



Hematology  
is in our blood



## **Boule Diagnostics AB**

Company overview and Q3 presentation  
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# Boule Diagnostics - a growth company specializing in near patient diagnostics

- Develops, manufactures, and markets complete blood count (CBC) analyzers for both human and veterinary markets, keeping quality in focus.
- Focus on the fast growing, near patient diagnostics segment.
- Strong heritage in hematology diagnostics, with the development of the very first automated European blood cell counter 1956.
- Products are manufactured and distributed from our production facilities in Sweden and in USA, and are currently available in more than 100 countries.
- One provider of instruments, reagents, blood controls, and calibrators, ensuring reliability and quality as well as a recurring revenue stream from consumables.



Courageous



Customer oriented



Innovative



Quality



Result oriented



Teamwork

# Boule Diagnostics – global presence

*Improving health for everyone, everywhere*



Through a network of more than 200 distributors, Boule products are available in more than 100 countries

# Boule Diagnostics – product portfolio 2019

*Significant additions in the past 12 months*

## Human diagnostics



Medonic

CBC 3-part differential



Swelab

CBC 3-part differential

## Human diagnostics



Medonic

CBC 5-part differential



Swelab

CBC 5-part differential



Quintus

CBC 5-part differential

## Veterinary diagnostics



exigo C200

Clinical chemistry



exigo H400

CBC 4-part differential

## POC Multi test



spinit®

## Digital cell imaging



CELLAVISION



