Hematology is in our blood

Boule Diagnostics AB
Company presentation, Q3 report 2018
November 06, 2018

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
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)
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
Q3 2018 in Summary

### Highlights Q3

<p>| | |</p>
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<tr>
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<td><strong>YoY Growth</strong></td>
<td>1.1%</td>
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<td><strong>Gross Margin</strong></td>
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<td><strong>EBIT-Margin</strong></td>
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<td><strong>Cash Flow</strong></td>
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**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%, 1161 (1116), 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.
Net Sales and EBIT R12 per quarter

- Revenue fluctuate 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.
Overview of sales by region

- Decrease in Africa/Middle East explained by Q3 2017 tender sales to Egypt. Sales to Iraq was strong in Q3 with growth of +28%.
- LATAM growth increase continues, emphasis on new markets and strengthening of distributor network.
- Sales in Russia was lower due to slow sales for one of our distributors, impacting revenue in East Europe.
- Q3 revenue in US was impacted positive by CDS Brand, OEM and exchange rate. Year to date sales of Boule systems (own instruments and own consumables) increased with 12% in fixed currencies with +25% units delivered compared to last year.
- Sales in Asia was driven by strong sales in India and deliveries towards the received tender. Reagent sales in India is growing as a consequence of the growing installed base.
## Net sales by region and product

### Net sales by region, SEK million

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<td>Consumables own instruments</td>
<td>45.8</td>
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<td>162.1</td>
<td>10%</td>
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<td>Consumables OEM and CDS-brand</td>
<td>15.1</td>
<td>12.3</td>
<td>23%</td>
<td>59.0</td>
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<td>Other</td>
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<td>Growth in sales, %</td>
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<td>2.3</td>
<td>-0.2</td>
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<td>47.2</td>
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<td>Operating profit/loss, SEK million</td>
<td>12.8</td>
<td>28.2</td>
<td>66.3</td>
<td>40.8</td>
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<tr>
<td>Operating margin, %</td>
<td>11.5</td>
<td>25.7</td>
<td>15.6</td>
<td>9.6</td>
</tr>
<tr>
<td>Net debt, SEK million</td>
<td>-92.9</td>
<td>-89.0</td>
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<td>-89.0</td>
</tr>
<tr>
<td>Return on equity, %</td>
<td>3.3</td>
<td>9.2</td>
<td>16.3</td>
<td>13.0</td>
</tr>
<tr>
<td>Net debt/EBIT (R12), times</td>
<td>-1.4</td>
<td>-2.2</td>
<td>-1.4</td>
<td>-2.2</td>
</tr>
<tr>
<td>Earnings per share, after dilution, SEK¹</td>
<td>0.50</td>
<td>1.12</td>
<td>2.20</td>
<td>1.58</td>
</tr>
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### Net sales (R12) and EBIT (R12)

- **Net sales**
- **EBIT**

[Graph showing net sales and EBIT from Q1 to Q3 for the years 2015 to 2018]
Number of instruments sold 2008 – Q3 2018

* No. of instruments sold 2018 is presented as rolling 12 months.
Number of instruments sold and consumables 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 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
### 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
Continued growth and efficiency initiatives

- New automation solutions for the production of instruments, expected to streamline the production of current and future instrument generations.

- Increasing production capacity and streamlining 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.
Broadening of the product portfolio in line with strategy

• The new system is a 5-part system focused on customers with relatively low test volumes and will be a good addition to both Boule’s current and future customer offering
  • Entry-level (open tube) 5-part system
  • Intended for the cost-conscious, smaller clinical laboratory
• Provides access to a reliable and user-friendly, yet cost-effective complete blood cell counter:
  • User-friendly: ergonomic design, easy operations, intuitive user interface
  • Reliable: quality system components, dependable operations, good correlation with reference
  • Cost-effective: affordable, compact, efficient
• The system has been developed in cooperation with an external supplier and will be sold under the Swelab and Medonic brands
  • Launch at Medica conference in November 2018
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
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.
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
• Two brand strategy, providing better market access, stronger market understanding and improved distributor management
We are active in an attractive market segment
*Decentralized, near patient market*

<table>
<thead>
<tr>
<th>USD bn</th>
<th>Market size</th>
<th>Market growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>0,5</td>
<td>0</td>
<td>2%</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>7%</td>
</tr>
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<td>1,5</td>
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<tr>
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Decentralized market is smaller...

