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## Forward-looking statement

This report contains certain projections and other forward-looking statements with respect to the financial condition, results of operations, businesses and prospects of New Xellia Group A/S ("Xellia"). These statements are based on current expectations and involve risk and uncertainty because they relate to events and depend upon circumstances that may or may not occur in the future.

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## Xellia at a Glance



Specialty pharmaceutical company focused on providing important anti-infective treatments against serious and often life-threatening infections.



Over **1.600** in 8 countries



Over **100** years' experience in the development, manufacture and supply of fermented and semi-synthetic APIs and FDFs



Supply our anti-infective products to more than 500 pharmaceutical companies in over **70** countries



Leading supplier of important anti-infectives Vancomycin and Colistimethate Sodium (CMS)



First launched several of our own-label products to the US hospital market in 2018



Our R&D team is providing innovative solutions to develop value-added anti-invectives from core portfolio products

New North American Headquarters and commercial office.

Chicago, USA

Acquired in 2015, the site will significantly strengthen Xellia's manufacturing capacity for sterile injectable products.

Cleveland, USA

State-of-the-art R&D Center of Excellence focused on API research and development as well as process optimization.

Oslo, Norway

Xellia's Corporate Headquarters.

Our biggest operation manufactures sterile APIs and FDFs. Provides lyophilized and dry powder fill vials, release and stability testing and packaging.

Copenhagen, Denmark

Manufactures several specialized APIs and provides Centralized Laboratory Services

Budapest, Hungary

for the group.

Product and Innovation R&D Center of Excellence focused on innovative formulation technologies and FDFs.

Zagreb, Croatia

Commercial organization handling the challenging Japanese market.

Tokyo, Japan

Divested to Sagent Pharmaceuticals in Q1 2019, and transitioning to new owner.

Raleigh, USA

Manufacturing Sites

Sales Offices

Other offices/R&D centres

CMO and commercial group established to manage growing network of CMOs and to capitalize on emerging market opportunities.

Bangalore, India

Established in 2008 as a partnership with Zhejiang Hisun Pharmaceutical Company, Ltd. Manufactures APIs.

Taizhou, P.R. China

Commercial organization supporting the work with partners in the Chinese market.

Shanghai, P.R. China

Xellia 2018

## **CEO's** Statement



2018 proved to be a transformative year for Xellia. We successfully established a new North American commercial organization and commenced sale of our anti-infective drug products under the Xellia brand directly to the United States (US) hospital market. At the start of 2019 we received US Food and Drug Administration (FDA) approval of our novel Premixed Vancomycin Injection in a Ready-to-Use (RTU) bag, the first product from our pipeline of innovative, value-added anti-infective therapies.



Carl-Åke Carlsson, Chief Executive Officer, Xellia Pharmaceuticals.



## Built a commercial pharmaceutical institutional business in the US

In April, we appointed Craig Boyd to the new leadership role of President, Xellia North America. Craig has been pivotal in helping us build an experienced commercial team of over 40 new employees focused on spearheading the launch and selling the Company's own branded high quality, specialty injectable anti-infective drugs to the US institutional markets. This commercial organization is now housed in our newly established North American headquarters in Chicago.

In November, we achieved an important milestone for our US market strategy as we successfully launched our first lyophilized vial product, Vancomycin Hydrochloride for Injection USP, under the Xellia label, within the US hospital market. During 2019 we will continue to launch a range of Xellia-branded important anti-infective injectable products.

Submission and US FDA approval of Premixed Vancomycin Injection RTU In 2018 we submitted a New Drug Application (NDA) to the US FDA for the first room temperature stable Premixed Vancomycin Injection RTU in a bag. In February 2019 we received regulatory approval enabling our commercial team to launch the product in the US market.

This regulatory approval is an important validation of our product strategy which we executed in 2014 and is based on developing a pipeline of innovative value-added anti-infectives that are centered on formulation improvements for established drugs from our core portfolio. During 2018 we continued to apply innovative science solutions to progress this work focusing on line extensions of other established anti-infectives. These products are designed to provide improved convenience and ease of use for healthcare professionals and enhance patient care.

# Strengthened role as leading global industry supplier of important anti-infectives

As a leading global industry supplier of several established anti-infective products including Vancomycin, Colistimethate Sodium (CMS), Bacitracin and Daptomycin our customers include over 500 branded, specialty and generic pharmaceutical companies across 70 countries. These customers rely on us to ensure continued supply and consistent quality. During 2018 we continued to work closely with our customers to meet the needs in their respective markets. To further enhance our customer focus during 2018 we re-organized our business into regional

## **CEO's** Statement



business units and established a dedicated organization to support our industrial customers in international markets.

Throughout the year we continued to witness strong demand for key products from our core portfolio. We continued to experience price pressure and increased competition particularly from manufacturers operating in Asia for certain markets and products. We were able to off-set the resulting decline in revenue through increased sales of other products in other markets. This serves to re-enforce the importance of our global business model and vertical integration strategy which enables us to provide customers with both Active Pharmaceutical Ingredients (APIs) and Finished Dosage Forms (FDFs) as well as our continued focus on delivering performance excellence whilst maintaining cost competitiveness. The year was also affected by an extended shut-down of a production line at one of our API manufacturing plants which resulted in limited supply and reduced sales of a key product in the first part of the year.

## Continued investment in enhanced capabilities

We made significant progress during 2018 at our new sterile injectables manufacturing facility in Cleveland, Ohio. We acquired the site in November 2015 with the objective to commence operations after implementation of substantial equipment upgrades and building improvements. These are now completed, but took longer than originally anticipated. We expect to commence the final FDA approval process in 2019 following which we will be able to commence full manufacturing operations at the site.

At our Copenhagen production site we also made substantial progress in the 25MUSD expansion and upgrade of the sterile manufacturing facilities that we initiated in 2017. We completed the construction of the new state-of-the-art multi-storey building and have commenced the installation of the latest sterile manufacturing equipment and containment solutions.

At the end of February 2019 we entered into an agreement to divest our Raleigh, North Carolina manufacturing plant to Sagent Pharmaceuticals. We will continue to operate the plant for a transitional period as we gradually transition the operations of the facility to the buyer. This strategic divestment allows us to focus investments on our two main sterile injectables facilities in Cleveland and Copenhagen and to strengthen and build new capabilities that are aligned with our innovative product portfolio.

