

# Medistim ASA Second Quarter 2015

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## 1. Highlights second quarter



## Highlights second quarter 2015

- Double digit growth in the second quarter
  - Strong development in the USA continues, with 40.6 % revenue growth in NOK, 8.8 % in USD
  - Sale of 3.party products up 20.9 % to MNOK 18.2
- MNOK 11.7 in EBIT for the quarter
  - Including a one-off accrual of 3.2 MNOK related to the termination of the Medtronic distribution agreement
- Building out the sales force in the USA
- Sponsoring the REQUEST study, a pioneering registry study done by leading hospitals in North America and Europe
- The general assembly decided a dividend of NOK 1.40 per share based upon 2014 results (NOK 0.80)

Q2 2015	Q o Q
Revenue MNOK 57.3 (47.9)	 19.6%
EBIT MNOK 11.7 (11.7)	 0.0%
Currency	 11.9%
No of units sold:	
Systems 19	 9.5%
Flow probes 1 506	 1.0%
Imaging probes 7	 -30.0%
Procedures (USA) 11 045	 12.7%



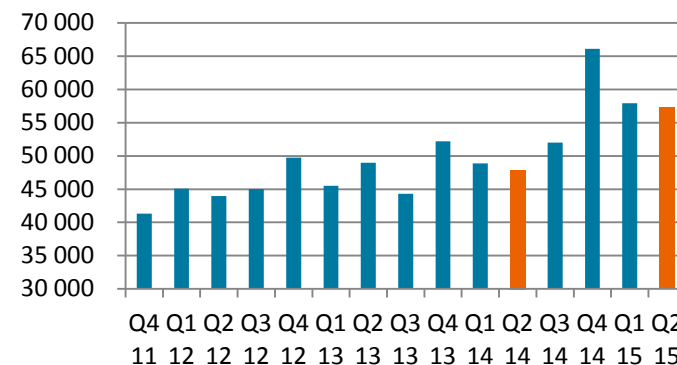
## 2. Financial statements



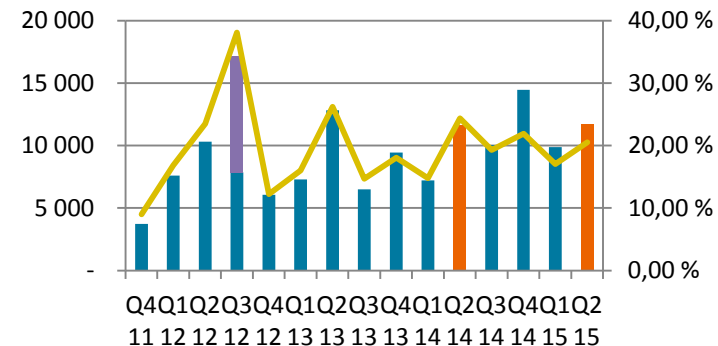
# Profit and loss Q2 2015

<b>Profit &amp; loss</b>	<b>Q2 2015</b>	<b>Q2 2014</b>
<i>All numbers in NOK 1000</i>		
<b>Sales</b>	<b>57 254</b>	<b>47 868</b>
Cost of goods sold	13 787	12 323
Salary and social expenses	15 513	12 947
Other operating expenses	10 365	8 855
Total operating expenses	39 666	34 125
<b>Op. res. before depr. and write-offs (EBITDA)</b>	<b>17 589</b>	<b>13 743</b>
<i>EBITDA %</i>	<i>30,7 %</i>	<i>28,7 %</i>
Depreciation	2 649	2 072
Write offs and provisions	3 200	-
<b>Operating result EBIT)</b>	<b>11 740</b>	<b>11 671</b>
<i>EBIT %</i>	<i>20,5 %</i>	<i>24,4 %</i>
Financial income	2 874	2 429
Financial expenses	1 279	2 178
<b>Net finance</b>	<b>1 595</b>	<b>251</b>
<b>Pre tax profit</b>	<b>13 335</b>	<b>11 922</b>
Tax	2 867	4 765
<b>Result</b>	<b>10 468</b>	<b>7 158</b>
<b>Dividend</b>	<b>25 362</b>	<b>14 481</b>

