Q4 and FY 2022 report

Conference call for investors and analysts

rare **strength**

8 February 2023

Forward-looking statements

In order to utilise the 'Safe Harbor' provisions of the United States Private Securities Litigation Reform Act of 1995, Swedish Orphan Biovitrum AB (publ) (Sobi®) is providing the following cautionary statement: This presentation contains forward-looking statements with respect to the financial condition, results of operations and businesses of Sobi. By their nature, forward-looking statements and forecasts involve risk and uncertainty because they relate to events and depend on circumstances that will occur in the future. There are a number of factors that could cause actual results and developments to differ materially from that expressed or implied by these forward-looking statements. These factors include, among other things, the loss or expiration of patents, marketing exclusivity or trade marks; exchange rate fluctuations; the risk that R&D will not yield new products that achieve commercial success; the impact of competition, price controls and price reductions; taxation risks; the risk of substantial product liability claims; the impact of any failure by third parties to supply materials or services; the risk of delay to new product launches; the difficulties of obtaining and maintaining governmental approvals for products; the risk of failure to observe ongoing regulatory oversight; the risk that new products do not perform as we expect; and the risk of environmental liabilities.

Agenda and presenters

Overview and business		Guido Oelkers, Chief Executive Officer
Financials		Henrik Stenqvist, Chief Financial Officer
Pipeline		Anders Ullman, Head of RDMA[1], Chief Medical Officer
Summary and Q&A		All

1. Research & Development and Medical Affairs.

Overview: a good year and a solid future

- **Revenue** +5% in Q4; strong quarter. +8% in FY; outlook fully met
- **Launch medicines**[1] +29% in Q4, driven by Doptelet®, and +37% in FY
- Haemophilia saw relative stability, Aspaveli® launch going well (SEK 87 M in Q4) but Immunology held back by COVID-19 comparison and softer Gamifant® sales

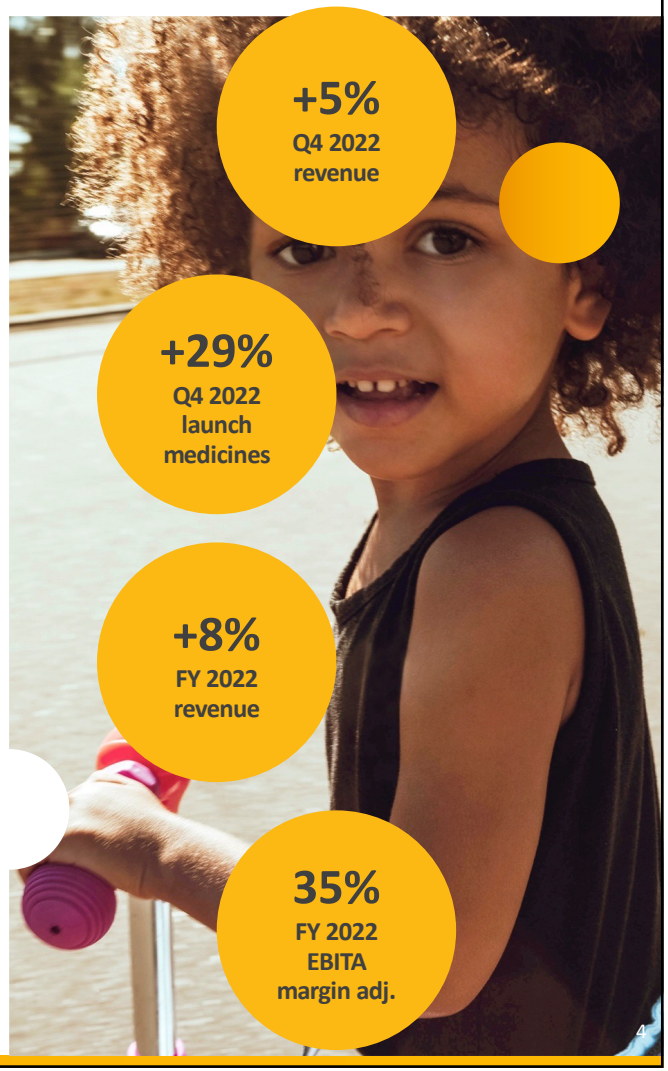
- **SG&A** costs slowed in Q4; **R&D** grew 6%. Continued cost control
- **EBITA** margin adjusted 41% in Q4 and 35% in FY; outlook fully met

