



**biovitrum.**

Fourth Quarter and Full Year Results 2009

2010-02-18

# FY 2009 – Strong revenue growth and profit turn around

- Total revenues were SEK 1,297 M (incl. upfront payment from AstraZeneca)
- Revenues before license revenues up 22% to SEK 1,234.4 M (1,008.1)
  - Driven mainly by Kineret<sup>®</sup> and Kepivance<sup>®</sup>
- EBITA of SEK 68 M (-34.1)
- Profit for the period SEK 32.5 M (-335.5)
  - Corresponding to a core EPS of SEK 0.84 (0.18)
- Cash and cash equivalents and short term investments Dec. 31 SEK 306.6 M (460.1)

## Q4 2009 – Key product sales drive growth

- Total revenues up 11 % to SEK 347.7 M (314.3)
- Kineret<sup>®</sup> and Kepivance<sup>®</sup> sales highest since acquisition: SEK 147.2 M
- ReFacto<sup>®</sup> co-promotion revenues up 25% to SEK 23.1 (18.5)
- EBITA of SEK 64.9 M (-62.4)
- Profit for the period SEK 31.5 M (-246.6).
  - Corresponding to a Core EPS of SEK 0.44 (-0.20)

## Q4 2009 - Positive clinical program progression

- Positive long-acting rFIXFc phase I/II hemophilia B study data
  - Well tolerated and demonstrated prolonged half-life in previously treated severe hemophilia B patients
- Decision to advance rFIXFc into registrational program – a Biovitrum milestone achievement
  - rFIXFc's ability to prevent bleeding will be assessed in the B-Long Study
- First hemophilia A patients dosed in phase I/IIa trial with long-acting rFVIII Fc
- Positive results from first of two preterm infant clinical phase II study with Kiobrina<sup>®</sup> (rhBSSL)
  - Statistically significant improvement of growth velocity and safety profile comparable to placebo
  - Second phase II study in final stage
- Primary end point not met in the Exinalda<sup>®</sup> exploratory phase II study

# Key figures Q4 and FY 2009

<i>Amounts in SEK million</i>	Oct 1 - Dec 31		Full year	Full year	
	2009	2008	2009	2008	
Total revenues before license revenues	285,1	314,3	1 234,4	1 008,1	+ 22%
<b>Total revenues</b>	<b>347,7</b>	<b>314,3</b>	<b>1 297,0</b>	<b>1 140,6</b>	
Gross profit	255,0	231,2	921,3	875,9	
Operating profit/loss before restructuring and other one-time expenses	51,4	-64,0	16,2	-40,1	
<b>Operating profit/loss before depreciations and amortizations (EBITDA)</b>	<b>77,0</b>	<b>-73,8</b>	<b>125,9</b>	<b>-118,8</b>	
<b>Operating profit/loss before amortizations (EBITA)</b>	<b>64,9</b>	<b>-288,6</b>	<b>68,0</b>	<b>-380,3</b>	
<b>Operating profit/loss (EBIT)</b>	<b>51,4</b>	<b>-290,2</b>	<b>16,2</b>	<b>-386,3</b>	
<b>Profit/loss for the period</b>	<b>31,5</b>	<b>-246,6</b>	<b>32,5</b>	<b>-335,5</b>	
Core EPS <sup>1) 2)</sup> (SEK)	0,44	-0,20	0,84	0,18	pos. EPS
Restructuring and other one-time expenses	-	-226,2	-	-346,2	
Research and development expenses	109,4	185,8	569,4	670,6	- 15%
Liquid funds and short-term investments	306,6	460,1	306,6	460,1	

<sup>(1)</sup> Adjusted for new share issue completed in January 2010, after which total number of shares are 151,704,533.

<sup>(2)</sup> Core EPS is calculated from P/L for the period excluding amortizations and restructuring and other one-time expenses and based on average number of shares.

# Kineret Q4 2009 sales the highest since the acquisition

Amounts in SEK million	Oct 1 - Dec 31		Full year	Full year
	2009	2008	2009	2008
Kineret® <sup>1)</sup>	120.9	25.8	440.7	25.8
Kepivance® <sup>1)</sup>	26.3	5.7	109.9	5.7
Aloxi®	2.3	1.0	9.4	5.3
Stemgen®	0.4	0.6	3.4	0.6
Novastan®	0.9	0.4	1.3	0.8
<b>Total revenues</b>	<b>150.9</b>	<b>33.5</b>	<b>564.8</b>	<b>38.2</b>

<sup>1)</sup>In 2008, until the time of the acquisition, Biovitrum reported sales of Kepivance and Kineret as co-promotion revenues. Kineret and Kepivance are sold globally; Stemgen is sold in Canada and Australia, while Aloxi and Novastan are sold in the Nordic countries.