**Sales per Quarter (TNOK)**



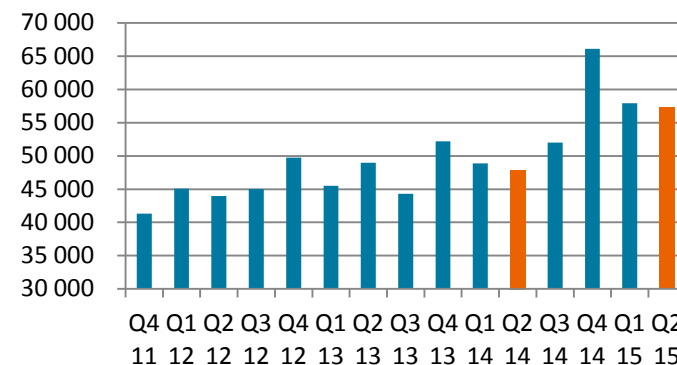
**EBIT per Quarter (TNOK)**



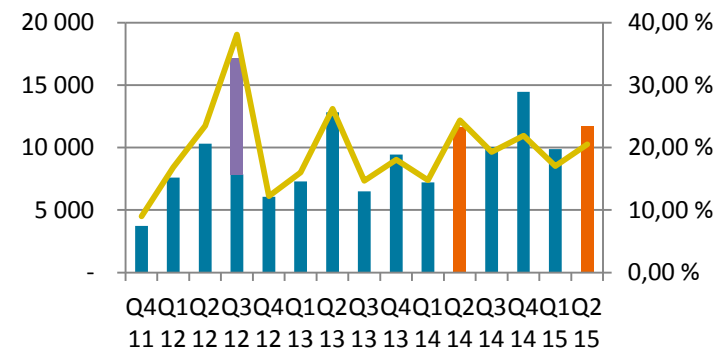
# Profit and loss H1 2015

<b>Profit &amp; loss</b>	<b>H1 2015</b>	<b>H1 2014</b>
<i>All numbers in NOK 1000</i>		
<b>Sales</b>	<b>115 161</b>	<b>96 725</b>
Cost of goods sold	30 767	25 304
Salary and social expenses	34 377	29 722
Other operating expenses	20 005	18 699
Total operating expenses	85 149	73 725
<b>Op. res. before depr. and write-offs (EBITDA)</b>	<b>30 013</b>	<b>23 000</b>
<i>EBITDA %</i>	<i>26,1 %</i>	<i>23,8 %</i>
Depreciation	5 202	4 110
Write offs and provisions	3 200	-
<b>Operating result (EBIT)</b>	<b>21 610</b>	<b>18 890</b>
<i>EBIT %</i>	<i>18,8 %</i>	<i>19,5 %</i>
Financial income	11 120	3 541
Financial expenses	8 487	3 269
<b>Net finance</b>	<b>2 633</b>	<b>272</b>
<b>Pre tax profit</b>	<b>24 243</b>	<b>19 162</b>
Tax	6 365	6 801
<b>Result</b>	<b>17 878</b>	<b>12 361</b>
Dividend	25 362	14 481