We also continued to focus on our vertical integration strategy which combines innovative R&D capabilities, quality APIs

and FDFs, and management of a lean, fast and complex supply chain which centres on excellence and redundancy. This approach enables us to ensure a reliable quality supply to our customers and avoid shortages for our key drug products.

In 2018 we strengthened our leadership team further by appointing Matthew Anderson as our new Chief Financial Officer and Jamie Judica as Senior Vice President of Global Product Supply. Both Matthew and Jamie bring the right competencies and drive to support the growth of our global business.

#### **Financial**

The 2018 financial performance was in line with expectations with a marginal reduction in revenue and a more substantial decline in profitability following the significant growth which we experienced in the previous years. Revenue for the year was 315.7 MUSD (2017: 317.1 MUSD) whereas EBITDA was 62.1 MUSD (2017: 86.5 MUSD). The reduced profitability for the year is due to significant investments in new manufacturing capabilities, new product development and the establishment of our North American commercial organization. These investments are designed to enable us to continue the substantial growth of the business, however, as anticipated did not have any impact on sales in 2018. The Net Result for the year was -17.7 MUSD (2017: 39.0 MUSD). This was further adversely impacted by an impairment of certain intangible assets related to on-going

development projects which, due to changes in accounting estimates were written-off at the end of 2018.

#### Outlook for 2019

We will continue to make substantial investments in 2019 as we complete the strategic projects we have undertaken over the recent years. We expect to start to see a positive impact in 2019 on sales of the strategic investments made over recent years including new product launches in the US, and we anticipate a significant increase in both revenue and profitability compared to 2018.

I would like to thank all our customers for their support and Board of Directors and Scientific Advisory Board for their continued strategic input and counsel.

Finally, a massive thank you to all our valued employees - or Xellians as we call ourselves - for all their hard work and loyalty, without which the transformation of our business from a supplier of established anti-infective drugs to a company with its own products on the market would not have been achieved.

Carl-Åke Carlsson. Chief Executive Officer

# 2018 Financial Highlights



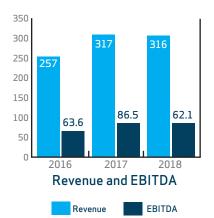
## Key figures

MUSD	2018	2017	
Revenue	315.7	317.1	
EBITDA	62.1	86.5	
Operating profit (loss) / EBIT*	-0.1	51.5	
Net profit (loss)*	-17.7	39.0	
Total assets	799.1	778.1	
Equity attributable to shareholders of the parent company	274.9	273.9	
Free cash flow before acquisition	-45.9	-2.5	
Total number of full time employees	1,642	1,497	

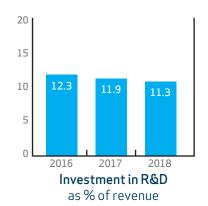
 $^*$ The 2018 Net Result was affected by an impairment charge of 27.7 MUSD. During 2018, management made the decision to change the estimation approach for valuation of on-going and future research and development projects. The company continues to be compliant with IAS 38 Intangible Assets and will also continue to capitalize development projects when IAS criteria are met. However, due to uncertain conditions inherent in the generic injectable marketplace, specifically associated with anticipated prices and competition, the company has elected to take a more risk-based approach to the analysis of these projects which currently results in fewer projects qualifying for capitalization.

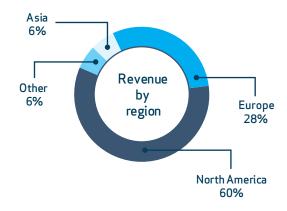
## **Key ratios**

Percentage (%)	2018	2017	
EBITDA margin	20	27	
EBIT margin	0	16	
Equity ratio	37	37	













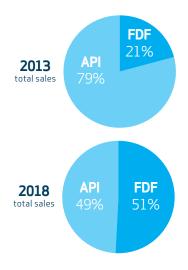
## Industrial



## Leading global, vertically integrated, supplier of important anti-infectives.

Our industrial (B2B) anti-infectives business manufactures and supplies Active Pharmaceutical Ingredients (APIs) and Finished Dosage Forms (FDFs) to over 500 pharmaceutical companies across 70 countries.

This business is rooted in a strong long standing heritage of manufacturing and supplying quality fermented and semi-synthetic APIs. Today, while API manufacture continues to form the backbone of our business, it is now strongly focused on producing FDFs which provide added value to our customers.



Our vertical integration strategy enables us to provide customers with a "one-stop-shop" offering for both the API and FDF, multiple product forms and improve supply security through redundancy.

## A focused core portfolio of established critical care, life saving anti-infectives

Xellia is the world leading provider of Vancomycin and Colistimethate Sodium and a leading provider of other important critical care anti-infectives including Bacitracin, Daptomycin and Polymixin B.

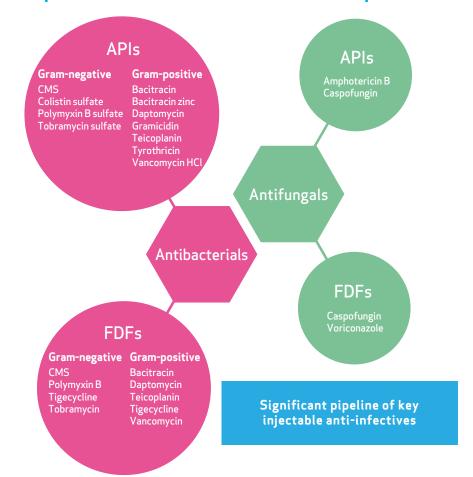
The majority of FDFs in Xellia's portfolio are injectables; however we also develop other forms when they are important for our key products.

## Global customer support

Xellia aims to be the preferred partner for the global supply of anti-infectives for critical care to the pharmaceutical industry.

Our customers consist of branded, specialty and generic pharmaceutical companies in more than 70 countries who rely on us to ensure continued supply of

## Our portfolio of established anti-infective products



Products protected by valid patents are not offered for sale in countries where the sale of such products constitutes a patent infringement.

first-class products thereby protecting their reputation and patients. The success of our business is based on customer satisfaction and loyalty, demonstrated by longstanding and often multi-product repeat orders.

Through our dedicated global customer service and technical support teams we build strong and lasting relationships with

our broad customer base by providing excellent quality and service.

Our outstanding technical services team work closely with customers to help them in developing their products for market entry and launch and resolving technical challenges to support business continuity and growth.

## Institutional



Moving closer to the patient and healthcare professionals through US institutional sales.