...but growing faster...

...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 convenience

Source: Kalorama IVD 2016, Boule data
## Future challenges and opportunities for Boule Diagnostics

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<th>Opportunities</th>
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<td>• Fragmented, competitive market</td>
<td>• Veterinary market</td>
</tr>
<tr>
<td>• Some fast growing markets (India in particular) have low price levels</td>
<td>• Improvements in manufacturing efficiency and structure</td>
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<td>• Important to deliver relevant product development to market in a timely manner</td>
<td>• Broadening portfolio through agreements and/or acquisitions</td>
</tr>
<tr>
<td>• Volatility caused by tenders and market specific variations</td>
<td>• More regional/local presence to improve customer experience (service, product specialists, etc.)</td>
</tr>
<tr>
<td>• quarter to quarter revenue variability</td>
<td>• Launching new products based on our reliable technologies</td>
</tr>
<tr>
<td>• Instrument sales increase revenue but reduce gross margin</td>
<td>• Continued growth in emerging markets</td>
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<td>• Volatility caused by currency fluctuations</td>
<td>• In developed markets focus on near-patient care to reduce healthcare cost and improve patient convenience</td>
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<td>162.1</td>
<td>10%</td>
</tr>
<tr>
<td>Consumables OEM and CDS-brand</td>
<td>15.1</td>
<td>12.3</td>
<td>23%</td>
<td>59.0</td>
<td>66.0</td>
<td>-11%</td>
</tr>
<tr>
<td>Other</td>
<td>10.2</td>
<td>12.9</td>
<td>-21%</td>
<td>39.7</td>
<td>34.2</td>
<td>16%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>110.9</strong></td>
<td><strong>109.7</strong></td>
<td>1%</td>
<td><strong>425.4</strong></td>
<td><strong>426.3</strong></td>
<td><strong>0%</strong></td>
</tr>
</tbody>
</table>
Key figures Q3 and R12

<table>
<thead>
<tr>
<th>Key figures</th>
<th>Jul-Sep 2018</th>
<th>Jul-Sep 2017</th>
<th>Oct 17-Sep 18 (R12)</th>
<th>Oct 16-Sep 17 (R12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Growth in sales, %</td>
<td>1.1</td>
<td>2.3</td>
<td>-0.2</td>
<td>11.2</td>
</tr>
<tr>
<td>Net sales, SEK million</td>
<td>110.9</td>
<td>109.7</td>
<td>425.4</td>
<td>426.3</td>
</tr>
<tr>
<td>Gross margin, %</td>
<td>42.7</td>
<td>51.8</td>
<td>46.5</td>
<td>47.2</td>
</tr>
<tr>
<td>Operating profit/loss, SEK million</td>
<td>12.8</td>
<td>28.2</td>
<td>66.3</td>
<td>40.8</td>
</tr>
<tr>
<td>Operating margin, %</td>
<td>11.5</td>
<td>25.7</td>
<td>15.6</td>
<td>9.6</td>
</tr>
<tr>
<td>Net debt, SEK million</td>
<td>-92.9</td>
<td>-89.0</td>
<td>-92.9</td>
<td>-89.0</td>
</tr>
<tr>
<td>Return on equity, %</td>
<td>3.3</td>
<td>9.2</td>
<td>16.3</td>
<td>13.0</td>
</tr>
<tr>
<td>Net debt/EBIT (R12), times</td>
<td>-1.4</td>
<td>-2.2</td>
<td>-1.4</td>
<td>-2.2</td>
</tr>
<tr>
<td>Earnings per share, after dilution, SEK¹</td>
<td>0.50</td>
<td>1.12</td>
<td>2.20</td>
<td>1.58</td>
</tr>
</tbody>
</table>

![Net sales (R12) and EBIT (R12) graph](chart.png)
Number of instruments sold 2008 – Q3 2018

* No. of instruments sold 2018 is presented as rolling 12 months.
Number of instruments sold and consumables 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 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
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
Continued growth and efficiency initiatives

New automation solutions for the production of instruments, expected to streamline the production of current and future instrument generations.

