

Sustainability Accounting Standards Board (SASB)

2023/2024 Index

BIOMARIN®

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SASB Topic	Code	Accounting Metric	BioMarin 2023/24 Disclosure
Safety of Clinical Trial Participants	HC-BP- 210a.1	Discussion, by world region, of management process for ensuring quality and patient safety during clinical trials	BioMarin is committed to the safety of the patients and healthy volunteers who take part in our clinical trials, maintaining the highest ethical, scientific and clinical standards in all of our research initiatives worldwide. To ensure appropriate protection and respect for the rights of study participants, all BioMarin-sponsored clinical trials are designed and conducted to meet or exceed all applicable local laws and regulations and globally recognized principles of international ethics, such as the International Conference on Harmonization (ICH) E6 Good Clinical Practice (GCP) Guidelines. BioMarin maintains detailed internal procedures to ensure rigorous compliance with these laws and regulations and cultural alignment with the countries in which studies are conducted. The procedures include active safety surveillance and high quality, science-based proactive risk management by our Global Pharmacovigilance team. Every potential new BioMarin therapy undergoes preclinical and clinical testing and review to establish its safety and efficacy profile, with each clinical trial reviewed and approved prior to its start by a specific Independent Review Board (IRB) or Ethics Committee (EC) including medical, scientific and non-scientific members. Following product marketing approval from health authorities, safety data collection reporting continues through multiple channels, including additional clinical and post-marketing studies, patient and healthcare professional (HCP) reports, registries and scientific literature.
	HC-BP- 210a.2	Number of FDA Sponsor Inspections related to clinical trial management and pharmacovigilance that resulted in: (1) Voluntary Action Indicated (VAI) and (2) Official Action Indicated (OAI)	In 2023 and 2024, the FDA did not issue any GCP inspection findings that resulted in VAIs or OAIs. Details on BioMarin's performance in FDA inspections can be found in the FDA's Inspection Classification Database.
	HC-BP- 210a.3	Total amount of monetary losses as a result of legal proceedings associated with clinical trials in developing countries	In 2023 and 2024, BioMarin did not incur any monetary losses as a result of legal proceedings associated with clinical trials in developing countries.
			BioMarin discloses all material legal and regulatory proceedings in our <u>Annual Reports</u> and Quarterly Reports on Form 10-Q, found here: <u>BioMarin Investors – 2024</u>

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Access to Medicines	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 Medicine Index	Access to Our Therapies in Low- and Middle-Income Regions At BioMarin, it's not enough to make transformative medicines: we work to ensure that people from low- and middle-income regions have access to our therapies. Treatment for rare conditions comes with unique challenges, and the path to access varies in each region. For these reasons, we partner with all those involved in breaking down regional obstacles and facilitating paths to care, including doctors, health officials, researchers, community advocates, suppliers and patients themselves. Our approach includes: Reaching national pricing agreements with a number of low- and middle-income countries Adjusting established agreements following major regional events such as armed conflict and natural disasters Tailoring drug delivery processes to meet unique regional needs: for example, identifying ways to maintain frozen medicines in route to areas with infrastructure challenges Partnering in initiatives to improve diagnostic capacity and identify those in need of treatment Designing patient support programs that address specific barriers to care in individual regions
	HC-BP- 240a.2	List of products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP)	BioMarin has no products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP).
Affordability & Pricing	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 generic product to market for a defined time period	In 2023 and 2024, BioMarin did not enter into any pay for delay settlement agreements with an ANDA filer relating to any authorized generic product.

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Affordability & Pricing	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	Discussion regarding drug pricing can be found in the Risk Factors section of our 10-K.
	HC-BP- 240b.3	Percentage change in: (1) list price, and (2) net price of product with largest increase compared to previous year	Discussion regarding drug pricing can be found in the Risk Factors section of our 10-K.
Drug Safety	HC-BP- 250a.1	List of products listed in the Food and Drug Administration's (FDA) MedWatch Safety Alerts for Human Medical Products database	There were no BioMarin products for which a safety alert or a potential safety issue had been identified in the FDA's Medwatch Safety Alerts database as of the end of 2024.
	HC-BP- 250a.2	Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System	This information is publicly available via the FDA's Adverse Event Reporting System (FAERS) Public Dashboard
	HC-BP- 250a.3	Number of recalls issued, total units recalled	BioMarin issued no recalls in 2023 or 2024. This information is publicly available via the <u>FDA</u> <u>Data Dashboard</u> .