Xellia launched its institutional business in 2018 to sell its own brand of established and value-added injectable anti-infective products into the US hospital market to drive further sustainable, profitable growth.

## North American commercial organization

In September 2018 we opened our North American Commercial office in Buffalo Grove, near Chicago, Illinois to accommodate the Company's growth in this geography.

Led by Craig Boyd, President Xellia North America, our commercial organization has a talented team of over 40 industry professionals experienced in marketing and selling injectable hospital products. We have formed our own infrastructure and sales force to support our North American institutional business.

#### **Product launches**

During 2018 we began launching our portfolio of Xellia labeled products in the US hospital market. As of early 2019, we have commercialized Xellia labeled lyophilized Vancomycin HCL for Injection, Polymyxin B for Injection, Colistimethate for Injection, Bacitracin for Injection and we are preparing the launch of our first value-added product, Premixed Vancomycin Injection RTU which was approved by the US FDA in February 2019.

TODAY MARKS AN IMPORTANT MILESTONE FOR OUR US MARKET STRATEGY AND REPRESENTS A SIGNIFICANT STEP FORWARD IN THE COMPANY'S EVOLUTION AS WE BRING THE FIRST PRODUCT TO THE US MARKET UNDER THE XELLIA BRAND.

Carl-Åke Carlsson, Xellia's CEO on 17th September 2018.



## What makes our institutional business unique?



#### Science

Our innovative, value-added medicines are made possible through our team of 150 scientists working across Xellia's two R&D centres.



#### Supply

Our significant injectable manufacturing footprint and vertically integrated supply chain which includes R&D, APIs and FDFs provide multiple supply options for medicines.



## X-Factor

Our unique company structure which is autonomous and nimble with best-in-class people and culture, wholly owned by Novo Holdings A/S, a strong supporter of research in life sciences.

## Our partners/customers

Despite its recent inception, our North American sales team is already working closely with a number of US hospitals, clinics, key Group Purchasing Organizations (GPOs), Integrated Delivery Networks (IDNs) and other institutions to successfully make several of our Xellia branded products available in the US market.

## Why now?

2018 was the ideal time to establish Xellia's US institutional business.

This decision was based on the considerable advancement of our value added pipeline and Xellia's significant investment and progress in developing sterile injectable

manufacturing capabilities in Cleveland, Ohio which will enable the production of our own products.

Since the US hospital market is one of the largest for critical life-saving injectable anti-infectives it represents a significant opportunity for Xellia's growth. It values innovation and stable supply -both areas in which Xellia excels.

By working directly with US healthcare institutions and leveraging our US manufacturing capabilities, Xellia intends to achieve its ambition of mitigating drug shortages in the US.



## Innovation



Building a pipeline of novel anti-infective therapies through science and innovation.

At Xellia our global R&D growth strategy is rooted in a culture of innovation with a deep understanding of the ever changing regulatory and business environment

We have invested significantly in R&D over the past five years to create a platform to enable the development of a pipeline of more innovative anti-infective products that is focused around patients and aimed at solving unmet medical needs in the increasingly challenging anti-infective therapeutic area.



INNOVATION IS ROOTED IN OUR WAYS OF THINKING
AND WORKING. OUR R&D TEAM IS DEDICATED TO
PROVIDING SCIENCE EXPERTISE AND PHARMACEUTICAL
TECHNOLOGY EXCELLENCE TO CREATE INNOVATIVE
SOLUTIONS THAT EXTEND THE UTILITY OF OUR CORE
PRODUCTS AS WELL AS DEVELOP DIFFERENTIATED
AND NOVEL ANTI-INFECTIVE THERAPIES.

Dr Aleksandar Danilovski, CSO and Senior Vice President Global R&D and Regulatory Affairs, Xellia Pharmaceuticals.









## Enhancing patient care and improving convenience

Our innovation strategy is focused on enhancing patient care and improving convenience and ease of use for healthcare professionals based on improved formulations, specialty pharmaceutical dosage forms and more convenient administration paradigms of anti-infective products.

## **Drug/device combinations**

We are developing novel inhalation therapies for several of our anti-infectives drug products based on the proprietary ADI® platform through Pharmaero, a company that we formed as a 50:50 joint-venture with Scandinavian Health Ltd.

## Clinically differentiated and novel anti-infective products

Longer term, it is also our ambition to provide clinically differentiated and novel anti-infective products. We are continuously investigating numerous product innovation opportunities centered around providing solutions for unmet medical needs in the anti-infective therapeutic area, e.g. developing an innovative portfolio of products that have increased efficacy and safety with reduced harmful side effects such as those caused by toxicity.

#### **R&D** teams

Our experienced teams operate from Xellia's state-of-the-art R&D Centers of Excellence in Zagreb and Oslo and are supported by our Scientific Advisory Board.

## Developing a pipeline of value added anti-infectives

Program	Indication	Discovery	Formulation development	Pre-clinical	Clinical	Submission	Approval
XEL 1005	New formulation of Gram-positive a	ntibiotic					
XEL 1000	Inhaled antibiotic for lung infection						
XEL 1004	Inhaled antibiotic for lung infection					J	
XEL 1015	New formulation of Gram-positive a	ntibiotic					
XEL 1007	New formulation of Gram-negative a	intibiotic					
XEL 1012	New formulation of anti-fungal						
XEL 1011	New formulation of Gram-positive a	ntibiotic		J			
XEL 1013	New formulation of Gram-positive a	ntibiotic					
XEL 1018	New formulation of Gram-negative a	ntibiotic					
XEL 1022	New formulation of Gram-positive a	ntibiotic					



# Antimicrobial Resistance (AMR)

# and Antibiotic Stewardship



# Addressing the AMR global challenge through responsible manufacturing, continuity of anti-infective supply and innovation.

Antibiotics play a vital role in modern medicine, saving millions of lives worldwide. However some of these drugs are losing their effectiveness due to antimicrobial resistance, caused by a microbe's natural ability to evolve genetically and thereby counter the effects of these drugs.

The rise of antimicrobial resistance is a global crisis and is now recognized as one of the major threats to global health; it is an immense challenge to overcome. This means there are fewer, or sometimes no effective treatments available for infections caused by these multi-drug resistant microbes. This is further compounded by the gap that remains between new effective antibiotics reaching the market and existing antibiotics. Since the loss of effective antibiotics will reduce our ability to fight infectious diseases and manage the complications or secondary infections common in vulnerable patients such as immunosuppressed patients or ageing populations, it is becoming even more important to take control of existing antibiotics to help patients.

