

Sobi Q2 results presentation

rare **strength**

17 July 2019



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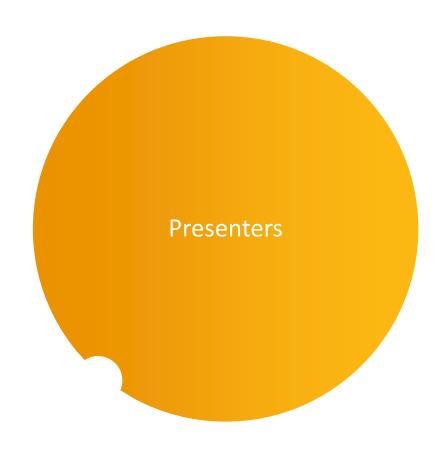
Guido Oelkers, CEO



Henrik Stenqvist, CFO



Milan Zdravkovic, Head of R&D and CMO





Strong performance, sharper focus

- Total revenue of SEK 3,163 M (2,289). 38 per cent revenue growth in the quarter compared with Q2 2018 (32 per cent at CER)
- Organic growth (adjusted for Synagis and measured at CER) amounted to 25 per cent compared with Q2 2018
- Adjusted EBITA^{1,2} was SEK 1,193 M, an increase of 25 per cent
- Sales for Elocta® were SEK 1,127 M (794), an increase of 42 per cent (37 per cent at CER)
- Sales for Alprolix® were SEK 382 M (263), an increase of 45 per cent (40 per cent at CER)
- Continued strong performance for Gamifant® with sales amounting to SEK 205 M
- Purchase agreement of CHF 515 M (SEK 4,897 M) to emapalumab and related assets was signed
- Sharpened strategic focus on core areas of Haematology in Sweden and in Immunology in Switzerland
- Investment into core business and late-stage assets to drive future growth







Haemophilia – strong position with substantial potential

Continued exceptional momentum

- Future growth driven by penetration and internationalisation

Individualised therapy only possible with factor replacement

- Ensuring best outcome for patients

Significant promise now and for the future

- Factor replacement will remain standard of care for people with haemophilia



Alprolix – impressive performance continues



- Q2 product sales of SEK 382 M (263)
 - Sales growth of 45 per cent (40 per cent at CER)
 - Majority of the growth derived from France, Italy and Germany
- Reimbursed in 23 countries

- Debate on clinical benefit of extra vascularisation is intensifying
- Alprolix showed zero bleeds unlike other EHLs in a real-world setting¹

¹ISTH 2019 Malic et al.



Elocta – factor replacement therapies keep up momentum

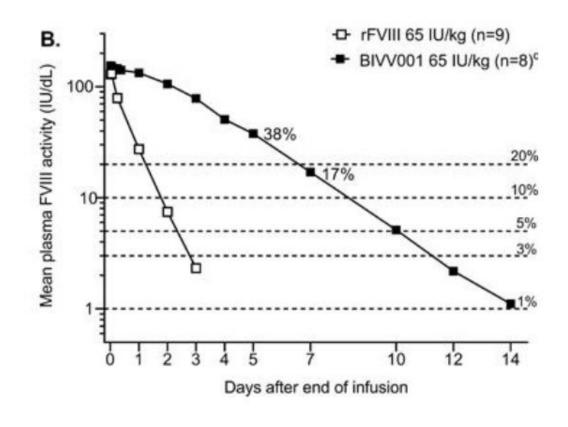


- Q2 product sales of SEK 1,127 M (794)
 - Revenue growth of 42 per cent (37 per cent at CER)
 - Majority of the growth derived from France, Italy and Germany
 - Sales positively impacted by order patterns in the Middle East
- Reimbursed in 27 countries
- Confidence in further development of the product



Single 65 IU/kg dose of BIVV001 extends FVIII half-life to 43 h and shows 17% activity seven days post-infusion

- Mean $t_{1/2}$ for BIVV001 at a dose of 65 IU/kg was longer than for rFVIII (43 vs 13 h)
- Average FVIII activities at 5 and 7 days post 65 IU/kg BIVV001 were 38% and 17% respectively







Interim results from a prospective study of first-time ITI with Elocta

Background

- Immune Tolerance Induction (ITI) is the standard of therapy for eradication of inhibitors
- Experimental data suggests immunomodulatory effects of Fc-fused factor therapy
- Encouraging retrospective clinical data in ITI

Study

- Interventional, multi-centre study of Elocta for first-time ITI in subjects with severe haemophilia A & high-titre inhibitors (historical peak ≥5 BU/mL)
- Pre-planned interim analysis when 10 subjects received at least 6 months of ITI (data cut-off as of 23 Jan 2019)

Results & Conclusion

- 6 out of 15 patients had ITI success after a median of 11.7 weeks (8 patients still ongoing)
- Interim results indicate that Elocta may offer rapid time to tolerisation





