

Zealand Pharma Corporate Social Responsibility Report 2018

Company reg. no. 20045078

Anders Stensbjerg Kristensen lives with type 1 diabetes

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About this Report

We believe in operating as a responsible company that serves broader economic, societal, and environmental interests. In addition to contributing to the sustainability of the world in which we live and work. acting responsibly will further our ability to develop meaningful and similarly sustainable relationships with customers, suppliers, investors, and key stakeholders including current and future employees. This statutory report on corporate social responsibility is for the financial year 2018, cf. section 99a and 99b of the Danish Financial Statements Act. This report is a supplement to the Management's review in the Annual Report 2018 covering the period January 1 – December 31, 2018.

We are passionate about changing the lives of people living with severe medical conditions through targeted development of next generation peptide therapeutics. To achieve this ambition, our organization is rapidly maturing towards a fully integrated biotech company with commercial operations in the U.S.

We have four late stage programs with the potential to launch into major markets in the next two to four years. Phase 3 is ongoing for **glepaglutide**, a long-acting GLP-2 analog for treatment of short bowel syndrome. Three late stage programs are based on **dasiglucagon**, a stable glucagon analog: positive Phase 3 results for treatment of severe hypoglycemia in diabetes with anticipated new drug application (NDA) submission within the coming year; Phase 3 ongoing for treatment of the rare pediatric condition, congenital hyperinsulinism; and a Phase 2b study planned for use in dual-hormone fully automated pump therapy for management of type 1 diabetes.

Our early development pipeline consists of two clinical programs partnered with Boehringer Ingelheim, and a GLP-1/GLP-2 agonist for treatment of short bowel syndrome that is approaching Phase 1. We continue to leverage our established discovery peptide platform, which has already led to two approved medicines and provides multiple opportunities for nearterm pipeline expansion.



Danish Biotech

Founded in Copenhagen (HQ) in 1998, opened U.S. subsidiary 2018

Four Late Stage

Programs

Accelerating late stage

programs to launch new

products into major markets

in 2 to 4 years



Leading Peptide Platform

A world leading peptide platform, with two medicines on the market



Expanding Capabilities

Transforming into a fully integrated biopharma company with U.S. commercial organization



Experienced Team

153 employees of which 87% are in R&D



Dual Nasdaq Listing

Traded in Copenhagen and New York

Find out more about Zealand on **zealandpharma.com/about-us**

Zealand in brief.

Changing lives with next generation peptide therapeutics.

Our Ambition and Business Model.

Our ambition is to provide next generation peptide therapeutics that change the lives of people affected by specialty gastrointestinal and metabolic diseases. To deliver bestin-class treatment options that meet patient medical needs and ease burden on the health care system, we utilize a business model with two approaches. First, within rare diseases, we aim to retain full ownership and control of product candidates all the way to market in selected geographies by transforming into a fully integrated R&D organization with commercial operations in the U.S. Our agile organization engages with partners across the value chain, such as leading CROs and CMOs. Second, within diabetes and other broad indications, we progress clinical development ourselves to the point at which it makes business sense to engage in partnerships that expand the opportunity and probability of success by providing additional resources and investment.



Optimizing value through internal drug development and partnerships

Changing Lives

We work every day with patient communities and thought leaders to change the lives of people with severe medical conditions.

Transforming Peptides

We leverage our 20 years of experience discovering and developing peptide drugs to transform peptide projects into next generation therapeutics.

Engaging Partnerships

We engage with development and commercial partners to enhance innovation and expand opportunities across markets and therapeutics areas.

Approaching Commercialization

We are building a fully integrated commercial organization with U.S. operations to market our own therapies for rare diseases.



Focus on Corporate Social Responsibility.

At Zealand, we work to improve care for patients and deliver value for our shareholders.

Zealand aims to change the lives of people affected by severe medical conditions, as well as contributing to the good health and well-being of our employees. All activities in connection with our business aim to protect human rights and to ensure that we avoid being complicit in human rights abuses.

