

#### **Boule Diagnostics AB**

Company presentation, Q2 report 2019 August 14, 2019

Fredrik Dalborg, CEO and Group President Christina Rubenhag, CFO

# 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.









Customer oriented

Innovative

Result oriented

Quality

Teamwork



# **Boule Diagnostics – product portfolio 2019**

Significant additions in the past 12 months

**Human diagnostics** 



Medonic Z CBC 3-part differential



Swelab CBC 3-part differential

Product added in past 12 months



Quintus CBC 5-part differential



Clinical chemistry



**exigo H400** CBC 4-part differential

**POC** Multi test



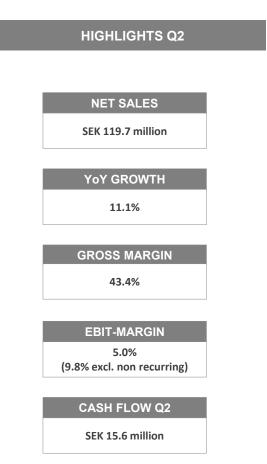
Spinit \*





Copyright © 2019, Boule Diagnostics AB

## Q2 2019 in summary - growth trend continues

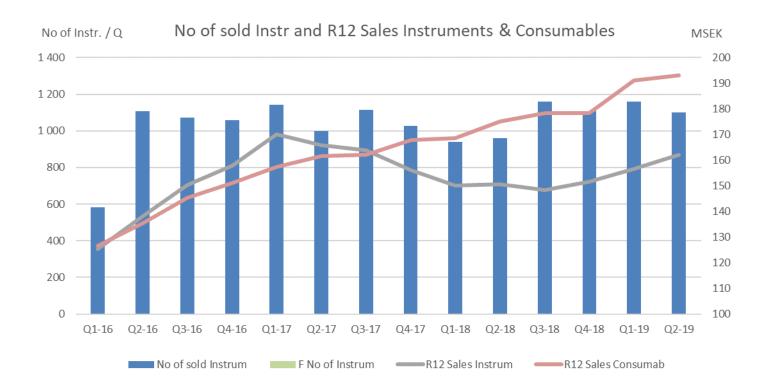


#### Strong growth trend continues

- Net sales was SEK 119.7 million, a new all-time high. This corresponds to a growth of 11.1% compared to the second quarter in 2018. Adjusted for exchange rates the growth was 5.3%
- Instrument unit sales increased by 14% to 1 100 (962) and instrument revenues increased by 14%. Instrument sales in Asia remained strong, further building market position and installed base, but also impacting average selling prices and gross margin to some extent
- Consumable sales for own instruments increased by 5% after a strong first quarter, growth YTD was 17%
- Gross margin was 43.4% (48.8%), impacted by region mix with high instrument sale to low price markets, India in particular, and distribution of free of charge RFID upgrade kits to certain markets to secure future reagent sales for a cost of SEK 1 million. Gross margin was also impacted by preparation for the FDA inspection
- S&M expenses include a bad debt provision of SEK 5.9 million related to restructuring of the distributor structure in Russia. Operating expenses excluding the provision was SEK 38.7 million (35.6) reflecting investments in and strengthening of the sales and marketing, development and quality assurance departments. Net of operating revenue and expenses was SEK -1.4 million (2.8).
- EBIT margin was 5.0% (18.4%). EBIT margin excluding the non-recurring provision EBIT margin was 9.8%.
- Cash flow from operating activities was SEK 15.6 million (10.0), impacted positive by lower inventory and high cash collection.

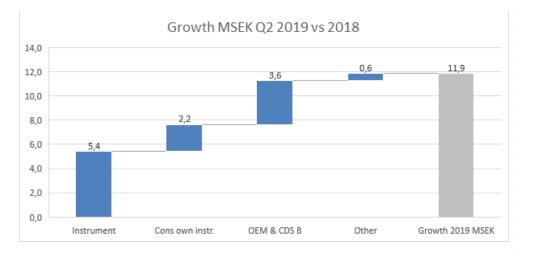


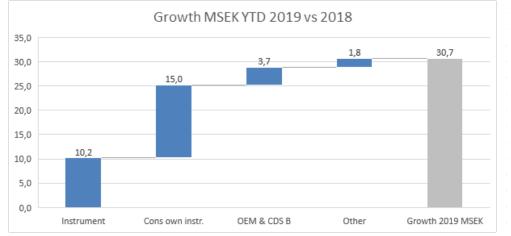
#### Instruments and consumables in a positive trend