Product added in past 12 months

# Q3 2019 in summary

## *Continued strong growth and significantly improved margins*

### HIGHLIGHTS Q3

#### NET SALES

SEK 131.2 million

#### YoY GROWTH

18.3%

#### GROSS MARGIN

47.5%

#### EBIT-MARGIN

24.6%

#### CASH FLOW Q3

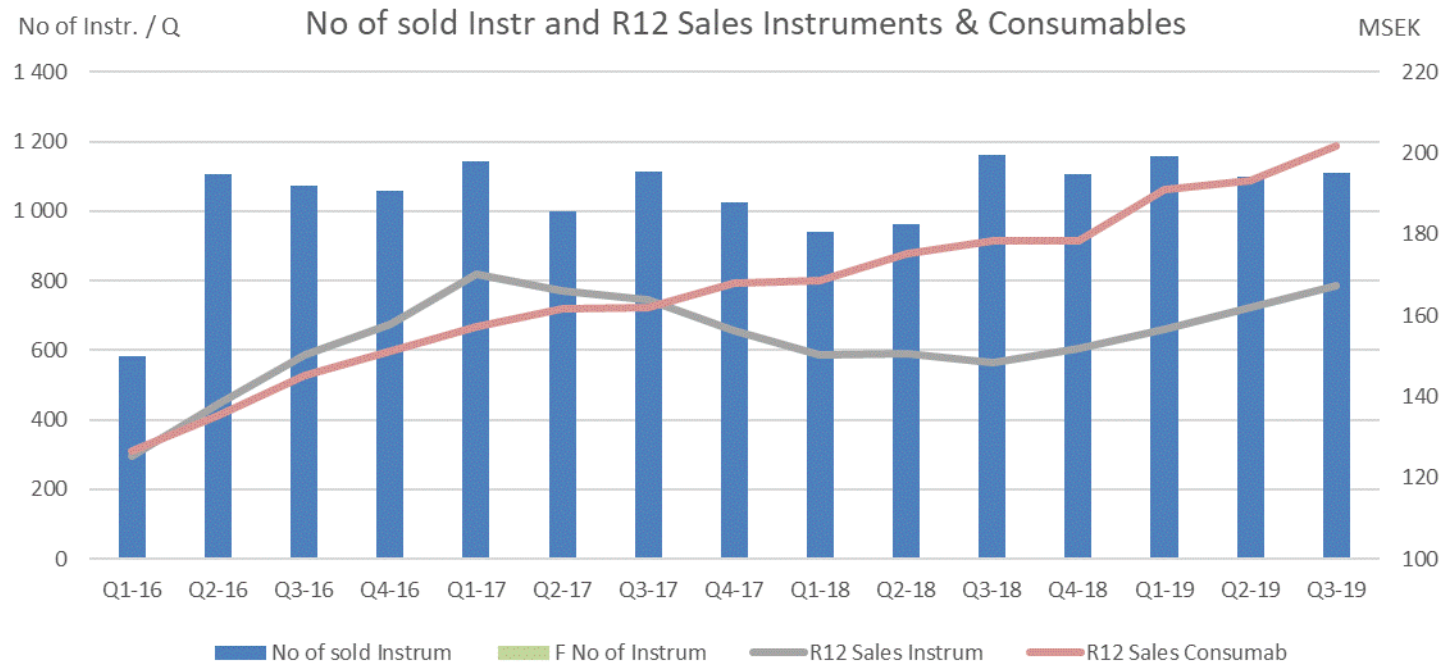
SEK 23.9 million

### The growth initiatives continue to yield results

- Net sales was SEK 131.2 million, another quarter of record level sales. This corresponds to a growth of 18.3% compared to the third quarter in 2018. Adjusted for exchange rates the growth was 13.4%
- Instrument unit sales decreased by 4.6% to 1 108 (1 161), but instrument revenues increased by 14% due to higher ASPs. Instrument revenues were positively impacted by product and regional mix
- Consumable sales for own instruments increased by 18% and growth R12 was 13%
- The strong growth is a result of the strategic initiatives taken in 2017 and 2018, which include a broadened product portfolio in the human and veterinary areas, strengthened sales and marketing resources and the work to improve and develop the distributor structure
- Gross margin was 47.5% (42.7%), as a result of strong sales of consumables, positive sales development in countries with good margins and the increased efficiency of the distributor network
- Operating expenses were SEK 33.8 million, in line with previous year (33.7)
- EBIT margin improved to 24.6% (11.5%)
- Cash flow from operating activities was SEK 23.9 million (-0.6), impacted positively by the operating profit



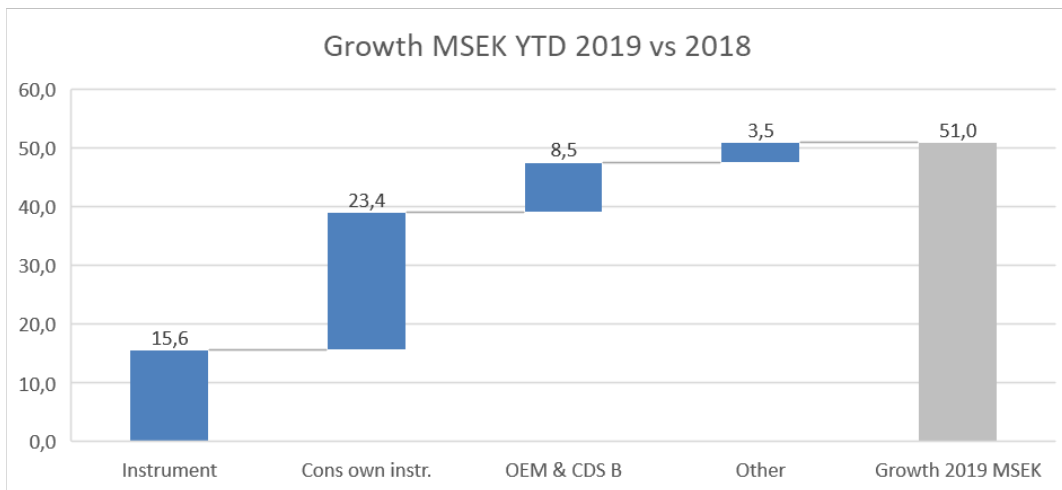
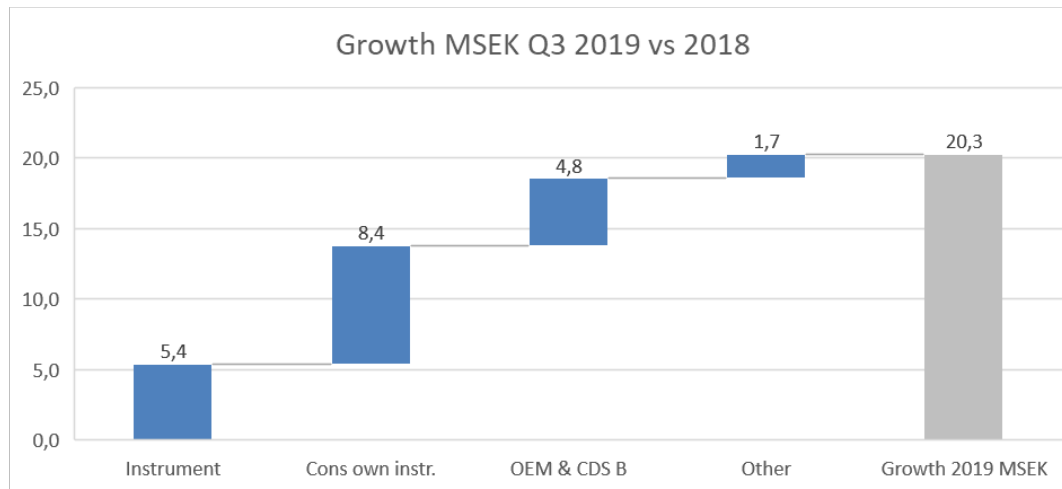
# Instruments and consumables in a positive trend



