

## Capital Markets Day



## Agenda

- Vistin history and long-term strategy
- Vistin metformin business
- The Fikkjebakke plant; Operations and strategy
- Plant Tour





## Producer of two different metformin products

- Metformin HCI (bulk API, "fine, dry powder")
- Metformin DC
   ("directly compressible",
   a granulated pre-tablet
   form)
- Metformin tablet dossiers and know-how

## Manufacturing capacity

- Decided in April '20 to invest MNOK 100 to increase the capacity up to 7000MT
- Installed ~5 500MT at end 2022

  six shifts (24/7)

  Expected to increase to approx. 7 000MT by end 2023

## Positioned as a premium producer in a competitive market

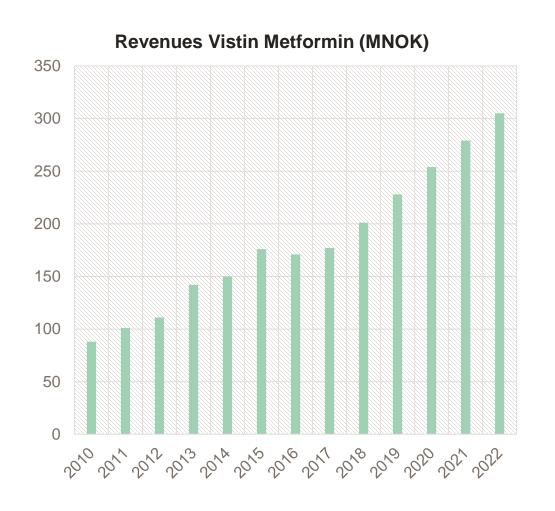
- Sales to reputable international pharmaceutical companies
- State-of-the-art, fully automated manufacturing plant in Kragerø
- Certified by all significant international regulatory bodies

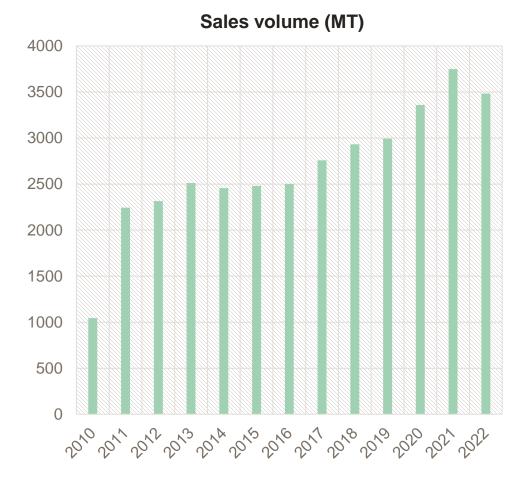
## Strategically positioned with proximity to key customers

- Delivery time less than 24 hours
- Competitive edge over Asian producers



## Long and successful growth track record







## **Experienced management team**

Name	Role	Experience
Kjell-Erik Nordby	Chief Executive Officer	<ul> <li>Previous experience includes several years in top management positions at Alpharma, a leading international generic pharmaceutical company</li> <li>Holds a Master's degree in Pharmacy and Master's degree in Business Administration</li> </ul>
Alexander Karlsen	Chief Financial Officer	<ul> <li>10 years at GE Healthcare in various financial management roles, latest role as Country Finance Manger (CFO) for GE Healthcare in Norway</li> <li>Holds a Master's degree in Finance from Norwegian School of Management (BI)</li> </ul>
Vegard Heggem	VP Operations	<ul> <li>Extensive experience from different managerial positions within operations, engineering and investment projects</li> <li>Holds a Master's degree in Chemical Engineering from The Norwegian University of Science and Technology (NTNU)</li> </ul>
Magnus Tolleshaug	Chief Commercial Officer	<ul> <li>20 years experience from International Pharmaceutical industry, covering various managerial positions in Global Manufacturing Operations and R&amp;D</li> <li>Holds a MSc in Chemistry and Chemical Technology from The Norwegian University of Science and Technology (NTNU)</li> </ul>
Hilde Merete Hagen	VP QA	<ul> <li>Previously spent 20 years at Pronova BioPharma, where she held several management positions within Quality Assurance</li> <li>Holds a Master of Science in Chemistry and a Master of Management</li> </ul>



