# *CSR REPORT 2016*



# DESPIENCREASED LOVERED OUR TOTAL CO2 EMISSIONS BY 13%

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#### About the report

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- 4 This Statutory Report on Corporate Social Responsibility
- 6 (CSR), cf. sections 99a and 99b of the Danish
- 8 Financial Statements Act, is part of the Management
- 11 commentary in the 2016 Annual Report and covers
- 13 the financial period January 1 December 31, 2016.



### OUR SCIENCE MAKES THE GREATER IMPACT LETTER FROM THE CEO

2016 was perhaps the busiest year thus far in our production. The transformation into a multiproduct facility has completed and we have manufactured a multitude of vaccines.

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We have leveraged the know-how and expertise derived from many years of experience in manufacturing IMVAMUNE smallpox vaccine, to expand our facility to produce other commercial vaccines as well as vaccines for clinical trials to support the advancement of our pipeline. IMVAMUNE remains a core asset which we continue to supply to the U.S. Government. Importantly, we are preparing for commercial manufacturing of our prostate cancer vaccine, PROSTVAC for a successful product launch, if approved.

In that light, it is very satisfying that, of all the years we have reported on our CO<sub>2</sub> emissions, 2016 was the least impactful – both in actual numbers and relatively. While it could be expected that our increased activity would entail higher emissions, the result is very satisfying, and gives evidence of our ability to improve the efficiency in our manufacturing process.

### It is our mission to make significant contributions to improve public health

2016 was also a year with significant investments in our pipeline. We continue to move forward our prioritized projects; CV301, an immunotherapy for lung cancer, and MVA-BN RSV for protection against respiratory syncytial virus, which both represent significant opportunities in areas of high unmet medical need. And with our partners we continue to progress our other product candidates in cancer and infectious diseases.

Albeit we continue to grow and mature our company, we are still a small organization with an agile mindset that allows us to adapt quickly to changes. We had a slight increase in our workforce in 2016, particularly in our production as result of increased activity. And we decided to close our operations in California to relocate to the U.S. east coast during first half of 2017. This will bring us closer to our partners, collaborators and influencers in the U.S., but not least also closer to our headquarters and operations in Europe, thus creating a stronger connection between our people.

Being a company in growth, we are not able to make pledges for lowering our overall emissions. The activity level in production in 2017 will be similar to 2016; however, we will continue our efforts to minimize our climate impact over time. Having said that, our impact is still modest and reasonable, considering our mission to make significant contributions to improve the public health. We are striving every day to make new discoveries and develop novel therapies that could help to protect or sustain people's lives. With that in mind, we believe our science makes the greater impact.

Paul Chaplin President & CEO

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## HOW WE WORK WITH CSR

Once a biotech company mostly focused on R&D, now a fully integrated vaccine manufacturer. The story of Bavarian Nordic goes back more than 20 years, and demonstrates the success of transforming science, innovation and technology into a sustainable business, focused on the development, manufacturing and commercialization of vaccines for the prevention of life-threatening infectious diseases and the treatment of cancer.

The real transformation though has taken place over just the last few years where we have built our manufacturing facility, capable of producing millions of vaccines that could potentially help protect and save people's lives, thus contributing to a healthier and safer society. That is a worthy mission.

And while pursuing our strategy and objectives to remain sustainable and grow our business further through continued investments in research and development, we recognize the importance of protecting the world around us. This commands us to work and act responsibly in all matters, and we aim to do this by:

- manufacturing high-guality vaccines.
- working actively and systematically
- to minimize our impact on the environment and climate.
- maintaining an active dialog with our stakeholders on a local, national and global level.
- actively supporting and respecting human rights and labor standards.
- providing a safe and healthy working environment for our staff that includes opportunities for professional and personal development.
- communicating our CSR policy to external collaboration partners, including our suppliers.
- conducting business according to highest ethical standards.

These are our guiding principles for working with CSR, upon which we have formulated our policies which are further specified in relevant areas throughout this report.

#### **Reporting framework**

Since the establishment of our production facility in Kvistgaard, Denmark in 2005, we have been subject to annual environmental reporting to the Danish authorities, and this has served as a framework for key areas of our sustainability reporting. In addition, we draw from the most pertinent elements of some of the most widely known CSR reporting frameworks globally, notably the Global Reporting Initiative (GRI) and the United Nations Global Compact (UNGC).

