

Hematology
is in our blood



Boule Diagnostics AB
Carnegie Healthcare Seminar
March 5, 2019

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About Boule – a 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.
- 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

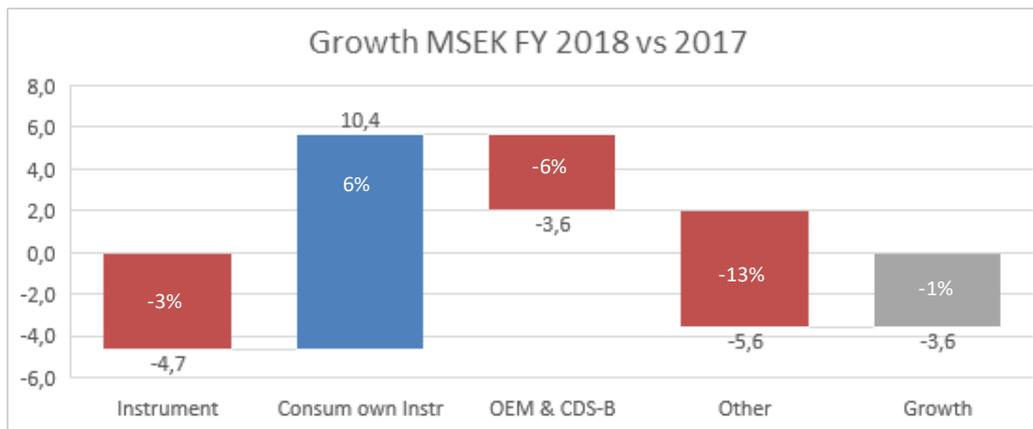
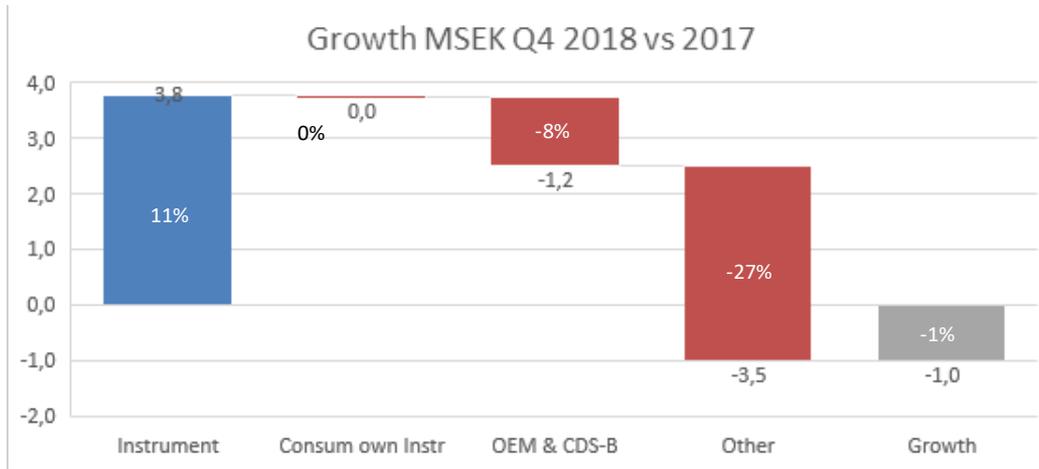