### Strategic intent:

# Optimize and grow our current business, strengthen our premium metformin supplier position...

### **Metformin leadership**

- Build a >7000 metformin business through world class operations and strategic customer partnerships
- Make Fikkjebakke the most technology advanced and environmentally sustainable state of the art metformin plant
- Investing in a 2nd production line at the Fikkjebakke site and expand the capacity by additional >3500+ MT
- Become a front runner on sustainability by continuous focus and innovations on reduction of emissions and waste production



### Strategic intent:

### ...and plan for the next wave of growth

### 2nd wave of growth

- Build a multi product API European Contract Development and Manufacturing business(API CDMO)
- A strong high margin API focus where the company is a leading player
- Supplier of "short travelled" European APIs to international pharmaceutical companies
- Offering should include contract development/tech transfer services to companies that either need API supply/synthetic process expertise for their clinical programs and/or want to outsource the manufacturing of their APIs for strategic reasons

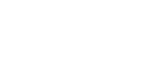
### CDMO market is divided into 4 activities according to drug product development stage - API production and FDF as main segments



Overview of CDMO activities

#### Drug production value chain

#### Development



#### API Production





### Description

- > Formulation development, incl. dosage forms
- > Scale-up methods definition
- > Development and implementation of API manufacturing process, e.g. chemical synthesis (small molecules), fermentation (large molecules)
- > Manufacturing of final
- formulated drug product/ final dosage form

packaging

### Main services provided

- > Process analytics to monitor quality processes
- > Quality assurance
- > Quality control
- > Enhance the purity level of API
- > API production for clinical development (early and late phases) and commercialization
- > Quality assurance control
- > Association of API and excipients
- > Fill-finish: final formulated product filled into primary packaging
- > Quality assurance and control

Share of total CDMO market [%]



(Development & primary packaging)



~25

represents a small share of CDMO market, it is increasingly necessary for CDMOs to include development services in their offer to attract clients."

Key highlights

and FDF

production.

"Development goes

together with both

API manufacturing

Even if development

**ICDMO Market** Director

Packaging



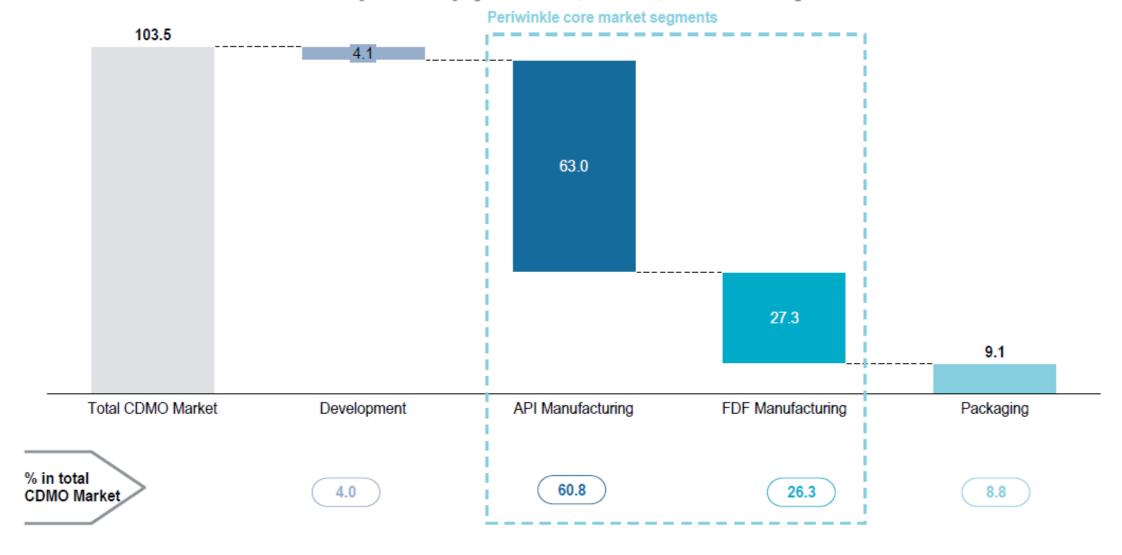
> Secondary and tertiary

~10 (Secondary packaging only)

