Orion Diagnostica

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Forward-looking statements

This presentation contains forward-looking statements which involve risks and uncertainty factors. These statements are not based on historical facts but relate to the Company’s future activities and performance. They include statements about future strategies and anticipated benefits of these strategies.

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Orion Diagnostica – Building Well-being
The In Vitro Diagnostics (IVD) market is changing - Openings for growth potential

Sources:

IVD market

- Shortage of skilled laboratory personnel
- Aging population
- Increase of chronic diseases
- Increased patient awareness
- Focus towards personalised medicine
- Guidelines
- Cost pressure on healthcare system
- Health economics
- Industry & provider consolidation
- Technological advances
Characteristics of diagnostics business
Time, cost and risk level

Diagnostics compared with Pharmaceutical business

- **Shorter time**
  - typical time to market 2-5 yrs

- **Lower cost**
  - 0.1-10 mEur

- **Lower technical risk**
  - not 0/1, can be managed

- **Different type of market risk**
  - influenced mainly by changes in business environment – can be managed by strong intellectual property (IP) and/or by complex technical solutions

Leveraging the assets

**Pharma**
- Proprietary NCE
  - Rx products
  - OTC products
  - Animal Health products

**Diagnostics**
- Solution = diagnostic test, reader and/or instrument and service
  - Central laboratories
  - Point-of-Care
  - Etc.
Global IVD market is expected to grow 5% annually

- An estimated USD 50 billion market. Expected to exceed USD 64 billion in 2016. Annual growth in developed countries ~5%.¹

- Europe, North America and Japan about 75% of the total IVD market.¹

- BRIC countries (Brazil, Russia, India, China) are expected to grow at a 12% rate.¹

- Molecular testing forecasted to grow 7-11% annually.¹,²

- POC testing expected to see continued growth at an annual rate of 4 -7%.¹,²

Sources:
Point-of-Care market is broad & fragmented - and growing

Total POC testing market
- 2011: USD 15.300 million
- 2016: USD 18.400 million
- CAGR: 4%

OTC/Self testing market
- 2011: USD 9.624 million
- 2016: USD 11.616 million
- CAGR: +4%

Professional POC market
- 2011: USD 5.660 million
- 2016: USD 6.765 million
- CAGR: +4%

Source:

OTC/Self testing market

- Sales by test category & percentage of market, CAGR
  - Glucose ($8,673, 90% CAGR 4%)
  - Pregnancy, ovulation ($685, 7% CAGR 1%)
  - Coagulation / PT ($60, 1% CAGR 5%)
  - Faecal occult blood ($115, 1% CAGR 7%)
  - Drugs of abuse ($35, 0.4% CAGR 3%)
  - H pylori ($5, 0.1% CAGR 4%)
  - HIV ($11, 0.1% CAGR 22%)
  - Cholesterol ($15, 0.2% CAGR 0%)
  - Other ($25, 0.3% CAGR 4%)

Professional POC market

- Sales by test category & percentage of market, CAGR
  - Glucose ($1,530, 27% CAGR 1%)
  - Critical care ($725, 13% CAGR 4%)
  - Pregnancy ($130, 2% CAGR 1%)
  - Infectious disease ($810, 14% CAGR 3%)
  - Cardiac markers ($500, 9% CAGR 5%)
  - Cholesterol / Lipids ($275, 5% CAGR 5%)
  - Coagulation / PT, ACT ($400, 7% CAGR 2%)
  - HbA1c ($150, 3% CAGR 15%)
  - Haematology ($430, 8% CAGR 3%)
  - Faecal occult blood ($295, 5% CAGR 9%)
  - Drugs of abuse ($265, 5% CAGR 0%)
  - Bilirubin ($30, 1% CAGR 6%)
  - Other ($120, 2% CAGR 5%)
Point-of-Care testing holds a lot of promise

- **POC testing**
  - shortens time between sample taking and analysis
  - speeds up diagnosis and treatment
  - improves clinical outcome
  - allows patients to be managed efficiently and more cost effectively

- **POC tests are used in**
  - primary care locations, remote settings with no laboratory infrastructure and by patients themselves for home-testing

- **Success of POC systems will rely on**
  - easy and error-free operation, portability, robustness, low cost, miniaturisation, small sample volume, simple sample preparation and improved sensitivity
  - POC instrument connectivity to electronic medical records for device control, management of patient and user data as well as test results
  - smartphones?

**Sources:**
Orion Diagnostica: Smart Solutions for Healthcare & Hygiene Monitoring

- Accurate and affordable clinical diagnostic and hygiene monitoring tests, which are easy to use and provide fast results.

- Focus on point-of-care diagnostic (POC) tools, which enable healthcare professionals to detect disease quicker, make evidence based diagnoses and treatment decisions and follow up treatment outcome.

- Close to 40 years’ experience in clinical diagnostics and hygiene monitoring businesses.

- Quality and regulatory requirements form the foundation of our activities. Full compliance with ISO 9001, ISO 13585 and FDA requirements.
Business areas

• **Point-of-Care**
  - **QuikRead®**
    Rapid tests to general practitioners, family doctors, paediatricians, healthcare centres, occupational healthcare, nursing homes, emergency departments

• **Small and mid-sized laboratories**
  - **High quality test kits and reagents**
    For clinical chemistry laboratories
  - **Orion GenRead®**
    Front line Nucleic Acid Tests (NAT = Molecular Diagnostics) for microbiology labs

• **Healthcare, industrial processes**
  - **Orion CleanCard® PRO**
  - **Dipslides**
    Novel and conventional tests for monitoring cleanliness and contamination
Point-of-Care Tests

The QuikRead® System

- For measuring C-reactive protein (CRP) from a small finger-stick blood sample
- Result in two minutes
- A CRP test performed during patient consultation helps clinicians to differentiate between bacterial and viral infections and target antibiotic treatment
- Includes also tests for Strep A, CRP+Hb, hsCRP+Hb, FOB (faecal occult blood) and U-ALB (urinary albumin)
- Over 30,000 QuikRead units in use globally
Orion GenRead®
Our newest platform for Molecular Diagnostics

• Built on SIBA®, a rapid and reliable isothermal nucleic acid amplification technology.

• Orion Diagnostica has all rights to this patented, proprietary technology.

• A flexible benchtop solution including a small instrument and ready to use kits.

• First-phase tests will target pathogens causing gastrointestinal disease. Future product portfolio will cover a wider range of pathogen tests.
Conventional PCR vs. Isothermal NAT

Some features

- Result in ~2 hours
- Requires skills & special facilities
- Complex & costly instrumentation
- High multiplexing capability

- Result in <one hour
- Easy-to-use, user-friendly format
- Simple & affordable instrumentation
- Multiplexing more complex
Hygiene Monitoring

Simple and practical tools for settings where surface cleanliness is crucial

• Healthcare settings:
  For effective infection control

• Food processing and food service:
  For ensuring a safe food chain

• Industrial enterprises:
  For checking microbial burden in various industrial fluids
Orion Diagnostica Network

Distributor

- In addition to own products, Orion Diagnostica sells products by well-established diagnostics manufacturers.
- Own sales units in Finland, Sweden, Norway, Denmark, Czech Republic, and Germany with an established customer base, local market insight and a motivated and professional sales team.

OEM partner

- With a close to 40 years’ experience in clinical diagnostics and hygiene monitoring businesses and a certified quality management system, Orion Diagnostica offers its expertise and top-quality solutions to companies interested in OEM cooperation.

Collaborator / Partner

- Orion Diagnostica collaborates with research groups and development partners to discover new ways to address customers’ needs for novel and rapid diagnostics.
THANK YOU!