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Drug Safety	HC-BP- 250a.4	Total amount of product accepted for takeback, reuse, or disposal	 BioMarin is a member of the Pharmaceutical Product Stewardship Work Group (PPSWG), which: coordinates pharmaceutical industry members' efforts to respond to household pharmaceutical products and sharps take-back laws, provides legislative and regulatory updates to its members on developing and existing laws, and provides strategic guidance for stewardship programs. MED-Project USA serves as the stewardship organization designated by PPSWG members to implement and operate mandated take-back programs. As part of this effort, MED-Project USA provides and publicizes locations to dispose of unwanted, unused or expired household medicines. BioMarin does not receive data from PPSWG tracking the amount of product accepted for takeback, reuse or disposal. However, BioMarin manufactures and sells specialty products for rare diseases, many of which are administered in clinic. Thus, while BioMarin engages with PPSWG to maintain awareness of, and compliance with, relevant laws, BioMarin would not expect any significant volume of unwanted, unused or expired product to be found in US households.
	HC-BP- 250a.5	Number of FDA enforcement actions taken in response to violations of current Good Manufacturing Practices (cGMP), by type	BioMarin had no cGMP enforcement actions in 2023 or 2024, as defined by the US FDA.

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Counterfeit Drugs	HC-BP- 260a.1	Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting	BioMarin complies with applicable provisions of the U.S. Drug Supply Chain Security Act and with EU rules introduced to fight falsified medicines, and we use appropriate serialization and track-and-trace techniques to protect our products and patients. We use serialization and anti-tampering devices on the outer packaging of drugs such that each carton of commercial product approved for sale in the U.S. and EU has a unique, identifying code to facilitate the tracking and verification of the medicine throughout the supply chain. Our practices include aggregating serialized information to enable track-and-trace and utilizing relevant national alert systems, such as the National Medicines Verification Organisation (NMVO). In addition to these internal processes, BioMarin participates in industry-wide partnerships with other pharmaceutical companies and organizations focused on protecting public health, sharing information on falsified medicines (and approaches to counter illicit trade), and engages with local and national-level authorities when enforcement actions are appropriate.
	HC-BP- 260a.2	Discussion of process for alerting customers and business partners of potential or known risks associated with counterfeit products	BioMarin has several established procedures for global reporting and notification in the event of a potential or known risk associated with the safety or quality of our products. These procedures detail our process for reporting of falsified medicines and suspect and illegitimate products. They also establish the process for notification to and coordination with our affected trading partners and regulatory authorities; follow up investigations in accordance with applicable laws and regulations, such as the Drug Supply Chain Security Act (DSCSA); and, if necessary, recall strategy and execution.
	HC-BP- 260a.3	Number of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products	BioMarin had no raids, seizure, arrests and/or filing of criminal charges in 2023 or 2024 related to counterfeit products.

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Ethical Marketing	HC-BP- 270a.1	Total amount of monetary losses as a result of legal proceedings associated with false marketing claims	BioMarin had no monetary losses in 2023 or 2024 as a result of legal proceedings associated with false marketing claims.
	HC-BP- 270a.2	Description of code of ethics governing promotion of off- label use of products	BioMarin is committed to complying with good marketing practices by adhering to applicable laws, regulations, relevant industry codes and internal policies and procedures. BioMarin regularly trains employees on the <u>Global Code of Conduct & Business Ethics</u> , which prohibits off-label promotion, and provides a wide range of additional internal and external educational activities around good marketing practices for employees and healthcare professionals (HCPs).

Forward-Looking Statements

This non-confidential report contains forward-looking statements about environmental, social and governance (ESG) activities at BioMarin Pharmaceutical Inc. (BioMarin), including, without limitation, statements regarding BioMarin's expectations and plans for ESG-related matters. These forward-looking statements are predictions and involve risks and uncertainties such that actual results may differ materially from these statements. These risks and uncertainties include, among others, those factors detailed in BioMarin's filings with the Securities and Exchange Commission, including, without limitation, the factors contained under the caption "Risk Factors" in BioMarin's Annual Report on Form 10-K for the year ended December 31, 2024 as such factors may be updated by any subsequent reports including BioMarin's Quarterly Report on Form 10-Q. You are urged not to place undue reliance on forward-looking statements, which speak only as of the date hereof. BioMarin is under no obligation, and expressly disclaims any obligation to update or alter any forward-looking statement, whether as a result of new information, future events or otherwise.

