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Impact and Sustainability Update

Q2 2023 for investors and analysts

Dear investors and analysts

In our Q2 update, we highlight developments on Sandoz, progress on access and health equity efforts which include the Beacon of Hope and collaboration with The Max Foundation.

We share a conversation with **Marc Boutin, Global Head of Patient Engagement**, and hear how his experiences as a cancer survivor have shaped his views on patient engagement and access to medicines. Some of the biggest challenges remain paternalism and unconscious bias, with a need for consistent and systematic patient engagement across the lifecycle of medicine development.

We appreciate your engagement on all impact and sustainability-related topics and include the top 10 questions from you with our responses.

Thank you.

Key takeaways from this update

- Sandoz spin-off on track for early Q4 2023.
- Post-spin-off, Novartis access strategy to focus more on access to innovation whilst Sandoz focus will be on affordable healthcare and patient reach.
- Sandoz financial and non-financial carve-out numbers will be published in August 2023, and Q1 2024 respectively.
- Novartis is developing and integrating a Patient Engagement strategy into its business processes.
- Novartis has put in place resources to comply with upcoming new regulatory requirements for non-financial disclosure. We are on track for requirements under the Corporate Reporting Sustainability Directive (CSRD) in Europe, and relevant regulation in Switzerland and US.
- Novartis access strategy also incorporates equitable health. Recent expansion include collaboration with The Max Foundation (partnership of over 20 years) and the Beacon of Hope.

For further questions or comments please contact:

Samir Shah

Global Head of
Investor Relations

samir.shah@novartis.com

+41 795 964 645

Madeleine Szeluch

Investor Relations
ESG Director

madeleine.szeluch@novartis.com

+41 795 481 267

Maria Victoria Cuevas

Investor Relations
IR Director & ESG Head

maria.cuevas@novartis.com

+41 61 324 9669

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The Novartis Board of Directors has unanimously endorsed the proposed separation of Sandoz by way of a 100% spin-off. Novartis shareholders will vote at the EGM on September 15, 2023.

Novartis will become a stand-alone Innovative Medicines company, after the Sandoz spin-off. Going forward, **Novartis (Innovative Medicines) will focus more on access to innovation/innovative medicines** in low to-middle income countries (LMICs) and high income countries (HICs), ensuring that access and health equity are at the foundation of our future efforts.

Sandoz will focus more on affordable healthcare and patient reach. With both Innovative Medicines and Sandoz becoming more focused on their respective businesses and sustainability and access efforts, the benefits of the spin-off are expected to be far greater than the combined approach to date, with advantages on impact and access and value enhancement in the long-term.

Novartis will continue to focus on applying our Access Principles to our innovative medicines portfolio.

Material factors	Access	Innovation	Other material topics
Access and Equity to Healthcare Innovation Human capital Ethical business practices Environment	100% of launches with access strategy Sustainability-Linked Bond targets on track (LMICs): 3x patient reach with innovative therapies, 1.5x through flagship programs Equity Collaborating with universities/communities/companies to increase diversity among clinical trial investigators and participants	Innovative therapies reaching more LMIC patients faster R&D for neglected tropical diseases Clinical trial diversity	Human capital diversity targets Net zero carbon emissions by 2040 High ethical standards Leading position in third-party ESG ratings

Sandoz will continue access to affordable healthcare.

Material factors	Access	Innovation	Other material topics
Access to Medicines Patient Reach Ethics and Compliance Environment	#1 European Generics company and a global leader in Biosimilars Strengthening healthcare systems through affordable medicines	Responsible manufacturing, access and use of antibiotics Democratizing biologics	Governance and Ethics Committed to publishing an ESG Report by Q1 2024 Leading with currently 40% female representation on Board of Directors

We plan to publish the Sandoz **financial** and **non-financial** carve-out numbers in **August 2023**, and **Q1 2024** respectively.

Sandoz is planned to be listed on the SIX Swiss Exchange, with an American Depositary Receipt (ADR) program in the US. The proposed spin-off is planned to occur early in the fourth quarter of 2023. In addition to Novartis shareholder approval, completion of the proposed Sandoz spin-off is subject to satisfaction of certain conditions, including obtaining the necessary approvals for the listing of the Sandoz shares, no event outside the control of Novartis preventing the spin-off and no material adverse change. There can be no assurance regarding the ultimate timing of the proposed transaction or that the transaction will be completed. Further details of the proposed spin-off will be provided at a later date.