We adhere to requirements of the Danish Financial Statements Act, and comply with relevant laws, standards and guidelines for reporting on corporate social responsibility activities. We respectfully adhere to the UN Guiding Principles on Business and Human Rights, and we are implementing considerations for six selected UN Sustainable Development Goals in 2019.

Our commitment to respecting human rights is represented in several of our policies, with

related achievements and actions described in this report:

- We enable employee competency development, health and well-being;
- We ensure occupational safety and health in the workplace;
- In our partnerships with vendors, we focus on business ethics inclusive of human rights and reputation:
- For patients, we collaborate with advocacy groups to consolidate relations and obtain better treatment options:
- We ensure a high standard of data protection, taking actions aligned with the EU General Data Protection Regulation (GDPR).

At Zealand, our particular emphasis is on the areas that are most relevant to our business and operations:

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Working environment and employee well-being



Diversity



Quality in relation to research, development, and supply chain activities



Business ethics



Find out more about Zealand on zealandpharma.com/csr

Patient-centric approach











Commitment to Sustainable Development Goals.

Zealand is making a commitment to Sustainable Development Goals established by the United Nations. This introduces yet another perspective to making effective and sustainable business decisions, and will connect Zealand's efforts with those of other companies to address global challenges. We will focus on six selected sustainable business goals that are relevant to our business. Additional goals may be considered as our company continues to grow and evolve.

16 Peace, justice and strong institutions We operate according to the highest ethical standards and safeguards against corruption and noncompliance. Trust by every member within the health care ecosystem is critical to Zealand's success, and we believe it can be earned and encouraged by operating with sound business ethics.

12 Responsible consumption and production

To present day, our focus on responsible consumption and production has ensured our daily internal operations run efficiently and with minimal waste. Looking to the future, we are building a supply chain organization to facilitate delivery of our products to the market. Commitment to responsible consumption and production will guide our decisions and ongoing activities relating to supply chain partners, production and transportation bi-products, and value chain optimization. **17** Partnerships for the goals We engage in partnerships around the world to provide access to novel medicines.

SUSTAINABLE

DEVELOPMENT

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Good health and well-being

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Good health and well-being are at the core of Zealand's business. We are passionate about changing the lives of people affected by severe medical conditions. We deliver next generation peptide therapeutics to target diseases with significant health care burden, or where treatment options are insufficient. We collaborate with advocacy groups and patient organizations to improve standards of care and create better lives for patients.

> Employees are Zealand's most valuable asset. We work to ensure employee well-being, to provide a safe working environment, and to help employees develop competencies.

05 Gender equality We aim to achieve equal representation of both genders at all management levels, and encourage female candidates to take on managerial tasks.

10 Reduced inequalities We foster a diverse workforce to increase our ability to work cross-culturally and to understand better the communities in which we operate. Our policies comply with Danish regulations on equal opportunity employment.

Employees.

At Zealand, employees are our most important resource, and we believe that an engaged, skilled, and motivated workforce results in better quality work.

www

Find out more about Zealand on **zealandpharma.com/careers**

Engagement

Highly qualified and motivated employees are a prerequisite for achieving the ambitious Zealand business goals. Zealand's annual employee engagement survey helps leaders and employees to continuously improve the working environment. Results from the 2018 survey show that Zealand employees are both dedicated and motivated.

Competency development

Ensuring every employee has opportunity to improve upon their existing strengths while developing skills is critical to attracting and retaining qualified and engaged employees. An analysis of all competency development plans made in 2018 showed that the quantity and quality of competency development plans has increased compared to previous years. A number of initiatives will be implemented in 2019, including training about the pharmaceutical development value chain, and more systematic on-the-job training developed by and for lab technicians.

Health and well-being

We work to ensure our employees' well-being and have a number of policies in place to promote physical and psychosocial health.

