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FINANCIAL RESULTS | RÉSULTATS FINANCIERS | FINANZERGEBNISSE

Novartis delivers strong sales growth, robust margin expansion and major innovation milestones. Raises FY guidance

- **Q1 sales grew +8% (cc[1], +3% USD) and core operating income grew +15% (cc, +8% USD)**
  - Innovative Medicines (IM) sales grew +7% (cc, +3% USD) and core operating income +18% (cc, +11% USD)
  - IM core margin 38.7%, +360 bps cc, driven by higher sales and productivity programs
  - Growth driven by strong performance of *Entresto*, *Pluvicto*, *Kesimpta*, *Kisqali* and *Scemblix*
  - Sandoz sales grew +8% (cc, +4% USD) and core operating income +3% (cc, -2% USD)
- **Operating income grew +9% (cc, 0% USD)** mainly driven by higher sales
- **Net income grew +14% (cc, +3% USD)** mainly due to higher operating income and higher interest income
- **Core EPS grew +25% (cc, +17% USD) to USD 1.71**, mainly due to higher operating income and lower shares outstanding
- **Free cash flow[2] was USD 2.7 billion** (+95% USD) mainly due to higher operating income adjusted for non-cash items and favorable working capital
- **Q1 key innovation milestones:**
  - ***Kisqali* –** Ph3 NATALEE trial met primary endpoint (iDFS) at interim analysis in adjuvant breast cancer
  - ***Cosentyx* –** 52 weeks positive readout from the pivotal trials in moderate-to-severe HS
  - ***Entresto* –** positive CHMP opinion for pediatric heart failure; if approved, RDP extends to November 2026
  - ***Pluvicto* –** In April FDA approved Millburn facility for commercial production of *Pluvicto*
- **Full-year 2023 group guidance raised** based on strong Q1 momentum[3]
  - **Group Sales** expected to grow **mid-single digits** (from low-to-mid single digits)
  - **Group Core Opinc** expected to grow **high single digits** (from mid-single digits)

Basel, April 25, 2023 - commenting on the quarter, Vas Narasimhan MD, CEO of Novartis, said: *"Novartis delivered strong growth to start 2023, driven by our in-market growth brands, in particular* Entresto, Kisqali *and* Kesimpta. *The* Pluvicto *and* Scemblix *launches continue on their strong trajectory, and the* Leqvio *launch is progressing steadily. In addition, we are driving R&D productivity by prioritizing high-value medicines across our five core therapeutic areas. Our pipeline momentum gives us confidence in our growth outlook, highlighted by the NATALEE Phase 3 positive readout for* Kisqali *in early breast cancer, and we look forward to upcoming readouts for iptacopan in multiple indications and* Pluvicto *in earlier lines of therapy. Our strong start to the year and confidence in our growth drivers allow us to raise guidance for the full year 2023."*

Key figures[1]

	Q1 2023 USD m	Q1 2022 USD m	% change USD	% change cc
Net sales	**12 953**	12 531	3	8
Operating income	**2 856**	2 852	0	9
Net income	**2 294**	2 219	3	14
EPS (USD)	**1.09**	1.00	9	20
Free cash flow[2]	**2 720**	1 392	95	
Core operating income	**4 413**	4 083	8	15
Core net income	**3 614**	3 251	11	18
Core EPS (USD)	**1.71**	1.46	17	25

[1] Constant currencies (cc), core results and free cash flow are non-IFRS measures. An explanation of non-IFRS measures can be found on page 35 of the Condensed Interim Financial Report. Unless otherwise noted, all growth rates in this Release refer to same period in prior year. [2] Effective January 1, 2023, Novartis revised its definition of free cash flow, to define free cash flow as net cash flows from operating activities less purchases of property, plant and equipment. To aid in comparability, the prior year free cash flow amounts have been revised to conform with the new free cash flow definition. See page 35 of the Condensed Interim Financial Report.
[3] Please see detailed guidance assumptions on page 6.

Strategy Update

Our focus

With our new focused strategy unveiled in 2022, Novartis is transforming into a “pure-play” Innovative Medicines business. We have a clear focus on **five core therapeutic areas** (cardiovascular, immunology, neuroscience, solid tumors and hematology), with multiple significant in-market and pipeline assets in each of these areas, that address high disease burden and have substantial growth potential. In addition to two established **technology platforms** (chemistry and biotherapeutics), three emerging platforms (gene & cell therapy, radioligand therapy, and xRNA) are being prioritized for continued investment into new R&D capabilities and manufacturing scale. Geographically, we are focused on growing in our **priority geographies** - the US, China, Germany and Japan.

