49 549	53 509 / 51 497	53 729 / 53 096
Temporary	1881/1709	1 854 / 1 539	1 935 / 1 629
Full time	47 631/50 084	48 618 / 51 904	48 472 / 53 507
Part-time	6 573 / 1 175	6 755 / 1 133	7 204 / 1 219
Number of employees by region, by contract type (p	permanent / temporary)		
Asia-Pacific	27 197 / 486	28 229 / 420	27 711 / 300
Europe, Middle East and Africa	54 892 / 2 943	55 362 / 2 752	56 852 / 3 016
Latin America	4 508 / 92	5 101 / 127	5 092 / 157
North America	15 263 / 69	16 314 / 94	17 170 / 91

<sup>&</sup>lt;sup>1</sup> "Headcount" reflects the total number of employees in payroll systems. "Full-time equivalent positions" adjusts headcount for employees working less than 100%.

<sup>&</sup>lt;sup>2</sup> Since 2022, Novartis reports training hours for internal employees only

<sup>&</sup>lt;sup>3</sup> Management defined by Global Job Level Architecture and Novartis Top Leaders

<sup>&</sup>lt;sup>4</sup> Generally non-management employees

<sup>&</sup>lt;sup>5</sup> Data include all work-related injuries and illnesses, whether leading to lost time or not.

<sup>&</sup>lt;sup>6</sup> Fewer than 0.5% of employees have unknown classification. Some indicators do not add up to 100%.

<sup>&</sup>lt;sup>7</sup> Novartis Top Leaders comprise the approximately 300 most senior managers at Novartis, including the Executive Committee of Novartis.

<sup>8</sup> Revenue-producing roles defined as the sum of the following Novartis job families: BD&L and strategic planning; commercial and general; market access; marketing and sales.

<sup>9</sup> STEM roles defined as the sum of the following Novartis job families: R&D; Technical Operations; Information Technology & Technology Transformation.

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Access to healthcare performance indicators	2022	2021	2020
Overall patients reached (millions)			
Patients reached through access approaches 1	54.6	56.2	66.4
Sustainability-linked bond (September 23, 2020 – September 23, 2028)			
Patients reached with strategic innovative therapies	1 197 352	947 699	695 669
Patients reached through flagship programs	31 157 087	32 695 224	43 912 152
Novartis Global Health Health system strengthening performance indicators²	2022	2021	2020
Health educators trained	4 477	2 827	671
Healthcare providers trained	12 035	10 719	12 648
Points of service provision <sup>3</sup>	1 313	4 365	5 902
People reached at points of service provision	979 755	360 356	486 642
Awareness events held	297 700	412 872	424 878
People reached at awareness events	12 960 922	9 678 360	8 048 360
Animals needed for research <sup>4</sup>	2022	2021	2020
Total	332 668	353 772	410 359
Rodents	261 256	265 111	312 332
% of total	78.5	74.9	76.1
Zebrafish	70 826	88 229	97 596
% of total	21.3	24.9	23.8
Other species	586	432	431
% of total	0.2	0.1	0.1

Ethical business practices performance indicators	2022	2021	2020
Code of Ethics			
Employees trained and certified (%) <sup>5</sup>	98	98	98
Grievance indicators: SpeakUp Office – central matters 6,7			
Misconduct cases reported	385	174	157
Total allegations <sup>8</sup>	544	296	284
Allegations substantiated 9	257	137	118
Total allegations substantiated per category (%): SpeakUp Office – central matters	3		
Fraud/asset misappropriation	7	13	7
Expense fraud	2	4	2
Books and records, accounting irregularities	0	0	1
Improper professional practices	12	20	14
Bribery, kickbacks	0	2	1
Discrimination and sexual harassment	3	8	11
Retaliation	1	5	3
Other employee relations issues	5	14	18
Conflict of interest	5	12	13
IT security breach	41	4	4
Quality assurance / data integrity	2	3	8
Data privacy	12	3	2
Antitrust, fair competition	0	1	1
Company confidential / trade secret information	1	2	4
Other	9	9	11
Dismissals and resignations related to misconduct	116	62	101

<sup>&</sup>lt;sup>1</sup> Includes patients reached with medicines through Novartis Global Health, as well as patients reached through support programs, emerging market brands and donations

<sup>&</sup>lt;sup>2</sup> Data reflect the full scope of access approaches managed by the Novartis Global Health organization.

<sup>&</sup>lt;sup>3</sup> Points of service provision include facilities and health camps where healthcare services are provided.

<sup>&</sup>lt;sup>4</sup> Data refer to animals needed for internally conducted animal studies for Novartis. For data on animals needed for both internally and externally conducted animal studies, please see our corporate website.

<sup>&</sup>lt;sup>5</sup> Active Novartis employees with an email address, trained via e-learning.

<sup>&</sup>lt;sup>6</sup> A central matter applies to issues where a senior leader or manager is involved, or issues which may have a potentially disruptive reputational impact. Also, central matters can involve sexual harassment, discrimination, retaliation and issues with significant financial impact.

<sup>&</sup>lt;sup>7</sup> The number of misconduct cases, allegations reported/substantiated, and dismissals/resignations may change year-on-year as matters may be reassessed in the course of the case life cycle. As a result, we may restate data from previous years.

<sup>&</sup>lt;sup>8</sup> The number of allegations is higher than the actual number of cases as a case can have more than one allegation.