#### **CSR organization**

To ensure that our CSR initiatives are carried out timely and efficiently and to improve transparency on the activities, we have established a CSR steering committee comprised of senior representatives in the Company, in addition to a CSR working group comprised of representatives from human resources, investor relations & communications and our environmental, health and safety specialist.

### HOW WE WORK WITH CSR - continued

#### Scope of our reporting

In order to always focus on business relevance, we selected the areas to be reported based on a principle of materiality: we endeavored to include the most important ways in which our company has either a direct or an indirect impact on the world around us. Our manufacturing facility in Kvistgaard, Denmark, where also our headquarters are located, is one of the chief sources of our environmental impact, and we seek to provide a high degree of transparency by calculating our CO<sub>2</sub>-emissions and reporting additional environmental data from this site.

Furthermore it represents almost two thirds of our employees. In addition, we have included our research and development facilities in Germany and the USA, which represent the last third of employees and contribute to our global emissions by approximately 25%.



## ENVIRONMENT AND CLIMATE IMPACT

Our primary impact on the environment and climate is derived from our vaccine production in Kvistgaard, Denmark, and we endeavor to reduce our environmental and climate impact by improving our manufacturing efficiency and processes in order to optimize energy consumption and to minimize emissions and waste.

We wish to be at the forefront of environmental work and we seek to be so by maintaining a high degree of compliance and systematization in our organization, driven by our environment, health and safety specialist who proactively works to ensure that we comply with environmental protection regulations and relevant requirements as defined by the authorities. In general, we consider informal visits by the authority as a benefit for information sharing and joint risk perception as we may become aware of issues that we did not consider before. We furthermore encourage environmentally aware behavior throughout the Company as a whole.

#### Non-financial key figures, environment and climate

The presented key figures relate to our production facility in Kvistgaard, Denmark, which also comprises our headquarters with administrative functions and quality laboratories. However, we also present our global emissions, which include all other company-owned or controlled locations, except for single-person offices.

	Unit	Note	2016	2015	2014	2013	2012
(D)							
<b>CO</b> <sub>2</sub>							
CO₂ emissions, total	metric tons	1	2,695	3,103	3,543	3,345	3,662
- of which is related to production	metric tons	1	1,995	2,178	2,417	2,102	2,319
Energy							
Energy used in production	mWh	2	9,602	8,449	7,905	8,470	8,472
Water							
Waste water from production	m3	3	8,689	7,660	7,856	8,218	6,829
Waste							
Waste from production	metric tons	4	154	145	117	125	162
Recycling			43%	9%	11%	10%	7%

### **ENVIRONMENT AND CLIMATE IMPACT** – continued

#### 2016 developments

Production activities were further increased in 2016 as we reinitiated production of smallpox vaccines for the U.S. Government, but also continued production of vaccines for our increasing number of clinical trials as well as continued our preparations for commercial manufacturing of PROSTVAC. Overall, we increased our production output by 51% as measured by batches compared to 2015.

We have continued to optimize the consumption of raw materials and additives in the production, again reducing the relative consumption on several parameters, compared to 2015. We remain focused on avoiding any unnecessary use of chemicals and additives, thereby also seeking to minimize the amount of waste requiring special treatment.

Based on the energy screening performed in 2015, additional energy-saving initiatives were implemented in our production during the year. Notably, we have introduced more energy-efficient light sources, implemented natural ventilation in a boiler room and replaced traditional gas boilers with condensing boilers. These and additional initiatives have helped to contain our overall energy consumption despite increased activity.

During the year, we initiated construction of a new cold storage facility at the Kvistgaard site. The facility will be taken into operation in 2017.

There were two, non-material breaches of the environmental terms at the facility. One was a damaged filter from a deactivation tank. It was assessed to have no impact on the external environment. The authorities were informed and the procedure was changed in order to ensure a future lower burden on the filters. The second was a noise complaint related to a temporary breakdown of a refrigeration compressor.