**Sales per Quarter (TNOK)**



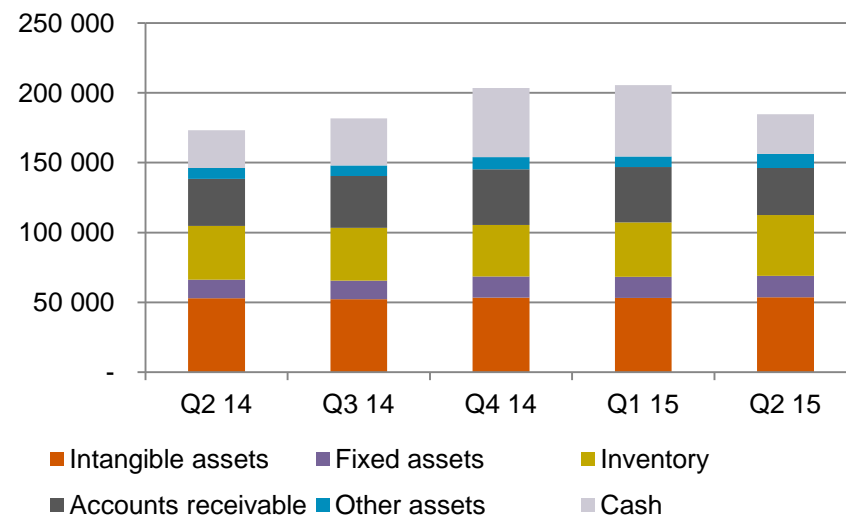
**EBIT per Quarter (TNOK)**





## Balance sheet - Assets

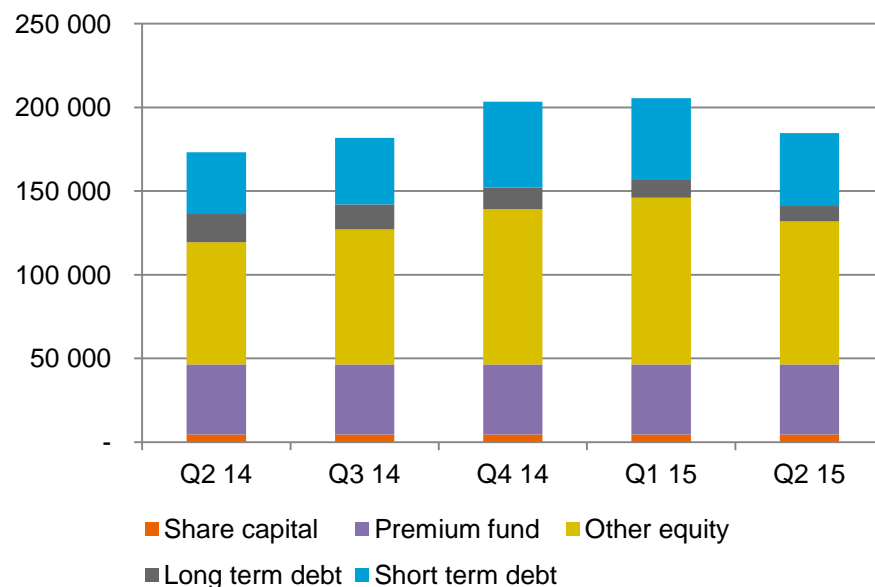
<b>Balance sheet</b>	<b>30.06.2015</b>	<b>31.12.2014</b>
<i>All numbers in NOK 1000</i>		
<b>Assets</b>		
Intangible assets	53 581	53 257
Fixed assets	15 414	15 276
<b>Total intangible and fixed assets</b>	<b>68 994</b>	<b>68 533</b>
Inventory	43 387	36 874
Customers receivables	33 787	39 948
Other receivables	10 034	8 658
Cash	28 442	49 475
<b>Total current assets</b>	<b>115 650</b>	<b>134 955</b>
<b>Total assets</b>	<b>184 644</b>	<b>203 488</b>



- Inventory build up related to MiraQ product line introduction
- Cash reduced due to dividend payment of MNOK 25,4 in May 2015

## Balance sheet - Equity and liability

<b>Balance sheet</b>	<b>30.06.2015</b>	<b>31.12.2014</b>
<i>All numbers in NOK 1000</i>		
Share capital	4 585	4 585
Premium fund	41 852	41 852
Other equity	85 431	92 659
<b>Total equity</b>	<b>131 868</b>	<b>139 096</b>
<b>Total long term debt</b>	<b>9 226</b>	<b>13 117</b>
<b>Total short term debt</b>	<b>43 550</b>	<b>51 275</b>
<b>Total equity and liability</b>	<b>184 644</b>	<b>203 488</b>