Increasing production capacity and streamlining 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.
Broadening of the product portfolio in line with strategy

- The new system is a 5-part system focused on customers with relatively low test volumes and will be a good addition to both Boule’s current and future customer offering
  - Entry-level (open tube) 5-part system
  - Intended for the cost-conscious, smaller clinical laboratory
- Provides access to a reliable and user-friendly, yet cost-effective complete blood cell counter:
  - **User-friendly**: ergonomic design, easy operations, intuitive user interface
  - **Reliable**: quality system components, dependable operations, good correlation with reference
  - **Cost-effective**: affordable, compact, efficient
- The system has been developed in cooperation with an external supplier and will be sold under the Swelab and Medonic brands
  - Launch at Medica conference in November 2018
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
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.
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
• Two brand strategy, providing better market access, stronger market understanding and improved distributor management
We are active in an attractive market segment

*Decentralized, near patient market*

**Decentralized market is smaller...**

<table>
<thead>
<tr>
<th>USD bn</th>
<th>Market size</th>
</tr>
</thead>
<tbody>
<tr>
<td>3,5</td>
<td>Centralized Hematology 3 part</td>
</tr>
<tr>
<td>3</td>
<td>Centralized Hematology 5 part</td>
</tr>
<tr>
<td>2,5</td>
<td>Decentralized Hematology 3 part</td>
</tr>
<tr>
<td>2</td>
<td>Decentralized Hematology 5 part</td>
</tr>
<tr>
<td>1,5</td>
<td>Decentralized Hematology 5 part</td>
</tr>
<tr>
<td>1</td>
<td>Decentralized Hematology 5 part</td>
</tr>
<tr>
<td>0,5</td>
<td>Decentralized Hematology 5 part</td>
</tr>
<tr>
<td>0</td>
<td>Decentralized Hematology 5 part</td>
</tr>
</tbody>
</table>

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

**...but growing faster**

**...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 convenience

**Market size**

- Centralized Hematology
- Decentralized Hematology

**Market growth**

- Overall Hematology Market: 2%
- Decentralized Hematology: 7%

Source: Kalorama IVD 2016, Boule data
# Future challenges and opportunities for Boule Diagnostics

<table>
<thead>
<tr>
<th>Challenges</th>
<th>Opportunities</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Fragmented, competitive market</td>
<td>• Veterinary market</td>
</tr>
<tr>
<td>• Some fast growing markets (India in particular) have low price levels</td>
<td>• Improvements in manufacturing efficiency and structure</td>
</tr>
<tr>
<td>• Important to deliver relevant product development to market in a timely manner</td>
<td>• Broadening portfolio through agreements and/or acquisitions</td>
</tr>
<tr>
<td>• Volatility caused by tenders and market specific variations</td>
<td>• More regional/local presence to improve customer experience (service, product specialists, etc.)</td>
</tr>
<tr>
<td>• quarter to quarter revenue variability</td>
<td>• Launching new products based on our reliable technologies</td>
</tr>
<tr>
<td>• Instrument sales increase revenue but reduce gross margin</td>
<td>• Continued growth in emerging markets</td>
</tr>
<tr>
<td>• Volatility caused by currency fluctuations</td>
<td>• In developed markets focus on near-patient care to reduce healthcare cost and improve patient convenience</td>
</tr>
<tr>
<td>• Higher regulatory compliance requirements</td>
<td>• Higher regulatory compliance requirements</td>
</tr>
</tbody>
</table>
Thank you!