#### **Results and targets**

#### **Emissions** (note 1)

Despite increased manufacturing activities, our total CO<sub>2</sub> emissions were 13% lower compared to 2015, and our relative climate impact from production dropped by impressive 39%, reaching the lowest level in both absolute and relative terms since we started our CSR reporting. These improvements result from a better utilization of the production facility, but also from our ability to make further optimizations of the manufacturing process. In 2017, we expect a similar activity level in production as in 2016 and thus do not foresee emission reductions.

The chart shows the relative  $CO_2$  emission from production per batch.





### **ENVIRONMENT AND CLIMATE IMPACT** – continued

#### **Energy** (note 2)

Energy consumption increased by 14%, but the relative consumption decreased by 25% compared to 2015. While the facility has seen several expansions over the years, resulting in a higher base consumption of electricity and heating, the variable energy consumption largely depends on the activity level in the production. Therefore we have abandoned our previous target, which was defined as a relative number based on the area of the facility (kWh per m2). We will maintain a high focus on energyefficient solutions in all new projects.

#### Water (note 3)

Given the increased manufacturing activities, reductions in the water consumption were not possible in 2016. However, the relative consumption was lowered by 25% compared to 2015 due to better production efficiency. While we will continue to monitor for inappropriate consumption and make corrective actions accordingly, it is our assessment that the current relative consumption likely cannot be further lowered.

#### Waste (note 4)

The amount of waste was slightly higher than compared to 2015, which is largely attributed to higher manufacturing activity. However, as we succeeded in implementing new procedures for separation and handling of waste, we increased the share of waste for recycling from 9% in 2015 to 43% in 2016. Importantly, the fraction of waste requiring special treatment was slightly reduced.

As the new waste handling procedures were only implemented during second quarter of 2016 and thus did not reach full effect, we expect to further increase the share of waste for recycling in 2017.



## BUILT ON SCIENCE, DRIVEN BY PEOPLE

Our employees are our most valuable asset and as an innovative, knowledgebased company, it is important for us to attract and retain highly qualified workers. For this reason, we want to offer our staff a good and inspiring working environment that also provides them with development opportunities.

Being a global organization, we support a diverse, accommodating and non-discriminatory working environment where, regardless of gender, age, ethnicity, physical impairment, religion or sexual orientation, we all aspire to the same objectives.

We strive to maintain a good work-life balance, and we focus on employee health, safety and job satisfaction. We systematically map both the physical and psychosocial working environment so that the necessary preventive steps can be taken, for the benefit of both individual employees and the Company as a whole. We do so in a close dialogue between management and employees through a number of established committees, including local works councils and a health and safety committee.

The overall objectives of our occupational health and safety policy are to enable ourselves to control our occupational health and safety risks and improve our occupational health and safety performance in order to eliminate or minimize risks to personnel and guests who could be exposed to hazards associated with our activities. To help achieve these objectives, we have laid down the following principles:

Risks that might lead to an occupational health injury or ill health have to be assessed in order to determine actions (risk mitigation) that can reduce the impact or the likelihood
Adverse incidents are evaluated in order to learn and to consider if changes of the working conditions or

the occupational health and safety policy are warranted

- Education and training support the members of the occupational health and safety organization
- The organization is prepared to respond to any emergency situations and prevent or mitigate associated adverse consequences

#### 2016 developments

Our workforce increased by 7% in 2016, primarily as result of increased activity at our Kvistgaard site where we – as planned – conducted workplace assessments among all employees. The assessments focused on both the physical and psychosocial working environment and provided important learnings to help mitigate risks through identification of potential issues related to the safety and well-being of our employees. Based on the output from the assessments, the local health and safety committee will develop and implement action plans during 2017.

A collective agreement was entered with laboratory workers at the Kvistgaard site, where technicians and production operators were already covered by collective agreements.

We conducted a global leadership training program. The vision of the program was to empower the organization through leadership development and create a common leadership foundation across the organization.

We maintained an equal distribution of men and women in managerial positions with 48% and 52% respectively. While we aim to maintain an equal gender distribution among the managers, they are selected on the basis of their qualifications and not on gender.

### BUILT ON SCIENCE, DRIVEN BY PEOPLE - continued

#### **Results and targets**

**Occupational accidents** (note 5) We recorded just one occupational accident in 2016, resulting in injuryrelated absence of only one day. This translates into an accident frequency rate of 1.3 accidents per million working hours compared to 8.2 in 2015, and thus we met our reduction target. The safety organization has continued its focus on reporting and handling of near-misses and observations, which we believe has contributed to the overall improvement in safety at our manufacturing site. These preventative efforts remain in focus and the safety organization has set specific targets for its analytical work and follow-up on reports and observations, which aims to eliminate or minimize risks across the site.