Our priorities

1. **Accelerate growth**: Renewed attention to deliver high-value medicines (NMEs) and focus on launch excellence, with a rich pipeline across our core therapeutic areas.
2. **Deliver returns**: Continuing to embed operational excellence and deliver improved financials. Novartis remains disciplined and shareholder-focused in our approach to capital allocation, with substantial cash generation and a strong capital structure supporting continued flexibility.
3. **Strengthening foundations**: Unleashing the power of our people, scaling data science and technology and continuing to build trust with society.

Sandoz planned spin-off

The planned spin-off remains on track for the second half of 2023. 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.

Financials

First quarter

Net sales were USD 13.0 billion (+3%, +8% cc) in the first quarter driven by volume growth of 16 percentage points, price erosion of 4 percentage points and the negative impact from generic competition of 4 percentage points.

Operating income was USD 2.9 billion (0%, +9% cc), mainly driven by higher sales. Other income from legal matters was more than offset by higher restructuring and impairment charges.

Net income was USD 2.3 billion (+3%, +14% cc), mainly due to higher operating income and higher interest income.

EPS was USD 1.09 (+9%, +20% cc), growing faster than net income, benefiting from lower weighted average number of shares outstanding.

Core operating income was USD 4.4 billion (+8%, +15% cc). Core operating income margin was 34.1% of net sales, increasing by 1.5 percentage points (+2.2 percentage points cc).

Core net income was USD 3.6 billion (+11%, +18% cc), mainly due to higher core operating income and higher interest income.

Core EPS was USD 1.71 (+17%, +25% cc), growing faster than core net income, benefiting from lower weighted average number of shares outstanding.

Free cash flow amounted to USD 2.7 billion (+95% USD), compared to USD 1.4 billion in the prior year quarter, mainly due to higher operating income adjusted for non-cash items and favorable changes in working capital.

Innovative Medicines net sales were USD 10.6 billion (+3%, +7% cc), with volume contributing 16 percentage points to growth. Sales growth was mainly driven by *Entresto*, *Pluvicto*, *Kesimpta* and *Kisqali* partly offset by generic competition mainly for *Gilenya*. Generic competition had a negative impact of 5 percentage points. Pricing had a negative impact of 4 percentage points. Sales in the US were USD 4.1 billion (+11%) and in the rest of the world were USD 6.5 billion (-1%, +5% cc).

Sandoz net sales were USD 2.4 billion (+4%, +8% cc), with volume contributing 15 percentage points to growth. Sales growth was mainly driven by Europe, which benefited from strong volume growth driven by continued momentum from prior year launches and a strong cough and cold season. Pricing had a negative impact of 7 percentage points. Ex-US sales grew by +12% in cc. Global sales of Biopharmaceuticals grew to USD 518 million (+11%, +17% cc), driven by ex-US growth.

Q1 key growth drivers

Underpinning our financial results in the quarter is a continued focus on key growth drivers including:

Entresto	(USD 1,399 million, +32% cc) sustained robust demand-led growth, with increased patient share across all geographies
Pluvicto	(USD 211 million) with strong US launch performance, with demand continuing to exceed supply
Kesimpta	(USD 384 million, +100% cc) sales growth across all geographies driven by increased demand and strong access
Kisqali	(USD 415 million, +81% cc) grew strongly across all geographies, based on increasing recognition of its overall survival and quality of life benefits in HR+/HER2- advanced breast cancer
Promacta/Revolade	(USD 547 million, +15% cc) grew across most regions, driven by increased use in chronic ITP and as first-line and/or second-line treatment for severe aplastic anemia
Tafinlar + Mekinist	(USD 458 million, +18% cc) sales grew across all geographies, driven by demand in BRAF+ adjuvant melanoma and NSCLC indications
Ilaris	(USD 328 million, +19% cc) showed continued growth across all geographies
Scemblix	(USD 76 million, +202% cc) continued its strong launch uptake demonstrating the high unmet need in CML
Leqvio	(USD 64 million) launch progressing steadily including expansion into new geographies
Jakavi	(USD 414 million, +13% cc) sales grew in Emerging Growth Markets, Europe and Japan, driven by strong demand in both myelofibrosis and polycythemia vera
Piqray	(USD 116 million, +61% cc) sales grew mainly in the US, benefiting from indication expansion into PIK3CA-related overgrowth spectrum (PROS)
Lutathera	(USD 149 million, +22% cc) sales grew mainly in the US and Japan due to increased demand
Cosentyx	(USD 1,076 million, -4% cc) continued demand growth across key geographies, offset by revenue deduction adjustments in the US. Ex-US sales grew +17% (cc)
Sandoz Biopharmaceuticals	(USD 518 million, +17% cc) driven by ex-US growth
Emerging Growth Markets*	Overall, grew +14% (cc). China returned to growth post COVID lockdowns. (+1% cc, USD 829 million), with Innovative Medicines growing +5% *All markets except the US, Canada, Western Europe, Japan, Australia, and New Zealand