## 2019 CDMO global market reaches ~EUR 100 bn with API manufacturing accounting for the largest market share (~60%)

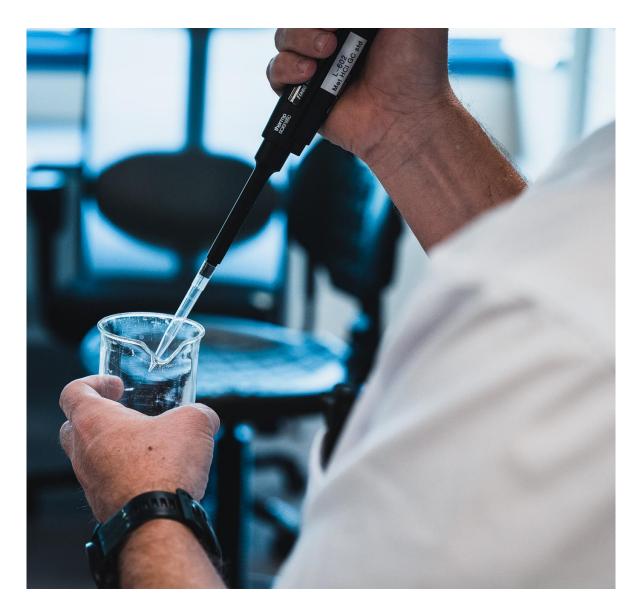


CDMO market breakdown by activity [EUR bn; 2019; worldwide]





## Vistin metformin business





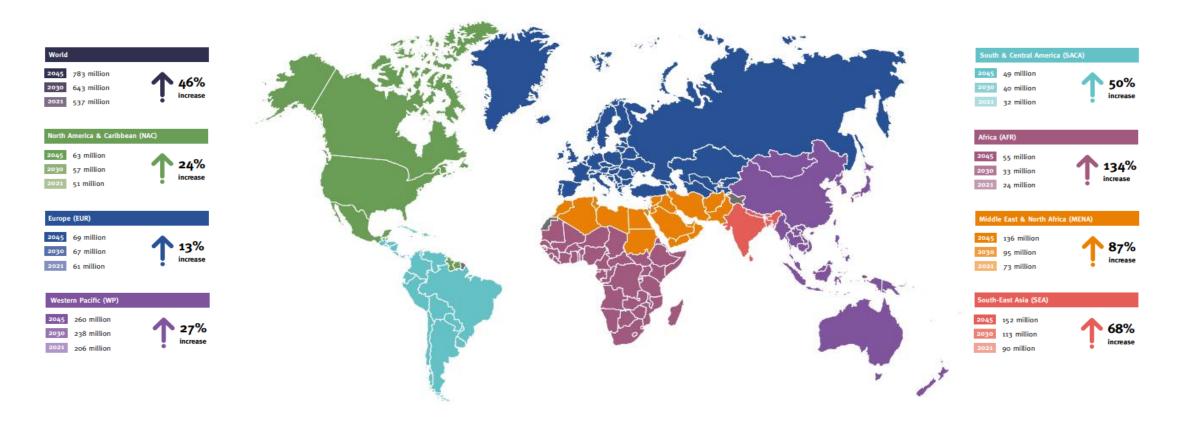
Metformin is the 1st-line treatment for type 2 diabetes, being cost-efficient with limited side effects

An estimated 537 million adults aged 20–79 years are currently living with diabetes. This represents 10.5% of the world's population

Today Vistin contribute to deliver Metformin diabetes type 2 medication to more than 50 million patients every day



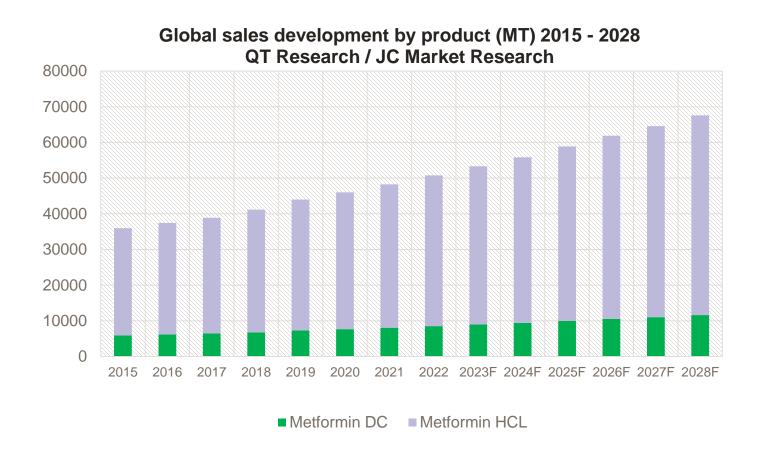
## Total number of diabetes patients expected to rise to 783 million by 2045 (+46%)