#### Absence (note 5)

The absence rate was 3.6% in 2016 (2015: 3.9%) and thus we met our

target to maintain the rate below 4%. At our Kvistgaard site we have previously implemented dialog-based absence management, which has proven successful, and we expect to roll out this and other management initiatives at our other sites during 2017, aiming to reduce illness-related absence.



• Bavarian Nordic • All companies Number of accidents per million working hours compared with DI (Confederation of Danish Industry) statistics for work-related accidents (all occupational groups).



Comparison with DI (Confederation of Danish Industry) statistics for sickness absence (all companies).



### **PRODUCT SAFETY**

Product safety is crucial in our business, and quality and responsibility are important elements of our corporate culture.

Vaccine development is a highly regulated area, in which a strong regulatory regime of inspections and approvals sets a high standard for all areas of our disciplines.

We work according to Good Manufacturing Practice (GMP), which are rules laid down by the European and U.S. health authorities. GMP includes strict requirements with respect to a product's traceability, quality and purity, which means that quality management is built into each step of the manufacturing process.

To-date, we have produced and delivered more than 30 million vaccine doses. Even though largely all these vaccines have been stockpiled for emergency use only, we and our partners have conducted various clinical trials of our product candidates in more than 10,000 people, demonstrating that our vaccine platform technology has a favorable safety profile.

## **SUPPLIERS**

In accordance with both GMP and our own supplier management system, we perform a risk assessment of all new suppliers of critical materials and equipment used in our production and laboratories.

Suppliers whose products are considered to have a material impact on our products' quality and safety, will undergo an initial audit, followed by an evaluation every third year as a minimum, either by way of a visit or a questionnaire, depending on the situation. The structured audit process helps us to gauge the quality and CSR mindset of our suppliers. Through this close collaboration with our key suppliers, we are gaining a deep insight into their business processes and capabilities, which provides important learnings for optimizing our own processes.

Our suppliers of raw materials are mainly located in North America and the EU, which are areas with a high level of regulation of social and environmental parameters in place.

## **BUSINESS ETHICS**

#### Bavarian Nordic prioritizes business ethics as a natural part of its underlying business concept.

We want to be seen as credible and reliable by all our stakeholders, and we are committed to work actively against corruption in all its forms.

Our Code of Business Conduct and Ethics ("the Code") describes the ethical requirements for all employees' and the Board of Directors' behavior in relation to customers, employees, shareholders, society, suppliers and partners. The Code includes the rules and regulations in the Foreign Corrupt Practices Act (FCPA) and the Truth in Negotiations Act (TINA) that are relevant in connection with the Company's business transactions and negotiations in the United States, but equally relevant in other markets, where the Company operates.

All employees receive yearly training in the Code, and new employees will receive training as part of their introductory program. Thus the observation of the Code rests upon all employees and all employees are encouraged to report issues, concerns and any breach of the Code. For this purpose, the Company has established a whistleblower system, which provides our employees with an opportunity file reports in a secure and confidential manner.

### HUMAN RIGHTS

We support and respect human rights. Our compliance in this area is widely covered by our health and safety policies as well as observance of the national labor laws in the countries in which we operate.

While the scope of these efforts is mainly directed towards our own employees, we seek to conduct our business with third parties in compliance with the principles as well. In 2015, we performed a screening to assess how our business may impact human rights, and it indicated no actual adverse impacts. We will continue to monitor for potential adverse impacts, in order to determine if additional actions are required. As part of our procurement policies, we perform regular audits of our suppliers, whom we encourage to act responsibly in all matters relating to CSR, including observing international human rights. Also, we conduct our clinical trials in a manner that recognizes the importance of protecting the safety of and respecting the research participants. We do this by applying the highest legal, ethical and scientific standards, in addition to complying with applicable laws and regulations.