#### Xellia's role in fighting AMR

As a leading global producer of established or "old" anti-infectives that still provide a meaningful treatment for serious infections, we take our role in preventing AMR as well as antibiotic stewardship very seriously by supporting the following:



## Manufacturing responsibly

All our APIs and FDFs are contained during production and distribution and a range of techniques are employed to ensure that discharge of waste is to a pre-defined acceptable standard. These procedures are designed to reduce environmental impact and mitigate risk of AMR development.



## Supplying consistently

We enable stewardship of existing antibiotics through compliant manufacturing to provide a consistent supply of quality established anti-infectives for responsible, human medical use only. In addition our products are affordable and responsibly priced as part of our commitment to a reliable supply.



#### Investing in new innovative treatments based on established antibiotics

We invest significantly in R&D and are dedicated to preserving the safety and long term effectiveness of existing anti-infectives by developing and commercializing safer, easier to use and more efficient new value-added products.

Xellia is also an active member of the AMR Industry Alliance. With over 100 life science companies and associations joining forces, this is one of the largest private coalitions set up to provide sustainable solutions to curb antimicrobial resistance.



# Responsible use of Colistin (available in 2 different forms; Colistimethate Sodium and Colistin Sulfate)

In 2015, scientists from Britain and China identified a gene called mcr-1 that allowed bacteria to develop resistance and therefore survive the "last-resort" antibiotic colistin<sup>1</sup>. This major discovery indicated that some bacterial infections would be impossible to treat with current antibiotics, a scenario known as the "post-antibiotic future". Although first identified in China, mcr-1 has now been shown to exist in over 30 countries. spanning four continent. As China is one of the world's largest users of colistin in agriculture, where it serves as a growthpromoter in animal feed, it is probable that colistin resistance evolved in this situation. Since discovering mcr-1, the scientists then worked closely with the Chinese government to combat the spread of antibiotic resistance through initiating an unprecedented policy change in 2016 which banned the use of colistin in animal feed.

 $^1 \, https://mrc.ukri.org/news/browse/amr-research-leads-to-china anning-antibiotic-from-animal-feed$ 





# Corporate Responsibility



At Xellia we value integrity and openness, and are committed to a high level of compliance in all aspects of our work. As a global business with international customers it is vital that we have a uniform set of standards that can be applied to our business regardless of the country in which we operate.



Over the following pages we have provided an overview of our corporate responsibility activities and performance, focusing on economic, environmental and social areas. We are actively working to expand our corporate responsibility policies across the entire business and to update or introduce systems and platforms that will progress our corporate responsibility practices further. We also continue to work on alignment of the content in this report with the relevant standards on sustainability reporting produced by the Global Reporting Initiative (GRI).

We have established a Corporate Social Responsibility (CSR) steering group headed by our CEO with the participation of senior management representatives from functions including Operations, Human Resources, EHS (Environment, Health and Safety), Finance, Communications and Legal. The role of the group is to monitor and drive the progress of corporate responsibility initiatives across different areas of our business.



WE ENSURE CONSISTENT AND CONTINUOUS

MANUFACTURE AND SUPPLY OF THE PRODUCTS

THAT OUR CUSTOMERS, HEALTHCARE PROFESSIONALS

AND THEIR PATIENTS RELY ON FROM OUR GLOBAL

PRODUCTION SITES.



# **Economic** Sustainability



Continuing sustainable growth and development, and the protection of our employees is paramount to our future success. Many internal and external stakeholders rely on us to maintain a consistent supply of high quality products and to invest and borrow wisely to create a strong and stable business.



## **Continuity of production**

The sustainable production of antiinfectives for critical care forms the foundation of Xellia. We ensure consistent and continuous manufacture and supply of the products that our customers, healthcare professionals and their patients rely on from our global production sites through:

- Rigorous monitoring of quality and manufacturing systems
- Investment in new capacity and equipment
- Improvement of existing products and processes

In the full year of 2018, we invested 32.6 MUSD in tangible assets to increase and improve our production capacity (up from 27.5 MUSD in 2017). In addition, we invested significantly in the additional manufacturing facilities in Cleveland, Ohio which we acquired in November 2015. We will continue to invest considerably in these facilities as we prepare to start-up commercial production.

In February 2019 we divested our Raleigh, North Carolina manufacturing plant to Sagent Pharmaceuticals. This strategic divestment allows us to focus investments on our two main sterile injectables facilities in Cleveland and Copenhagen and to strengthen and build new capabilities that are aligned with our innovative product portfolio.

## Financial stability

We believe that a stable and sustainable business benefits us all and we work hard to ensure financial sustainability. At the end of 2018 our external bank debt including mortgages amounted to 175.3 MUSD (120.6 MUSD in 2017) with substantial additional loan facilities available with our banks. This enables us to invest in future growth plans to create long-term value.



# **Economic** Sustainability



## High level of health protection and occupational safety

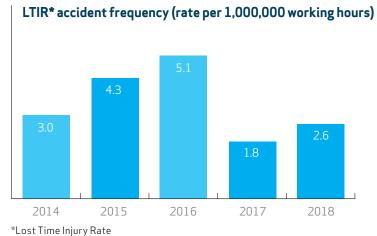
At Xellia, we have over 1,600 employees. We constantly strive to create a healthy, safe and secure working environment across all of our locations and are committed to maintaining high standards of occupational health and safety. We have adopted an Environment, Health and Safety (EHS) policy which sets out our key principles for EHS management and detailed EHS standards that we apply across our manufacturing sites.

As a pharmaceutical manufacturing company producing anti-infectives, our operations involve certain inherent risks. We promote a culture where these risks are clearly recognized and mitigated, and employees take personal responsibility for their safety.

We apply the internationally recognized OHSAS 18001 standard which provides an occupational health and safety framework from which to implement effective management and control

associated risks. In 2018, our three production sites in Europe and China all remained certified under OHSAS 18001. Our US facilities are not OHSAS 18001 certified but are included under our health and safety management and reporting systems.

We are responsive in accident reporting and in ensuring that we take action to prevent reoccurrence of any accidents. Our long-term 2020 target is to maintain the maximum frequency of work-related accidents at below 3.0 per 1,000,000 working hours in addition to ensuring that we continue to avoid all serious incidents. We use the OHSAS standard to measure the frequency of occupational accidents. While, we experienced a small increase in work-related accidents during 2018 compared to 2017, we are still at a level that is below both the KPI for the year and our long-term target.