#### Growth in all product categories

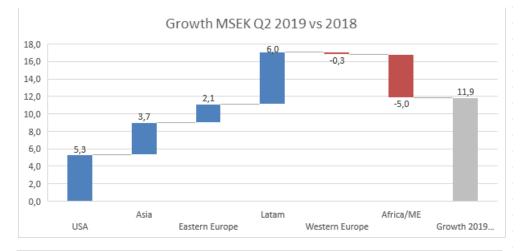


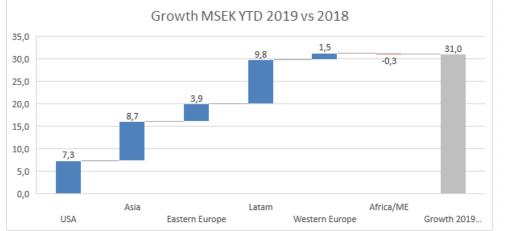


- Strong instrument growth in Q2, driven by Asia. Significant part of the growth relates to the recently launched 5 part instruments
- Sales of veterinary products continued to develop in a favorable way, both on established markets as well as on new markets via new distributors.
- Growth in consumables for own instruments was 5% in Q2 after a strong first quarter. Year to date growth was 17%.
- OEM (relatively low gross margin) and CDS Brand growth was 30% in the second quarter



## Solid growth in most regions

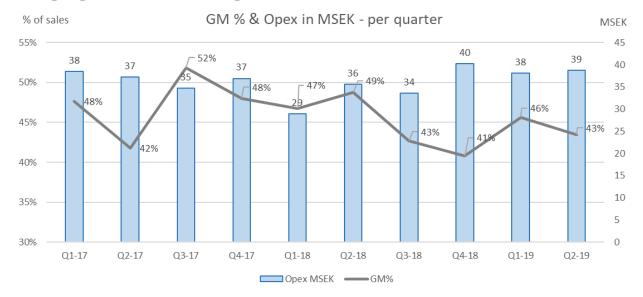




- Growth in US was 18% in Q2, impacted positive by currency, CDS Brand and OEM. Sales of Boule systems (own instruments and own consumables) increased with 8% in fixed currencies
- Strong growth in Asia in Q2 as well as year to date, driven by instrument sales
- Sales growth in Latam was 91% in Q2, driven by instrument and reagent sales. Growth in fixed currencies was 48%. Growth is a result of development of distributors and a strengthened, dedicated, local team
- Africa / Middle East was -32% in Q2, impacted by the last partial delivery to Egypt last year.



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



- Gross margin in line with previous quarters, but below Q2 2018 and not satisfactory
- Prices and gross margins are very dependent on geographical market. Variation is greatest for instrument sales
- In the last four quarters sales on instruments have grown faster in low-priced markets vs high-price markets
- Main reason is India, where we have had strong sales of instruments at very low margins as a result of a major tender (prices set several years back in time)
- The margins on reagent sales in India meet our margin targets
- Increased focus on gross margin improvements going forward, including 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.

#### **Progress update**

- The work on the action plan to improve quality systems and to meet the FDA's requirements progresses according to the timetable, the action plan is close to completion (will be completed during the third quarter of 2019)
- In July, the FDA conducted an on-site inspection at the instrument manufacturing site in Spånga, Sweden, to follow up on our work. The result of the inspection indicates that we are on the right track. Some improvements remain.
- In summary, the organization has responded well to the challenges we faced last fall and we are experiencing a positive dialogue with the FDA



## Key activities during Q2

#### **Evolving commercial activities**

- 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
- In the US market Boule have entered into a Preferred Vendor status with the largest medical surgical distributor in the U.S. The Preferred Vendor agreement was effective as of April 1, but has not yet had any significant revenue impact
- Boule has been building the commercial resources to develop stronger scientific, clinical and health economics messaging and communication, and to drive more regional marketing and education activities.

#### **Product launches**

- Significant efforts to launch the two new 5 part systems resulting in strong sales growth and very good customer feedback
- Previous issues with Quintus system solved, and a sales campaign has been initiated resulting in good sales growth
- Veterinary sales developing strongly, and new test parameters will be added to the C200 system in the coming months
- Released new improved versions of spinit system tests for CRP (infection) and HbA1c (diabetes) and the first units have been sold through Boule's distributor network
- 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
Veterinary market			<ul> <li>Strong growth due to product launches and strengthened distributor network</li> <li>Good margins</li> </ul>
Distributed products			<ul> <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> <li>Increased value selling</li> <li>Better support for distributors and end customers</li> <li>Reduced overall cost</li> </ul>
Increased importance of emerging markets			<ul> <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> <li>Process efficiency improvements</li> <li>Redesign for cost reduction</li> <li>Strengthening competitive position, reducing logistics cost</li> </ul>



### Thank you!