## **INDEPENDENT AUDITOR'S ASSURANCE REPORT**

#### To the Board of Directors of Bavarian Nordic A/S

We have assessed Bavarian Nordic A/S' 2016 CSR report ("the Report") to provide limited assurance that the data provided in notes 1-5 have been prepared in accordance with the reporting practice described. The Report covers Bavarian Nordic's international activities from January 1 to December 31, 2016.

We express a conclusion providing limited assurance.

#### **Management's responsibility**

The Management of Bavarian Nordic is responsible for collecting, analyzing, aggregating and presenting the information in the report, ensuring that the report is free from material misstatement, whether due to fraud or error. Bavarian Nordic's reporting practice contains Management's defined reporting scope for each data type.

#### Auditor's responsibility

Our responsibility is to express a limited assurance conclusion based on our engagement with Management and in accordance with the agreed scope of work.

We have conducted our work in accordance with ISAE 3000, Assurance Engagements Other than Audits or Reviews of Historical Financial Information, and additional requirements under Danish audit regulation to obtain limited assurance as to whether data in notes 1-5 are free from material misstatement. Deloitte Statsautoriseret Revisionspartnerselskab is subject to International Standard on Quality Control (ISQC) 1 and, accordingly, applies a comprehensive quality control system, including documented policies and procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.

We have complied with the independence and other ethical requirements of the Code of Ethics for Professional Accountants issued by FSR – Danish Auditors (Code of Ethics for Professional Accountants), which are based on the fundamental principles of integrity, objectivity, professional competence and due care, confidentiality and professional behavior.

A limited assurance engagement is substantially lighter in scope than a reasonable assurance engagement in relation to both of the risk assessment procedures, including an understanding of internal control, and the procedures performed in response to the assessed risks. 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.

Considering the risk of material misstatement, we planned and

### **INDEPENDENT AUDITOR'S ASSURANCE REPORT** – continued

performed our work to obtain all information and explanations necessary to support our conclusion. We performed our on-site reviews at Bavarian Nordic's head office in Kvistgaard, Denmark in February 2017. Our work included interviews with key functions at Bavarian Nordic, inquiries about procedures and methods to ensure that data and information have been presented in accordance with the reporting practice. We have assessed the processes, tools, systems and controls for gathering, consolidating and aggregating data, performed analytical review procedures and tested data prepared for consistency with underlying documentation.

#### Conclusion

Based on our work, nothing has come to our attention that causes us to believe that the data in notes 1-5 to the CSR report for 2016 are not prepared in accordance with the reporting practice described.

Copenhagen, March 15, 2017

#### Deloitte

Statsautoriseret Revisionspartnerselskab Business Registration No. 33 96 35 56

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### NOTES TO STATEMENTS ON ENVIRONMENTAL AND SOCIAL PERFORMANCE

#### Note 1 **CO<sub>2</sub> emissions** (all sites<sup>\*</sup>)

CO <sub>2</sub> emissions		2016		2015
	Production	Total	Production	Total
Direct emissions (Scope 1)	tCO <sub>2</sub>	tCO <sub>2</sub>	tCO <sub>2</sub>	tCO <sub>2</sub>
Heating	1,006	1,024	799	935
Electricity generation	10	10	-	-
Fugitive emissions	30	30	18	19
Transport in company–owned cars	46	70	48	65
Internal transportation of goods	-	-	1	1
Indirect emissions (Scope 2)				
Electricity, purchased	903	1,418	1,313	1,983
Heating, purchased	-	142	-	101
Cooling, purchased	-	-	_	-
Emissions, total	1,995	2,695	2,178	3,103

\* The emission calculations presented in this report include all company-owned or controlled entities which employ more than one person.

#### **Reporting practice**

Calculations of CO<sub>2</sub>-emissions are based on the Corporate Standard of the Greenhouse Gas Protocol Initiative<sup>1</sup> and include the greenhouse gasses addressed by the UNFCCC<sup>2</sup>/Kyoto Protocol (CO<sub>2</sub>, CH4, N2O, HFCs, PFCs, SF6 and NF3) calculated in metric tons of CO<sub>2</sub> equivalents.

Our reporting covers scope 1 (emissions from sources that are owned or controlled by the Company) and scope 2 (emissions from purchased electricity), thus adhering to the Corporate Standard.

