



## **Boule Diagnostics AB**

Company presentation, Q4 report 2018

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Fredrik Dalborg, CEO and Group President  
Christina Rubenhag, CFO

# About Boule – a growth company specializing in near patient diagnostics

- Founded in 1996
- The company develops, manufactures and sells complete blood cell counting (CBC) systems
- Business model
  - Boule sells own-developed CBC systems in the global hematology market and earn the recurring revenue streams through the sale of reagents, controls, calibrators and service/support.
  - The instruments are designed and optimized for proprietary reagents, ensuring quality and accurate analysis results and recurring revenue over the life of the instruments.
  - The systems are used both for human and animal diagnostics.
- Business concept
  - Commercializing high-quality systems to the decentralized market for blood diagnostics.
  - Global sales by parallel distribution channels to quickly and effectively meet local demand.
  - Secure consumable supplies for own instruments to ensure system quality and integrity of business model.
  - Active acquisition and cooperation strategy to broaden the product offering.
- Listed on Nasdaq Stockholm since 2011



# The Boule offer – a growing portfolio



**Medonic**  
Human diagnostics  
3-part system



**Swelab**  
Human diagnostics  
3-part system



**Medonic**  
Human diagnostics  
5-part system



**Swelab**  
Human diagnostics  
5-part system



**Quintus**  
Human diagnostics  
5-part system



**Exigo H400**  
Veterinary hematology  
3 & 4 part system



**Exigo C200**  
Veterinary Chemistry  
System



Tied consumables for  
proprietary instruments



Consumables for  
OEM customers



Open consumables for other  
manufacture's open systems



Reagents



Blood controls and calibrators



Cleaning products



Reagents rotor



# Q4 2018 in summary

## HIGHLIGHTS Q4

### NET SALES

SEK 106.2 million

### YoY GROWTH

0.9%

### GROSS MARGIN

40.7%

### EBIT-MARGIN

3.2%

### CASH FLOW Q4

SEK 6.6 million

## High sales of instruments, gross margins impacted by region- & product mix

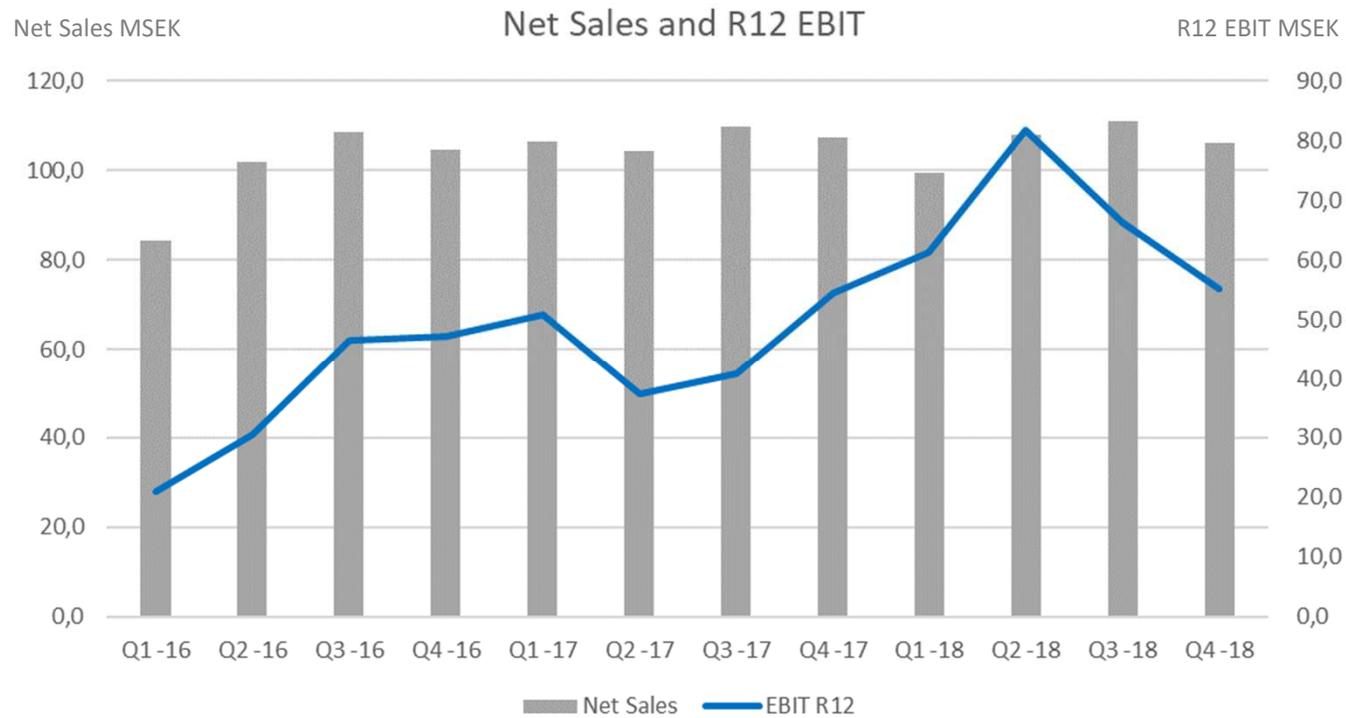
- Net sales was SEK 106.2 million with a growth of -0.9% compared to the fourth quarter in 2017. Adjusted for exchange rates the growth was -6.4%
- Instrument unit sales increased by 8% to 1 104 (1 024) and instrument revenues by 11%. Average selling prices increased due to increased veterinary and new 5-part system sales. Shipment of 250 instruments for the India tender were included in the quarter.
- Consumable sales for own instruments was flat, mainly explained by tender sales to Africa including a year of consumption in the fourth quarter 2017
- Gross margin was 40.7% (48.0%), impacted by region- and product mix as well as non-recurring cost of 4 MSEK
- The costs of R&D increased in line with the investments in the development of the next generation hematology system. The quarter also include costs related to the management of the FDA warning letter
- EBIT margin was 3.2% (13.9%). EBIT margin excluding capitalized R&D was -4.5% (9.3%).
- Cash flow from operating activities was SEK 6.6 million (24.1) as a result of low operating profit and increased inventory

