



# Full Year 2010

February 23, 2011

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# Executive Management Team

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- Kennet Rooth, CEO (pro term)
- Lars Sandström, CFO
- Göran Arvidson, VP Mergers & Acquisitions
- Anders Edvell, VP Marketing & Sales
- Peter Edman, VP R&D
- Stefan Fraenkel, VP Business Development
- Åsa Stenqvist, VP IR & Communication (pro term)
- Lena Nyström, VP Operations
- Maria Berggren, VP Human Resources
- Fredrik Berg, VP, General Counsel
- Sylvain Forget, Regional Director Western Europe

## Summary Q4 2010

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- Net sales declined 15% to SEK 465.0 M
- Sales, excluding Tracleer<sup>®</sup> and milestone revenues, increased by 3% at CER
- EBITA, excl. non-recurring items, was SEK 192.2 M
  - Sales rights for Mimpara<sup>®</sup> was sold back to Amgen
- Core EPS was 0.60

# January – December 2010

- Net sales declined 7.7% to SEK 1 906.7 M (2 065.6)
- Sales, excluding Tracleer<sup>®</sup> and milestone revenues, increased by 2% at CER
- EBITA, excl. non-recurring items, increased to SEK 371.9 M (273.6)
  - Sales rights for Mimpara<sup>®</sup> were sold back to Amgen
- Core EPS was 1.87 (0.84)

# Revenues by product

Amounts in SEK million	Oct 1 - Dec 31				Jan 1 - Dec 31			
	2010	CER 2010	Pro forma 2009	CER change	2010	CER 2010	Pro forma 2009	CER change
ReFacto	157.5	158.7	124.3	28%	587.1	593.5	631.9	-6%
<i>of which Manufacturing revenues</i>	119.9	119.9	69.2	73%	388.0	388.0	376.5	3%
<i>of which Co-promotion</i>	18.4	19.5	23.1	-16%	89.4	93.9	89.7	5%
<i>of which Royalty</i>	19.2	19.3	32.0	-40%	109.7	111.6	165.7	-33%
Kineret	101.3	108.9	120.5	-10%	422.3	454.1	440.8	3%
Orfadin	75.0	81.9	84.2	-3%	321.8	350.5	310.0	13%
Kepivance	18.3	19.1	26.2	-27%	94.8	101.7	109.9	-7%
Ammonaps	13.6	15.0	16.0	-6%	69.1	76.0	69.9	9%
Yondelis	13.4	14.8	12.5	18%	40.6	43.8	43.9	0%
Willfact	4.4	4.8	1.2	300%	13.1	13.9	1.2	1058%
Other product revenues	81.7	87.7	89.6	-2%	328.4	348.4	328.4	6%
<b>Total revenues continued products</b>	<b>465.2</b>	<b>490.9</b>	<b>474.5</b>	<b>3%</b>	<b>1,877.2</b>	<b>1,981.9</b>	<b>1,936.0</b>	<b>2%</b>
Tracleer	-	-	10.4	-100%	5.9	5.9	66.9	-91%
Other revenues	-	-	62.6	-100%	23.6	23.6	62.6	-62%
<b>Total revenues</b>	<b>465.2</b>	<b>490.9</b>	<b>547.5</b>	<b>-10%</b>	<b>1,906.7</b>	<b>2,011.4</b>	<b>2,065.5</b>	<b>-3%</b>

# Product revenues by region

(excl. ReFacto manufacturing, royalty and milestones)

<i>Amounts in SEK million</i>	2010	Oct 1 - Dec 31			Jan 1 - Dec 31			
		CER 2010	Pro forma 2009	CER change	2010	CER 2010	Pro forma 2009	CER change
Nordic	103.0	109.4	129.7	-16%	450.4	473.3	511.9	-8%
Europe	140.5	156.6	156.1	0%	551.3	610.4	587.7	4%
North America	69.0	71.3	82.1	-13%	340.2	359.5	318.2	13%
RoW	13.7	13.9	14.4	-3%	43.5	44.3	43.0	3%
<b>Total revenues</b>	<b>326.2</b>	<b>351.2</b>	<b>382.3</b>	<b>-8%</b>	<b>1,385.4</b>	<b>1,487.5</b>	<b>1,460.8</b>	<b>2%</b>