Net sales of the top 20 Innovative Medicines products in Q1 2023

	Q1 2023	% change	
	USD m	USD	cc
Entresto	1 399	28	32
Cosentyx	1 076	-7	-4
Promacta/Revolade	547	11	15
Tasigna	462	0	4
Tafinlar + Mekinist	458	14	18
Lucentis	416	-20	-15
Kisqali	415	74	81
Jakavi	414	6	13
Kesimpta	384	97	100
Xolair	354	-4	2
Sandostatin	329	3	5
Ilaris	328	15	19
Zolgensma	309	-15	-14
Gilenya	232	-62	-60
Pluvicto	211	nm	nm
Exforge Group	186	-7	-1
Galvus Group	183	-15	-9
Diovan Group	158	-17	-11
Lutathera	149	19	22
Gleevec/Glivec	147	-26	-21
Top 20 products total	8 157	4	8

nm= not meaningful

R&D update - key developments from the first quarter

New approvals

Pluvicto	In April FDA approved Millburn facility for commercial production of *Pluvicto*. Expected to contribute meaningfully to supply in Q3 after the anticipated approval of additional lines
Tafinlar + Mekinist	Approved in the US for the treatment of pediatric patients ≥1 year of age with low-grade glioma with a BRAF V600E mutation who require systemic therapy
***Hyrimoz* (adalimumab)**	FDA approved biosimilar *Hyrimoz* (adalimumab-adaz) high-concentration formulation to treat seven indications covered by the reference medicine, Humira® EC approved (April 3, 2023) citrate-free high concentration formulation of adalimumab biosimilar to treat all indications covered by the reference medicine, Humira®

Regulatory updates

Entresto	Positive CHMP opinion for pediatric heart failure indication. If approved, this would support extension of regulatory data protection in Europe to November 2026
Denosumab biosimilar	FDA accepted BLA for proposed biosimilar denosumab. The application includes all indications covered by the reference medicines Prolia® and Xgeva®

Results from ongoing trials and other highlights

Kisqali	Ph3 NATALEE trial met its primary endpoint (iDFS) at an interim analysis. *Kisqali* plus ET significantly reduced the risk of disease recurrence, compared to ET alone, demonstrating consistent benefit in a broad population of patients with stage II and III HR+/HER2- early breast cancer, including those with no nodal involvement. Data will be presented at an upcoming meeting and submitted to regulatory authorities
Cosentyx	Long-term data from the pivotal SUNSHINE and SUNRISE trials evaluating *Cosentyx* in moderate-to-severe HS, demonstrated continued improvement in treatment response rates with over 55% of patients achieving a HiSCR at Week 52 and over 50% of patients demonstrating a meaningful reduction in pain. Data published in Lancet and presented at the 2023 AAD annual meeting
Zolgensma	Data from two long-term follow-up studies, LT-001 and LT-002, show continued efficacy and durability of *Zolgensma* up to 7.5 years post-dosing, across a range of patient populations, with an overall benefit-risk profile that remains favorable. All pre-symptomatic children treated maintained or achieved all assessed motor milestones. Data presented at the 2023 MDA conference
R&D Portfolio Prioritization	Novartis continues to focus its R&D portfolio prioritizing high value medicines with transformative potential for patients. During the quarter, a comprehensive review of R&D projects resulted in decisions to discontinue or out-license projects for reasons including strategic fit and commercial potential, representing approximately 10% of the Novartis pipeline.
FAP-2286	Acquired FAP-2286 (Ph1/2), a potential first-in-class radioligand therapy with the respective radioligand imaging agent, from Clovis Oncology
Bicycle Peptides	Novartis entered into research collaboration on bicyclic peptides with Bicycle Therapeutics

Capital structure and net debt

Retaining a good balance between investment in the business, a strong capital structure and attractive shareholder returns remains a priority.