## Global metformin demand expected to grow by approximately 16.000MT to 67.000MT by 2028

- Steady 4-6% annual CAGR growth
- Asia Pacific (APAC) is the leading region with the largest expected volume growth
- Estimated volume growth by product category in the period 2022-2028
  - HCL: +33% (+13.700 MT)
  - DC: +36% (+3.100 MT)





## Successfully transformed from sales via agents & distributors to direct sales to customer





## New sales volume from 3 main pilars

## 1. Existing customers

- Grow with existing customer demands
- Increase volume
   share from existing multi
   sourced customers to achieve
   preferred/primary supplier
   status via competitive pricing
   and satisfied customers

### "Switch market"

- Recruit new generic highvolume customers to fill available capacity and ensure capacity utilization
- Recruit new premium customers by adopting Vistin API as alternative source for supply security

## 3. New R&D pipeline market

 Early introduction as primary API source in new customer R&D pipeline products





The Fikkjebakke plant;

## **Operations** and strategy





## Continued increase in production volum

### 2010-2016, installed capacity @3000MT

- Full utilisation of capacity in 2015
- Development of Creep 1 project during 2016

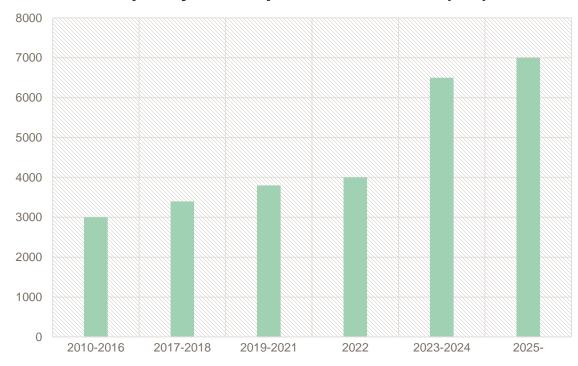
#### 2017-2018, Creep 1 project

 Process stabilisation and Debottlenecking of existing process

#### 2019-2021, Creep 2 project incl 2nd Reactor

Further debottlenecking and installation of 2nd Reactor

### Capacity development 2010-2025 (MT)





## Continued increase in production volum

#### 2022, MEP installation, Q1&Q2

Utilisation of new line excl. solvent recovery part

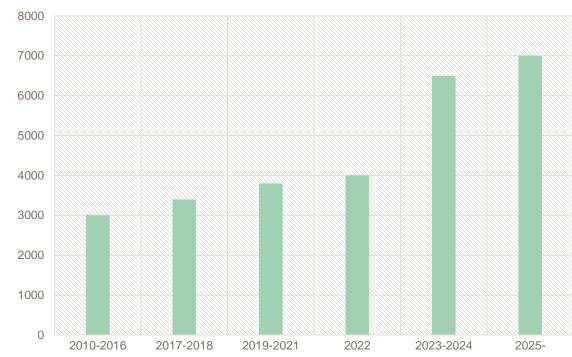
#### 2023, Ramp up solvent recovery

· New equipment and debottlenecking

#### 2024-2025, Full effect from MEP

 Ramp up of production in accordance with sales volume

### Capacity development 2010-2025 (MT)





## Production facility, -"beyond" state of the art

### Competitive edge by:

- Fully automated process. Cost effective, accuracy in operations
- Use of non-hazardous solvents. Butanol, not Xylene/Tolouen, etc
- One step synthesis. Cost effective, low loss high yield
- Inhouse designed filtering unit. Particle contamination of raw materials removed
- Real time online analyzers (PAT) to be installed in 2023
  - Integrations with process control system. Global frontrunner and first in Norway
  - Prepared for Industry 4.0 / 5.0 & AI
- R&D lab installed in 2023 for process and product development
- Two parallel production lines to reduce risk of product shortage



Vistin has high focus on reducing local and global emissions, and programs are in place to consume responsibly and recycle where possible





## Sustainable Operations, HSE and ESG

- · Zero impact on surrounding environment and safe workplace
- Double production volume without increased impact on environment
- Invested more than EUR 4 mill in sustainable initiatives, 2020-2023
- Reduced emissions to air by 90%
- Recycle cooling water project in 2023 to reduce consumption by ~90%
- Cooling water project provides energy available for Kragerø Industrial area
- Close cooperation with waste treatment receivers to optimize waste to raw materials
- Biannual effluent surveillance of Kragerø fjords since 2017. 2022 report concludes, no trace of Vistin in fjords of Kragerø
- Target to reach United Nations sustainability vision of zero emission when planning for the future



## Vistin Pharma