- **Pipeline** moved ahead: Zynlonta® EU approval, Doptelet China submission in ITP[2], Kineret® US emergency use in COVID-19 and nirsevimab US regulatory submission
- **News flow** to increase in 2023

- **2023 outlook** solid with continued growth

Continued performance:	**2022 outlook fully met** **2023 outlook solid with continued growth**

Change at constant exchange rates.
1. Launch medicines include Doptelet (outside China), Aspaveli and Gamifant 2. Immune thrombocytopenia.



Business: growth driven by Doptelet in Haematology and Rest of World

	Q4 '22	change	ratio	FY '22	change	ratio
	SEK M	%	%	SEK M	%	%
Haematology	3,025	19	51	10,831	15	58
– Haemophilia	*2,106*	*2*	*35*	*7,714*	*2*	*41*
Immunology	2,643	-6	44	6,679	-1	35
Specialty Care	323	-12	5	1,280	-5	7
Total	**5,991**	**5**	**100**	**18,790**	**8**	**100**

	Q4 '22	change	ratio	FY '22	change	ratio
	SEK M	%	%	SEK M	%	%
Europe	1,876	-3	31	7,484	2	40
North America	2,879	5	48	7,441	2	40
Rest of world	894	47	15	2,438	85	13
Other[1]	342	-11	6	1,427	-4	7
Total	**5,991**	**5**	**100**	**18,790**	**8**	**100**

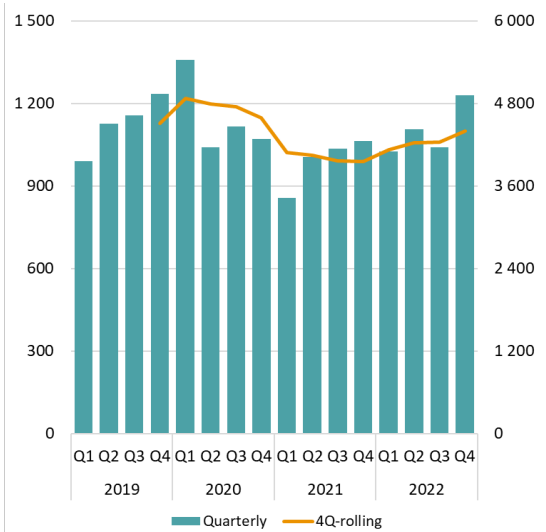
Revenue at actual exchange rates; change at constant exchange rates (by segment and geographic area).

1. Royalty revenue.

Haematology: haemophilia up in the quarter and in the year

Elocta®

+6% Q4 | +5% FY



Haemophilia expected to continue stability in 2023

Elocta

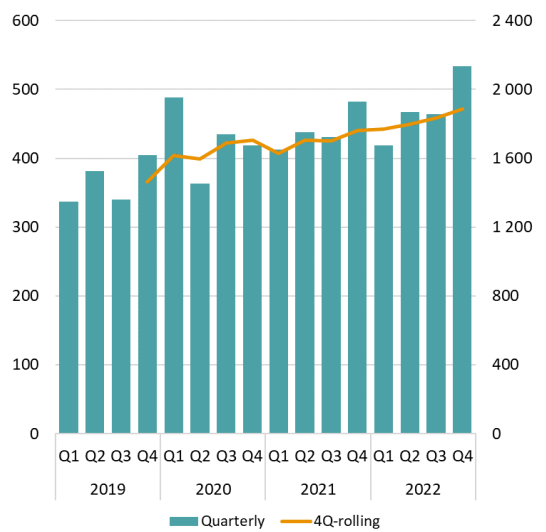
- Timing of orders, growth in patients and consumption somewhat offset by price