Zealand has taken Danish Labor Law as a starting point for related policies and, in some cases, has gone beyond what is required of public companies in order to be more considerate of and responsive to the needs of our workforce. These policies are described in our employee handbook.

We make it easier for our employees to stay healthy by providing gym and exercise facilities as well as

Zealand's engagement survey focuses on four themes:



Meaning – Do I spend my time on meaningful tasks? Mastery – Does my job give me the opportunity to use and develop my skills?

Good relationships – Am I taken serious as a person? **Autonomy** – Do I have a significant influence on my work?

Engagement in 2018: All questions received a positive average score. A secondary indicator is the number of questions that received a favorable response from the vast majority (>66%) of employees, and where only a very small minority (<10%) gave an unfavorable response. Of the 31 questions comprising Zealand's 2018 engagement survey, 30 received favorable response from the majority of employees.

healthy food options. In addition, our employees are covered by health insurance.



Safe work environment

Zealand works systematically to maintain a safe and healthy work environment. Numerous procedures are in place, including a manual describing our policies on occupational safety and health (OSHA). All Zealand employees are trained in the standard safety protocol, whereby they are given the tools to manage their own occupational safety.

We have a number of committees, including a Works Council and an Occupational Safety and Health Committee (OSHA Committee), on which both management and employees are represented and regularly discuss matters related to our work environment. Employees are also represented with two seats on Zealand's Board of Directors.

Labor unions currently representing our employees include HK it, medie & Industri Hovedstaden. Zealand negotiates a collective agreement in good faith every three years. The next negotiation is scheduled for 2020.

Risk and mitigation

Zealand is not a high-risk company regarding safety, yet we do work systematically to maintain a safe and healthy work environment. Our highly educated and skilled workforce poses low risk of labor violations.

Workplace audits (*Arbejdspladsvurderinger*, APV) are conducted regularly. Risk assessments are reviewed quarterly, and Zealand's OSHA Committee conducts surveys on a regular basis. A near-accident reporting initiative is maintained to build on Zealand's strong safety track record and safeguard against potential future accidents.

	Achievements in 2018	Focus areas in 2019
Engage- ment	 Annual engagement survey to help leaders and employees continuously improve the working environment. The response rate was 85% (127 respondents; 2017: 93% or 120 respondents). 97% of responses were favorable (2017: 89% favorable). 	 Maintain employee engagement as reflected in the annual engagement survey scores.
Personal and Organ- izational Competen- cy Develop- ment	 Activities conducted to continue focus on the Zealand DNA, which was introduced in 2017 as a set of common values uniting all employees in their daily work. All management levels have received leadership training. 	 Leadership training will continue. We will focus on competency development and improve employability with the following objectives: Zealand's ability to execute the business strategy Employees' opportunity to get motivating tasks Enhance employees' employability Workshops based on the trends from the com- petency development plans will be conducted with the objectives to strengthen skills and improve the ability to work effectively across organizational borders.
Employee health and well-being	 Workshops to avoid stress among employees were conducted. The absence rate was 2.8% (2017: 2.0%). Employee turnover was 6% (2017: 9%). 	 We aim for an absence rate at the same level, or lower, as in previous years. Zealand will continue to work on maintaining a healthy and motivating working environment.
Safety	 Seven near accidents were reported under our near accident reporting initiative (2017: 2). No "obligated to notify" accidents were reported. Zealand had no significant injuries in 2018 (2017: 0), as measured by days off due to work-related injury. 	• We aim for a high rate of reporting.

2 Employee turnover percentage is calculated by the number of employees, who voluntarily left the company during a year, divided by the average number of employees over the year.

Diversity.

A diverse workforce enhances innovation, and increases our ability to work crossculturally. Diversity provides better understanding of the communities in which we operate, so that we can create value for patients and our stakeholders. We aspire to attract, develop and retain the best people and to be a company where employees thrive, regardless of their background. Zealand's culture and policies are rooted in respect for diversity and, as such, are fully compliant with Danish regulations on equal opportunity employment.