## Key events during the quarter

- Warning letter received from FDA
- Investment in strategic near-patient diagnostic partnership with biosurfit
- A new five-part system was launched for the Swelab and Medonic brands



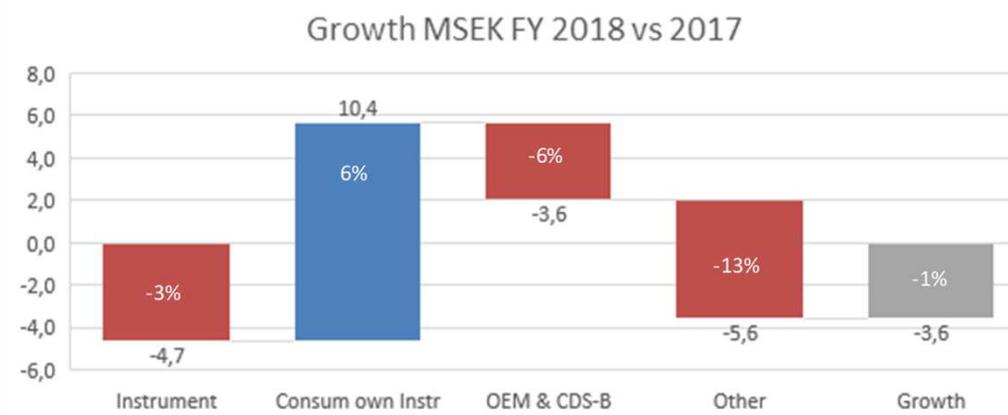
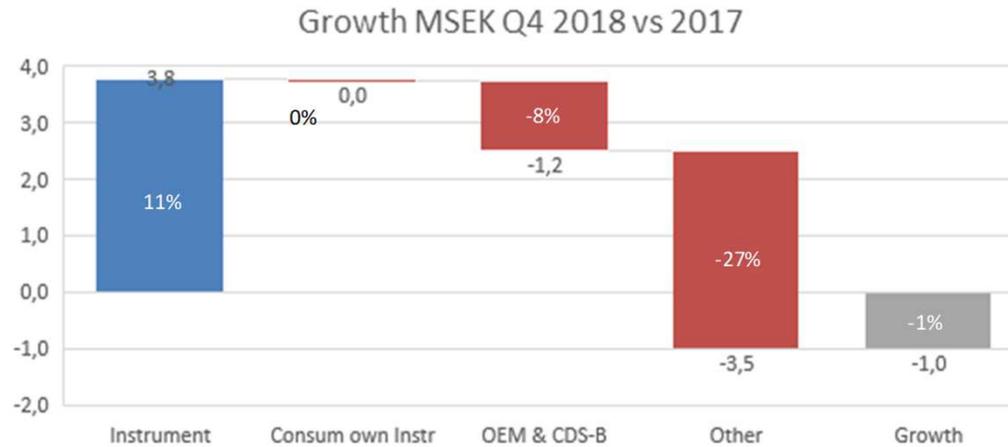
# Net Sales and EBIT R12 per quarter