<sup>9 &</sup>quot;Allegations substantiated" and "total allegations substantiated per category" may include allegations from previous years. Whereas "misconduct cases reported" and "total allegations" refer to allegations reported within each calendar year.

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## **Global Reporting Initiative (GRI) Index**

Disclosure Number	Disclosure Title	Reference
GRI 1	Foundation 2021	
GRI 2	General disclosures 2021	
The organia	zation and its reporting practices	
2-1	Organization details	Annual Report 2022, p. 21 p. 10
2-2	Entities included in the organization's sustainability reporting	p. 80
2-3	Reporting period, frequency and contact point	p. 80
2-4	Restatements of information	p. 3
2-5	External assurance	p. 93-94
Activities a	nd workers	
2-6	Activities, value chain and other business relationships	p. 8 p. 20
2-7	Employees	p. 48-51 p. 83
2-8	Workers who are not employees	p. 83
Governanc	е	
2-9	Governance structure and composition	p. 63 p. 66
2-10	Nomination and selection of the highest governance body	p. 63 Annual Report 2022, p. 130
2-11	Chair of the highest governance body	Annual Report 2022, p. 130
2-12	Role of the highest governance body in overseeing the management of impacts	p. 63 p. 65
2-13	Delegation of responsibility for managing impacts	p. 63 p. 65
2-14	Role of the highest governance body in sustainability reporting	p. 80
2-15	Conflicts of interest	Annual Report 2022, p. 143
2-16	Communication of critical concerns	p. 60 p. 75 p. 83
2-17	Collective knowledge of the highest governance body	p. 63
2-18	Evaluation of the performance of the highest governance body	p. 63
2-19	Remuneration policies	p. 76
2-20	Process to determine remuneration	p. 63
2-21	Annual total compensation ratio	Confidentiality constraints: Novartis does not publicly disclose this data.

Disclosure Number	Disclosure Title	Reference
Strategy, p	olicies and practices	
2-22	Statement on sustainable development strategy	p. 5 p. 17
2-23	Policy commitments	p. 54 p. 60 p. 75
2-24	Embedding policy commitments	p. 54 p. 60 p. 75
2-25	Processes to remediate negative impacts	p. 21 p. 60 p. 75
2-26	Mechanisms for seeking advice and raising concerns	p. 54 p. 73
2-27	Compliance with laws and regulations	Annual Report 2022, F-44
2-28	Membership associations	p. 60
Stakeholde	er engagement	
2-29	Approach to stakeholder engagement	p. 21
2-30	Collective bargaining agreements	p. 48
GRI 3	Material topics 2021	
3-1	Process to determine material topics	p. 15
3-2	List of material topics	p. 15
3-3	Management of material topics	p. 24-62
GRI 201	Economic Performance 2016	
201-1	Direct economic value generated and distributed	Annual Report 2022, F-1 – F80
201-2	Financial implications and other risks and opportunities due to climate change	p. 89
201-3	Defined benefit plan obligations and other retirement plans	Annual Report 2022, F-53
201-4	Financial assistance received from government	Annual Report 2022, F-1 - F80
<b>GRI 203</b>	Indirect Economic Impacts 2016	
203-1	Infrastructure investments and services supported	p. 57 Annual Report 2022, F-1 – F80
203-2	Significant indirect economic impacts	p. 20
GRI 205	Anti-Corruption 2016	
205-1	Operations assessed for risks related to corruption	p. 43 p. 68-69
205-2	Communication and training about anti-corruption policies and procedures	p. 60 p. 73
205-3	Confirmed incidents of corruptions and actions taken	p. 84

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GRI 206	Anti-Competitive Behavior 2016	
206-1	Legal actions for anti-competitive behavior, anti-trust, and monopoly practices	Annual Report 2022, F-45
GRI 207	Tax 2019	
207-1	Approach to tax	Novartis Tax Policy Statement (updated June 2022)
207-2	Tax governance, control, and risk management	p. 60 Novartis Tax Policy Statement (updated June 2022)
207-3	Stakeholder engagement and management of concerns related to tax	Novartis Tax Policy Statement (updated June 2022)
207-4	Country-by-country reporting	Confidentiality constraints: Novartis does not publicly disclose this data.
GRI 301	Materials 2016	
301-1	Materials used by weight or volume	p. 82
301-2	Recycled input materials used	p. 45
301-3	Reclaimed products and their packaging materials	p. 45
GRI 302	Energy 2016	
302-1	Energy consumption within the organization	p. 82
302-2	Energy consumption outside of the organization	p. 82
302-3	Energy intensity	p. 82
302-4	Reduction of energy consumption	p. 82
302-5	Reductions in energy requirements of products and services	p. 45
GRI 305	Emissions 2016	
305-1	Direct (Scope 1) GHG emissions	p. 82
305-2	Energy indirect (Scope 2) GHG emissions	p. 82
305-3	Other indirect (Scope 3) GHG emissions	p. 82
305-4	GHG emissions intensity	p. 45 p. 82
305-5	Reduction of GHG emissions	p. 82
305-6	Emissions of ozone-depleting substances (ODS)	Environmental performance indicators
305-7	Nitrogen oxides (Nox), sulfur oxides (Sox), and other significant air emissions	Environmental performance indicators