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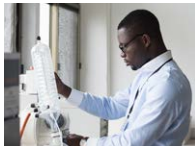
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During Q2, we extended our range of new initiatives to enhance our impact on global health and health equity. Our initiatives build on the key issues identified in our materiality assessments, such as access through health systems strengthening and improving outcomes through innovation.

Initiative	Activity	Potential outcome/impact
The Max Foundation¹  Material factor addressed Equitable access to Innovative Medicines in LMICs	<p>In Q3 2023, Novartis will partner with The Max Foundation to launch the Max Access Solutions program for patients with HR+/HER2- advanced breast cancer in collaboration with oncologists and select partners in LMICs.</p> <p>Two Novartis medicines will initially be available - ribociclib (Kisqali®) and letrozole (Femara®).</p>	<p>The program will actively continue to expand treatment access in LMICs with the focus on providing health care providers the tools necessary to improve outcomes for women living with advanced breast cancer.</p> <p>In 2022, Novartis expanded its 20-year collaboration with The Max Foundation to drive access for breast cancer. We aim to treat up to 36,000 patients in over 70 LMICs by 2025.</p>
Beacon of Hope  Material factor addressed Equitable access to innovation in HICs	<p>Expansion of Beacon of Hope to include six new collaborators. These include two pharmaceutical companies and three companies, Advarra, BeekeeperAI and Virb,</p> <p>The Global Black Economic Forum (GBEF) will support by empowering the next generation of diverse leaders in STEM to address economic disparities.</p>	<p>This partnership aims to increase the representation of minorities in clinical trials and ensure trials are targeted at those who need it most.</p> <p>In future, we will track the progress made on indicators:</p> <ul style="list-style-type: none">• number of investigators of color• number of patients enrolled

Looking ahead

Impact & Sustainability Annual Event, November 13

Novartis will hold its annual Impact & Sustainability Event (formerly known as ESG Day). The event will bring together leaders and experts from Novartis to discuss access and sustainability efforts and challenges and provide an opportunity for analysts and investors to share feedback.

We will share more details in due course.

For interest, please email investor.relations@novartis.com

1. Breast cancer is the most common cancer in women with 25% of all cancers diagnosed in women being breast cancer. Approximately 2.2 million cases occur each year worldwide with about 700,000 deaths annually. An estimated 45% of newly diagnosed cases each year, and more than 55% of breast cancer-related deaths occur in LMICs. LMICs: Low to-middle income countries. HICs: High income countries.

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Patient Engagement and Access to Medicines

Marc Boutin

Global Head of Patient Engagement



What motivates you?

I lost multiple family members to diseases without effective treatments or meaningful access to care. I am a cancer survivor living with an autoimmune condition and have spent hours navigating healthcare systems and clinical trials. **I have seen first-hand that health is done to people, not with them.**

More than 20 years ago, I began volunteering with the patient advocacy community and eventually left legal practice to work with several organizations, including the American Cancer Society, and most recently was the CEO of the National Health Council, where we drove patient-centered healthcare policy, including meaningful access to care and making treatments better.

“ My experiences as a cancer survivor and living with an autoimmune condition have shaped my personal purpose, which is to ensure that everyone has access to affordable healthcare that enables them to live their best life possible. ”

Medicines that address the outcomes that matter most to patients are critical to realizing that vision.

How does Patient Engagement fit within ESG?

In my previous role at the National Health Council, we collaborated with the patient community on legislation that created the Patient Focused Development Program at the FDA and the resulting guidelines. Even as a patient advocate, it was clear to me that **consistently and systematically engaging patients across the lifecycle of medicine development creates value for patients, pharmaceutical companies and society overall.**

A safe and effective medicine is required, but not enough. We need to understand the burden of disease, the burden of existing treatments, and how patients prioritize the outcomes that matter to them and incorporate that into how we make our medicines.

As a result, patients are happier, more productive, and often tax healthcare systems and government programs less.

Patient engagement helps Novartis to avoid research and development costs on products that do not address the outcomes that patients care about. In addition, patient engagement helps us to unburden clinical trial protocols, increasing enrollment, retention and the avoidance of protocol amendments.