# **Environmental** Responsibility



We understand the importance of preserving our environment and natural resources today and in the future. We accept that the responsibility lies with us to minimize the impact we have on the environment. We comply with all relevant laws, regulations and our own EHS policy and standards. In addition, we are constantly looking for ways to improve our operations, products and services as well as using chemicals and natural resources responsibly. With careful management we can grow our business, increase production volumes, but still reduce our environment impact.



#### **Management systems**

In addition to our overall EHS policy, we have developed and applied detailed EHS standards and standard operating procedures to ensure the quality of the EHS management system across our production and R&D facilities. Our three production sites in Europe and China are certified under the internationally recognized ISO14001 environment management system. Our US facilities are not ISO14001 certified, however, the sites are included under our environmental management and reporting systems.

## **Environmental compliance**

Environmental compliance is a central pillar of our business and we strive for complete adherence to all environmental laws and regulations. Over the past three years we have received one fine that related to an environmental non-compliance issue concerning a minor breach of a regulatory limit. We take such non-compliance very seriously and have implemented measures to ensure that we maintain a high compliance level.

#### **Stakeholders**

We know that the impact of our business can stretch beyond the boundaries of our production and R&D sites around the world and therefore encourage open, reliable communication on environmental matters with all stakeholders both internally and externally. Most of our sites are located in urban areas and we work to minimize any negative impact on the people living in close proximity to us. We receive very few complaints regarding odor and noise from our local community; in 2018 we received only one complaint across all sites. We take complaints very seriously and have implemented measures to ensure that we remain good neighbors to the communities in which we are based. We constantly monitor noise levels from machinery and take steps to limit noise and odor wherever possible.



# **Environmental** Responsibility



## Identifying environmental risks to minimize incidents

The manufacture, quality control and development of anti-infectives involve the use of certain hazardous materials and processes from which there is an inherent risk to the environment. By understanding and identifying these risks we have implemented standards and policies to protect the environment by preventing incidents before they can take place.

We are committed to the identification and prevention of potential environmental accidents. It is our ambition to prevent any environmental incidents, and when incidents do occur we perform a thorough analysis of the causes to ensure that we implement action plans to prevent reoccurrence. As in previous years, in 2018 we achieved our corporate KPI to avoid all major environmental incidents across our global production sites. We were also able to avoid any minor environmental incidents.

We are building a risk-aware culture amongst our employees and encourage a sense of personal responsibility towards preventing incidents. All sites incorporate emergency response and crisis management programs into management plans. These programs ensure that if incidents do occur they are effectively

managed and that any impact on the environment, the local community and our business is minimized.

## Carbon footprint and sustainability

We take a collective approach to sustainability and encourage our employees to take an active interest in minimizing the impact of our operation on the environment. We welcome input, feedback and suggestions from all staff as to how we can further improve our commitment to the environment. We have set short and long term targets for improving the carbon footprint of both our API and FDF production over the coming years. In 2018 the carbon dioxide (CO<sub>2</sub>) emissions from our manufacturing sites increased by approx. 6 % compared to 2017. This was mainly due to increased production volumes at several manufacturing sites. Our long term target is to reduce our carbon footprint by 20% by 2020 compared to the baseline which we established in 2014.

## **Energy and water efficiency**

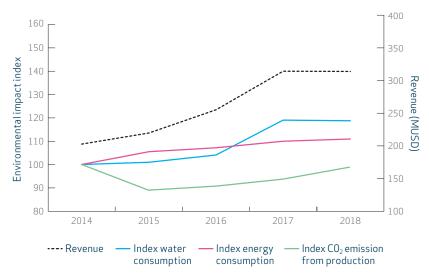
We understand the importance of managing the use of energy and water sustainably and take our responsibility to protect this precious resource very seriously. We have established short and long term targets for improving our efficiency with respect to energy and water consumption.

All our sites employ a specialist team focusing solely on energy use and how to improve energy consumption efficiencies. Our energy consumption strategy is defined in close collaboration with each site's EHS teams, purchasing departments and engineering departments (energy management specialists). In 2018 we were able to limit the growth of the total energy consumption at our manufacturing sites to 4% compared to 2017 while increasing production volumes and maintaining a stable revenue level. Our long term target is to make

a 20% improvement to our energy efficiency by 2020, compared to a baseline established in 2014.

Our sustainable water management process is focused both on creating efficiencies in the use of water at our manufacturing sites and on improving our discharge treatment systems. By implementing systematic quality controls for effluents we are helping to preserve the availability of drinking water as well as preventing any risk of contamination.

## Development in environmental impact and revenue





# Social Responsibility



Our people make us what we are. We aim to attract the most talented, productive employees in our industry and to earn their loyalty and commitment. We support and protect our employees through comprehensive human resources processes ensuring that every employee is treated fairly and has a voice which is listened to and valued.



## Business ethics and legal compliance

#### **Code of Conduct**

The Xellia Code of Conduct contains our values and standards for ethical business conduct and reflects our commitment to meeting the expectations of our stakeholders. The code sets out the principles that must be adhered to by all employees within key areas that are essential to our business including compliance and fair dealings in relevant areas. A copy is presented to each employee when joining Xellia. In addition, all senior employees are required to certify annually that they have acted in compliance with the guidelines. Any alleged or suspected cases where the guidelines may have been violated are investigated by selected members of our corporate functions. In 2018 there were no reported cases of alleged or suspected violations.

## Conflict of interest

It is imperative to the maintenance of our good reputation that business decisions are made independently from conflicts of interest and on an objective basis. These decisions must not be influenced by any personal interests which employees may have, wherever in the world they work, and at whatever level of seniority they operate. We have established procedures including the pre-approval of any 'related party'

transactions by the Board of Directors as well as an annual certification of compliance by all senior employees.

## **Anti-bribery program**

Xellia's anti-bribery program aims to reduce the risk of non-compliance. The program includes annual risk assessments, due diligence procedures for agents and other business partners and adoption of corporate guidelines for gifts, hospitality and entertainment. We believe that a successful anti-bribery program is spearheaded by informed, aware employees and we ensure that all relevant parts of the organization receive regular training in the program. In 2018 we introduced a new anti-bribery online training which has been rolled out globally to all relevant employees.

## General data protection regulation

In 2018 Xellia implemented new policies and procedures across its different functions in order to meet the new requirements in the EU General Data Protection Regulation ("GDPR"). We ensure that our processes are secure with respect to the protection of personal data. GDPR awareness material has been rolled out across Xellia's business, including new training and e-learning on Xellia's compliance with GDPR.