Alprolix

- Growth in patients and consumption offset by price

Alprolix®

+1% Q4 | +1% FY



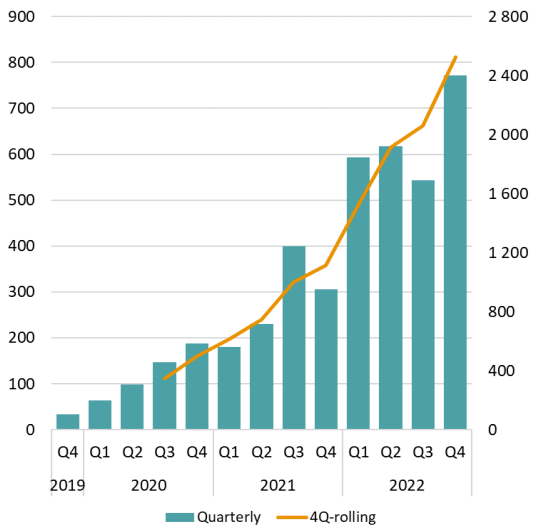
Sales in SEK million at actual exchange rates; change at constant exchange rates.

Sales in SEK million at actual exchange rates; change at constant exchange rates.

Haematology: Doptelet up 72% in Q4 excluding sales to the partner in China

Doptelet

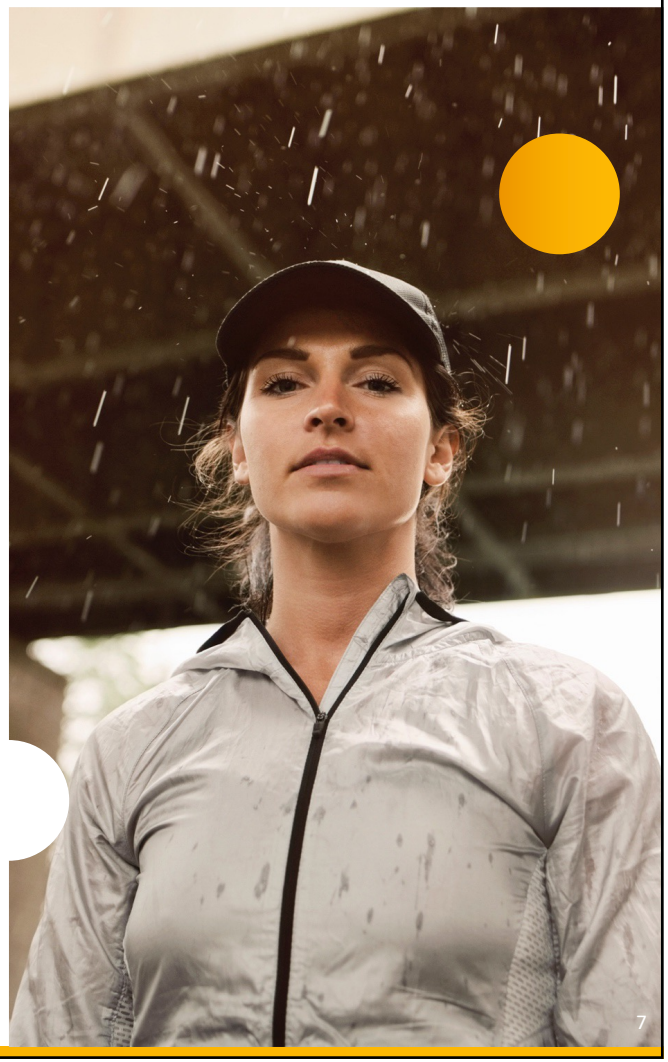
+107% Q4 | +91% FY



Sales in SEK million at actual exchange rates; change at constant exchange rates.

- US: new patients, new prescribers, higher market share and longer duration of treatment
- Europe: strong growth from Germany and recent reimbursements, e.g. Italy, Spain
- China: sales SEK 317 M (85)[1]

1. Doptelet entered the China National Reimbursement Drug List (NRDL) in 2020 with renewal confirmed from 1 March 2023. Doptelet, and any approved avatrombopag generic from 2023, are anticipated to remain on the NRDL until three avatrombopag generics have been approved for sale in China. At this point, a transfer to competitive volume-based procurement is anticipated.