- Individual quarters can be affected by one time events like major tenders, but in the third quarter the growth was not driven by any such event
- The growth is mainly due to previous strategic initiatives as well as a favorable product and geographical mix
- Growth R12 was 11.9%, and YTD 16.2%, ie above growth target of 10% on an annual basis.

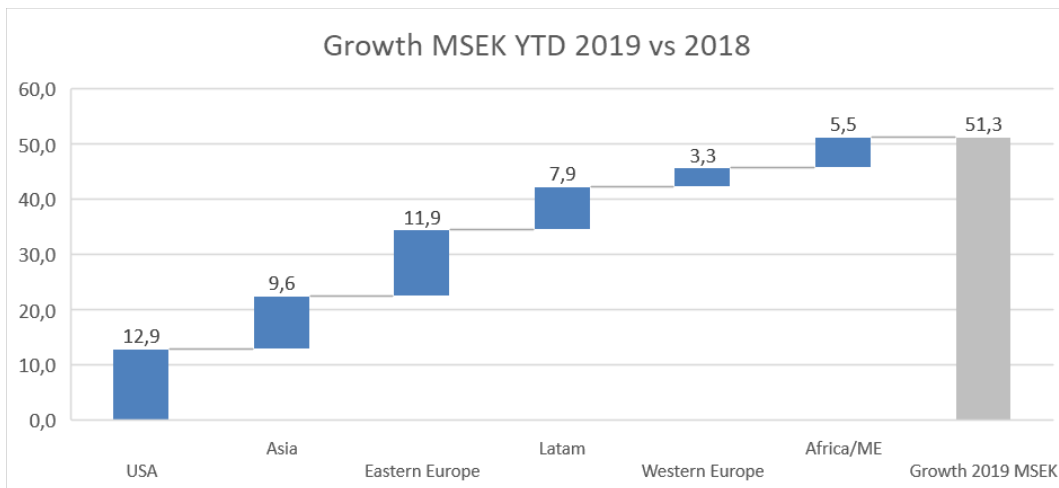
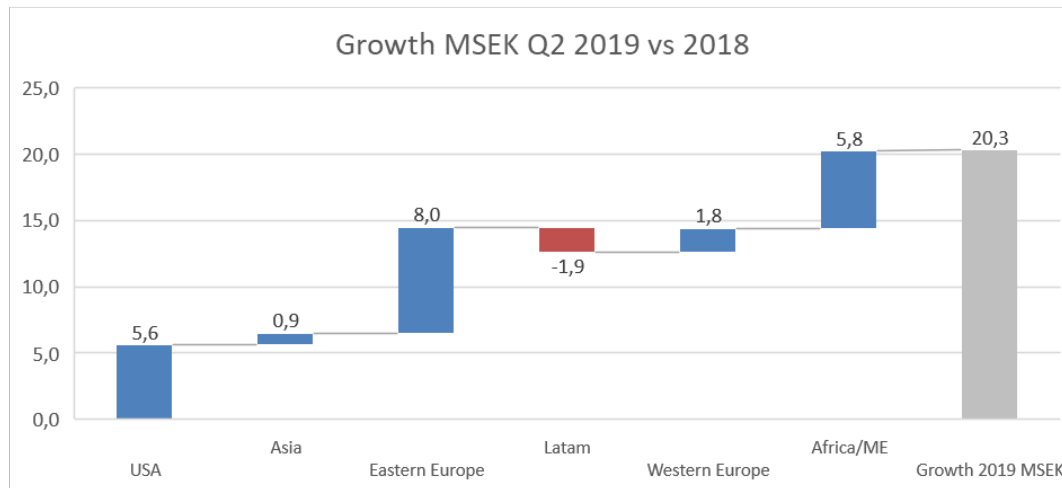
Note: R12 = Rolling 12 months