# Social Responsibility



## Change, diversity and employee turnover

## Managing change

Our business exists in a highly competitive, dynamic environment. Our commitment to open communication and engagement remains strong as we support employees through the internal and external changes that influence us.

## **Employee relations**

We operate across diverse social backgrounds and locations where continued and constructive dialogue with our employees is important. Without this interchange, labor disputes can occur which are disruptive to our business, and affect a wide range of stakeholders beyond the working site. We aim to foster a culture based on trust, mutual respect and communication. Our employee relations strategy encourages open dialogue with employees and external stakeholders. We support collective dialogue and negotiations with unions and other representative associations within the local legal framework. We have maintained good relationships with the unions and in 2018 there were no industrial actions resulting in lost working time.

## **Employee surveys**

We ask all employees to participate in surveys at regular intervals, usually on a biannual basis, the next being in 2019.

These surveys address a number of areas such as motivation, satisfaction and communication. The data from the survey is followed up both at a senior management level and in each function and department. The latest employee survey from 2017 showed an overall index of 73% employees responding positively about their experience at Xellia, this is similar to the previous 2015 survey results and a marked improvement on the 67% results obtained in 2014. We have established a long term target to further improve the overall index to 75% employees responding positively by 2020. One area that we are particularly focused on is the "engagement" category which remained at 82% of employees responding favorably in 2017.

## **Diversity**

As a truly international company, we benefit from a diverse, multicultural workforce. Across our sites in eight countries we employ more than 30 nationalities. Although located around the world we have an integrated, open and transparent culture built on mutual respect, trust and accountability. We aim to recruit competent and motivated people who respect our values, and we in turn provide equal opportunities for their development, and protect their privacy. We do not tolerate any form of

harassment or discrimination for any reason and strive to maintain a culture that provides equal opportunities for all.

## **Gender diversity**

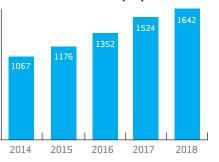
In 2018 we adopted a new Diversity Policy that sets out the key principles for our commitment and focus in this area. Xellia is committed to building a workforce through the entire company that is represented equally by both genders across both our management team and other managerial positions (directors, managers, and team-leaders). In 2018, for all companies in the Group there was an average of 58% male and 42% female employees (2017: 59% male and 41% female). At the manager level the average was 68% male managers and 32% female managers (2017: 65% male and 35% female).

Qualified women are encouraged to apply for managerial positions within the Group and gender diversity is an area of focus in our development and succession planning initiatives. Our staff policies and HR processes are directed at retaining qualified female employees by addressing the work/life balance in order to create a desirable working environment as well as supporting personal development through performance reviews, feedback and leadership training. We will continue to work towards increasing gender diversity throughout our organization.

## Employee turnover

In 2018, the number of full time employees in Xellia increased by 145 to 1,642.

## Total number of employees



The main reasons for the increase were new hires to support our new commercial organization in Buffalo Grove, near Chicago, Illinois and the continued expansion of the experienced team supporting our new production facility in Cleveland, Ohio.

The voluntary employee turnover in 2018 was 7.7%, up from 6.4% in 2017 and above the target for 2018. We continue to analyze and evaluate the appropriate target for turnover in view of Xellia's business transformation as well as developments in local labor markets.

## Employee turnover rate (voluntary resignations)



The figures outlined in the graphs above cover the rate of voluntary resignations and, therefore, do not include the employees affected by redundancies.

The employee turnover rates vary between countries.



# Social Responsibility

## **Development and training**

To remain competitive, we need to ensure that our employees have the opportunity to continually advance and extend their skills and knowledge. We achieve this by providing employees with the possibility to grow in their current positions or discover new working areas, functions or locations.

This initiative is facilitated within our newly implemented internal mobility framework. During regular performance feedback meetings with employees we draw up a plan for the next steps in their development and set performance milestones, as well as personal and professional goals. We actively promote the principle of lifelong learning, which also means that we provide the opportunity for professional and behavioral training, linked to the agreed individual plan.

#### **Our values**

Xellia continually strives to be an appealing, stimulating and high-performing workplace with a culture based on Xellia's goal, purpose and values.

## Our leadership promise

The substantial transformation of Xellia's business means that effective leadership is more important than ever. As a result during 2018 we instigated our Leadership Promise which builds on our values and lays out the attributes and behaviors that Xellia expects from all individuals

in a leadership role. We put this Promise into action during the year across all our sites by running workshops, 1:1 sessions, peer-coaching and mentoring. This effort will also be continued throughout 2019.

## **Onboarding process**

To support the high volume of new employees joining Xellia we have focused on improving our onboarding process in 2018 to ensure a smooth integration into the company. Based on both internal and external best practices we implemented a globally aligned process with supportive Leadership Tools, across our sites. Our onboarding process and Leadership Tools support the professional and personal integration into our working environment by providing preboarding information, welcoming events, dedicated managerial attention and buddy support. The individual onboarding plan and follow-up meetings accelerate the systematic induction into the new tasks and responsibilities. In order to engage our new employees for our company culture we implemented the so-called DNA Day, as well as we seek for feedback by our new hire survey for further development in our onboarding practice. We will continue to sharpen our onboarding practice in 2019, for example by implementing possible integrated IT solutions or e-learning opportunities.





# SOS Children's Villages

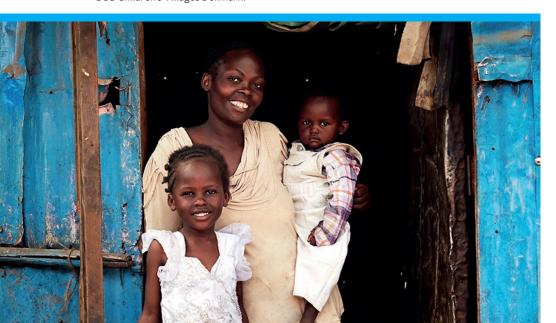


SOS Children's Villages has been Xellia's nominated charity since 2005, becoming a long-term partner to the organization.