Disclosure Number	Disclosure Title	Reference
GRI 306	Waste 2020	
306-1	Waste generation and significant waste-related impacts	p. 45
306-2	Management of significant waste-related impacts	p. 45 p. 82
306-3	Waste generated	p. 82
306-4	Waste diverted from disposal	p. 82
306-5	Waste directed to disposal	p. 82
GRI 308	Supplier Environmental Assessment 2016	
308-1	New suppliers that were screened using environmental criteria	p. 45
308-2	Negative environmental impacts in the supply chain and actions taken	p. 45 Environmental sustainability criteria for suppliers
GRI 401	Employment 2016	
401-1	New employee hires and employee turnover -	p. 83
401-2	Benefits provided to full-time employees that are not provided to temporary or part-time employees	p. 51
401-3	Parental leave	p. 49
GRI 403	Occupational health & safety 2018	
403-1	Occupational health and safety management system	p. 51 p. 83
403-2	Hazard identification, risk assessment, and incident investigation	p. 52 p. 83
403-3	Occupational health services	p. 52 p. 83
403-4	Worker participation, consultation, and communication on occupational health and safety	HSE policy
403-5	Worker training on occupational health and safety	p. 51
403-6	Promotion of worker health	p. 50-51
403-7	Prevention and mitigation of occupational health and safety impacts directly linked by business relationships	p. 51
403-8	Workers covered by an occupational health and safety management system	p. 51
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403-10	Work-related ill health	p. 51

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GRI 404	Training and Education 2016	
404-1	Average hours of training per year per employee	p. 50
404-2	Programs for upgrading employee skills and transition assistance programs	p. 50
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GRI 405	Diversity and Equal Opportunity 2016	
405-1	Diversity of governance bodies and employees	p. 66 p. 83
405-2	Ratio of basic salary and remuneration of women to men	p. 49
GRI 406	Non-Discrimination 2016	
406-1	Incidents of discrimination and corrective actions taken	p. 83
GRI 407	Freedom of Association and Collective Bargaining 2016	
407-1	Operations and suppliers in which the right to freedom of association and collective bargaining may be at risk	p. 48 p. 83
GRI 413	Local Communities 2016	
413-1	Operations with local community engagement, impact assessments, and development programs	p. 57
413-2	Operations with significant actual and potential negative impacts on local communities	p. 45
GRI 414	Supplier Social Assessment 2016	
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GRI 416	Customer Health and Safety 2016	
416-1	Assessment of the health and safety impacts of product and service categories	p. 43-44
416-2	Incidents of non-compliance concerning the health and safety impacts of products and services	p. 43-44
GRI 417	Marketing and Labeling 2016	
417-1	Requirements for product and service information and labeling	p. 43-44
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## **Sustainability Accounting Standards Board (SASB) Index**

## Healthcare sector Biotechnology and pharmaceutical industry

The Novartis Sustainability Accounting Standards Board (SASB) Index aligns with the biotechnology and pharmaceutical industry guidelines. Data and information disclosed are sourced from the Novartis 2022 corporate reporting suite (Novartis in Society Integrated Report and Annual Report/Form 20-F), our corporate website, and Novartis public policies and positions.

SASB indicator		Reference	SASB indicator		Reference
Safety of clinic	al trial participants		HC-BP-250a.5 Number of FDA enforcement actions taken		p. 43
HC-BP-210a.1	Discussion, by world region, of management process for ensuring quality and patient safety	p. 37 p. 81		in response to violations of current Good Manufacturing Practices (cGMP), by type3	
	during clinical trials	Novartis Commitment to Patients and Caregivers	Counterfeit Dru	ugs	
HC-BP-210a.2	Number of FDA Sponsor Inspections related to clinical trial management and	Human Rights Commitment Statement p. 43	HC-BP-260a.1	Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting	p. 44
	pharmacovigilance that resulted in: (1) Voluntary Action Indicated (VAI) and (2) Official Action Indicated (OAI)		HC-BP-260a.2	Discussion of process for alerting customers and business partners of potential or known risks associated with counterfeit products	p. 44
HC-BP-210a.3	Total amount of monetary losses as a result of legal proceedings associated with clinical trials in developing countries	All material legal proceedings are disclosed within the Annual Report and accounts (F-48).	HC-BP-260a.3	Number of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products	p. 44
Access to medi	cines		Ethical Marketi		
HC-BP-240a.1	Description of actions and initiatives to promote access to health care products for priority diseases and in priority countries as defined by the Access to	p. 56 p. 59	HC-BP-270a.1	Total amount of monetary losses as a result of legal proceedings associated with false marketing claims	Annual Report, F-45
LIC DD 040a 0	Medicine Index	Navartic has tubous design and malaric mandrate as	HC-BP-270a.2 Description of code of ethics governing promotion of off-label use of products		Professional Practices Policy Payments to Healthcare Professionals
HC-BP-240a.2	List of products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of	Novartis has tuberculosis and malaria products on the WHO List of Prequalified Medicinal Products.	Employee Recr	uitment, Development & Retention	-
	Medicines Programme (PQP)	Novartis products Sandoz products	HC-BP-330a.1	Discussion of talent recruitment and retention	p. 50
Affordability &	Pricing			efforts for scientists and research and development personnel	
HC-BP-240b.1	Number of settlements of Abbreviated New Drug Application (ANDA) litigation that involved payments and/or provisions to delay bringing an authorized	not reported	HC-BP-330a.2	(1) Voluntary and (2) involuntary turnover rate for: (a) executives/senior managers, (b) midlevel managers, (c) professionals, and (d) all others	p. 83
UO DD 0401 0	generic product to market for a defined time period		Supply Chain Management		
HC-BP-240b.2	Percentage change in: (1) average list price and (2) average net price across U.S. product portfolio compared to previous year	not reported	HC-BP-430a.1	Percentage of (1) entity's facilities and (2) Tier I suppliers' facilities participating in the Rx-360 International Pharmaceutical Supply Chain	p. 43 Novartis Quality Management System (QMS)
HC-BP-240b.3	Percentage change in: (1) list price and (2) net price of product with largest increase compared to previous year	not reported		Consortium audit program or equivalent thirdparty audit programs for integrity of supply chain and ingredients	
Drug Safety			Business Ethics	s	
HC-BP-250a.1	List of products listed in the Food and Drug Administration's (FDA) MedWatch Safety Alerts for Human Medical Products database	Available via FDA Adverse Event Reporting website	HC-BP-510a.1	Total amount of monetary losses as a result of legal proceedings associated with corruption and bribery	Annual Report, F-45
HC-BP-250a.2	Number of fatalities associated with products	Available via FDA Adverse Event Reporting website	HC-BP-510a.2	Description of code of ethics governing interactions with health care professionals	p. 60
	as reported in the FDA Adverse Event Reporting System		Activity Metrics	s	
HC-BP-250a.3	Number of recalls issued, total units recalled	p. 43	HC-BP-000.A	Number of patients treated	p. 54
HC-BP-250a.4	Total amount of product accepted for takeback, reuse, or disposal	p. 43	HC-BP-000.B	Number of drugs (1) in portfolio and (2) in research and development (Phases 1-3)	1) Novartis Global Product Portfolio 2) p. 31