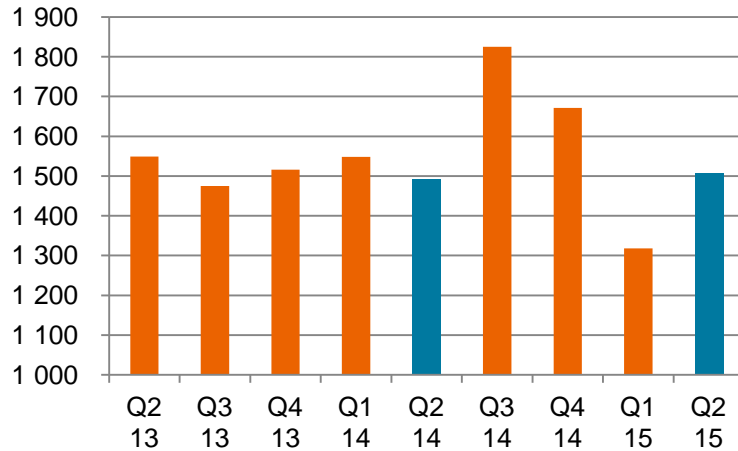
- 14.6 MNOK in interest bearing debt

### 3. Business segments update

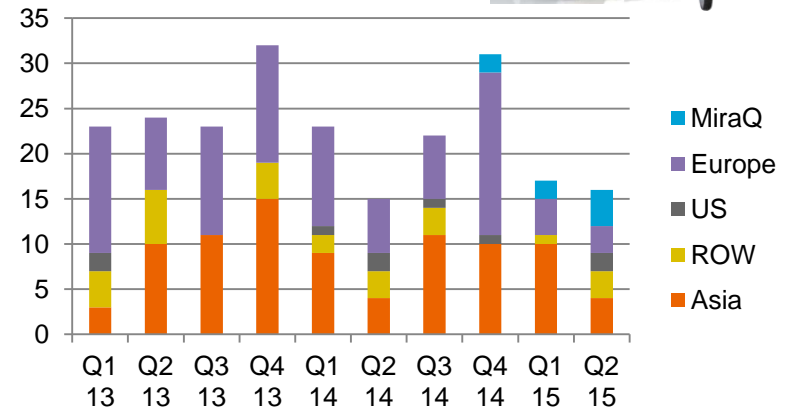


# Flow probes and systems in units

## Flow probes in units



## VeriQ and MiraQ systems



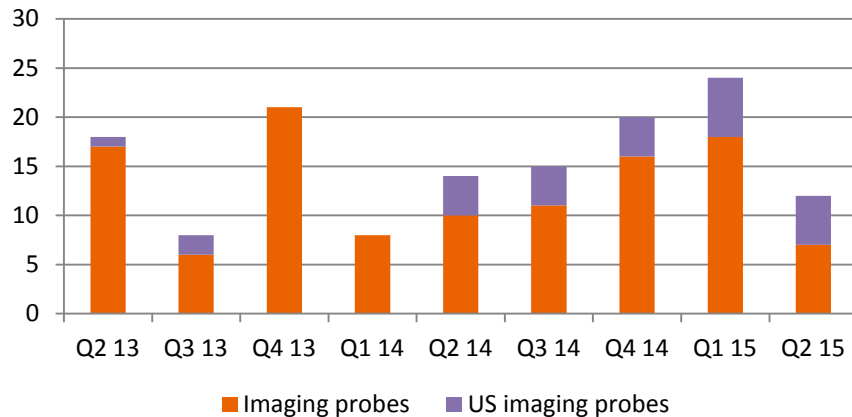
- The number of flow probes sold are up by 1% over Q2 last year
- System sales at the same level as Q2 last year
- Of the 4 MiraQ systems sold, 3 were sold in Europe and 1 in the Middle East



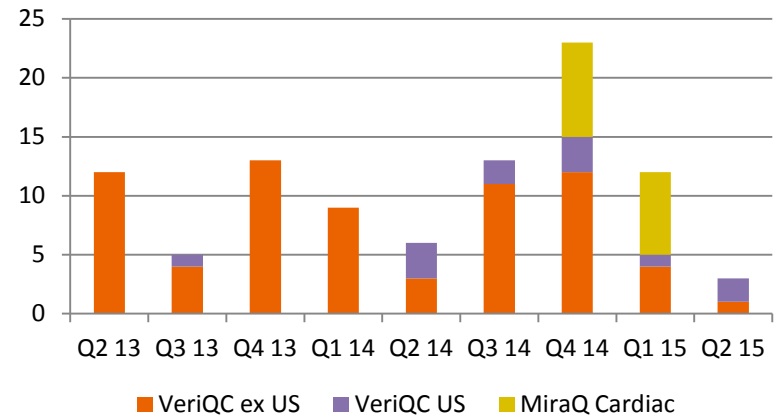
# Imaging probes and systems in units



## Imaging probes in units



## VeriQ C & MiraQ systems in units



- 12 imaging probes sold when including sales to capital accounts in the USA
- Slow quarter after an increasing trend for the previous 4 quarters

- Slow quarter for imaging systems due to timing of project closing

## Q2 revenue performance by region

Mill NOK	Q2 '15	Q2 '14	Q / Q	H1 15	H1 14	H / H
Europe	31,6	27,5	15,1 %	65,0	59,4	9,4 %
USA	20,5	14,6	40,6 %	36,5	25,2	44,7 %
Asia & Jp	2,9	3,3	-13,2 %	8,7	7,7	13,6 %
ROW (MEA, CAN, SA)	2,3	2,5	-9,3 %	4,9	4,3	12,0 %
<b>Total</b>	<b>57,3</b>	<b>47,9</b>	<b>19,6 %</b>	<b>115,2</b>	<b>96,7</b>	<b>19,1 %</b>