Cleaning products



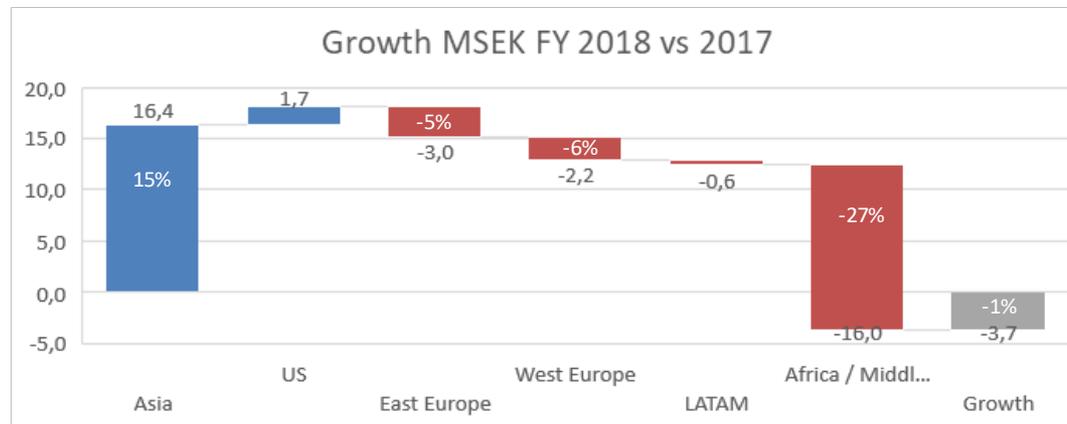
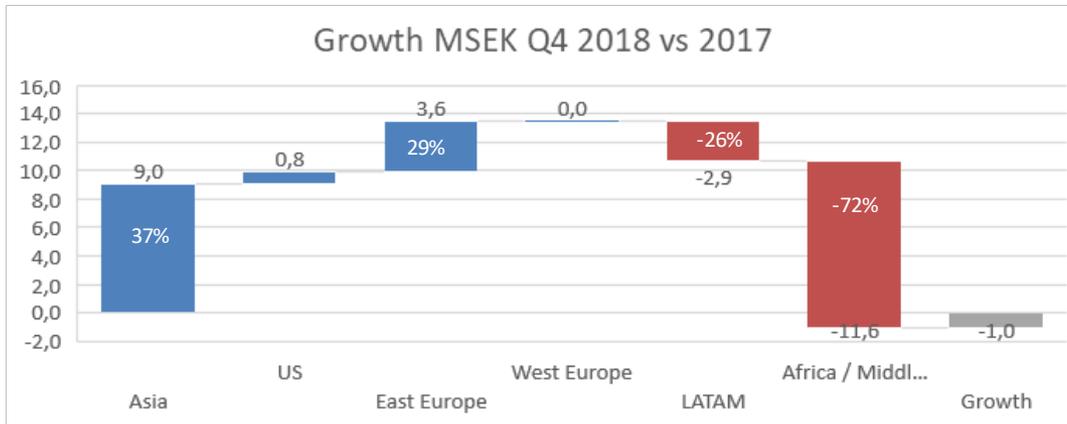
Reagents rotor