WE ARE INCREDIBLY GRATEFUL FOR XELLIA'S LONG-TERM SUPPORT WHICH HAS MEANT THAT WE ARE ABLE TO CREATE CONTINUAL SOCIAL AND ECONOMIC IMPROVEMENT AND PROGRESS IN ELDORET. THIS IS OF ABSOLUTE IMPORTANCE FOR THE VULNERABLE FAMILIES INVOLVED IN THE FAMILY STRENGTHENING PROGRAM. ON BEHALF OF THE CHILDREN WHO WILL BENEFIT FROM THIS PARTNERSHIP I WOULD LIKE TO EXPRESS MY SINCERE GRATITUDE.

Mads Klæstrup Kristensen, Managing Director, SOS Children's Villages Denmark.



SOS Children's Villages is an independent social development organization that promotes the rights of children in over 130 countries and territories around the world, providing over 2 million children and their families with a safe place to live, learn and grow up.

## Xellia's corporate partnership with SOS Children's Villages

Between 2015 and 2017 a partnership between Xellia and SOS Children's Villages Denmark provided financial support to the SOS Medical Center in Eldoret, Kenya. This enabled the Center to expand its services such that it is now self-sufficient and can provide free medical services to those in need. Following on from this successful outcome, Xellia and SOS Children's Villages Denmark have joined forces again with a new three year partnership, and have pledged to fund operations from 2018 until 2020 for the SOS Family Strengthening Program in Eldoret, Kenya. Organized by the SOS Children's Villages Social Center in Eldoret, this Program is intended to support families experiencing crisis or extreme hardships and may have difficulty in caring for their children. By building capabilities and resources for families and their communities the Program allows children to be well cared for and stay together with their families.

The Program provides access to essential healthcare and education, however, as many of the families are very poor they are also assisted with vital "everyday needs." This can include materials for their shelter, daily living and schooling, while the most vulnerable families receive supplementary rations of the necessary food types. With this new partnership Xellia intends to fund and help improve the lives of over 70 vulnerable and

poor families in the local Eldoret community reaching approximately 250 children.

## Xellia's annual fundraising event 2018

Xellia held its fourth annual fundraising event for its employees' to further complement our backing of the Family Strengthening Program. Our colleagues raised sufficient funds to help 45 young women and men from vulnerable families in Eldoret with technical and vocational training during 2019. This type of education should give these individuals the skills to enter the job market with the ultimate aim of helping them become financially independent. In connection with the annual fundraising event, three Xellia employees were chosen in a lucky draw to make a trip to Eldoret, Kenya in the spring of 2019, to visit the SOS Children's Village and see the work we are contributing towards.

## Employee driven initiatives - beyond corporate value

In addition to Xellia's corporate funding and the annual fundraising event, colleagues from various Xellia sites were actively fundraising during 2018 for three additional important causes to further support SOS Children's Villages in Eldoret. These initiatives helped provide sanitary towels, the renovation of a local preschool and for the treatment for jiggers. a common parasitic insect that causes painful wounds that can be further infected leading to amputation of limbs or death. Furthermore, our sites in Chicago, II, USA, Zagreb, Croatia, Taizhou, China and Budapest, Hungary, have supported their local SOS Children's Villages as well through either monetary donations or volunteer time.

Xellia 2018





# Corporate Governance



New Xellia Group A/S has adopted a governance and management structure that allows the Group to manage its business successfully and mitigate risk on an on-going basis.

In accordance with Danish company law, Xellia has a two-tier management system comprising the Board of Directors and a Managing Director (CEO). As outlined in the Company's Articles of Association, the Board of Directors should consist of between three and seven independent directors. Currently, the Board has seven members; a Chairman and six independent directors. Directors are appointed for one year at a time, and can be re-elected at the annual shareholders meeting. The CEO is not a member of the Board of Directors.

The Board of Directors has adopted the Rules of Procedure for the Board of Directors which sets out the responsibilities of the Board of Directors in a number of areas. These include determining Xellia's overall strategy and actively contributing to developing the Group as a focused, sustainable, global specialty pharmaceutical company and supervising Executive Management in its decisions and operations.

The Board of Directors has also adopted an annual meeting framework consisting of six

meetings annually comprising of four regular Board meetings, one end-of-year meeting to review the annual operating plan and budget for the following year and one meeting focused on the long-term strategy of the Group. In 2018 a total of eight meetings were held.

The Board has established a Finance and Audit Committee, consisting of members of the Board of Directors and management, which assists the Board in areas relating to accounting, audit, internal control and financial reporting. Chaired by Benny Loft, a member of the Board, the Finance and Audit Committee held seven meetings during 2018. The Board also has established sub-committees within the areas of operations, commercial and new product development.

## Compensation

Compensation for the Chairman of the Board of Directors, other members of the Board and the CEO is based on market terms and conditions.

Members of the Board of Directors receive annual compensation which is not dependent on Xellia's performance or results. Some member of the Board have also invested in the Company under the Board Investment Program.

In 2018 management and other employees received, in addition to basic salary, variable compensation dependent on the achievement of operational and strategic targets in addition to financial targets.

Our Long Term Incentive Program (LTIP) qualifies management and senior employees at director level and above to receive annual grants of restricted share awards (RSAs) as part of their variable compensation package. In 2018 Xellia granted a total of 714,629 RSAs under the enhanced LTIP that was established in 2017. These RSAs entitle the recipient to receive B-shares in 2021 subject to certain vesting conditions and adjustment mechanisms linked to the company's financial performance in the period from 2017 through 2020.

We have also adopted an Executive Management Share Program under which RSAs may be granted to the CEO. In 2018 the company granted 11,369 RSAs under this program each giving the right to receive one B-share in January 2020.

## Share capital

Share capital of New Xellia Group A/S is divided into A and B shares. These two share classes have identical rights, with the exception that the A-shares hold 10 votes

per share and the B-shares hold 1 vote per share.

The A-shares, which total 100,500,000, are held by Xellia Holdco A/S, which is owned by Novo Holdings A/S.

The B-shares are owned by members of management and other senior employees of the Group as well as certain members of the Board of Directors. In connection with the acquisition of Xellia in July 2013 a Management Investment Program was established. At the end of 2018 a total of 1,421,580 B-shares were subscribed to by 39 managers and senior employees. In addition to the B-shares, managers and senior employees have subscribed warrants in the Company with a right to subscribe by up to 5,621,402 additional B-shares. In 2017, a Board Investment Program was established under which certain members of the Board of Directors have subscribed for a total of 123.076 B-shares as well as warrants with a right to subscribe for up to 323.596 additional B-shares.



## **Board** of Directors





Steen Riisgaard Chairman of the Board

Steen is the former President and CEO of Denmark based biotech company Novozymes A/S. He has also held senior level positions at Novo Nordisk A/S and Novo Industri A/S.