- Revenue fluctuate between the quarters mainly due to tenders and region specific events
- Profitability trend impacted by low gross margins in Q3 and Q4 due to low ASP deliveries towards the large tender in India and by non-recurring costs in Q4

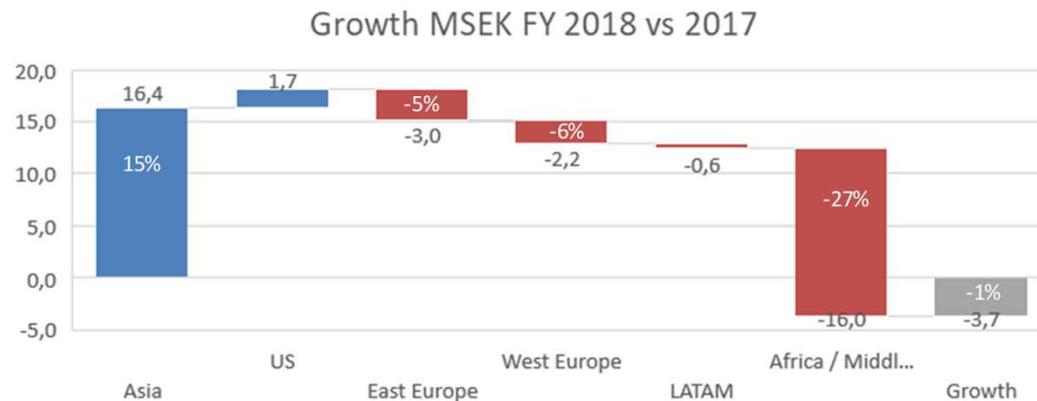
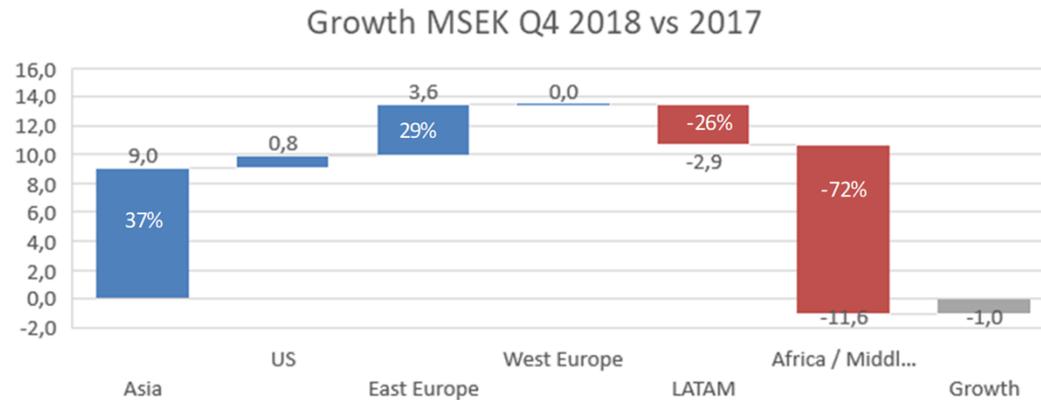