2018 revenue development 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

2018 revenue development 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

Delivering on the major tender in India



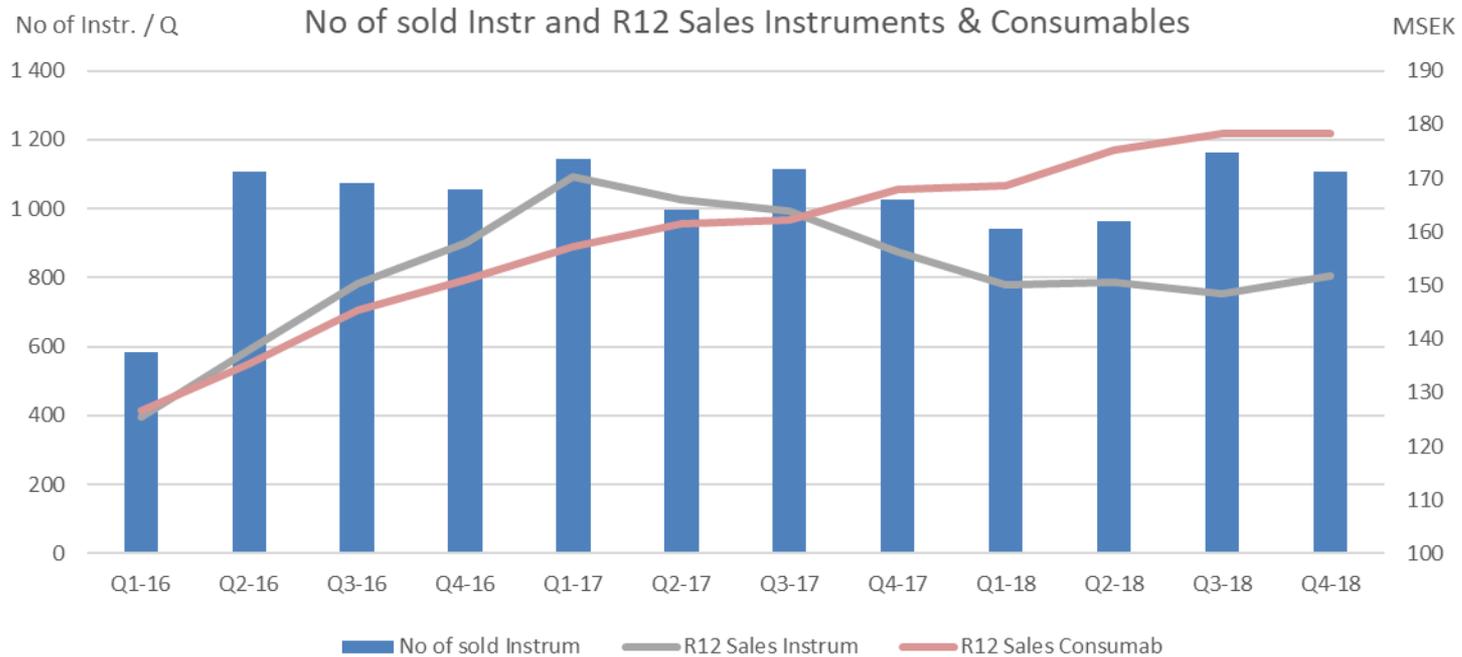
India is an important market

- 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

Number of instruments sold and revenue trend



Instrument and consumables sales dynamics

- Instrument lifetime is approximately 8-10 years
- Distributors place or sell instruments, Boule does not control individual instrument location in many regions
- Boule instruments are designed for exclusive use of Boule consumables. Boule reagents identified with bar code or RFID
- Global average consumables sale per instrument is approximately SEK 6 500 and has been fairly stable of the past few years
- Consumable sales per instrument varies by region due to size of labs/clinics targeted, use of controls, etc,

Region	Consumables sales per instrument	Trend in consumables sales per instrument
US	High	Flat (slight decline) ¹
Asia	Low	Increasing ²
LATAM	Medium	Flat ²
Eastern Europe	High	Flat
Western Europe	Medium	Flat
Africa/Middle East	Medium	Increasing (long term trend) ²

1) Replacing older Boule instruments, targeting new segments with lower volumes, etc.

2) Reagent sales short term trend highly dependent on tenders

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

Sequence of events

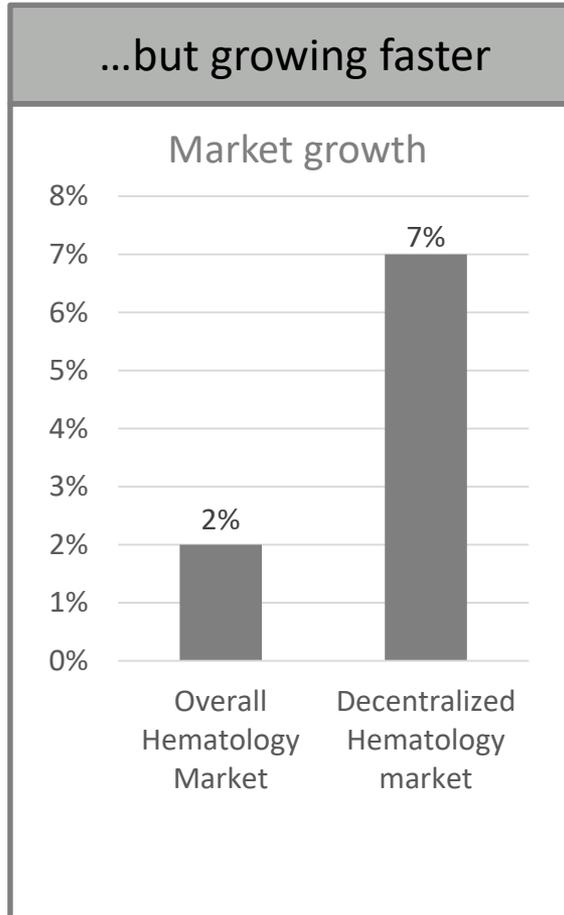
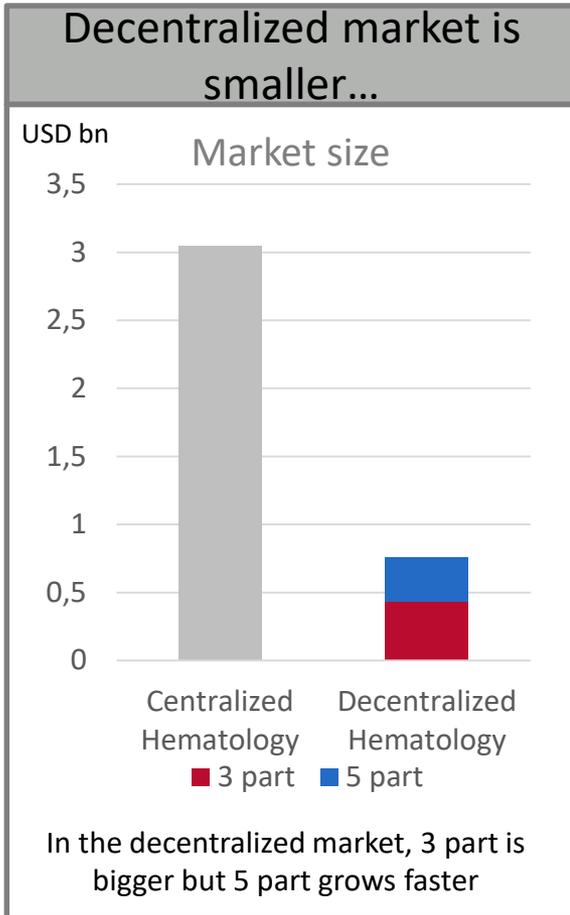
- The US FDA conducted a routine inspection at the Boule instrument manufacturing site in Sweden in May 2018
- Boule received inspectional observations from the FDA after the inspection, Boule responded to the observations with an action plan and started implementing improvements
- On October 5th Boule 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 additional quality and compliance resources since 2017
 - 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 is active in an attractive market segment