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When we co-create patient-relevant endpoints with the patient community, we identify and validate fit-for-purpose measures, core outcome assessments, and the need for patient preference studies, all of which informs our regulatory submission. The resulting label defines our commercial strategy and informs our efforts to ensure that the right patients get access to life-altering medicines as quickly as possible.

As a former patient advocate and now a pharmaceutical executive, this is a true win/win.

[Can you explain how you are driving consistent and systematic patient engagement?](#)

We believe that patient engagement is an investment in good decision-making. Together with patients and associates, we developed a vision, strategy and framework for ensuring patient input into key decisions across Novartis. Rather than create a separate patient engagement process, **we embedded our work in existing processes like the target product profile**, integrated evidence, clinical development, and one-impact planning. As the patient voice permeates every aspect of the company, it reinforces our collective and personal purposes.

[What is the biggest challenge you are facing?](#)

Paternalism and unconscious bias. Too often, we make assumptions about the outcomes we think are important. Just because we make life-altering medicines does not mean that we understand the lived experience of the people who will take those medicines.

When you engage patients, you learn that how they feel, function and survive are all important but weighted differently depending on their disease progression and personal goals. For example, some people living with schizophrenia do not want their treatments to stop their hallucinations – it's part of their creativity.

“ People who are blind from birth often do not want sight; they want to be able to navigate their neighborhoods. ”

Some young people diagnosed with breast cancer want to pursue a career and eventually have a family, while other people with metastatic breast cancer are focused on their relationships. Sometimes patients with Alzheimer's prioritize being able to stay in their home over short-term memory gain.

Some boys with Duchenne muscular dystrophy prefer the ability to text their friend over an extension of life.

The only way to understand the lived experience is to engage patients and their caregivers – and the insights can have profound implications for research, development, and the commercialization of our medicines.

[How do you define success?](#)

Consistent and systematic engagement of patients across the medicines lifecycle. That means prioritizing research that addresses the outcomes that matter most to patients, ensuring that all patient-relevant endpoints are co-created with patients, co-designing clinical trial protocols with patients, and informing commercial strategies with patient insights.

Patient engagement helps us focus on the right outcomes, unburden our clinical trials, and differentiate our products, which enables patients to select the treatments that address what's most important.

“ Short answer, success is making medicines with patients – not for them. ”

[Can you share some specific patient engagement examples across the lifecycle of medicines development?](#)

In early research, we learned that while people living with breast cancer care about overall survival, they also care about the side-effects of the treatments that hinder adherence.

The CML community helped us unburden our clinical trial protocols for a pediatric study by removing a bone marrow biopsy which led to faster recruitment and a less costly trial.

On the advice of a German patient organization, we included a disease-specific quality of life patient-reported outcome measure in a paroxysmal nocturnal hemoglobinuria (PNH) study that will improve the value discussion and help ensure appropriate access in country.

In both axial spondylarthritis and hidradenitis suppurativa, the patient community have clarified the burden of their diseases, leading to efforts that improve awareness, diagnosis, and treatment.

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How will patient engagement evolve over the next 1-3 years?

In the near term, we will implement a new impact measurement framework designed to ensure systematic patient engagement, insight-driven decision-making, and the generation of value for patients, healthcare systems and Novartis. We have already implemented key structures and processes to capture our engagement work, including a progress tool and heatmaps that, at a global and major market level, have already generated thousands of pages of data. We are also capturing our outputs, including key learnings and actions taken as a result of those learnings.

Novartis has already implemented the key structures for implementation of patient engagement. By the end of 2023, we will begin to systematically evaluate and capture the outcomes and impact that demonstrate value to society and the company.

Our hope is that this will help us create better medicines that help improve the lives of people living with serious disease or help them live their full lives.

Patients will expect all pharmaceutical companies to engage them across the lifecycle to ensure that the medicines we bring to market address the outcomes that matter most to them, reduce burden in clinical trials, and enable meaningful access. Regulators increasingly demand patient experience data, and Health Technology Assessment (HTAs) bodies are looking for patient-relevant data that demonstrates value – all of which is best co-created with the patient community.

Patient engagement is good for society, business, investors and patients.