In Q1 2023, Novartis repurchased a total of 31.5 million shares for USD 2.8 billion on the SIX Swiss Exchange second trading line under the up-to USD 15 billion share buyback announced in December 2021. In addition, 1.2 million shares (for an equity value of USD 0.1 billion) were repurchased from associates. In the same period, 10.5 million shares (for an equity value of USD 0.3 billion) were delivered as a result of options exercised and share deliveries related to participation plans of associates. Novartis aims to offset the dilutive impact from equity based participation plans of associates over the remainder of the year. Consequently, the total number of shares outstanding decreased by 22.2 million versus December 31, 2022. These treasury share transactions resulted in an equity decrease of USD 2.5 billion and a net cash outflow of USD 2.7 billion.

As of March 31, 2023, net debt increased to USD 15.1 billion compared to USD 7.2 billion at December 31, 2022. The increase was mainly due to the USD 7.3 billion annual dividend payment and net cash outflow for treasury share transactions of USD 2.7 billion, partially offset by USD 2.7 billion free cash flow in Q1 2023.

As of Q1 2023, the long-term credit rating for the company is A1 with Moody’s Investors Service and AA- with S&P Global Ratings.

2023 outlook raised due to strong growth momentum

Barring unforeseen events; growth vs prior year in cc

Innovative Medicines	Sales expected to **grow mid-single digit** (from low-to-mid single digit) Core OpInc expected to **grow high single to low double digit** (from mid-to-high single digit)
Novartis ex. Sandoz (IM + Corporate)	Sales expected to **grow mid-single digit** (from low-to-mid single digit) Core OpInc expected to **grow high single digit to low double digit** (from mid-to-high single digit)
Novartis incl. Sandoz (IM + Sandoz + Corporate)*	Sales expected to **grow mid-single digit** (from low-to-mid single digit) Core OpInc expected to **grow high single digit** (from mid-single digit)

* Novartis Group guidance, assuming Sandoz would remain within the Group for the entire FY 2023

Barring unforeseen events; growth vs prior year in cc

Sandoz	Sales expected to **grow mid-single digit** (from low-to-mid single digit) Core OpInc expected to **decline low double digit**, reflecting required stand-up investments to transition Sandoz to a separate company and continued inflationary pressures

Our guidance assumes that no *Sandostatin* LAR generics enter in the US in 2023. We continue to expect that the planned Sandoz spin-off is completed in H2 2023.

Foreign exchange impact

If late-April exchange rates prevail for the remainder of 2023, the foreign exchange impact for the year would be negligible on net sales and negative 3 to negative 4 percentage points on core operating income. The estimated impact of exchange rates on our results is provided monthly on our website.

Key figures[1]

Group	Q1 2023	Q1 2022	% change	
	USD m	USD m	USD	cc
Net sales	**12 953**	**12 531**	**3**	**8**
Operating income	**2 856**	**2 852**	**0**	**9**
As a % of sales	*22.0*	*22.8*		
Core operating income	**4 413**	**4 083**	**8**	**15**
As a % of sales	*34.1*	*32.6*		
Net income	**2 294**	**2 219**	**3**	**14**
EPS (USD)	**1.09**	**1.00**	**9**	**20**
Core net income	**3 614**	**3 251**	**11**	**18**
Core EPS (USD)	**1.71**	**1.46**	**17**	**25**
Cash flows from operating activities	**2 957**	**1 649**	**79**	
Free cash flow[2]	**2 720**	**1 392**	**95**	

Innovative Medicines	Q1 2023	Q1 2022 restated[3]	% change	
	USD m	USD m	USD	cc
Net sales	**10 570**	**10 230**	**3**	**7**
Operating income	**2 675**	**2 627**	**2**	**11**
As a % of sales	*25.3*	*25.7*		
Core operating income	**4 088**	**3 672**	**11**	**18**
As a % of sales	*38.7*	*35.9*		

Sandoz	Q1 2023	Q1 2022 restated[3]	% change	
	USD m	USD m	USD	cc
Net sales	**2 383**	**2 301**	**4**	**8**
Operating income	**319**	**394**	**-19**	**-14**
As a % of sales	*13.4*	*17.1*		
Core operating income	**504**	**513**	**-2**	**3**
As a % of sales	*21.1*	*22.3*		

Corporate	Q1 2023	Q1 2022 restated[3]	% change	
	USD m	USD m	USD	cc
Operating loss	**-138**	**-169**	**18**	**16**
Core operating loss	**-179**	**-102**	**-75**	**-78**

[1]Constant currencies (cc), core results and free cash flow are non-IFRS measures. An explanation of non-IFRS measures can be found on page 35 of the Condensed Interim Financial Report. Unless otherwise noted, all growth rates in this Release refer to same period in prior year.