# Growth in all product categories



- Strong instrument growth in Q3, driven by East Europe and Middle East. Significant part of the growth relates to the recently launched 5 part instruments
- Sales of veterinary products continued to develop in a favorable way, both on established markets as well as on new markets via new distributors.
- Growth in consumables for own instruments was 18% in Q3 and 17% year to date.
- OEM and CDS Brand growth was 31% in the third quarter thanks to the OEM business developing in a positive way.

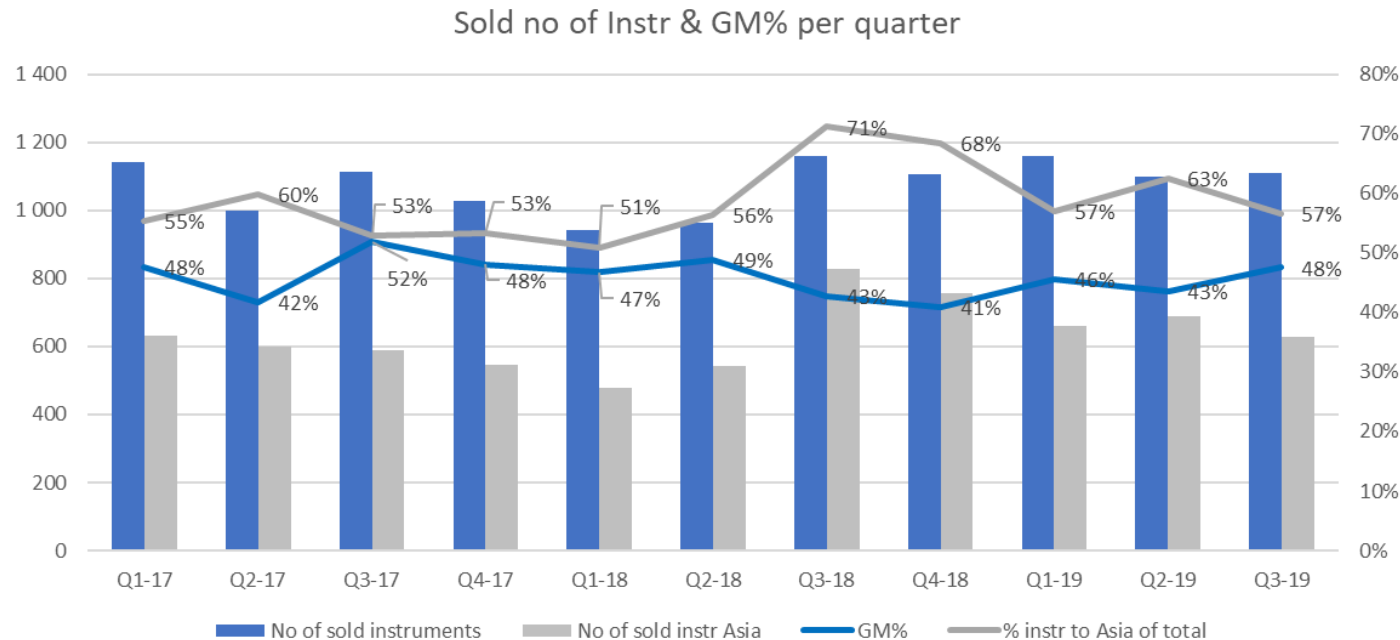
# Solid growth in most regions



- Growth in US was 16% in Q3, impacted positively by currency and OEM. Sales of Boule systems (own instruments and own consumables) decreased with 2% in fixed currencies due to low instrument sales
- Slower quarterly growth in Asia compare to last year impacted by tender deliveries in Q3 2018
- Strong growth in East Europe as a result of improved and developed distribution structure in Russia
- Middle East is positive impacted by strong quarterly instrument sales



# With strong sales growth trend established, focus on improving gross margins



- Improved gross margin in Q3 2019 after four quarters with weaker gross margins
- Gross margins are very dependent on geographical and product mix. Instrument prices vary a lot by market, consumable prices are fairly consistent globally
- In the previous four quarters sales on instrument sales have increased, and have grown faster in low-priced markets
- Increased focus on gross margin improvements going forward, including growth initiatives in higher price countries, manufacturing cost reductions and price increases

# Progressing with quality system improvements

## Background

- Boule Diagnostics takes compliance with regulations very seriously, and this matter has the highest priority in the company.
- Boule products are known for high quality, and the high quality of current and future products is ensured through rigorous quality assurance processes.
- The work to diligently follow and develop the quality assurance processes involves the entire organization as well as external parties.