- **In Europe**, the regional performance for Q2 was driven by strong 21% growth from 3. party products. For the first half, 3. party products increased with 6,8 MNOK or 22 % over last year. Sale of own products ended at 27.0 MNOK in first half, down 4.5 %. However, the sale recovered from the slow Q1 performance and grew 8.0 % to 13.4 MNOK in Q2.
- **In the USA**, the strong growth continues, partly driven by favorable currency. Currency neutral growth was 8.8 % for Q2 and 13.0 % for the first half.
- **Both Asia/Japan and ROW** are so far smaller sales territories for Medistim, and quarterly performance varies significantly. Performance at first half is positive for both territories.

*Positive currency effects for Q2 with 5.2 MNOK and for the first half with 9.6 MNOK.*

*Average rate to USD was 7.73 in H1 2015 vs 6.04 in 2014. Average rate to EUR was 8.64 in H1 2015 vs 8.28 in 2014.*

## Q2 revenue performance by product

Mill NOK	Q2 '15	Q2 '14	Q/Q	H1 15	H1 14	H15/H14
Procedures (USA)	17,9	11,7	53,1 %	33,3	22,1	50,7 %
Flow probes	15,0	13,9	7,5 %	28,8	28,3	1,7 %
Flow systems (VeriQ & MiraQ)	3,4	2,8	23,6 %	6,1	6,9	-11,4 %
Imaging systems (VeriQ C & MiraQ)	2,1	3,3	-35,5 %	6,8	6,4	5,6 %
Imaging probes	0,3	0,4	-34,1 %	1,2	0,9	31,7 %
3rd party	18,2	15,1	20,9 %	38,0	31,2	22,0 %
Other	0,4	0,7	-49,3 %	1,0	1,0	5,8 %
<b>Total revenues</b>	<b>57,3</b>	<b>47,9</b>	<b>19,6 %</b>	<b>115,2</b>	<b>96,7</b>	<b>19,1 %</b>

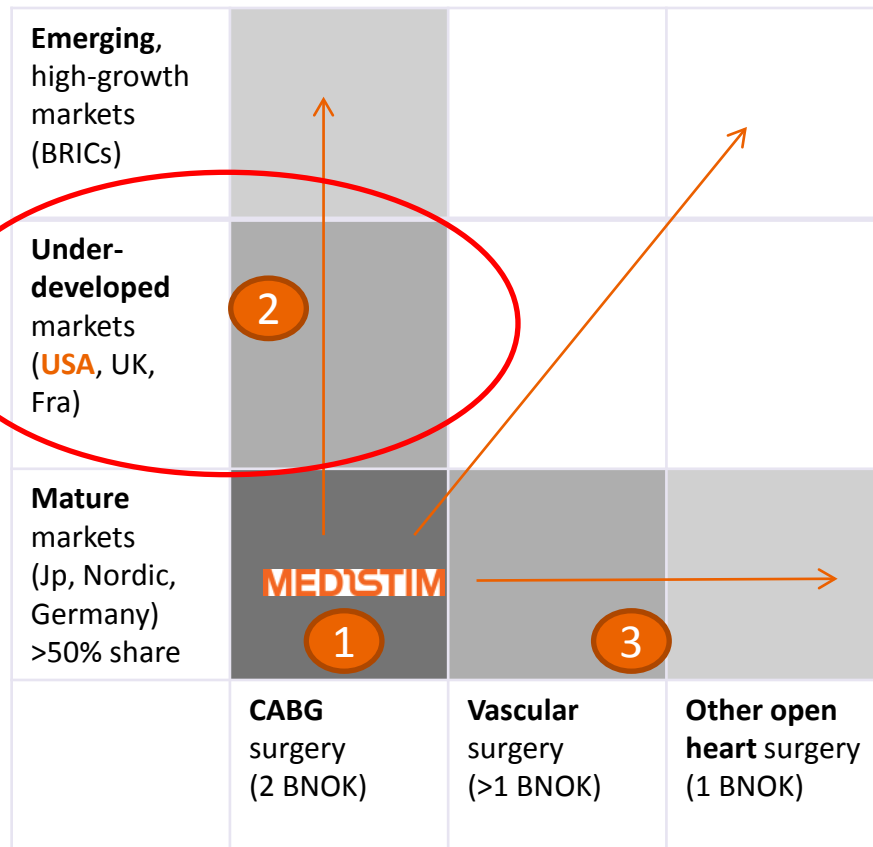
- **Procedure sale in the USA:** The number of flow procedures is up 14.0% and imaging procedures up 1.0 %. For the first half flow procedures is up with 10.1 % and imaging procedures is up with 41.3 %. Positive contribution from currency.
- **Flow probes revenue:** At the same level as last year. Number of procedures are growing, however part of this increase is absorbed by reduced pricing of probes in Germany.
- **Flow systems:** The number of systems sold in Q2 is at the same level as LY. The growth in NOK is related to currency and split between distributor and direct sales. First half is down due to the weak Q1.
- **Imaging systems and probes:** Slow quarter but at the same level as last year for the first half.
- **3<sup>rd</sup> party products:** Very strong quarter and first half with 21 % and 22 % growth respectively.