Driving growth in Immunology

Strong base business with Kineret – back to double-digit growth

Gamifant – high unmet medical need driving growth

Continuously reviewing opportunities for external growth



Immunology – strong overall growth

Color vovenue (CEV NA)



- Total Immunology revenue of SEK 773 M
- Synagis sales impacted by seasonal variations
- Purchase agreement of CHF 515 M (SEK 4,897 M) for the global rights to emapalumab and related assets was signed
- Double-digit growth for Kineret



Kineret – continued solid growth



- Revenue of SEK 419 M (340 M)
 - Increase of 23 per cent (16 per cent at CER) compared with Q2 2018
- Double-digit growth seen across all regions
- High demand in the US related to:
 - Changed distribution channel provider
 - New patient enrolments
 - More patients continuing on treatment
 - Improved prescription fill rates



Synagis opportunity

- Q2 sales of SEK 148 M
 - Sales strongly influenced by seasonal effects
 - Virus season lasted longer this year
 - Increased focus on achieving full adherence among patients.
 - Sales also include one-offs of SEK 81 M
- Underlying demand increasing (2.5%)
- Ongoing activities to unlock meaningful value across the patient funnel
 - Reduce leakages across the chain
 - Improve adherence





Gamifant – strong US growth

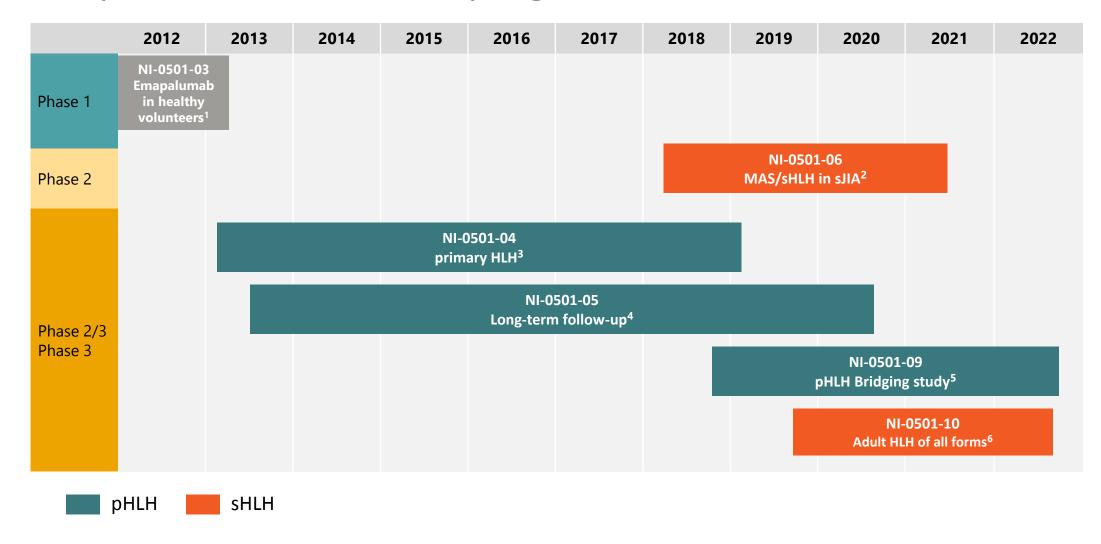


- Q2 sales of SEK 205 M
- Growth mainly driven by high demand due to unmet medical need
- The regulatory dialogue and process ongoing with CHMP in Europe for the potential approval of emapalumab for primary HLH
- Based on current estimates and anticipated timelines for questions and answers, approval expected around mid-2020.
- Continue investments into further indications and new markets





Emapalumab clinical trial programme (as of June 2019)



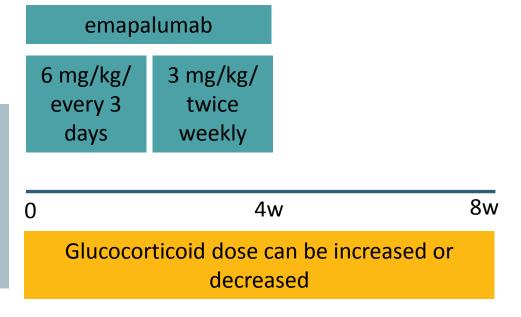
^{1.} https://clinicaltrials.gov/ct2/show/NCT01459562 2. https://clinicaltrials.gov/ct2/show/NCT03311854 3. https://clinicaltrials.gov/ct2/show/NCT01818492 4. https://clinicaltrials.gov/ct2/show/NCT03312751 6. https://clinicaltrials.gov/ct2/show/NCT03312751 6. https://clinicaltrials.gov/ct2/show/NCT03985423



Emapalumab leads to complete response in patients with secondary HLH (MAS) induced by sJIA

- interim results from a pilot phase 2 study

sJIA patients with sHLH (MAS) having shown inadequate response to high-dose glucocorticoid treatment