# Growth by Product Line



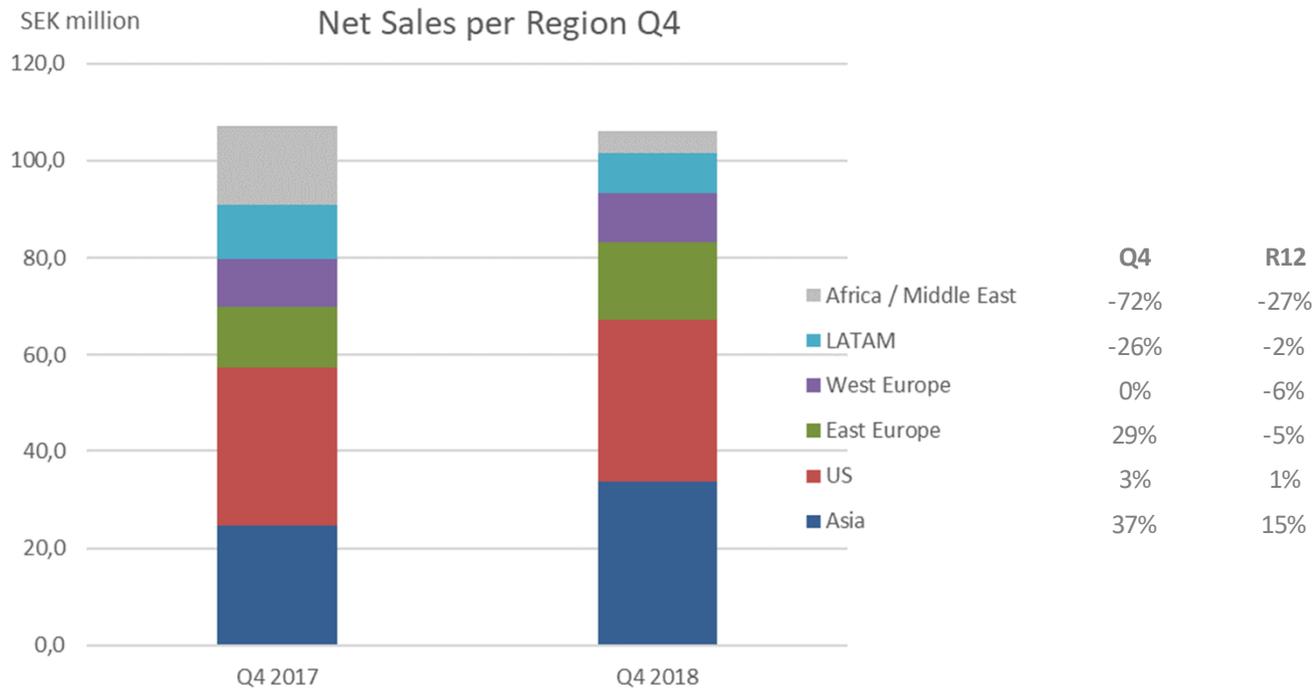
- Strong instrument growth in Q4, driven by Asia and mainly India. Instrument sales decline for full year due to limited 5-part offering. 3-part instruments increased
- Consumables own instruments was flat in Q4, mainly due to tender sales to Africa including a year of consumption in the fourth quarter 2017
- CDS Brand is declining as a result of fewer open systems in the market
- Other revenues include Service, spare parts, external products and revenue corresponding to agent commission for direct tender sales in Africa