## 4. Implementing the strategy





# Growth opportunities – underdeveloped markets

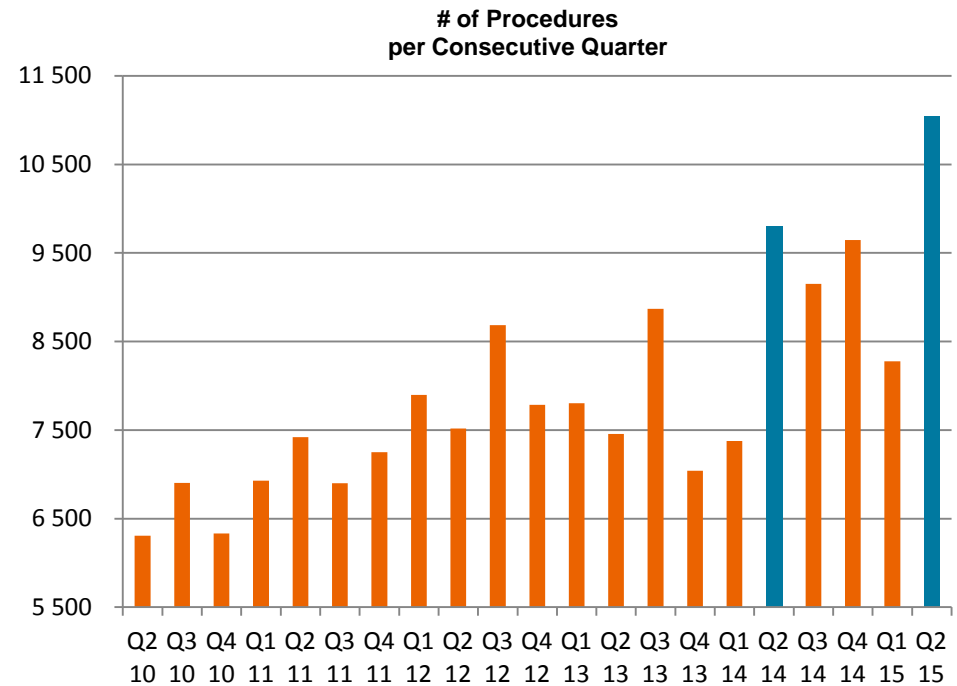


- 1. Strengthen our position as market leader** by establishing combined TTFM & Imaging as the new standard of care through
  - Early adopter KOL support
  - Easier conversion to imaging with MiraQ
- 2. Fight ignorance and indifference to QA** by increasing the level of evidence and awareness through
  - Clinical marketing
  - Educational programs
  - Increase sales capacity
- 3. Product innovation** and positioning to target new segments in vascular and open heart surgery
  - MiraQ Vascular

# High performance US sales organization

## RESULTS H1 2015

- Revenues up by 45 % in NOK, 13 % in USD
- Number of procedures up by 12.7 %
  - 41 % growth in imaging procedures
- 14 new accounts
- 6 TTFM accounts converted to Imaging



## Time to expand the US sales operations

### A large untapped market

- The US market represents about 1/3 of the global opportunity, with 230 000 CABG procedures
- Medistim has 14% market penetration in the USA vs. 70-80% of the European and Japanese markets
- Sales revenues from the US in 2014 was MNOK 56.5