- Complete response to emapalumab was observed in 6 out of 6 patients, all of whom had failed conventional therapy
- Rapid decrease in CXCL9 demonstrating complete neutralisation of IFNg
- Response occurred early with clinically meaningful tapering of glucocorticoids observed from week 1
- Emapalumab was well tolerated; a few infections emerged (mostly positive tests); one CMV reactivation was considered related and serious

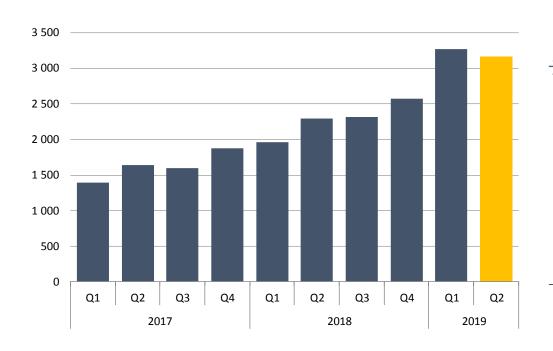






Financial results

Total revenue (SEK M)



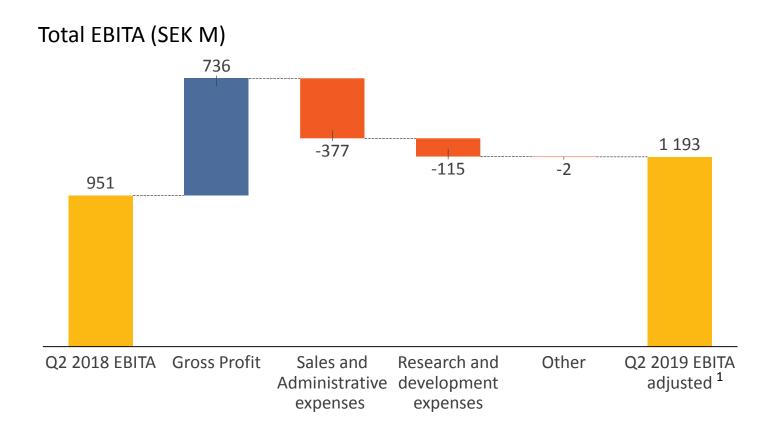
	Q2	Q2		H1	H1		FY
Amounts in SEK M	2019	2018	Change	2019	2018	Change	2018
Total revenue	3,163	2,289	38%	6,427	4,253	51%	9,139
Gross profit	2,413	1,677	44%	4,907	3,089	59%	6,723
Gross margin	76%	73%		76%	73%		74%
EBITA adjusted ¹	1,193	951	25%	2,665	1,722	55%	3,571
EBITA margin adjusted ¹	38%	42%		41%	40%		39%
Profit for the period	499	685	-27%	1,402	1,200	17%	2,418
Earnings per share, SEK adjusted ^{1,2}	2.12	2.54	-17%	5.14	4.45	16%	8.97
Operating cash flow	1,275	564	126%	1,663	841	98%	2,090
Net debt(+) / Net cash(-)	4,403	-2,300		4,403	-2,300		-2,999

¹EBITA excluding non-recurring items; restructuring costs of SEK 157 M in Q2 2019 and gain from divestment of SOBI005 in Q1 2019 of SEK 37 M.

 $^{^2}$ EPS excluding impairment of intangible assets of SEK 18 M related to the restructuring in Q2 2019.



Q2 Adjusted EBITA¹ walk-through





Important events – financial impact

Intention to discontinue early research and programmes outside of core areas:

- Restructuring costs for the quarter amounted to SEK 175 M, whereof SEK 157 M impacted EBITA and SEK 18 M related to impairment of intangible assets
- Expected to generate annual savings of SEK 200 300 M in 2020, with the intention to invest the freed up capital in strategic core areas

Sobi signed a purchase agreement for emapalumab and related assets

- Consideration for the acquisition is CHF 515 M (SEK 4,897 M), of which CHF 400 M was previously committed in the exclusive license agreement
- The acquisition is debt-financed, with new credit facilities made available by current funding banks
- Sobi has net debt of SEK 4,403 M at 30 June 2019. Pro forma leverage remains under 2. Additional debt capacity remains for further M&A.







Key messages

- Committed to our strategic direction
- Develop Immunology and expand within Haematology
 - Drive Haemophilia penetration
 - Grow US business and strengthen position in EMENAR
 - Strengthen late-stage pipeline
 - Committed to M&A
- Updated 2019 guidance:
 - Sobi expects revenue for the full year to be in the range of SEK $13,000 13,500 \, M^1 \, (12,500 13,000)^2$.
 - EBITA for the full year is expected to be in the range of SEK 5,300 5,500 M¹ (5,000 5,300)², excluding restructuring costs.
 - The updated outlook reflects the continued strong product sales in Haemophilia and the promising uptake of Gamifant in the US.









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