Other Board positions: Chairman of the Boards of ALK Abelló A/S and COWI Holding A/S. Vice Chairman of the Boards of the Novo Holdings A/S and the Villum Foundation. Member of the Boards of Novo Nordisk Foundation, Corbion, the University of Aarhus, Denmark, the Bird Protection Fund, Denmark and VKR Holding A/S.

**Education:** MSc in Microbiology, University of Copenhagen, Denmark.



**Andreas Rummelt** 

#### **Board Member**

Andreas is a Partner and CEO of InterPharmaLink AG, Basle, Switzerland. His international career spans over twenty years in executive management positions at Novartis.

**Other Board positions:** Partner and CEO of InterPharmaLink AG. Member of the Boards of Alexion Pharmaceuticals, Inc., Alvogen, Leukocare AG and, Cypralis Ltd.

**Education:** MSc and Ph.D. in Pharmaceutical Sciences, University of ErlangenNuremberg, Germany.



Benny D. Loft

#### **Board Member**

Benny was EVP and CFO at Novozymes A/S until 2017, he has also worked on acquisitions and negotiations and played an active role in steering groups for numerous corporate functions including ethics, sustainability and business development.

**Other Board positions:** European Freeze Dry ApS.

**Education:** MSc in Accounting, Tax and Auditing, Copenhagen Business School, Denmark and State Authorized Public Accountant.



Per Valstorp

#### **Board Member**

Per Valstorp has a long track record attained from senior executive positions held at Novo Nordisk A/S within Pharma Operation Management, Quality, Regulatory Affairs and Medical Devices.

**Other Board positions:** Member of the Boards of Roto Health ApS, DBI Plastics A/S, European Freeze Dry ApS, Orana A/S (Chairman) and Scanbur A/S.

**Education:** MSc in Operational Research & Planning, Technical University of Denmark.



## **Board** of Directors





Julie McHugh Board Member

Julie McHugh has a track record that spans 27 years in the biopharmaceutical industry. Most recently, she was the COO at Endo Health Solutions, Inc., with responsibilities for both the specialty and generic pharmaceuticals businesses.

Other Board positions: Chairman of the Board of Visitors for the Smeal College of Business, Pennsylvania State University. Member of the Board of Directors of Aerie Pharmaceuticals, Inc., Ironwood Pharmaceuticals, Inc., Lantheus Holding Inc. and Trevena Pharmaceuticals, Inc.

**Education:** BSc in Finance, Pennsylvania State University, USA and an MBA Administration in International Management, St. Joseph's University, USA.



Henrik Kjær Hansen

#### **Board Member**

Henrik joined Novo Holdings A/S in January 2017 as a Senior Director, Principal Investments, where he leads on the investment process and takes an active part in managing and developing the growing portfolio of investments. Prior to this, Henrik held a number of positions in the City of London. Most recently he was a Senior Vice President at Moelis & Co., focusing on healthcare buy and sell side M&A transactions. Previously he was with Deutsche Bank and ABN AMRO.

**Other Board positions:** Member of the Board of Directors of Orexo AB.

**Education:** BSc. in Business Administration and an MSc. in Applied Economic and Finance from the Copenhagen Business School, Denmark.



**Barbara Purcell** 

## **Board Member**

Barbara is President of the Diversified Portfolio at multinational specialty pharmaceutical company Bausch Health and is a member of its Executive Management team. She has spent the past 25 years working in the pharmaceutical industry mostly managing mature brands and generics. Most recently she was instrumental in building the generic division at Bausch Health as well as revitalizing several mature brand assets there.

Previously, Barbara was Executive Director Global Sales and Marketing for Bausch + Lomb's generics division, having also worked at Valeant, Novartis/Sandoz and Zydus.

**Education:** MBA from Rutgers University and a BA from the University of Pittsburgh and qualified as a Certified Public Accountant (CPA).



# Scientific Advisory Board



# The Scientific Advisory Board is playing an important role in directing our R&D activities and focus on innovative anti-infectives.

The Board brings together leading international experts in infectious diseases, clinical microbiology, respiratory medicines and pharmaceutical research and development. The Board's insight and guidance combined with Xellia's specialist expertise are being harnessed to overcome the challenges associated with anti-infective discovery and development activities.



Professor George E Griffin Chairman of the Scientific Advisory Board

Emeritus Professor of Infectious Disease and Medicine at St George's, University of London, UK.



Professor Keith S Kaye

Professor of Internal Medicine, Director of Clinical Research, Division of Infectious Diseases, University of Michigan Medical School, Ann Arbor, Michigan, US.



**Dr Andreas Rummelt** 

Member of Xellia Board of Directors supporting R&D. Also CEO and Partner at InterPharmaLink AG, Basel, Switzerland.



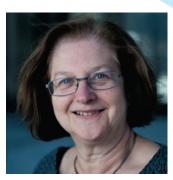
**Professor Gerhard Winter** 

Department of Pharmacy, Ludwig Maximilian University of Munich, Munich, Germany.



**Professor Christoph Tang** 

The Sir William Dunn School of Pathology, University of Oxford, Oxford, UK.



Dr Tania Pressler

Chief Attending Physician, Rigshospitalet, Copenhagen, Denmark



Professor Anne O'Donnell

Professor and Chief, Division of Pulmonary, Critical Care, and Sleep Medicine, Georgetown University Hospital, Washington DC, US.



Professor Arjana Tambić Andrašević

Head of the Department of Clinical Microbiology at the University Hospital for Infectious Diseases, Zagreb, Croatia.



Professor Matthew Falagas

Director, Department of Internal Medicine and Infectious Diseases, Iaso General Hospital, Iaso Group, Athens, Greece.



Professor Radan Spaventi

Founding Partner, Triadelta Partners Ltd, Zagreb, Croatia.

Xellia 2018



# **Executive** Management



Carl-Åke Carlsson
Chief Executive Officer
and President



Craig Boyd
President, Xellia North
America



Daniel Schwartzlose President, Xellia International



Aleksandar Danilovski Chief Scientific Officer



Jamie Iudicia
Senior Vice President,
Global Product Supply



Geelanie Briones Corporate Vice President Quality



Matthew Anderson
Chief Financial Officer



Mikkel Lyager Olsen Chief Legal Officer



Bjørn Thonvold Corporate Vice President Human Resources



Kristin Lund Myrdahl
Corporate Communications
and Brand Management



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