# Growth by Region



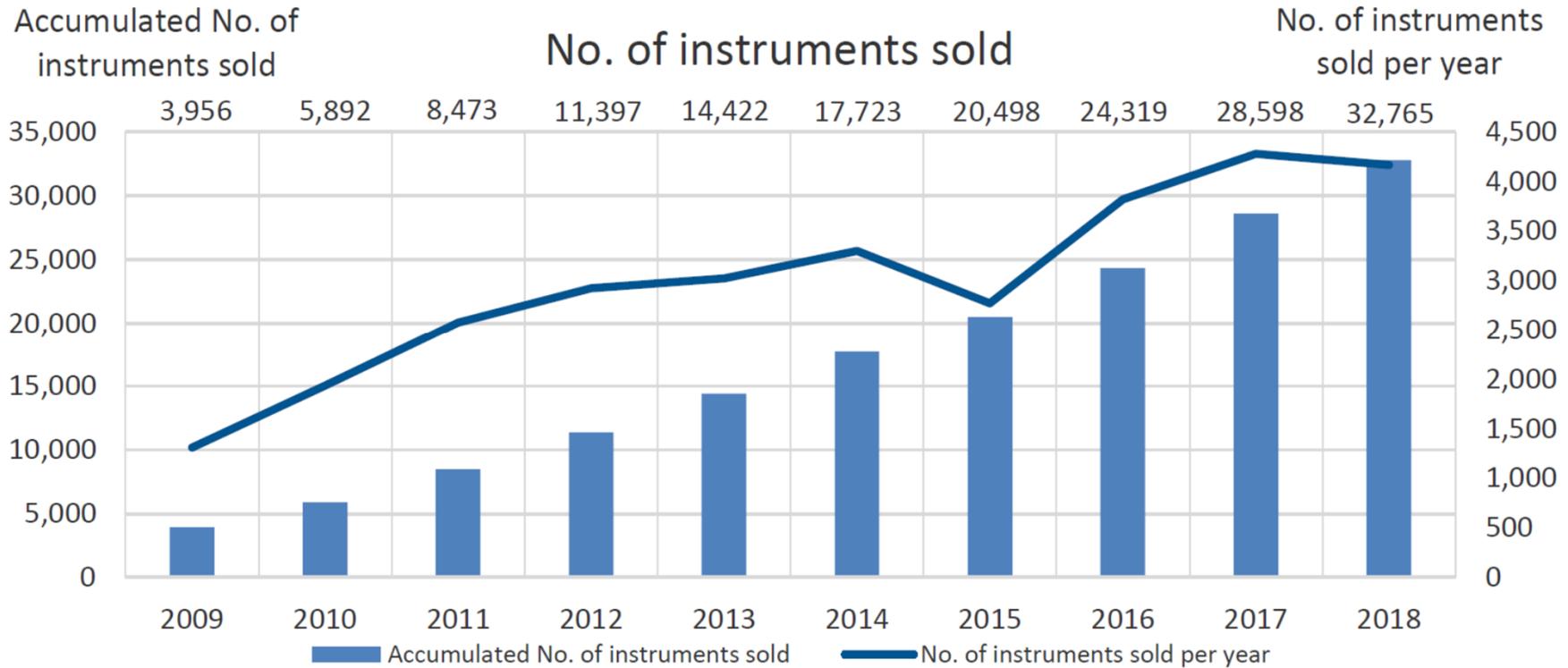
- Strong instrument growth in Asia in Q4, driven by instrument sales. Year to date growth in both consumables and instruments
- Growth in US was 3% in Q4 and 1% year to date, impacted negative by CDS Brand and OEM. Year to date sales of Boule systems (own instruments and own consumables) increased with 10% in fixed currencies
- Africa / Middle East was -72% in Q4 and -27% year to date, explained by tender sales last year (including a year of reagent consumption) not repeated this year