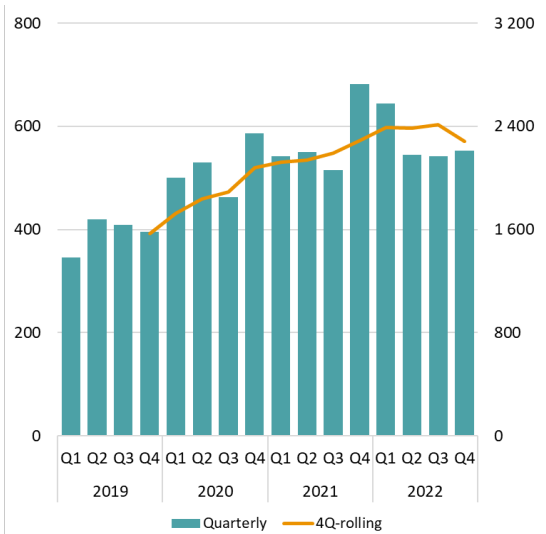


1. In the EU and the UK, Aspaveli is indicated for the treatment of adults with paroxysmal nocturnal haemoglobinuria (PNH) who are anaemic after treatment with a C5 inhibitor for at least three months. Sales in SEK million at actual exchange rates.

Immunology: Kineret COVID-19 impact; Gamifant softer

Kineret

-30% Q4 | -11% FY



Sales in SEK million at actual exchange rates; change at constant exchange rates.

Kineret

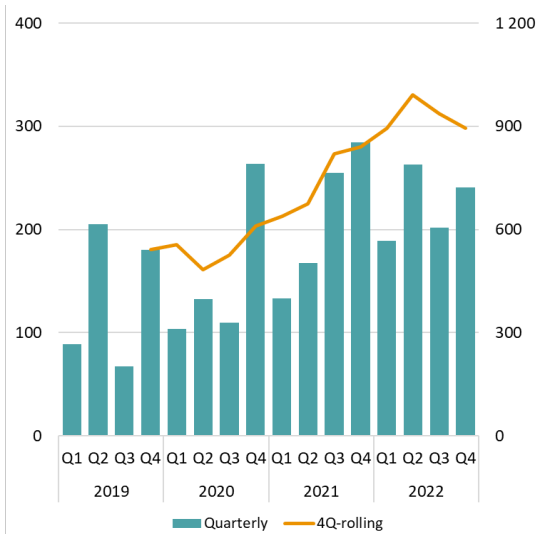
- Sales down from no use in COVID-19. Rebasing to be completed by next quarter

Gamifant

- High adoption in the US and declined mainly due to lower use in adults

Gamifant

-31% Q4 | -10% FY

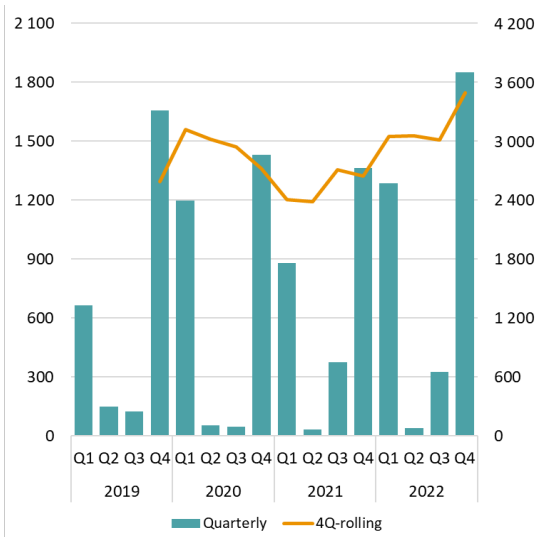


Sales in SEK million at actual exchange rates; change at constant exchange rates.

Immunology: strong Synagis quarter

Synagis®

+12% Q4 | +12% FY



Sales in SEK million at actual exchange rates; change at constant exchange rates.