Zealand aims to achieve equal representation of both genders at all management levels – from the Board of Directors to the heads of departments. We want to encourage female candidates to take on managerial tasks.

The table below shows that Zealand has an even distribution of female and male managers and slightly more women than men across the organization in general. The corporate management team was made up of 17% female at the end of 2018 (2017: 25%), and people managers were made up of 46% female at the end of 2018 (2017: 46%). The overall management level is made up of 41% females (2017: 43%) and is regarded to be an even gender distribution.

The average age of Zealand employees was 46.3 at the end of 2018 (2017: 46.8). At the end of 2018, 16% of our employees had another nationality than Danish (2017: 15%) and in corporate management the number of non-Danish nationalities was 50% (2016: 50%). Out of the total workforce, 87% of our employees work in R&D (2017: 82%).



Diversity in the Board of Directors

In 2013, the Board of Directors set a target to have a minimum of 25% female board members elected by the shareholders within the following three years. The target was met in 2015. As of December 31, 2018, the Board of Directors consisted of four women and four men, of whom three women and three men were elected at the Annual General Meeting in 2018, giving a female representation of 50% (2017: 40%).

Other employees figures

	2018	2017
A () (46.7	16.0
Average age of workforce	46.3	46.8
% of non-Danish employees	16%	15%
Ph.D. students	3	2
Other students	0	1

Job training for Syrian refugees

Since 2017, Zealand Pharma has provided internships to Syrian refugees in Denmark. During the three-month internship period, we foster their learning of the Danish language, build practical work skills, and generally encourage their integration into the local community and culture. Our objective is to enable each refugee intern to gain employment in Denmark.



Quality.

Zealand's quality policy describes compliance with rigorous internationally recognized standards and guidelines at all stages of research and development, to ensure that we do not place patients at risk due to inadequate safety, quality or efficacy. Zealand outsources GxP activities to qualified and approved vendors, where the sponsor responsibilities remain at Zealand. Oversight of the activities ensures vendor compliance with the requirements of pharmaceutical quality standards as articulated in Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), Good Clinical Practice (GCP), Good Pharmacovigilance Practice (GVP), and others.

We work in close partnerships with vendors, and when evaluating these partners we focus both on business ethics, i.e. human rights and reputation, as well as capability and capacity of the service. Elements in the assessment include quality audits, supplier management assessment, and financial stability. Zealand's Pharmaceutical Quality System for development activities is described in our Quality Manual, which also defines our Quality Policy. Ongoing evaluation of our quality system is performed continuously.

Risk and mitigation

Our reliance on external partners to perform GxP activities poses risk that partners do not follow requirements of pharmaceutical quality standards. Such noncompliance would in turn jeopardize patient safety, quality and efficacy of our medicines. Our vendor oversight program is intended to mitigate this risk through thorough and ongoing assessment of all GxP vendors.

	Achievements in 2018	Focus areas in 2019
Quality assurance and vendor management	 Zealand launched an NDA-readiness program to ensure that required processes for commercial operations are in place before a §39 inspection. 	 Zealand will initiate the launch readiness pro- gram to ensure delivery to the market once regulatory approval is obtained.
indiagenetic	 Zealand strengthened our quality team and final- ized a new strong quality policy. 	 Zealand will apply for a manufacturing authoriza- tion §39 at the Danish Medicines Agency.
	 Zealand has an outsourced business model for GxP work and matured the vendor oversight pro- gram to cover all GxP vendors. 	 Zealand will continue to mature and continuous- ly improve the Quality System required for late stage and commercial operations.
	 As an integrated part of the Vendor Oversight Program, Zealand successfully conducted 21 external audits. 	 Zealand will continue oversight of outsourced activities based on our quality risk management principles.

3 139 inspection is conducted by the Danish Medicines Agency (DMA) in order to obtain a manufacturing authorization

Patients.