# Overview of sales by region

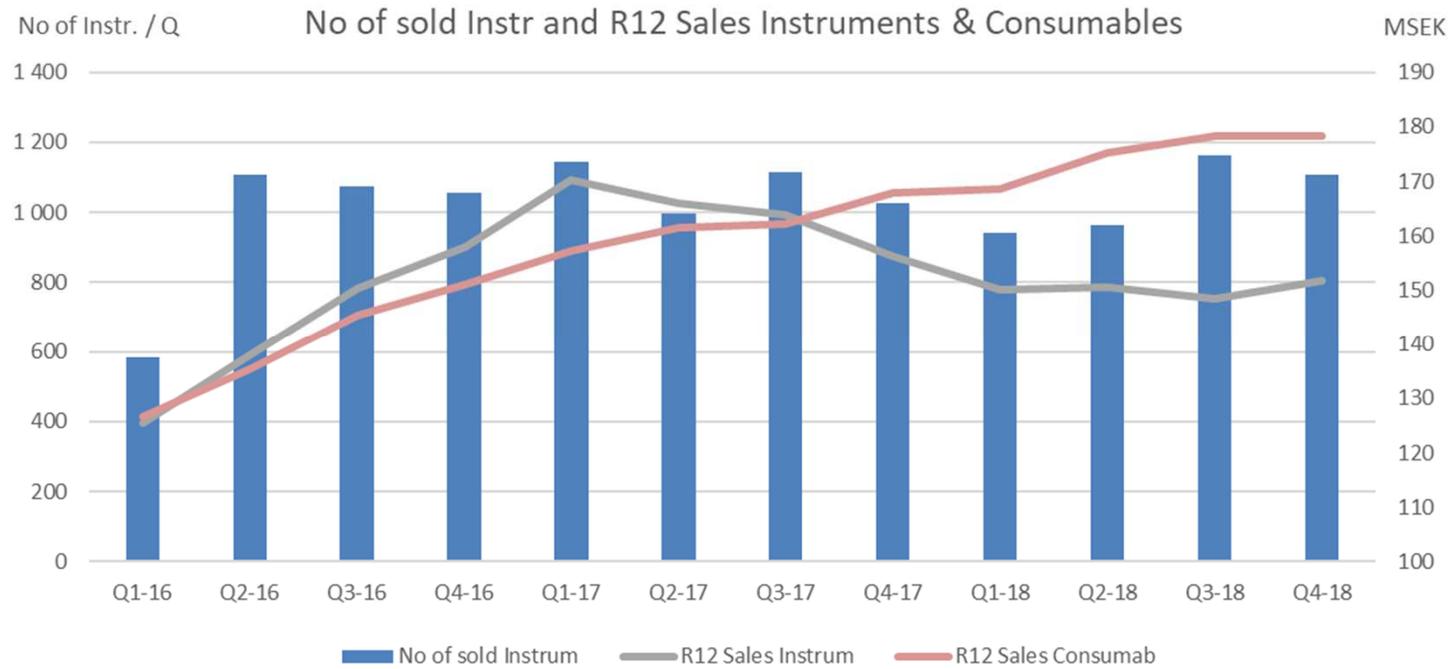


- Asia growing in importance
- US still largest market (full year) negatively impacted by OEM and CDS. Boule systems growth in US 11% (10% fixed currencies)
- Investing in regional resource LATAM, Eastern Europe, Western Europe

# Number of instruments sold 2008 – 2018



# Number of instruments sold and revenue trend



# Delivering on the major tender in India



## India is an important market

- India is the largest market in Asia for Boule
- Boule has No 2 market position in the decentralized segment
- Indian Hematology market growing 18-20%
- Government ambition to extend insurance coverage and healthcare access to underprivileged and in smaller cities and rural areas

## Major tender secured

- 400 instruments delivered in Q3 and 250 instruments delivered in Q4
- Due to general price conditions in India, and the size of the tender the selling price per instrument is relatively low
- Reagent sales per instrument is expected to be above the average in the Indian market
- The tender may also lead to sales of additional of instruments



# Warning Letter from the US FDA (Food and Drug Administration)

## Sequence of events

- The US FDA conducted a routine inspection at the Boule instrument manufacturing site in Sweden in May 2018
- Boule received inspectional observations from the FDA after the inspection, Boule responded to the observations with an action plan and started implementing improvements
- On October 5<sup>th</sup> Boule received a Warning Letter, and a press release was issued
- Boule has responded within the stipulated 15 working days, providing evidence of implementation, and a plan with a time line for further actions and improvements, etc.
- The work is proceeding according to plan, most of the process improvements have been implemented and Boule submits data and reports to the FDA monthly.
- In January, a comprehensive report was submitted, which among other things included a retrospective analysis requested by the FDA.
- Boule has also established a dialogue with the FDA regarding the reporting process.
- The reporting in accordance with Boule's action plan is expected to be completed during the third quarter of 2019.

## Context

- Boule Diagnostics takes compliance with regulations very seriously, and this matter has the highest priority in the company
- Quality is key for Boule Diagnostics
  - Crucial for patient
  - A key value that the customers expect from Boule
  - Quality and compliance are part of strategies and values
- Boule Diagnostics has invested in quality and compliance resources in the past 18 months
  - Debbie Herrera promoted to SVP Quality & Regulatory, joined the Executive Team June 1 2017 (joined Boule early 2017)
  - Strengthening QA/Reg team, manufacturing team and service team
  - Engaged external consultants to review ISO and quality procedures
- Boule Diagnostics will continue to dedicate required resource to this matter, and intends to fully cooperate with the FDA to resolve the issues and to fully comply with all relevant FDA regulation
- The warning letter does not cause limitations on production or sale of products



# Boule Diagnostics strategies



# Boule Diagnostics strategies: Key actions in 2018



**Protect and grow our core business:**  
Continued efficiency improvements and capacity expansion, quality and regulatory compliance, developing and launching next generation product platforms.

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- Significant strengthening of quality resources and processes
  - Cost reduction actions, investment in automation for productivity
  - Capacity expansion and process improvements in controls manufacturing
  - Building R&D capability, investment in laser technology for 5-part development
  - Product launches in veterinary market

# Boule Diagnostics strategies: Key actions in 2018

## Grow in emerging markets:

Evolving distributor relationships and strengthening local presence.

- LATAM sales and service team strengthened
- Created Russian legal entity and local team
- Strengthening relationships with US distributors
- Preparing increased local manufacturing reagents

## Grow in new customer segments and markets:

Resource, sales approaches and partnerships to enter new customer segments and geographical markets.

- Key account market initiative in the US
- Assessment of pharmacy market
- African market study conducted

## Evolve OEM and CDS brand business:

Selective initiatives in profitable growth segments.

- Negotiations with new OEM accounts
- Price and contract term review with OEM customers
- Controls manufacturing capacity increase and cost reduction

## Broaden the product portfolio:

Develop new product platforms and broaden the product portfolio through partnerships and acquisitions.