- Boule has increased investments in quality resources, competencies and processes since 2017

## FDA progress update

- During the third quarter of 2019, Boule has completed the warning letter action plan addressing the seven observations from the May 2018 audit in accordance with the timeline commitments to the FDA
- In July 2019, the FDA conducted an on-site audit at the instrument manufacturing site in Sweden, to follow up on the action plan improvements. The company received two observations from the audit. The observations are being addressed according to committed plans and will be finalized in mid-January 2020
- Boule is fully committed to meeting all the requirements from the FDA and the dialogue with the agency continues in a positive way

# Key activities during Q3

## Initiatives for future growth and profitability











- In Eastern Europe Boule has taken action to strengthen local presence and to evolve and improve the distributor network and improve customer support. This has resulted in increased growth and improved margins
- Boule has decided to move forward with plans to establish local manufacturing of hematology reagents in Russia, in line with growing demand and strive for regional supply of consumables. The project has been started and is expected to be completed in 2020.
- Boule has been building the commercial resources to:
  - Develop stronger scientific, clinical and health economics messaging and communication
  - Support broader product portfolio
  - Drive more regional marketing and education activities

## Product launches

- Significant efforts to drive the two new 5 part systems resulting in strong sales growth and very good initial customer feedback
- Continued growth in veterinary market. Launched new parameters (CRP and electrolytes) for C200 platform
- Released new improved versions of spinit system tests for CRP (infection) and HbA1c (diabetes) in May and July. Strong sales in September, both through biosurfit and Boule channels
- The spinit system attracted a lot of interest at the AACC conference in California in August, and the US registration process for spinit has been initiated