We work to create better lives for patients through collaborations with advocacy groups and patient organizations. We demonstrate our commitment to patients and caregivers by consolidating relations and obtaining better treatment options.

	Advocacy groups and patient organizations	Type of collaboration
Short bowel syndrome	The Oley Foundation, U.S.	Patient insights and support of educational initiatives in short bowel syndrome. part of the Oley Corporate Partnership Program
	Short Bowel Syndrome Foundation, U.S.	Patient insight and support to short bowel syndrome educational initiatives
	Association for Crohn's and Colitis, Denmark	Membership
	Association for Users of Home Parenteral Nutrition, Denmark	Educational grant to support initiatives for home parenteral nutrition consumers
Diabetes	Juvenile Diabetes Research Foundation	Patient insights and general diabetes collaboration
	DiaTribe, U.S.	Collaboration and patient journey insight
	T1D Exchange, U.S.	Patient insights on diabetes management, education al and scientific publications
	American Diabetes Association, U.S.	Collaboration and support of furthering the cause to drive awareness of diabetes and its complications
Rare Diseases	NORD – National Organization of Rare Diseases, U.S.	Corporate Council Membership, rare disease advo- cacy
	CHI – Congenital Hyperinsulism International	Patient insights, collaboration on global patient registry and global development program, generally supporting the CHI community

Risk and mitigation

The safety and efficacy of our therapeutics is the foremost concern regarding patients. Such risk is addressed throughout the development process and within the rules and guidance provided by regulatory entities.

	Achievements in 2018	Focus areas in 2019
Patients focus	 Zealand increased the collaboration with patient organizations and advocacy groups to better understand patients' needs, align our development programs, and support disease education initiatives. 	 Patient-centric development includes patient ad- vocacy as a partner in the clinical development, in dialogue with regulatory bodies as well as in disease educational initiatives. In short bowel syndrome, Zealand will expand patient education initiatives.
		 In rare disease, major development milestones will be met in collaboration with CHI patient advocacy.

Marianne lives with short bowel syndrome. Read her story at zealandpharma.com/mariannes-story



Environment.

Zealand's environmental policy outlines our commitment to minimizing our impact on the environment and climate through responsible consumption and production. By conducting business in a safe and environmentally friendly manner, we aim to reduce our impact on the environment and climate as far as possible. However, as we do not have any manufacturing, we consider our impact on the environment and climate to be very limited.

We encourage employees to be mindful about the environment and climate, and to produce as little waste as possible. We include a "please consider the environment before printing" message in our standard e-mail signature; when printing is necessary, we have implemented double-sided, black and white printing as our office standard to reduce print output.

We have procedures for recycling paper and cardboard, as well as for efficient use of electricity and heating. Zealand contributes to energy savings by selecting energy-efficient office and laboratory equipment wherever possible.

Our travel guidelines limit unnecessary air travel by employees and encourage the use of our video- and teleconference facilities and as alternatives to business travel.

Risk and mitigation

Handling of materials and waste from our laboratories poses risk of spills. Thorough employee training as well as proper outsourced removal mitigates this risk.

	Achievements in 2018	Focus areas in 2019
Environmental sustainability and climate	• Zealand continued to encourage employees to take environmental and climate friendly initia-tives.	 We consider our environmental impact as very limited, and have not included any indicators for this area at present.
	• We initiated an agreement to recycle aluminum capsules from our office coffee machines.	 Zealand will continue to minimize the environ- mental impact and encourage employees to continue with environmental and climate friendly initiatives.

Ethics.

We strive to operate according to the highest ethical standards, and safeguard our business against corruption and noncompliance.

Business Ethics

Zealand's reputation as a trusted business and scientific partner are of the utmost importance. Therefore, our employees are trained and kept updated with policies on good business practice and compliance, insider trading, and appropriate legal management of third party intellectual property.