- Driving 5 part development, laser module acquisition to de-risk and speed up process
- Added entry level 5 part platform, launched in Nov
- Two product launches in Veterinary (H400 and C200)
- Partnership with biosurfit



# Biosurfit spinit<sup>®</sup> : Unique multi test platform for near patient use



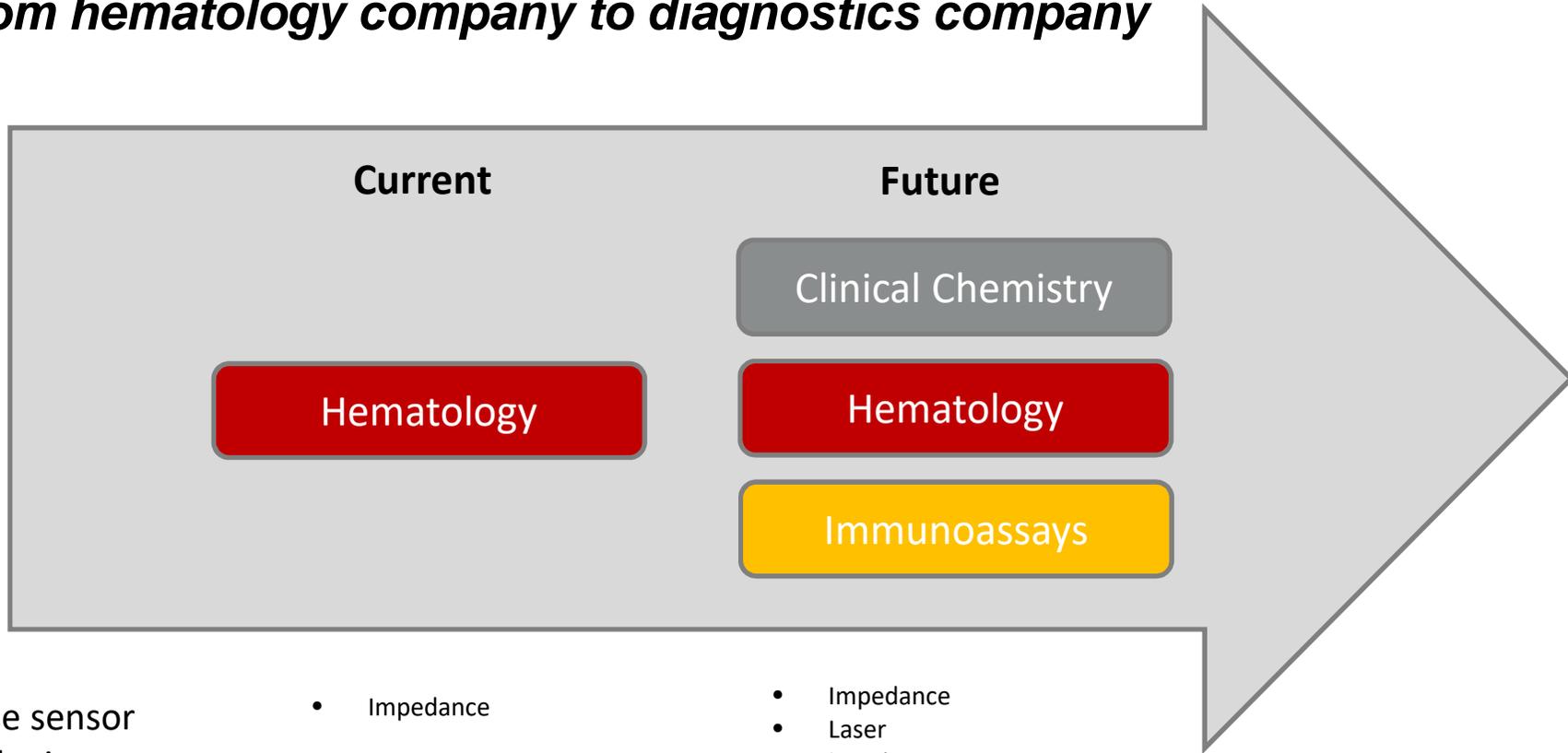
- **Small footprint**
- **User-friendly operation**
- **Reliable results in minutes - short test time**
- **Lab quality precision**
- **All reagents on discs**

- Multi test platform spinit<sup>®</sup> for near patient use: hematology, clinical chemistry and immunoassays
- Designed for ease of use, finger stick sample
- Current CE marked applications: CRP (infection), Blood Count (5part), HbA1c (diabetes).
- Multiple planned additional applications: Lipids (heart disease), D-dimer (blood clotting), etc.
- Highly innovative technology: 31 patent families
- Early stage commercial phase, 700 instruments sold to date in Europe
- Main competitors are multi test platforms such as Eurolyser and Abbott Afinion. The spinit<sup>®</sup> combination of applications is unique, being the only instrument with a hematology application (Blood Count)