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Employee Recruitment, Development & Retention	HC-BP- 330a.1	Discussion of talent recruitment and retention efforts for scientists and research and development personnel	At BioMarin, we believe scientific breakthroughs happen when different perspectives come together to solve complex problems. Our commitment to this work ensures that we are harnessing the full range of our talent to drive innovation. This includes partnering with community organizations that share our commitment to fostering the next generation of biomedical leaders to further our pipeline of talent and equipping them to influence the industry broadly. Our major partnerships and programs include:

- Biotech Partners (BP): This award-winning, independent, Bay Area-based nonprofit organization focuses on helping students who are underrepresented in the field of biotechnology to attain personal, academic and professional development experiences through in-classroom instruction and paid internships within the biotech and health industries. BP has educated over 3,915 youth and made more than 1,564 placements into paid training positions, with student earnings totaling more than \$3.4 million. BioMarin has partnered with BP to provide special internships with our Research and Development teams, where these students are immersed in real-world science initiatives with our researchers.
- Undergraduate Programs: The Robinson Life Science, Business, and Entrepreneurship (LSBE)
 Program and Project Onramp offer paid summer internships at BioMarin to undergraduates
 from diverse backgrounds, experiences, and perspectives. These initiatives aim to remove
 barriers to accessing the biotech field while providing students with essential skills to
 address complex research problems and establish a robust network in the life sciences
 sector.
- Post Doctoral Fellowship Programs: Designed to foster a pipeline of professionals in biotech that spans a broad range of backgrounds and experiences: the Regulatory Affairs Fellowship in partnership with STEM field leader, Howard University, and the Research & Early Development (RED) fellowship. These programs aim to support early career scientists in growing their careers at BioMarin while deepening their understanding of the biopharmaceutical industry. We strive to bring new perspectives and experiences to our scientific team. These initiatives help us achieve our goal of developing innovative medicines for people with genetic diseases, as we benefit from the insights and ideas of the next generation of scientists.
- BioMentoring Program: This program is a key part of our commitment to employee growth, fostering a culture where learning, development, and career advancement thrive. BioMarin colleagues serve as development partners, providing coaching, guidance, and support to help junior employees navigate their careers with confidence. By investing in mentorship, we strengthen our talent pipeline, create a more inclusive workplace, and empower all employees to reach their full potential.

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SASB Topic Employee Recruitment, Development & Retention	HC-BP- 330a.2	Accounting Metric (1) Voluntary and (2) involuntary turnover rate for: (a) executives/senior managers, (b) midlevel managers, (c) professionals, and (d) all others	BioMarin's total voluntary turnover rate in 2024 was 5.4%.
Supply Chain Management	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 Consortium audit program or equivalent third-party audit programs for integrity of supply chain and ingredients	BioMarin has a GMP Audit Program that includes a risk-based approach to the auditing and monitoring of our supply chain partners through a mix of third-party audit programs and internal audits conducted by BioMarin Global Compliance and Ethics. The audits help to ensure that our supply chain is meeting regulatory requirements as well as BioMarin internal procedures, including the correct implementation of our Quality Management System.
Business Ethics	HC-BP- 510a.1	Total amount of monetary losses as a result of legal proceedings associated with corruption and bribery	BioMarin had no monetary losses in 2023 and 2024 as a result of legal proceedings associated with corruption and bribery.

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Business Ethics	HC-BP- 510a.2	Description of code of ethics governing interactions with healthcare professionals	BioMarin is committed to conducting all aspects of our business in compliance with all applicable laws, as well as in accordance with the highest standards of ethical behavior. BioMarin's Global Compliance & Ethics program is an enterprise-wide global initiative that addresses the seven elements discussed in the OIG Compliance Program Guidance for Pharmaceutical Manufacturers. BioMarin's Global Code of Conduct & Business Ethics and the Company's various compliance policies, procedures, and/or processes are integrated across the organization with department specific procedures or guidance as needed. Among other things, our policies and procedures address the PhRMA Code and gifts to medical or health professionals. BioMarin Directors, officers, and employees are expected to comply with all of BioMarin's global compliance policies, procedures, and processes. To ensure compliance, BioMarin regularly trains employees on the Global Code of Conduct & Business Ethics and provides a wide range of additional internal and external educational activities around good marketing practices for employees and healthcare professionals (HCPs).
Activity Metrics	HC-BP- 000.A	Number of patients treated	As of the end of 2024, BioMarin was providing therapies to approximately 14,000 patients worldwide. This includes patients receiving commercial therapy as well as patients provided free treatment as part of our expanded access or bridge programs.
	HC-BP- 000.B	Number of drugs (1) in portfolio and (2) in research and development (Phases 1-3)	As of year-end 2024, BioMarin had 8 products approved for commercial use in one or more countries and 5 treatments in research and development (phases 1 – 3). Please see Our Treatments – BioMarin for additional information.