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## **Task Force on Climate-related Financial Disclosures (TCFD)**

Novartis supports the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD). This is our third TCFD disclosure. It is based on updated TCFD guidelines published in October 2021.

We are committed to reducing the impact of our business activities on the environment, and have set clear targets covering climate, water and waste (see page 45). These targets relate to both our own manufacturing operations and to our wider supply chain.

In 2022, we carried out an in-depth assessment of the company's climate-related risks and opportunities. The results form the basis of this disclosure. While we believe our business strategy is well-adapted to current climate risks and opportunities, we continue to work to improve our approach where possible, particularly as it relates to risk management and governance of climate issues.

## Governance

## **Board oversight**

Ultimate responsibility for our climate strategy lies with the Novartis Board of Directors. The Board has delegated primary responsibility for climate strategy and governance, including progress on metrics and targets, to the Governance, Sustainability and Nomination Committee (GSNC). Climate-related topics were on the agenda at two out of three GSNC meetings in 2022.

In addition, several other Board committees have responsibilities that relate to environmental sustainability. These are:

- The Audit and Compliance Committee, which is responsible for internal controls and all compliance processes and procedures, including those related to climate
- The Risk Committee, which oversees the company's risk management (including both physical and transition climate risk)
- The Compensation Committee, which determines how environmental, social and governance (ESG) issues (including climate) should be incorporated into compensation plans for members of the Executive Committee of Novartis (ECN)

Several Novartis Board members have competence on ESG issues. We assess Board-level competence through criteria that include, but are not limited to, the following:

- Whether the respective Board member has comprehensive/expert understanding of ESG-related issues
- Whether the respective Board member has led a company/organization to adopt ESG goals or shape external sustainability leadership initiatives

For more information on the composition and expertise of the Novartis Board, please see our Annual Report.

## **Management oversight**

The ECN, led by the Chief Executive Officer (CEO), is responsible for implementing the company's climate strategy.

Environmental sustainability is included in the CEO's Balanced Scorecard under the "Strategic Objectives" component, which is weighted at 40% of the annual incentive. Performance measures for other members of the ECN include emissions reductions targets where relevant for their area of responsibility.

The CEO chairs our ESG Committee, which oversees the company's ESG strategy, including progress against our climate, water and waste targets. The ESG Committee meets every two months. Climate is included as a specific agenda item at least once a year. In 2022, it was discussed two times.

The Chief Ethics, Risk & Compliance Officer (CERCO) is responsible for ensuring climate risk is fully integrated into our Enterprise Risk Management (ERM) processes. The CERCO reports quarterly to the Risk Committee, including on climate-related physical and transition risks as appropriate.

The President, Global Health & Sustainability, is responsible for integrating ESG matters into the company's business. The President, Operations, is responsible for leading the delivery of environmental sustainability targets.

An annual climate scenario analysis is carried out by the Environmental Sustainability Operations team, which updates both the ESG Committee and the Board at least once a year. Novartis also has an ESG Council and a Sustainability & ESG Office to further embed ESG priorities across the business.

## Main governance and management bodies with climate-related responsibilities



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## **Strategy**

Climate issues are integrated into our strategy, business model and financial planning process. Environmental sustainability spans two of our strategic priorities: 'Embed operational excellence' and 'Build trust with society'!. It is also included in our materiality assessment (see pages 15, 41 and 54).

## **Financial planning**

All capital projects over USD 20 million require a formal Environmental Impact Assessment (EIA) to determine possible impact on the climate and/or company exposure to climate risks. We also apply an internal shadow carbon price of USD 100 per metric ton in our strategic decision-making and financial planning.