- Synagis accelerated after a later start to the RSV[1] season. Growth included favourable price effects
- US RSV infections have started to decrease markedly
- Sobi continues to anticipate a 2022-2023 season that will follow a pattern closer to a normal season than in 2021

1. Respiratory syncytial virus.

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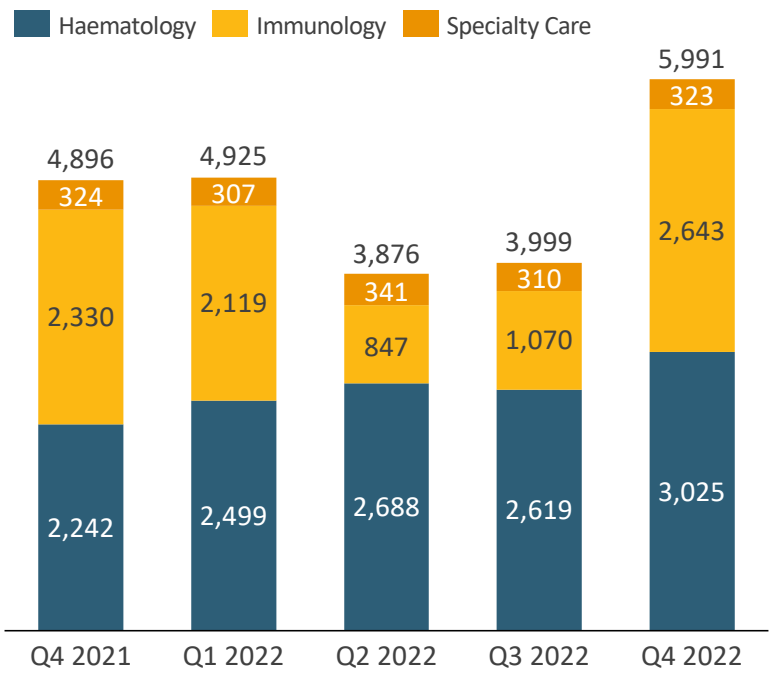
Revenue, profit & loss

Total revenue (SEK M)



	Q4 2022	Q4 2021	Change	FY 2022
Total revenue	**5,991**	4,896	22%	18,790
Gross profit	**4,683**	3,880	21%	14,014
Gross margin[i]	**78%**	79%		75%
EBITA[i]	**2,455**	2,002	23%	5,930
EBITA adjusted[i,ii]	**2,455**	2,002	23%	6,605
EBITA margin[i]	**41%**	41%		32%
EBITA margin adjusted[i,ii]	**41%**	41%		35%
Profit	**1,386**	1,241	12%	2,638
Earnings per share (EPS), before dilution, SEK	**4.68**	4.21	11%	8.92
EPS, before dilution, adjusted[i,ii], SEK	**4.68**	4.21	11%	10.77
Operating cashflow	**1,898**	2,121	-11%	4,665
Net debt (+)/net cash (-)	**7,406**	9,500		7,406

i. Alternative performance measure; see the quarterly report for further information.
ii. Items affecting comparability, see report for further information.

Absolute amounts in SEK million (except EPS) and at actual exchange rates; change at actual exchange rates (statutory view).

2023 outlook

Revenue

Anticipated to grow by a low-to-mid single-digit percentage at CER[1]

EBITA margin adjusted[2]

Anticipated to be at a low 30s percentage of revenue

1. Constant exchange rates 2. Excluding items affecting comparability. This outlook continues to exclude any elements of Sobi's right to the full share of US profits and losses for nirsevimab.