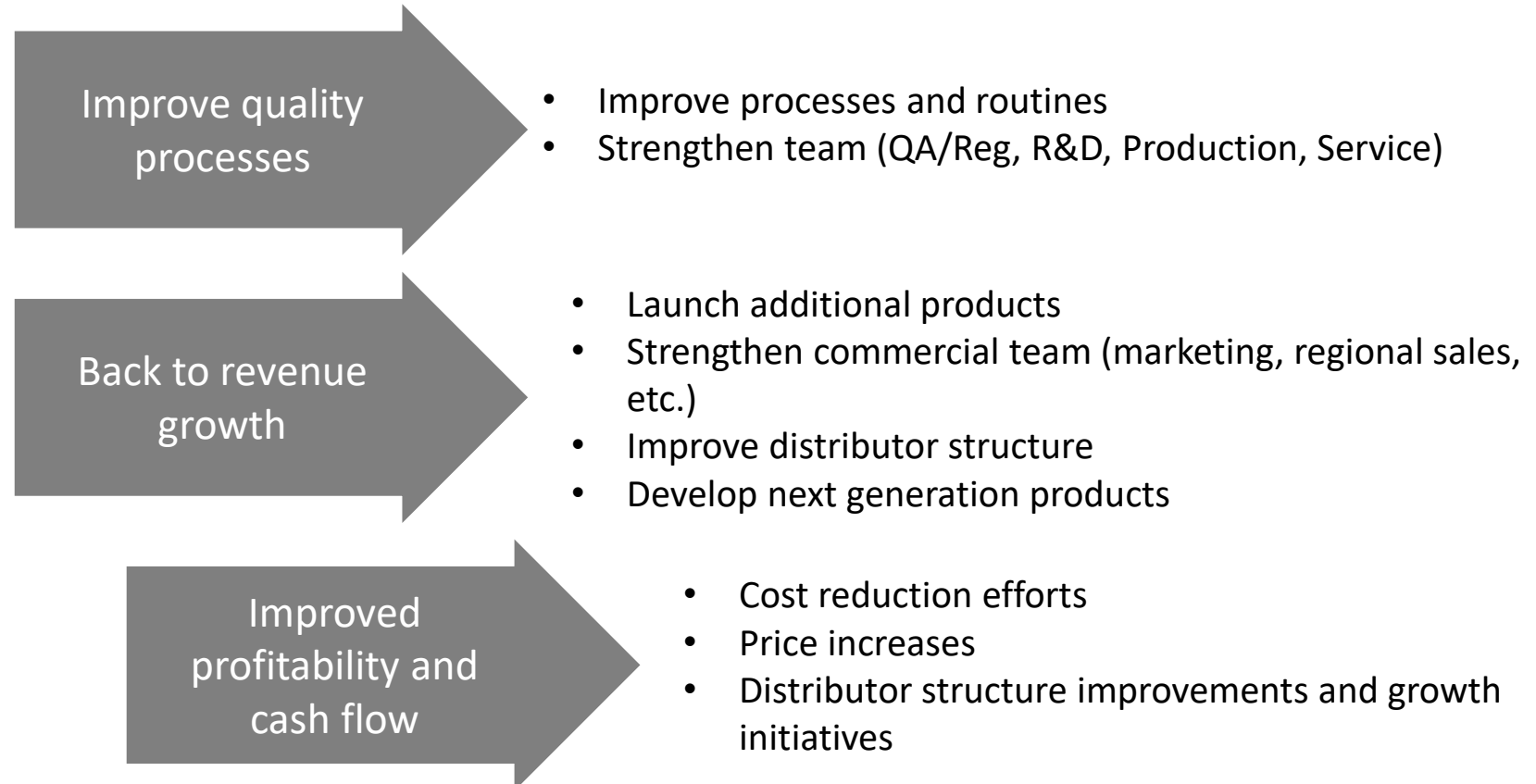


# Key revenue and margin drivers in 2019

Driver	Revenue growth impact	Gross margin % impact	Comment
<b>Veterinary market</b>			<ul style="list-style-type: none"> <li>• Strong growth due to product launches and strengthened distributor network</li> <li>• Good margins</li> </ul>
<b>Distributed products</b>			<ul style="list-style-type: none"> <li>• Strengthening portfolio and distributor network</li> <li>• Distributed products also contribute to core product growth (combined tenders, etc.)</li> </ul>
<b>Developing distributor network, strengthening local presence</b>			<ul style="list-style-type: none"> <li>• Increased value selling</li> <li>• Better support for distributors and end customers</li> <li>• Reduced overall cost</li> </ul>
<b>Increased importance of emerging markets</b>			<ul style="list-style-type: none"> <li>• Lower instrument prices in some markets (India)</li> <li>• Lower reagent consumption at early stage in some markets</li> </ul>
<b>Cost reduction efforts, including regional manufacturing</b>			<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>

# Progressing with high level priorities

***With improvements in quality systems and revenue growth,  
increased profitability focus***



**Thank you!**