In 2022, Novartis deployed approximately USD 30 million in capital expenditure on environmental projects to reduce consumption of natural resources, improve energy efficiency and adopt renewable energy solutions across our operations.

#### **Material climate-related issues**

Results from our 2022 scenario analysis show that: a) climate change potentially presents both risks and opportunities for Novartis, and b) the company's current strategy and financial position remain resilient to the possible impact of climate change.

To conduct our analysis, we used the scenarios listed on page 91, based on input from both the Intergovernmental Panel on Climate Change (IPCC) and the International Energy Agency (IEA). All risks and opportunities were assessed on a short-, medium- and long-term basis, in line with TCFD guidance.

## **Financial quantification**

When assessing risks, including climate-related risks, Novartis defines the financial impact as the potential loss of annual sales, trade receivables or market share according to the following thresholds: <1% (insignificant); 1–2% (minor); 2–3% (moderate); 3–5% (major); and >5% (severe).

## Results of 2022 scenario analysis

Our scenario analysis covered eight physical risks and thirteen transition risks and/or opportunities. Only the most significant items were carried forward for further quantitative analysis. These are set out in the table on page 91. For purposes of comparison, impact is shown for the 2030 and 2050 time horizons only. Please note the physical and transition risks identified below all fall within the "insignificant" level of financial impact (i.e., less than 1% loss of annual sales, trade receivables or market share).

ea-Bissau, an increasinaly severe rainy seasor makes the 12-kilometer journey to the neares nealth center even more difficult.

<sup>&</sup>lt;sup>1</sup> For reporting purposes, we cover the topic under "Embed operational excellence" on page 44

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## Physical and transition risks and opportunities

	High emissions pathway	Low emissions pathway	Time horizons		High emissions pathway	Low emissions pathway	Time horizons
Scenario analysis for physical risks¹	IPCC SSP5-8.5: +4.4°C mean warming by 2100 (equivalent to RCP 8.5)	IPCC SSP1-2.6: +1.8°C mean warming by 2100 (equivalent to RCP 4.5)	2030, 2050	Scenario analysis for transition risks and opportunities	IEA STEPS: +2.6°C average temperature rise by 2100	IEA NZE: +1.5°C average temperature rise by 2100	2025, 2030, 2040, 2050

	Impact	Description	Potential 2030 financial impact	Potential 2050 financial impact	Risk treatment		Impact	Description	Potential 2030 financial impact	Potential 2050 financial impact	Risk treatment
Physical ris	ks					Transition r	isks				
Tropical Insignificant cyclones	ificant Potential financial implications through interruptions at our sites (e.g., property damage, equipment repairs) or via disruption to transport	USD 16-18 million	-18 USD 25-43 million	Carbon price	Carbon price	Insignificant	Carbon prices are likely to increase further across major operating countries. This may increase our future operating costs.	USD 4-22 million in additional annual carbon costs	USD 5-53 million in additional annual carbon costs	Reducing emissions as part of our environmental sustainability targets will limit exposure to carbon pricing.	
		networks (e.g., delaying delivery of raw materials to sites or finished products)			geographic footprint, dual h	Net-zero healthcare systems	Insignificant	Requirements to rapidly decarbonize may drive up capital expenditure (while failure to decarbonize may threaten the company's	•	ied as "at risk"³ narkets with	For the most part, our net-zero targets are aligned with health system goals. In our key markets our net-zero commitment will require us to decarbonize at a
Flooding	looding Insignificant	ant Flooding could lead to disruption or delays in manufacturing processes (e.g. through property and		USD 35-95 million				license to operate in certain countries).			faster rate than required. "At ris revenues relate to a relatively small, low-footprint region.
	infrastructure damage or repairs, fresh-water			generators), supported by administrative controls (e.g.	Transition opportunities						
		availability etc.) and interruptions in product distribution.			emergency response / business continuity plans). We are also implementing energy efficiency initiatives across our operations to	Circular economy	Insignificant	We may face potential increases in operating costs driven by higher plastic prices/ taxation	USD 21–60 million in savings <sup>4</sup> (from avoidance of	USD 10-120 million in savings <sup>4</sup> (from avoidance of	We will reduce exposure to prices as we move closer to our plastic-neutral goal, particularly advanced economies where plas
Extreme heat		Extreme heat conditions could increase operating costs by augmenting our cooling needs and energy consumption to ensure	million	USD 9-19 million	reduce energy demand and transition to renewable energy solutions.			imposed by countries. However, this is also an opportunity for Novartis to switch away from "virgin" (non-recycled) plastic	increasing plastic costs)	increasing plastic costs)	is being phased out or replaced by recycled materials. Risk will be entirely mitigated by 2030 if company goals are met.
		processes and equipment operate efficiently.				Energy source	Insignificant	gnificant Impact of rising fossil fue prices may be avoided by		USD 80-320 million in	We will minimize exposure by increasing our use of clean energ
Water stress and drought <sup>2</sup>	Insignificant	Water stress and drought could potentially impact our operating costs through higher water prices, and/or a need to source water from alternative suppliers. This may also impact revenue by reducing efficiency or causing a shutdown of water-intensive production processes.	USD 250 000 - 940 000	USD 470 000 – 1 million	Sites have water management programs in place, including measures for reusing, recycling and storing water			switching to more sustainable sources (particularly in replacing natural gas for heating with electricity).	annual savings (by reducing proportional use of natural gas for heating)	(by reducing proportional use of natural	in heating and other infrastructur investments.