# The partnership creates broader potential and adds leading sensor technologies

*From hematology company to diagnostics company*



In house sensor technologies:

- Impedance

- Impedance
- Laser
- Imaging
- Surface Plasmon Resonance
- Spectrophotometry

# Significant additions to the Boule product portfolio

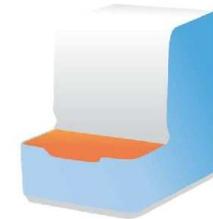
## Adding entry level 5 part system to the portfolio

- Strengthens portfolio, logical addition to current products
- Expected to create additional growth and also drive growth for current portfolio (combined tenders, strengthening commercial channel)
- Launch in November 2018, limited release (sales start) December 2018



## Providing new advanced hematology technology to the decentralized segment

- Advanced imaging technology through collaboration with CellaVision (launch of DC 1 imaging system for decentralized lab)



## Strengthening vet portfolio

- New 4 part hematology platform
- Clinical chemistry for veterinary market



## Adding new adjacent diagnostic tests for the near patient, (point of care) market

- Distributing point of care CRP testing in US and LATAM
- Spinit<sup>®</sup>: Hematology, clinical chemistry, immunoassays



# Strategies and high level priorities for 2019



**Protect and grow our core business:**  
Continued efficiency improvements and capacity expansion, quality and regulatory compliance, developing and launching next generation product platforms.

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- Further improve quality processes, address FDA warning letter
  - Develop next generation hematology platform
  - Cost efficiency and cash flow improvement
  - Get closer to end customers through strengthening service and marketing offering

# Strategies and high level priorities for 2019

## Grow in emerging markets:

Evolving distributor relationships and strengthening local presence.

- Evolve distributor network and strengthen local presence in key markets

## Grow in new customer segments and markets:

Resource, sales approaches and partnerships to enter new customer segments and geographical markets.

- Leverage broader product portfolio to enter new markets and segments

## Evolve OEM and CDS brand business:

Selective initiatives in profitable growth segments.

- Review and improve OEM and CDS business (controls in particular) with focus on improved profitability

## Broaden the product portfolio:

Develop new product platforms and broaden the product portfolio through partnerships and acquisitions.

- Ensure successful development, commercialization and support of new products (Swelab Lumi / Medonic M51, DC1, Spinit)

# Key revenue and margin drivers in 2019

Driver	Revenue growth impact	Gross margin % impact	Comment
Veterinary market			<ul style="list-style-type: none"> <li>• Growth potential</li> <li>• Good margins</li> </ul>
Distributed products			<ul style="list-style-type: none"> <li>• Strengthening portfolio and distributor network</li> <li>• Driving core product growth too (combined tenders, etc.)</li> </ul>
Developing distributor network, strengthening local presence			<ul style="list-style-type: none"> <li>• Access to new markets</li> <li>• Increased value selling</li> <li>• Better support for distributors and end customers</li> </ul>
Increased importance of emerging markets			<ul style="list-style-type: none"> <li>• Lower instrument prices in some markets (India)</li> <li>• Lower reagent consumption at early stage and in some markets</li> </ul>
Cost reduction efforts, including regional manufacturing			<ul style="list-style-type: none"> <li>• Process efficiency improvements</li> <li>• Redesign for cost reduction</li> <li>• Strengthening competitive position, reducing logistics cost</li> </ul>

# Future challenges and opportunities for Boule Diagnostics

## Challenges

- Fragmented, competitive market
- Some fast growing markets (India in particular) have low price levels
- Important to deliver relevant product development to market in a timely manner
- Volatility caused by tenders and market specific variations
  - quarter to quarter revenue variability
  - Instrument sales increase revenue but reduce gross margin
- Volatility caused by currency fluctuations
- Higher regulatory compliance requirements

## Opportunities

- Veterinary market
- Improvements in manufacturing efficiency and structure
- Leverage broader product portfolio to increase growth
- More regional/local presence to improve customer experience (service, product specialists, etc.)
- Launching new products based on our reliable technologies
- Continued growth in emerging markets
- In developed markets focus on near-patient care to reduce healthcare cost and improve patient convenience
- Higher regulatory compliance requirements

**Thank you!**