Decentralized, near patient market



- ...driven by fundamental factors**
- Large market potential: >100,000 small and mediums sized labs globally
 - Aging population globally: increasing demand for diagnostics and health care
 - Increased access to healthcare in emerging markets
 - Emphasis on smaller cities and rural areas
 - Near patient diagnostics is attractive to patients and healthcare systems
 - Cost efficiency and patient convenience

Source: Kalorama IVD 2016, Boule data

Boule Diagnostics strategies

Protect and grow our core business:

Continued efficiency improvements and capacity expansion, quality and regulatory compliance, developing and launching next generation product platforms.

Grow in emerging markets:

Evolving distributor relationships and strengthening local presence.

Grow in new customer segments and markets:

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

Evolve OEM and CDS brand business:

Selective initiatives in profitable growth segments.

Broaden the product portfolio:

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

Biosurfit spinit[®] : 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[®] 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[®] combination of applications is unique, being the only instrument with a hematology application (Blood Count)

Significant additions to the Boule product portfolio

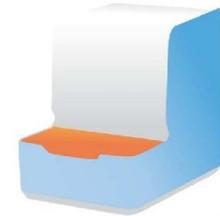
Adding entry level 5 part system to the portfolio

- 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[®]: Hematology, clinical chemistry, immunoassays



Overview of R&D projects in 2018

New veterinary platform Exigo H400

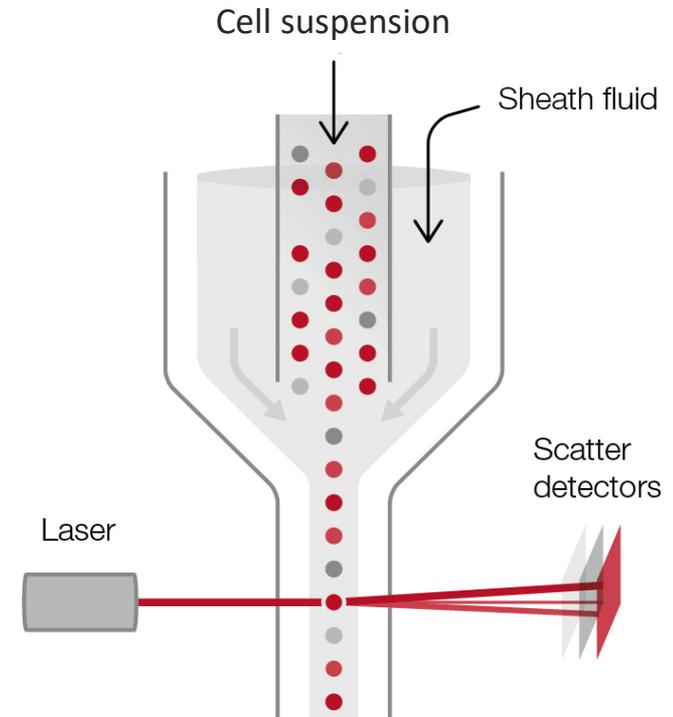
- 19 parameters including 4-part WBC diff (LYM, MONO, NEUT, EOS)
- 12 pre-installed species profiles
- Launched in Q2 2018

New 5 part system platform development

- Full blown development project started Q3 2017, resources gradually added during 2018
- Modular 5 part system with additional parameters and higher throughput
- Acquired laser optics technology, evolved further with internal development, new laser module design established and being tested
- Developing advanced cell detection and classification algorithms, using AI approaches
- Developing new and advanced IT connectivity approaches

Continuous product improvement, quality and cost reduction

- Completed software updates as well as new electronics module development
- Preparing system upgrades for 2019
- Supporting business development technology evaluation
- Working on multiple component redesign projects to reduce cost and increase efficiency



Key revenue and margin drivers in 2019

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

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

Financial targets

Financial targets:

- Annual operating margin (EBIT-margin) above 15 percent.
- Average long term growth in sales above 10 percent per year.
- Net debt (interest bearing debts minus cash and cash equivalents) no greater than three times operating profit (EBIT) on an annualized basis.

Dividend policy:

- The annual dividend should correspond to 25-50 percent of profit for the period, after taking due consideration to company liquidity.

Thank you!