<sup>&</sup>lt;sup>1</sup> With the exception of water stress/drought - see footnote 2 below.

<sup>&</sup>lt;sup>2</sup> Based on water scarcity data from the World Wildlife Fund's Water Risk Filter. Risk assessed using different scenarios to those used for other physical risks to reflect the WWF data, although these may be equated approximately to scenarios 1 and 2 above. WWF financial ranges use RCP4.5 / SSP1-2.6 and RCP6.0 / SSP3-7.0

<sup>3</sup> Markets have been categorized as "at risk" where regional and/or healthcare system targets are ahead of the Novartis target. Other regions have been categories as "neutral" where the Novartis target is equal to or ahead of regional targets.

<sup>&</sup>lt;sup>4</sup> Savings are derived assuming low and moderate growth scenarios in terms of projected increase in plastic costs

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## Risk management

In addition to our scenario analysis, climate risks are also in scope of our Enterprise Risk Management (ERM) framework, which ensures a consistent approach to risk assessment and treatment across our business.

Risks are identified through annual risk workshops and periodically reviewed. Our Sustainability & ESG Office takes part in this process to ensure environmental and climate risks are considered.

The outcomes are consolidated into the Novartis Risk Compass, which is a categorization and visualization of Novartis top risks by grouping them into Strategic Risks, Operational Risks, Emerging Risks and Awareness Topics, comprising a selection of the top three items for each category (see page 68). Climate is captured primarily under the following two risks:

- Environmental, social and governance matters: a strategic risk defined as failure to meet environmental, social and governance expectations
- Climate change: an emerging risk defined as impact of climate change and increased risk of major natural disasters

Risks are assessed based on their potential impact and likelihood over the next five years, using the "most probable worst-case" scenario as a reference point. These are the same criteria used for other enterprise risks. To ensure alignment, our scenario analysis applies similar definitions for likelihood and impact. Senior managers across the business also provide input as part of our risk assessment.

We take measures to avoid risks or reduce the risk exposure, where appropriate; these measures are determined by our risk appetite. We continually monitor risk and, if needed, periodically review our assessment and/or measures to be taken. The table below summarizes the outcome of our 2022 risk assessment for our two climate-related risks.

In 2023, we will explore ways of further integrating the scenario analysis into our ERM framework.

## Metrics & targets

We use various climate-related metrics and set targets relating to carbon emissions, water consumption, waste, and plastic use. See page 82 for a list of our metrics and page 45 for details of our environmental sustainability targets.



## **Enterprise risk management: Climate-related risks**

Risk	Description	Risk category	Riskrating	Risk treatment
Environmental, social and governance issues	Failure to meet environmental, social and governance expectations	Strategic	High	See page 72 for details
Climate change	Impact of climate change and increased risk of major natural disasters	Emerging	Medium	We have prepared global incident plans for specific types of events (e.g., earthquakes, flooding) which are available for local adaptation and specification.

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# Independent limited assurance report on selected Sustainability Information of Novartis AG

#### To the Board of Directors of Novartis AG

We have undertaken a limited assurance engagement on Novartis AG's (hereinafter "Novartis") Sustainability Information on pages 81 to 84 in the Novartis in Society Integrated Report (the Report) for the year ended 31 December 2022 (hereinafter "Sustainability Information").

Our assurance engagement does not extend to information in respect of earlier periods or to any other information included in the Report, the Novartis Annual Report, Form 20-F or displayed elsewhere on Novartis's website for the current year or for previous periods unless otherwise indicated, including any images, audio files or embedded videos.

### **Our Limited Assurance Conclusion**

Based on the procedures we have performed as described under the 'Summary of the work we performed as the basis for our assurance conclusion' and the evidence we have obtained, nothing has come to our attention that causes us to believe that the Sustainability Information in the Report for the year ended 31 December 2022 is not prepared, in all material respects, in accordance with the reporting criteria as included here (Reporting Criteria).

We do not express an assurance conclusion on information in respect of earlier periods or to any other information included in the Report, the Novartis Annual Report or Form 20-F, including any images, audio files or embedded videos.

## **Understanding how Novartis has Prepared the Sustainability Information**

The Reporting Criteria have been used as criteria references for the disclosures. Consequently, the Sustainability Information needs to be read and understood together with the Reporting Criteria.

## Inherent Limitations in Preparing the Sustainability Information

Due to the inherent limitations of any internal control structure, it is possible that errors or irregularities may occur in disclosures of the Sustainability Information and not be detected. Our engagement is not designed to detect all internal control weaknesses in the preparation of the Sustainability Information because the engagement was not performed on a continuous basis throughout the period and the assurance procedures performed were on a test basis.

The nature of non-financial information; the absence of a significant body of established practice on which to draw; and the methods and precision used to determine non-financial information, allow for different, but acceptable evaluation and measurement techniques and can result in materially different measurements, affecting comparability between entities and over time. The Reporting Criteria have been developed to assist Novartis in its purpose in producing the Report. As a result, the Sustainability Information may not be suitable for another purpose.