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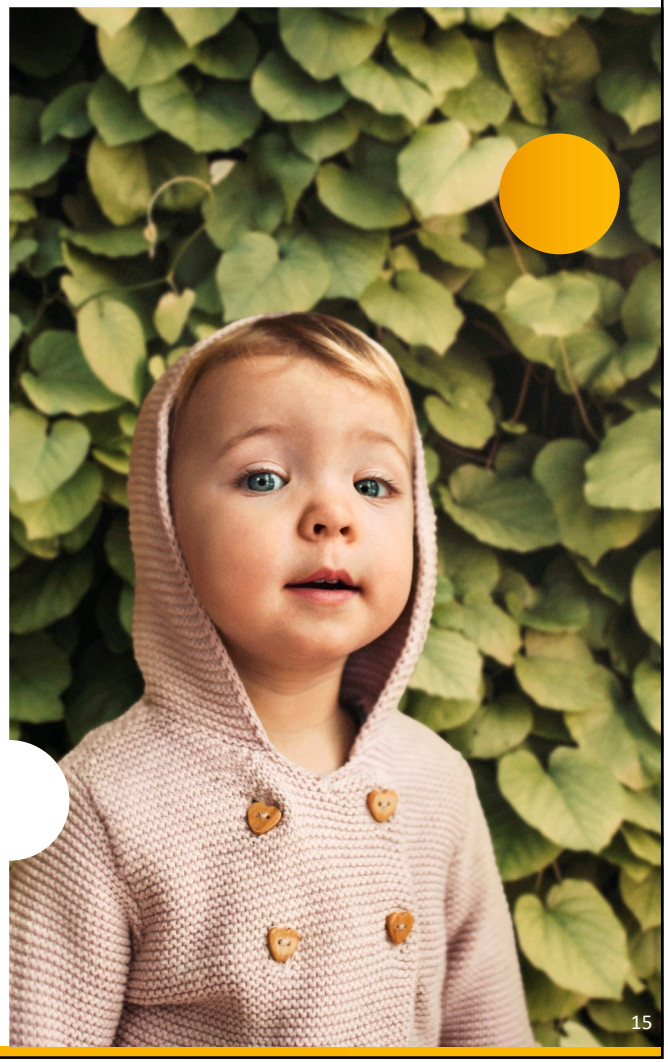
Pipeline: continued milestone progress

Major pipeline milestones since the previous report

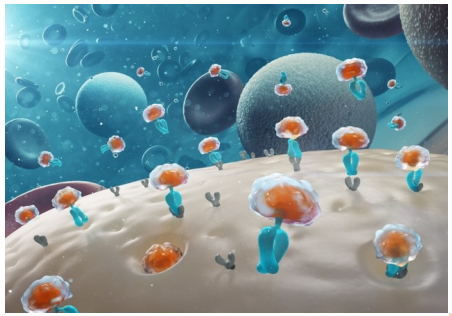
Significant milestones

Doptelet	ITP	regulatory submission in China
Zynlonta (loncastuximab tesirine)	DLBCL[1]	approval in the EU
Kineret	COVID-19	authorised for emergency use in the US
nirsevimab	RSV prevention	regulatory submission acceptance in the US (by AstraZeneca/Sanofi)[2]



1. Diffuse large B-cell lymphoma 2. Sobi has the right to AstraZeneca's full share of US profits and losses for nirsevimab. Status as of 7 February 2023.

ASH 2022: broadening the presence across haematology



Doptelet

Two poster presentations, including length of therapy/persistence across thrombopoietin receptor agonists in ITP and Doptelet real-world experience

Aspaveli/Empaveli

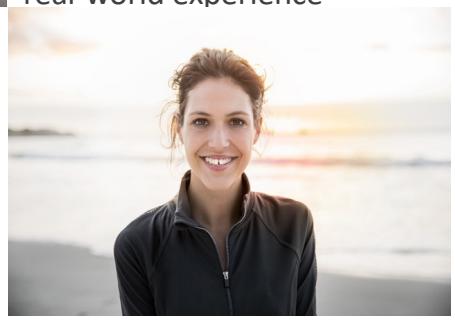
Three poster presentations, including long-term safety and efficacy and intensive dosing in PNH and study-in-progress in cold agglutinin disease

Gamifant

Poster presentation on the REAL-HLH real-world study in people with primary hemophagocytic lymphohistiocytosis in the US

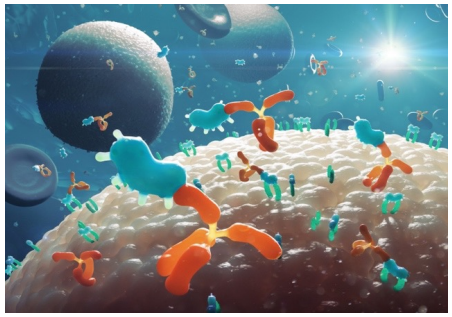
Efanesoctocog alfa

Two poster presentations focused on physical functioning and pain from the XTEND-1 phase 3 study supplemented by one on pharmacokinetics