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Question

1
What is your approach to risk and opportunities related to artificial intelligence?

Response

- Artificial intelligence is the ability of a computer/robot to perform tasks commonly associated with intelligent beings. We believe the opportunities associated with this are limitless. We need to also mitigate risks mainly (though not exclusively) related to ethics and data privacy.
- Novartis uses AI in three main areas
 - 1) Development of novel therapies and drug
 - 2) Optimization of business processes and operation
 - 3) Engagement with patients, healthcare professionals and partners
- We recognize the important ethical consideration in implementing AI systems, and have set out eight principles for the use of AI, based on a human-centered approach.
- In the ideation and creation of our eight principles, we engaged a team of specialists in Ethics, Risk & Compliance, Data Privacy, Legal and AI, as well as the Independent Bioethics Advisory Committee (IBAC).
- As we operationalize our eight principles, we are focusing on targeted awareness of risks and training for our associates. In this way, we are upskilling our organization to embed ethics in the design of AI systems.
- We have developed and are launching a novel risk and compliance framework for the responsible use of AI at Novartis. This framework allows us to assess and manage risks related to the exploration, design, development and usage of AI systems.
- Transparency is of utmost importance for our “digital responsibility” approach.
- Our AI/Ethics position paper can be found [here](#).
- Our approach and commitment to data privacy can be found [here](#).

2
How do you expect the planned separation of Sandoz to impact your Access to Medicines deliverables?

- Going forward, Novartis will focus more on access to innovation/innovative medicines and Sandoz will focus more on affordable healthcare and patient reach.
- Our strategy on sustainability and access remains unchanged post-spin-off. We are focused on working with healthcare systems to advance access for underserved patients in LMICs and leading on innovative efforts such as pricing and our Sub-Saharan Africa strategy.
- Sandoz will continue to focus on broadening and accelerating access to affordable medicines ensuring their sustainable and responsible use. As the leading global supplier of generic antibiotic medicines, it will continue its efforts to help combat AMR, taking a balanced approach across the four pillars of the global AMR response strategy: Responsible access, responsible use, responsible manufacturing, and innovation.
- Novartis launched a joint AMR program together with Sandoz in 2021. Novartis plans to continue providing programmatic interventions and drive innovation through the AMR Action Fund.

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Question

3

Can you share more detail on the AMR Action Fund and the role of Novartis?

Response

- The barriers to innovating in antibiotics are too great and the problem of appropriately managing antimicrobial resistance (AMR) is too complex for one company to tackle alone. Novartis has partnered with a broad group of stakeholders, including the International Federation of Pharmaceutical Manufacturers & Associations (IFMA) and 23 of its member biopharmaceutical companies, the World Health Organization, the European Investment Bank, and the Wellcome Trust to create the AMR Action Fund.
- Novartis is one of the members of the USD 1 billion **AMR Action Fund**, established in 2020 to invest in cross-industry antibacterial R&D. This partnership between pharmaceutical companies, philanthropic organizations, development banks and multilateral organizations aims to strengthen and accelerate antibiotic development and bring 2–4 new antibiotics to patients by 2030.
- The Fund is managed independently from the contributing organizations and has already made strategic investments in new antibiotic discovery and development.

4

Is Novartis ready for new regulatory requirements such as CSRD?

- Novartis is on track to meet applicable reporting requirements in Switzerland, Europe and US. These include Art. 964 of the Swiss Code of Obligations in Switzerland, Corporate Sustainability Reporting Directive (CSRD) in Europe and SEC proposed climate disclosures in US.
- CSRD regulation is part of the EU's non-financial reporting regulation, which Novartis is preparing for ahead of its implementation in 2025. We welcome the evolving regulation because it aims to address greenwashing and standardize difficult outputs across peers and sectors.

5

Can you comment on Principle Adverse Impacts required under CSRD and what you report on?

- We are aware of the Principal Adverse Impact (PAI) indicators defined by the Sustainable Finance Disclosure Regulation (SFDR) and the need of financial market participants to access information related to these indicators for companies in their portfolios. Most PAIs are part of or can be derived from our existing disclosures in the Novartis in Society Integrated Report (e.g. NiS 2022 – pages 49, 60, 82-84).
- We disclose non-financial information through our NiS, on Novartis.com, and in dedicated channels like CDP and the Communication of Progress (CoP) by the UN Global Compact. In addition, various ESG rating agencies collect information on PAIs based on our disclosures. We are evaluating the metrics we disclose based on new and upcoming regulations and we support further modifications where it is helpful and relevant.