The Report includes a deduction from Novartis's emissions for the year ended 31 December 2022 of 30.7 ('000 tCO<sub>2</sub> emissions) relating to offsets. The offsets are derived from Novartis's forestry projects and Novartis has engaged an external provider to calculate the amount of CO<sub>2</sub> emissions sequestered. We have performed procedures as to whether these sequestered CO<sub>2</sub> emissions relate to the current period, and whether the description of them in the Report and Reporting Criteria is inconsistent with the related documentation and calculations from the external provider. We have not, however, performed any procedures regarding the assumptions used in the calculation methodology for these offsets by the external provider, and express no opinion about whether the offsets have resulted, or will result, in a reduction of 30.7 ('000 tCO<sub>2</sub> emissions).

## **Novartis's Responsibilities**

The Board of Directors of Novartis is responsible for:

- Selecting or establishing suitable criteria for preparing the Sustainability Information, taking into account applicable law and regulations related to reporting the Sustainability Information:
- The preparation of the Sustainability Information that is free from material misstatement in accordance with the Reporting Criteria;
- Designing, implementing and maintaining internal control over information relevant to the preparation of the Sustainability Information that is free from material misstatement, whether due to fraud or error; and
- The contents and statements contained within the Report and the Reporting Criteria.

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### **Our Responsibilities**

We are responsible for:

- Planning and performing the engagement to obtain limited assurance about whether the Sustainability Information is free from material misstatement, whether due to fraud or error:
- Forming an independent conclusion, based on the procedures we have performed and the evidence we have obtained; and
- Reporting our opinion to the Board of Directors of Novartis.

As we are engaged to form an independent conclusion on the Sustainability Information as prepared by management, we are not permitted to be involved in the preparation of the Sustainability Information as doing so may compromise our independence.

## **Professional Standards Applied**

We performed a limited assurance engagement in accordance with International Standard on Assurance Engagements 3000 (Revised) Assurance Engagements other than Audits or Reviews of Historical Financial Information, issued by the International Auditing and Assurance Standards Board and, in respect of the greenhouse gas emissions information included within the Sustainability Information, in accordance with International Standard on Assurance Engagements 3410 Assurance Engagements on Greenhouse Gas Statements, issued by the International Auditing and Assurance Standards Board.

## Our Independence and Quality Control

We have complied with the independence and other ethical requirements of the International Code of Ethics for Professional Accountants (including International Independence Standards) issued by the International Ethics Standards Board for Accountants, which is founded on fundamental principles of integrity, objectivity, professional competence and due care, confidentiality, and professional behavior.

Our firm applies International Standard on Quality Control 1 and accordingly maintains a comprehensive system of quality control including documented policies and procedures regarding compliance with ethical requirements, professional standards, and applicable legal and regulatory requirements.

Our work was carried out by an independent and multidisciplinary team including assurance practitioners and sustainability experts. We remain solely responsible for our assurance conclusion.

## Summary of the Work we Performed as the Basis for our Assurance Conclusion

We are required to plan and perform our work to address the areas where we have identified that a material misstatement of the Sustainability Information is likely to arise. The procedures we performed were based on our professional judgment. Carrying out our limited assurance engagement on the Sustainability Information included, among others:

- Inquiries of employees responsible for the determination and consolidation, as well as the implementation of internal control procedures, regarding the Sustainability Information;
- Inspection of selected internal and external documents to determine whether qualitative and quantitative information is supported by sufficient evidence and presented in an accurate and balanced manner:
- Assessment of the data collection, validation and reporting processes as well as the reliability of the reported data on a test basis and through testing of selected calculations;
- Analytical assessment of the data and trends of the Sustainability Information included in the scope of the limited assurance engagement:
- Considering the appropriateness of the carbon conversion factor calculations and other unit conversion factor calculations used by reference to widely recognised and established conversion factors; and
- Reading the narrative within the Report with regard to the Reporting Criteria, and for consistency with our findings.

The procedures performed in a limited assurance engagement vary in nature and timing from, and are less in extent than for, a reasonable assurance engagement. Consequently, the level of assurance obtained in a limited assurance engagement is substantially lower than the assurance that would have been obtained had we performed a reasonable assurance engagement.

benge Richard

KPMG AG

KPMG

Richard Broadbelt Licensed audit expert

George Richard

Basel, 31 January 2023

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## **Abbreviations**

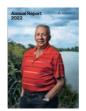
This report uses the following abbreviations:

ACT	Artemisinin-based combination therapy	GDD	Global Drug Development	NGE	Next Enga
AGM	Annual General Meeting of	GDP	Gross domestic product	NIBR	Nova
	Shareholders				BioN
Al	Artificial intelligence	GRI	Global Reporting Initiative	NME	New
AMR	Antimicrobial resistance	GSNC	Governance, Sustainability	NTD	Negl
API	Active pharmaceutical ingredient	dollo	and Nomination Committee	OECD	Orga
АТОМ	Access to Oncology	HIV	Human immunodeficiency virus	OCUA	Deve
0400	Medicines	HS	Hidradenitis suppurativa	OSHA	Occi Heal
CAGR	Compound annual growth rate	HSE	Health, safety and environment	Ph.D.	Doct
CEO	Chief Executive Officer	IASB	International Accounting	PhRMA	Phar and I
CML	Chronic myeloid leukemia	IAOD	Standards Board		Ame
CO <sub>2</sub> e	Carbon dioxide equivalent	IEA	International Energy Agency	PSCI	Phar Chai
CVD	Cardiovascular disease	IFPMA	International Federation	PVC	Poly
DEI	Diversity, equity and inclusion		of Pharmaceutical Manu-facturers and	R&D	Rese
DNA	Deoxyribonucleic acid		Associations	RLT	Radi
D. Phil	Doctor of Philosophy	IFRS	International Financial Reporting Standards	RNA	Ribo
ECN	Executive Committee of Novartis	ILO	International Labour Organization	SASB	Sust Stan
ЕМА	European Medicines Agency	IMB	Innovation Management Board	SDG	Sust Goal
EMAS	Eco-Management and Audit Scheme	IMF	International Monetary Fund	SEC	Secu Com
EPIC	Equal Pay International Coalition	IPCC	Intergovernmental Panel on Climate Change	SEE	Socia
ERC	Ethics, risk and compliance	ISO	International Organization for Standardization	TCFD	Task
ERM	Enterprise risk management	LDC	Lean Digital Core		relate Discl
ESG	Environmental, social and	LGBTQI	Lesbian, gay, bisexual,	TPP	Third
	governance		transgender, queer and intersex	UN	Unite
EU	European Union	LMIC	Low- and middle-income	UNEP FI	Unite
EUR	Euro		countries		Envir Finar
FDA	Food and Drug	M.D.	Doctor of medicine	USD	US d
EDEY	Administration	MDT	Multidrug therapy	WHO	Worl
FPFV	First patient/first visit	MS	Multiple sclerosis		
FTE	Full-time equivalent	NCD	Noncommunicable disease		

NGE	Next Generation Engagement
NIBR	Novartis Institutes for BioMedical Research
NME	New molecular entities
NTD	Neglected tropical disease
OECD	Organization for Economic Cooperation and Development
OSHA	Occupational Safety and Health Administration
Ph.D.	Doctor of philosophy
PhRMA	Pharmaceutical Research and Manufacturers of America
PSCI	Pharmaceuticals Supply Chain Initiative
PVC	Polyvinyl chloride
R&D	Research and development
RLT	Radioligand therapy
RNA	Ribonucleic acid
SASB	Sustainability Accounting Standards Board
SDG	Sustainable Development Goal
SEC	Securities and Exchange Commission
SEE	Social, environmental and economic
TCFD	Task Force on Climate- related Financial Disclosures
TPP	Third-party personnel
UN	United Nations
UNEP FI	United Nations Environment Program Finance Initiative
USD	US dollar
WHO	World Health Organization

## **Novartis annual reporting**

www.reporting.novartis.com



## **Annual Report and US Securities & Exchange Commission Form 20-F**

These reports, filed with the SIX Swiss Exchange in Switzerland and the Securities and Exchange Commission in the US, provide a comprehensive overview of Novartis, including our company structure, corporate governance and compensation practices. They also disclose our operating and financial results, accompanied by audited annual financial statements.





## **Novartis in Society Integrated Report**

The Novartis in Society Integrated Report covers our business, strategy and performance. It highlights progress against our strategic priorities and describes how we create value for diverse stakeholders.

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## **Forward-looking statements**

United States Private Securities Litigation Reform Act of 1995, that can generally be identified by words such as "potential," "expected," "will," "planned," "pipeline," "outlook," or similar expressions, or by express or implied discussions regarding potential new products, potential new indications for existing products, potential product launches, or regarding potential future revenues from any such products; regarding potential future sales or earnings of the Group or any of its divisions; or by discussions of strategy, plans, expectations or intentions; or regarding our intention to separate Sandoz by way of a 100% spin-off. 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. You should not place undue reliance on these statements. In particular, our expectations could be affected by, among other things: uncertainties regarding the success of key products and commercial priorities; global trends toward healthcare cost-containment, including ongoing government, payer and general public pricing and reimbursement pressures and requirements for increased pricing transparency; uncertainties 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 that commenced in prior years and is expected to continue this year; the potential that the strategic benefits, operational efficiencies or opportunities expected from our recent transactions or our organizational transformation programs objectives, including the implementation of our new organizational structure, may not be realized or may take longer to realize than expected; the potential that we may not be able to complete the planned 100% spin-off of Sandoz within the expected time frame, in the planned form, or at all; our performance on environmental, social and governance measures; uncertainties in the development or adoption of potentially transformational technologies and business models; uncertainties regarding potential significant breaches of information security or disruptions of our information technology systems; our reliance on outsourcing key business functions to third parties; our ability to attract, integrate and retain key personnel and qualified individuals; uncertainties regarding actual or potential legal proceedings, including, among others, litigation and other legal disputes with respect to our recent transactions, product liability litigation, litigation and investigations regarding sales and marketing practices, intellectual property disputes and government investigations generally; regulatory actions or delays or government regulation generally, including potential regulatory actions or delays with respect to the development of the products described in this Novartis in Society Integrated Report; our ability to comply with data privacy laws and regulations, and uncertainties regarding potential significant breaches of data privacy; safety, quality, data integrity or manufacturing issues; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; the impact of pandemic diseases such as COVID-19 on enrollment in, initiation and completion of our clinical trials in the future, and research and development timelines; uncertainties involved in predicting shareholder returns; uncertainties regarding the effects of recent and anticipated future changes in tax laws and their application to us; uncertainties regarding future global exchange rates; uncertainties regarding future demand for our 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 these materials 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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Bjoern Myhre

Back cover photo Maggie Perez, a health educator in Philadelphia, PA, checks the blood pressure of a local resident