#### Emission factors

In calculating CO<sub>2</sub> emissions, specific emission factors based on emissions type and geographic location were used. CO<sub>2</sub> emissions from the combustion of natural gas, oil, gasoline, diesel fuel and liquefied pressurized gas and from fugitive emissions were deemed to have a general global effect with minor local differences. Emission factors from these sources are based on data provided by the Danish Energy Agency. However, natural gas emission factors for California are based on figures from The Pacific Gas and Electric Company.

Emissions for locally purchased electricity were determined on the basis of local conditions. Emission factors for Kvistgaard are based on factors for Denmark as a whole. Emission calculations for electrical power in California are based on emission factors provided by The Pacific Gas and Electric Company. Emission calculations for electrical power purchased in Germany are based on historical German emission factors; emission calculations for district heating purchased in Germany are based on emission factors collected from local district heating companies.

<sup>1</sup> www.ghgprotocol.org <sup>2</sup> United Nations Framework Convention on Climate Change

#### Note 2 Energy (Kvistgaard site)

Energy	2016	2015
	mWh	mWh
Energy, total	9,602	8,449

#### **Reporting practice**

Energy consumption is calculated for the entire Kvistgaard facility, including laboratories and administrative functions. The figure includes purchased electricity and consumption of natural gas which is used for heating.

#### Note 3 Water (Kvistgaard site)

Water consumption	2016	2015
	m3	m3
Sanitary water	3,790	3,637
Process water	8,689	7,660
Total water consumption	12,479	11,298
Wastewater fractions	kg	kg
Phosphorus (kg)	80	13
Nitrogen (kg)	634	127
Total organic carbon (kg)	1,014	613
Chlorides (kg)	7,212	8,970

Process wastewater is heat-inactivated, cooled and pH adjusted before being discharged into the public sewer system. Inactivation is a procedure that ensures that all virus remnants are rendered 100% harmless, and the system is checked for operational problems before discharge. This treatment ensures that the discharged wastewater complies with the requirements in the Company's permit to use the municipal sewer system.

#### **Reporting practice**

Water consumption is measured for the entire Kvistgaard facility, including laboratories and administrative functions.

The fractions of phosphorous, nitrogen, carbon and chlorides in the waste water are based on a single analysis which is conducted once a year.

#### Note 4 Waste (Kvistgaard site)

Waste	2016	2015
	metric tons	metric tons
Total waste	154	145
– of which hazardous waste	16	16
Breakdown of waste disposed of:		
Incineration	46%	79%
Recycling	43%	9%
Special treatment	10%	11%

Waste consists primarily of disposable process equipment (production bags, tubing and other disposable equipment) and egg waste.

Paper, egg waste, metal, electronics and pallets are being recycled.

Hazardous waste includes organic solvents, acids, bases, hazardous clinical waste, etc.

#### **Reporting practice**

Waste volumes are calculated for the entire Kvistgaard facility and are based on annual statements from approved waste carriers handling ordinary and hazardous waste.

#### Note 5 Employees (All sites)

	2016	2015
Employees, total at year-end	457	426
Employees, average full-time employees over the year	429	420
Distribution:		
Denmark	278	260
Germany	123	113
Other countries	28	47
Absence	3.6%	3.9%
Employee turnover	15.0%	19.5%
Employee groups		
Ratio of men to women in management and executive positions	48% / 52%	51% / 49%
Employees under collective agreement	102	65
Other employees (white-collar workers with or without management responsibility)	355	361
Occupational accidents		
Accident frequency (number/million working hours)	1.3	8.2
Accidents in numbers	1	6
Average absence per accident in days	1	2.7

#### **Reporting practice**

Unless otherwise stated, the presented figures cover all Bavarian Nordic sites and employees.

#### Absence

Absence data includes recorded staff sick days and child sick days for employees in Denmark and Germany only. Leave – also parental leave – is not included in these figures. The absence rate calculation is based on the average number of full-time employees for the year and the number of effective work days in the calendar year, i.e. vacation days are excluded.

#### Employee turnover rate

The turnover rate expresses the ratio of employees who have left the company during a year. Employees with fixed-term contracts are not included. The calculation is based on the average number of employees over the year.

#### Occupational accidents

Occupational accident data relates to accidents resulting in at least one day of absence, in addition to the day of injury. The accident rate is the number of occupational accidents per one million effective working hours.

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#### www.bavarian-nordic.com

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