6

How do you ensure diversity in clinical trials?

- As we reimagine medicine, delivering on access and improving healthcare equity are key material factors, and essential to our commitment for patients and healthcare workers.

We have set our ambitions to enhance diversity in clinical trials. We evaluate for diversity in all Phase 3 studies with US country participation. Our long-term intention is to embed this evaluation throughout our global trials. These aims are embedded in the Novartis Code of Ethics and our Access Principles.
- In mid-2021, we developed 'Beacon of Hope', a 10 year collaboration with approximately 30 Historically Black Colleges, Universities and Medical Schools in the US, to address root causes of disparities in health and education.
- We work with policy makers through advocacy, we also partner with local authorities, expanding engagement with clinical sites/investigators to include areas where diverse patients with particular diseases may be located and collaborate with patient groups, medical institutions and communities to develop investigators of color and recruit broader patient populations.

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Question

7
What is your approach to improving access and pricing in LMICs?

Response

- Access to innovative therapies and addressing unresolved global health challenges is where the healthcare industry can drive the largest impact to society, as this is the highest unmet need in medicine.
- Some of our efforts at Novartis include our 2020 sustainability-linked bond (SLB), which will remain with Novartis after Sandoz spin-off, our emerging growth brands and our Sub-Saharan strategy which focus on innovation and creating value for different stakeholders, which include healthcare professionals, patients, and our shareholders. These efforts were intentional, created to have measurable KPIs and further access to innovative medicines.
- On pricing, our approach is similar. We believe that pricing of medicines should be based on the value they bring to patients, healthcare systems and society. We have been driving a shift to a value-based pricing approach with reasonable out-of-pocket costs for patients. Novartis believes that this approach contributes significantly to delivering access to medicines.

8
Have you quantified the carbon credits you plan to purchase to achieve your decarbonization goals?

- We commit to be fully in line with the Science-Based Targets Initiative (SBTi) net-zero standards, which recommend no more than 10% carbon removal offsets by 2040.

To support this, Novartis has developed a climate model which estimates the investments needed to achieve our decarbonization goals. This model will be revised when our net-zero glidepath has been updated and validated by the SBTi.
- Our climate model factors in our 2040 decarbonation goals across our value chain (scope 1, 2, 3).

9
How do you govern market-specific diversity, equity and inclusion programs at Novartis?

- Our Diversity, Equity and Inclusion (DEI) programs are integral to our Human Resources and management strategy and operationalized in every country.

For example, since 2021, Novartis offers at least 14 weeks of parental leave across geographies, regardless of gender, to help people support the wellbeing of their families after a birth or adoption.
- In 2022, we were recognized externally for the progress we continue to make in providing a positive and inclusive work environment for all employees through the Stonewall Top Global Employer Silver Award, and were included in the Bloomberg Gender Equality Index. These ratings and benchmarks provide valuable insights and our progress compared to industry standards and peers.

10
You have a commitment to invest USD 250 million between 2021-2025 in R&D for neglected diseases. Can you share an update on this?

- Our long-term ambition is to drive and deliver access to innovation, and we believe that there are significant unmet needs and opportunities in neglected diseases.
- Our commitment of USD 250 million over five years (2021-2025) includes: funding to advance research and development of our neglected tropical disease program with research efforts and collaborations to reduce the burden of Chagas disease, leishmaniasis, dengue and cryptosporidiosis; R&D for next-generation antimalarials to combat the emerging resistance to artemisinin and an optimized formulation for babies under 5kg, addressing the unmet needs of children.

Some highlights:

- **Malaria:** Delivered more than 1 billion treatment courses of our antimalarial, Coartem.
- **Leprosy:** Novartis is a founding member of the Global Partnership for Zero Leprosy, established in 2018 to help interrupt transmission and achieve zero new leprosy cases.
- **Chagas:** In 2022, we kicked off the **RAISE** Study: The buRden of ChAgas dISEase in the contemporary world under a research collaboration with the World Heart Federation and the University of Minas Gerais in Brazil.