## Sales at Fixed Exchange Rate (average Q1 2009)

Amounts in SEK million	2009			
	Q1	Q2	Q3	Q4
Kineret	104,0	113,5	114,9	133,5
Kepivance	29,6	28,1	30,4	29,9
<b>Total revenues</b>	<b>133,6</b>	<b>141,6</b>	<b>145,3</b>	<b>163,4</b>
<i>Revenue growth (%) in local currency per quarter</i>		6,0%	2,6%	12,5%

+22 % since Q1

The table shows sales development at fixed exchange rates using the average Swedish Krona exchange rate in Q1, 2009 as reference

# ReFacto<sup>®</sup> manufacturing revenues are in transition due to ReFacto AF<sup>®</sup> /Xyntha<sup>®</sup> switch

<i>Amounts in SEK million</i>	Oct 1 - Dec 31		Full year	Full year
	2009	2008	2009	2008
ReFacto	67.6	186.4	362.5	569.3
<i>of which validation batches</i>	–	47.0	–	47.0
Contract development	1.2	11.6	14.1	49.7
<b>Total</b>	<b>68.7</b>	<b>198.0</b>	<b>376.5</b>	<b>619.0</b>

# Co-promotion revenues (excluding Kineret) increased in Q4 and FY 2009

<i>Amounts in SEK million</i>	Oct 1 - Dec 31		Full year	Full year
	2009	2008	2009	2008
ReFacto®	23.1	18.5	89.7	80.2
BeneFIX®	3.6	2.2	11.2	10.4
Mimpara®	7.1	5.6	26.2	22.7
Kineret®	0.2	15.0	0.2	61.2
Kepivance®	0.0	–	0.0	0.2
Other	-0.4	–	–	–
<b>Total revenues</b>	<b>33.6</b>	<b>41.3</b>	<b>127.3</b>	<b>174.7</b>

<sup>1)</sup>In 2008, until the time of the acquisition, Biovitrum reported sales of Kepivance and Kineret as co-promotion revenues.



# Successful divestment and out-licensing of non-core R&D activities

- **Divestment of Cambridge Biotechnology Ltd to Proximagen Neuroscience plc.**
  - Deal structure contains future revenue sharing
  - Proximagen will own certain small molecule projects and associated IP and other assets:
    - The 5-HT<sub>2C</sub> agonist and 5-HT<sub>6</sub> antagonist clinical programs
    - Pre-clinical projects VAP-1, Trk A, and several other exploratory programs
- **AstraZeneca acquired rights to preclinical leptin modulator program aimed at treating obesity**
  - Euro 6M upfront payments
  - Biovitrum will receive milestone payments and royalties on future sales
- **Transfer of two metabolic disease projects to iNovacia AB**
  - Pre-clinical projects GPR 119 and SCD-1
  - Future revenues from the projects will be split of 70:30 (iNovacia:Biovitrum).
  - Biovitrum will receive royalties on future sales
- **Flt3 leukemia program to continue in company owned by Biovitrum and Karolinska Development AB**
  - Program financed by Karolinska Development.
  - Biovitrum will receive royalties on future sales

# New deals strengthening future business

- Acquisition of Swedish Orphan International
- rFVIII Fc and rFIX Fc collaboration agreement with Biogen Idec restructured
  - Biogen Idec assumes development responsibilities and costs as well as manufacturing rights
  - Biogen Idec gains marketing responsibility for the rest-of-world territories in addition to North America.
  - Swedish Orphan Biovitrum retains commercial rights in Europe, Russia, Turkey and the Middle East.
- Agreement with Amgen to expand Kineret<sup>®</sup> license to include certain orphan indications
- Collaboration agreement signed with Affibody AB, giving Biovitrum access to proprietary technology platforms of Affibody<sup>®</sup> molecules and unique albumin-binding technology
- Deal with Megapharm in Israel as first step in a program to expand geographical territories of Kineret<sup>®</sup> and Kepivance<sup>®</sup> sales

# FY 2009 - Swedish Orphan Biovitrum pro forma financial statement

<i>Amounts in SEK million</i>	<b>Biovitrum</b>	<b>Swedish Orphan Intl.</b>	<b>Pro forma adjustments</b>	<b>Swedish Orphan Biovitrum</b>
Total revenues	1,297.0	768.6	–	2,065.6
<b>EBITDA</b>	<b>125.9</b>	<b>218.2</b>	<b>–</b>	<b>344.2</b>
<i>EBITDA margin</i>	10%	28%		17%
Depreciations	-57.9	-2.5	–	-60.4
<b>EBITA</b>	<b>68.0</b>	<b>215.7</b>	<b>–</b>	<b>283.8</b>
<i>EBITA margin</i>	5%	28%		14%
Amortizations <sup>1)</sup>	-51.8	-6.1	-153.8	-211.7
<b>EBIT</b>	<b>16.2</b>	<b>209.6</b>	<b>-153.8</b>	<b>72.1</b>

<sup>1)</sup> Amortizations SEK 211.7 M consists of amortization of product rights (Kineret<sup>®</sup>, Kepivance<sup>®</sup> and Stemgen<sup>®</sup>) 47.9, amortization related to acquisition of Swedish Orphan 153.8 and other amortizations 10.0.

# Summary – Strong platform for profitable growth

- Financial results demonstrate strong revenue growth and profit turn around
  - 22% revenue growth
  - 15% R&D cost decrease
  - Core EPS of SEK 0.84
- Compelling platform for profitable growth by acquisition of Swedish Orphan International
- Positive clinical pipeline progressions
- Reduction of R&D cost base
- Successful out-licensing and divestments of non-core R&D projects and operations