Boule Diagnostics AB
Company presentation, Introduce Investor Day
December 4, 2018

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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
Complete blood count (CBC) – how it works

1. Blood sample
2. Analysis in an automated blood cell counter
3. Result in one minute

Clinical relevance

Red blood cells
- Anemia
- Bleeding
- Pregnancy
- Metabolic disorder

Platelets
- Coagulation disorder
- Chemotherapy
- Hemophilia
- Infection

White blood cells
- Bacterial infection
- Viral infection
- Parasitic infection
- Leukemia
- Allergy

- Red blood cells (oxygen supply)
- Platelets (coagulation)
- White blood cells (immune system)
Q3 2018 in summary

All-time high in number of delivered systems and net sales for an individual quarter

- Net sales was SEK 110.9 million with a growth of 1.1% compared to the previous record third quarter in 2017. Adjusted for exchange rates the growth was -4.7%
- The third quarter included tender sales to India, resulting in an increase in sold instruments by 4%, 1,161 (1,116), but to lower average selling prices why revenue for delivered instruments declined by -5%
- Consumables for own instruments continued to grow and revenues increased by 8%
- Gross margin was 42.7% (51.8%), impacted by the large tender in India with a higher share of sales at relatively low sales prices
- EBIT margin was 11.5% (25.7%). EBIT margin excluding capitalized R&D was 7.1% (23.8%). EBIT in Q3 2017 included non recurring items of SEK +4.5 million
- Cash flow from operating activities was SEK -0.6 million (10.0) due to increased A/R caused by high sales late in the quarter

Key events during the quarter

- In July, Boule secured a major tender in India, including 650 instruments, associated reagents and controls. Deliveries started during the third quarter and will continue in the fourth quarter of 2018.

Key events after the quarter

- Boule received a Warning Letter from US FDA
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 within the stipulated 15 working days
- The response included procedure improvements and a time plan to implement the procedures and providing the required documentation
- Boule has been working on implementation and documentation and has provided updates according to the time plan
- On October 5th Boule received a Warning Letter, and a press release was issued
- The warning letter states that the implemented procedure improvements are not adequate and that further evidence of implementation and staff training on the new procedures, as well as retrospective review, is required
- Boule has responded within the stipulated 15 working days, providing evidence of implementation, time line for further actions and improvements, etc.

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
Net Sales and EBIT R12 per quarter

- Revenue fluctuates between the quarters mainly due to tenders and region specific events.
- Strong operating profit improvement. The positive trend impacted by low gross margins in Q3 due to low ASP deliveries towards the large tender in India.
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 to be delivered in Q4
- Due to 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
- Production capacity has been increased to ensure instrument deliveries in 2018.
- The tender may also lead to sales of additional of instruments
Number of instruments sold and consumables trend
Boule is active in the decentralized, near patient diagnostics segment

In the decentralized market, 3 part is bigger but 5 part grows faster

...but growing faster

USD bn
3,5
3
2,5
2
1,5
1
0,5
0

Centralized Hematology
Decentralized Hematology

Market size

Market growth

8%
7%
6%
5%
4%
3%
2%
1%
0%

Overall Hematology Market
Decentralized Hematology market

...driven by major trends

- Large and growing market potential: >100,000 small and medium sized labs globally
- Increased access to healthcare in emerging markets
  - Emphasis on smaller cities and rural areas
- Near patient diagnostics is attractive to patients and healthcare systems in developed markets
  - Cost efficiency and patient convenience

Source: Kalorama IVD 2016, Boule data
Trends in the decentralized, near patient segment

- Patients expecting easy access to testing and quick results
- Use of finger stick (less invasive and allowing for less skilled staff)
- More advanced technologies made available for smaller lab applications
  - Broader types of diagnostic tests
  - More advanced sensor technologies
  - More parameters
  - Ease of use and analytical support
- Consolidation of small labs, volume requirements increasing in some segments
- New, near patient segments emerging (urgent care centers, pharmacies, home care, etc.)
What differentiates Boule from competitors

- Products and organization focused on the decentralized, near-patient market
- Recognized high quality and reliability, ease of use and low lifecycle cost
- Integrated supplier of the complete system (instruments, reagents, controls and calibrators, cleaners)
- Reputation for strong service and support
- Unique features (shear valve technology, finger stick sample method, autoloader system for high volume users, etc.)
- Global presence, strong market shares in developed and developing markets
- Dual brand strategy, providing better market access, stronger market understanding and improved distributor management
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, gradually adding resource
• 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 advances 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
Continued growth and efficiency initiatives in manufacturing

*Leveraging relatively high instrument volumes, and complete system offering*

- New automation solutions for the production of instruments, expected to streamline the production of current and future instrument generations
- Increasing production capacity, streamlining and automating the production process for controls at the Florida plant
- Implementing a cost-reduction in instrument electronics module manufacturing, expected to provide an annual cost-saving of approximately SEK 3 million, beginning in the first quarter of 2019.

*In addition, further regional reagent manufacturing options being evaluated*
Active business development work to broaden the 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

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)

Adding new adjacent diagnostic tests for the near patient, (point of care) market
- Distributing point of care CRP testing in US and LATAM
- Clinical chemistry for veterinary market

Assessing further business development opportunities
- Assessing further partnerships/acquisitions in current hematology and adjacent diagnostic areas
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
Investing for growth

The development of the next generation 5 part system platform is continuing with high priority
- Research and development resources in both Sweden and the US have been strengthened
- Higher throughput and additional parameters
- Important progress during quarter

Driving regional growth
- Market research and prioritization
- Strengthening regional sales and service teams in Russia, LATAM and US. Next steps Asia, Europe and Middle East

Efficient commercialization of broader product portfolio
- Adding new products
- Strengthening marketing and sales team
Thank you!