# Income

<i>Amounts in SEK million</i>	Oct 1 - Dec 31			Jan 1 - Dec 31		
	Pro forma			Pro forma		
	2010	2009	change	2010	2009	change
Total revenues	465,0	546,1	-15%	1 906,7	2 065,6	-8%
Cost of goods and services sold	-151,8	-166,5	-9%	-685,7	-664,3	3%
<b>Gross profit</b>	<b>313,2</b>	<b>379,6</b>	<b>-17%</b>	<b>1 221,0</b>	<b>1 401,3</b>	<b>-13%</b>
Sales and administration expenses	-135,6	-133,5	2%	-531,3	-499,7	6%
Research and development expenses	-124,6	-121,5	3%	-479,8	-603,1	-20%
Other operating revenues/expenses	139,2	-21,1		162,0	-24,9	
<b>Operating profit/loss before amortizations and non recurring items (EBITA)</b>	<b>192,2</b>	<b>103,5</b>		<b>371,9</b>	<b>273,6</b>	
Non recurring items	-29,8	–		-87,7	–	
Amortization	-139,0	-50,3		-294,4	-201,6	
<b>Operating profit/loss</b>	<b>23,4</b>	<b>53,2</b>		<b>-10,2</b>	<b>72,0</b>	
Financial income/expenses	-26,6			-82,2		
<b>Profit/loss after financial items</b>	<b>-3,2</b>			<b>-92,4</b>		
Income tax expense	-10,0			-12,0		
<b>Profit/loss for the period</b>	<b>-13,2</b>			<b>-104,4</b>		



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Kennet Rooth

CEO

# Product sales and launches

## • Americas

Orfadin® sales demonstrated a sharp increase 30% (F.Y. CER)

- Increased medical marketing
- Increased screening of newborns
- A higher number of newly diagnosed infants

Kineret® re-positioned for niche in the RA market and re-launch initiated

## • Europe outside the Nordics

European environment showed signs of improvement at the end of 2010

- Regulatory approvals
- P&R decisions made

Launches in preparation or ongoing in different countries

- Ruconest®
- Willfact®
- Yondelis ovarian®
- Promixin®
- Kineret® (re-launch)
- Multiferon®
- Removab®

# Products and launches (cont´)

## • Nordics

New product launches

- Ruconest®
- Wilfact®
- Yondelis® ova
- Kineret® (re-launch)
- Multiferon®
- Removab®

Several positive pricing and reimbursement decisions second half of 2010

Xagrid® tender won in Denmark

ViperaTab™ distribution agreement secured

## • ROW

New distributor in Korea

Expansion of distributor network a priority

Sales commence in Northern Africa

First sales (Ammonaps®) in Russia late 2010

First Orfadin® order in Russia early 2011

# R&D

Indication	Product/Project	Partner	Phase I	Phase II	Phase III	Reg phase
Hemophilia A	rFVIII Fc	Biogen/Dec				
Hemophilia B	rFIX Fc	Biogen/Dec				
Prevent growth retardation in premature infants	Kiobrina®					
CAPS	Kineret®					
Pernicious anemia	Nascobal®	Strativa				

Activity	Expected timing
Kiobrina (prevent growth retardation): start dosing phase III	H1 2011
Nascobal® (pernicious anemia): European registration application	H2 2011
rFIX Fc (hemophilia B): report phase III data	2012
rFVIII Fc (hemophilia A): report phase III data	2012

# Pipeline products; Factor VIII and IX

- Sobi and Biogen Idec remain confident that we will deliver program data for rFIXFc and rFVIII Fc in the 2012 time frame as recruitment is on track. We plan to initiate global pediatric (< 12 years) trials for both programs in order to ensure rapid enrollment and completion of the pediatric studies. This will allow us to file both the rFVIII Fc and the rFIXFc programs in EU in line with draft hemophilia guidelines which request pediatric data in the original file.
- In Europe the EMA has published guidelines to outline the requirements for the development of drugs aimed to treat hemophilia A and B. The current valid European guidelines were adopted in 2000. However, new draft guidelines, intended to replace the current guidelines covering recombinant FVIII and FIX have been released for public consultation. Sobi and Biogen Idec, as well as other stakeholders, have been in discussion with EMA regarding the final guidelines .

# Kiobrina®

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- Phase II studies completed with positive results
- Decision made to initiate a phase III study. Design discussed and agreed with EMA. PIP plan agreed with EMA
- Discussion on study ongoing with FDA
- FPFV planned for May
- Study data available 2013
- Partnering in China represents an additional opportunity

# Business Development

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- The Business Development function more than doubled; new experienced BD-Team in place
  - products
  - new distributors
  - expansion of existing territories for distribution products
- Competence and capacity for M&A
- Streamlining of existing distributor network
- Three new deals since December 1, 2010



# Summary

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- Seven new product launches
- Three new business development deals in two months; continued intensive BD-activities
- All phase III studies run according to plan
- Sobi cost structure being addressed
- Sobi's long term objectives remain the same:  
Revenue SEK 5 billion, EBITA margin > 30 % in 2015



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