We strive to operate according to the highest ethical standards, and safeguard our business against corruption and noncompliance where employees are most at risk. Zealand will practively engage in a positive dialogue with all regulatory and advisory authorities and with stakeholders from relevant industries in order to be inspired to make further imporvements.

As part of its program of maintaining a robust ethical working environment, Zealand maintains a whistleblower program that is monitored by an external law firm to ensure that issues that need to be examined by senior management and members of the Board of Directors are brought to their attention when appropriate.

We actively promote and maintain a policy of transparency and honesty with our employees. Zealand's Employee Handbook stipulates a set of policies that specify the company's standards regarding its employees' general and legal conduct. Zealand has taken every precaution to keep all employees, board members and certain stakeholders up to date and compliant with our internal rules. We distinguish carefully between those who are listed on its permanent insiders' list and those who are exposed to what is deemed insider information. In the latter case, Zealand takes every precaution to keep an up-to-date list of employees' knowledge of insider information. All new employees are introduced to our internal rules and have to sign a document stipulating that they have read and understood these rules.

We have strict policies regarding the proper use and transfer of intellectual property. Since it was founded, Zealand has refined its confidentiality and material transfer agreements to reflect critical changes in the industry, building on the extensive industry experience of many of its senior members.

Risk and mitigation

The main risks related to our activities include employees' and business partners' violation of our anti-corruption commitment and potential legal and financial consequences thereof. Zealand's whistleblower program and insider information list are two methods for mitigating such risk. We are developing programs to support ongoing maintenance of code of business conduct understanding among employees, as well as a more robust program to ensure data privacy and protection.

	Achievements in 2018	Focus areas in 2019
Business ethics	 All new employees have been introduced to Zealand's internal rules as part of the introduction program. No issues were reported under our whistle blower program. Zealand concluded an investigation of current processes in relation to the new EU General Data Protection Regulation (GDPR). As part of the implementation of the GDPR Regulation, an assessment of more than 250 IT systems has been performed, and relevant policies and procedures have been updated. 	 Zealand will continue to have focus on Privacy regulation and the GDPR. Zealand will continue to operate according to the highest ethical standards. Our code of business conduct is part of the introduction program for all new employees. All employees will be periodically reminded of its scope, and document that they are aware of it.

Animal Welfare

To allow for the discovery of new therapies and to ensure the efficacy and safety of new pharmaceuticals as required by regulatory authorities, it is necessary to conduct *in vivo* experiments using laboratory animal species.

Zealand's policy on animal ethics and welfare is to use animal studies only where no available and acceptable *in vitro* alternative exists. All laboratory animals used under our responsibility must be treated humanely and with respect, and only purpose-bred animals are used. Zealand adheres to the principles of the 3Rs (reduce, refine, replace) and works to integrate these principles in all studies carried out, wherever possible.

All in-house animal studies are carried out in accordance with specific licenses issued by the Ministry of Environment and Food of Denmark and international guidelines, as appropriate. Danish law stipulates regular inspections of the animal facilities as well as comprehensive reporting protocols overseeing experiments conducted during the year, processed through The Animal Experiments Inspectorate. The continuous dialogue between lab technicians, veterinarians, academic staff and heads of department, ultimately ensures the highest animal welfare standards in all studies conducted.

All employees working with laboratory animals have appropriate and documented education and training. Veterinary checks of our animals are performed regularly and always when needed.

In addition, Zealand's internal ethical committee scrutinizes all proposed in-house *in vivo* pharmacology, toxicology and PK experiments for compliance with regulatory permissions and highest ethical standards.

The necessity of animal experiments to Zealand's research and development activities cannot be overstated, and thus we constantly strive for the greatest vigilance and care in our treatment of animals.

	Achievements in 2018	Focus areas in 2019
Animal welfare	No incidents of negligence were reported.	 Zealand will continue to focus on animal welfare and comply with the principles of the 3Rs.