[2]To aid in comparability, the prior year free cash flow amounts have been revised to conform with the new free cash flow definition that was effective as of January 1, 2023.

[3] Restated to reflect the transfers of the Sandoz division's biotechnology manufacturing services to other companies' activities and the *Coartem* brand to the Innovative Medicines division that was effective as of January 1, 2023 (see Note 9 of the Condensed Interim Financial Report).

Detailed financial results accompanying this press release are included in the Condensed Interim Financial Report at the link below:

https://ml-eu.globenewswire.com/resource/download/c0540159-3aae-4e2d-9a9b-97f92af073e3/

Disclaimer

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995, that can generally be identified by words such as “continue,” “progresses,” “remain,” “growth,” “on track,” “confidence,” “upcoming,” “prioritizing,” “expect,” “continued,” “ongoing,” “optimistic,” “outlook,” “focus,” “pipeline,” “growth,” “potential,” “expected,” “will,” “guidance,” “continuing,” “estimated,” “launch,” “continue,” “to deliver,” “transformation,” “address,” “growing,” “accelerate,” “remains,” “scaling,” “expected,” “driven,” “long-term,” “innovation,” “transformative,” “priority,” “can,” “to develop,” “to experience,” “look forward,” “momentum,” 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; or regarding potential future, pending or announced transactions; or regarding the research collaboration with Bicycle Therapeutics; or regarding potential future sales or earnings of the Group or any of its divisions; or regarding discussions of strategy, priorities, plans, expectations or intentions, including our transforming into a “pure-play” Innovative Medicines business; or regarding the Group’s liquidity or cash flow positions and its ability to meet its ongoing financial obligations and operational needs; or regarding our planned spin-off of Sandoz. 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: liquidity or cash flow disruptions affecting our ability to meet our ongoing financial obligations and to support our ongoing business activities; the impact of a partial or complete failure of the return to normal global healthcare systems including prescription dynamics; global trends toward healthcare cost containment, including ongoing government, payer and general public pricing and reimbursement pressures and requirements for increased pricing transparency; uncertainties regarding potential significant breaches of data security or data privacy, or disruptions of our information technology systems; 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 press release; the potential that the benefits and opportunities expected from our planned spin-off of Sandoz may not be realized or may be more difficult or take longer to realize than expected; the 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; safety, quality, data integrity, or manufacturing issues; uncertainties involved in the development or adoption of potentially transformational technologies and business models; uncertainties regarding actual or potential legal proceedings, investigations or disputes; our performance on environmental, social and governance measures; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; 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 this press release as of this date and does not undertake any obligation to update any forward-looking statements as a result of new information, future events or otherwise.

About Novartis

Novartis is reimagining medicine to improve and extend people's lives. We deliver high-value medicines that alleviate society's greatest disease burdens through technology leadership in R&D and novel access approaches. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. About 103,000 people of more than 140 nationalities work together to bring Novartis products to nearly 800 million people around the world. Find out more at https://www.novartis.com.

Novartis will conduct a conference call with investors to discuss this news release today at 14:00 Central European time and 8:00 Eastern Time. A simultaneous webcast of the call for investors and other interested parties may be accessed by visiting the Novartis website. A replay will be available after the live webcast by visiting https://www.novartis.com/investors/event-calendar.

Detailed financial results accompanying this press release are included in the condensed interim financial report at the link below. Additional information is provided on Novartis divisions and pipeline of selected compounds in late stage development and a copy of today's earnings call presentation can be found at https://www.novartis.com/investors/event-calendar.

Important dates

June 04, 2023	ASCO Investor Event
June 08, 2023	Sandoz Capital Markets Day – New York
June 12, 2023	Sandoz Capital Markets Day – London
July 18, 2023	Second quarter & Half year 2023 results
October 24, 2023	Third quarter & Nine months 2023 results
November 28, 2023	R&D Day