### The organization is ready

- Strong leadership secures alignment around the commercial strategy
- Confident team after delivering double digit procedure and revenue growth over the past 5 quarters

### Time to expand

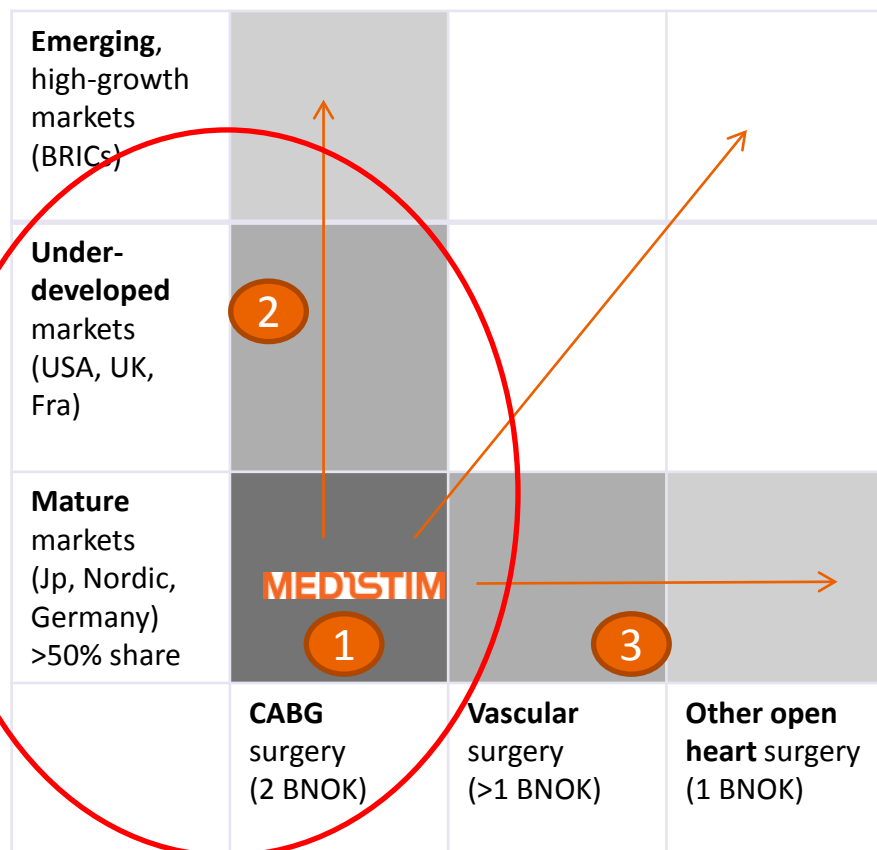
- Momentum is building
- Further interest expected from the REQUEST study and it's participating US centers
- Need to increase our capacity to reach more hospitals

### Action

- Building out the sales force from 13 to 18 sales representatives
  - 16 territories
  - 50-100 heart hospitals per territory



## Growth opportunities – all CABG markets



- 1. Strengthen our position as market leader** by establishing combined TTFM & Imaging as the new standard of care through
  - Early adopter KOL support
  - Easier conversion to imaging with MiraQ
- 2. Fight ignorance and indifference to QA** by increasing the level of evidence and awareness through
  - Clinical marketing
  - Educational programs
  - Increase sales capacity
- 3. Product innovation** and positioning to target new segments in vascular and open heart surgery
  - MiraQ Vascular



## The Challenge

- Clinical outcomes in CABG continue to be dissatisfactory
- Early postoperative graft failure is associated with high morbidity and mortality
  - Major adverse cardiac events (5-10%)
  - Stroke (1-3%)
  - Mortality (1-3% at 30 days)
  - Re-interventions (>5% within 12 months)

*"Over the next 5 years,*

*mortality should be reduced from the current 1.9% to < 1%*

*stroke should be reduced from the current 1.5% to < 0.5%"*



Michael J. Mack,  
Baylor Heart Hospital,  
STS conference, January 2012

A NEW WORKFLOW - A NEW STANDARD OF CARE

# Ultrasonic Surgical Guidance & Quality Assessment

**Reduce strokes**

**Optimize graft strategy**

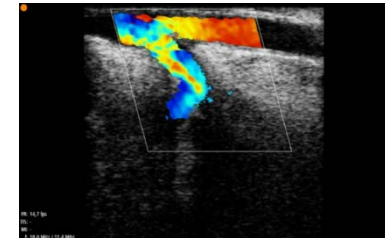
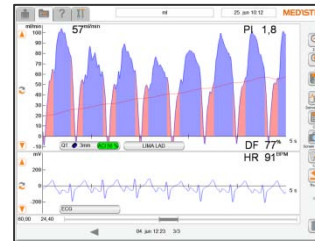
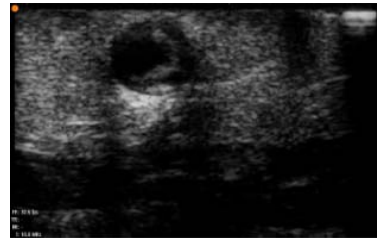
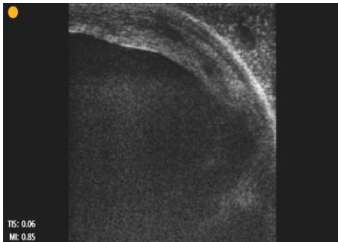
**Verify graft functionality...revise when needed**

Evaluate ascending aorta prior to any manipulation

Evaluate morphology of coronaries & IMA's

Assess graft functionality  
PI<5, DF>50%, Q>15ml/min

Evaluate morphology of anastomosis



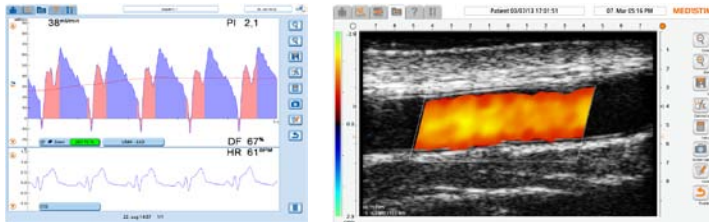
**Improve surgical outcome, demonstrate quality and increase cost efficiency**

# REQUEST

Registry for Quality Assessment  
with Ultrasound Imaging and TTFM in Cardiac Surgery

## What is the study protocol?

- Perform ultrasound imaging of the aorta, conduit arteries *in situ*, compromised coronary arteries and completed grafts (anastomosis)
- Perform TTFM on completed grafts
- The procedures will be done with Medistim's devices (VeriQ C™ and MiraQ™)



- Record all changes to the surgical procedure and the number of revisions done to the grafts based on the flow and imaging data
- Capture major adverse cardiac and cerebrovascular events (MACCE)

## Why are these data interesting to the surgical community?

- The hypothesis motivating the REQUEST registry study is that employing a new and unique combination of functional flow measurement and morphological ultrasound imaging data may enable surgeons to
  - make better informed decisions during coronary surgery
  - improve surgical quality and outcomes
  - contribute to improved healthcare efficiency from this surgical procedure
- The study is the first of its kind to investigate the value of implementing both TTFM and intraoperative ultrasound imaging as a concerted effort to provide surgical guidance and graft quality assessment

# REQUEST

Registry for Quality Assessment  
with Ultrasound Imaging and TTFM in Cardiac Surgery

- REQUEST – a prospective, multicenter registry study:
  - Performed by leading heart programs in Europe, USA and Canada:
    - Erasmus MC, Rotterdam, NL /  
Coordinating Investigator Prof. A. P. Kappetein
    - University of Oxford, UK /  
Principal Investigator Prof. David Taggart
    - University of Essen, GER /  
Principal Investigator Dr. Daniel Wendt
    - University G D'Annunzio-Chieti, IT /  
Principal Investigator Prof. Gabriele Di Giammarco
    - Mount Sinai Beth Israel, New York, USA /  
Principal Investigator Prof. John D. Puskas
    - George Wash. Univ., VA MC, Washington DC, USA /  
Principal Investigator Dr. Gregory D. Trachiotis
    - University of Calgary, CAN /  
Principal Investigator Dr. Teresa Kieser
- What is Medistim's interest?
  - Enhance the general interest for and attention to the need for improved surgical guidance and graft assessment in CABG
  - Gain support from leading experts in the field based on clinical evidence
  - Create consensus for a recommended workflow
  - Obtain endorsement for this workflow by medical associations and health authorities in the USA and other countries
- Medistim's role
  - Sponsoring with EUR 1 million
- Timelines:
  - Study kicked off in Q2 2015
  - Plan to enroll 1,000 patients over 18-24 months



Seeing is believing