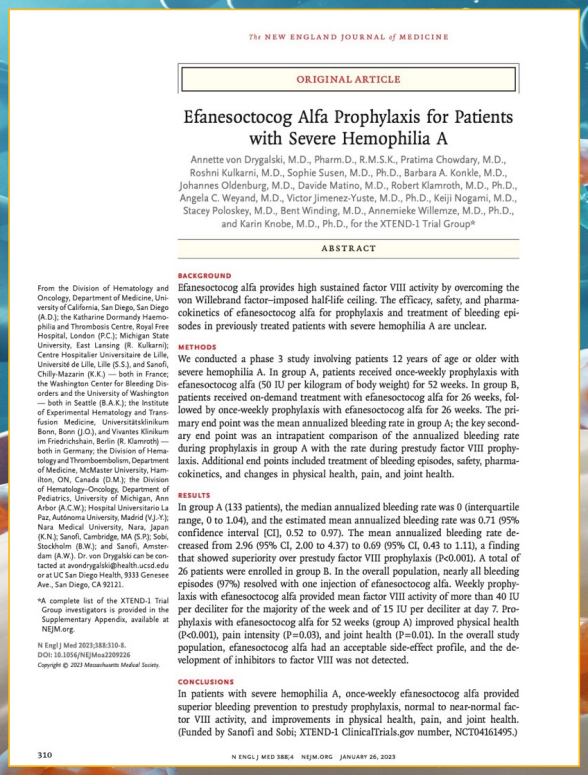
Zynlonta

ADC Therapeutics shared a number of poster presentations, including from the LOTIS clinical study development programme in malignant haematology



Source: 64th American Society of Hematology (ASH) Annual Meeting and Exposition 2022.

Efanesoctocog alfa: first phase 3 published



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Efanesoctocog Alfa Prophylaxis for Patients with Severe Hemophilia A

Annette von Drygalski, M.D., Pharm.D., R.M.S.K., Pratima Chowdary, M.D., Roshni Kulkarni, M.D., Sophie Susen, M.D., Ph.D., Barbara A. Konkle, M.D., Johannes Oldenburg, M.D., Davide Matino, M.D., Robert Klamroth, M.D., Ph.D., Angela C. Weyand, M.D., Victor Jimenez-Yuste, M.D., Ph.D., Keiji Nogami, M.D., Stacey Poloskey, M.D., Bent Winding, M.D., Annemieke Willemze, M.D., Ph.D., and Karin Knobe, M.D., Ph.D., for the XTEND-1 Trial Group*

From the Division of Hematology and Oncology, Department of Medicine, University of California, San Diego, San Diego (A.D.); the Katharine Dormandy Haemophilia and Thrombosis Centre, Royal Free Hospital, London (P.C.); Michigan State University, East Lansing (R. Kulkarni); Centre Hospitalier Universitaire de Lille, Université de Lille, Lille (S.S.), and Sanofi, Chilly-Mazarin (K.K.) — both in France; the Washington Center for Bleeding Disorders and the University of Washington — both in Seattle (B.A.K.); the Institute of Experimental Hematology and Transfusion Medicine, Universitätsklinikum Bonn, Bonn (J.O.), and Vivantes Klinikum im Friedrichshain, Berlin (R. Klamroth) — both in Germany; the Division of Hematology and Thromboembolism, Department of Medicine, McMaster University, Hamilton, ON, Canada (D.M.); the Division of Hematology–Oncology, Department of Pediatrics, University of Michigan, Ann Arbor (A.C.W.); Hospital Universitario La Paz, Autónoma University, Madrid (V.J.-Y.); Nara Medical University, Nara, Japan (K.N.); Sanofi, Cambridge, MA (S.P.); Sobi, Stockholm (B.W.); and Sanofi, Amsterdam (A.W.). Dr. von Drygalski can be contacted at avondrygalski@health.ucsd.edu or at UC San Diego Health, 9333 Genesee Ave., San Diego, CA 92121.

*A complete list of the XTEND-1 Trial Group investigators is provided in the Supplementary Appendix, available at NEJM.org.

N Engl J Med 2023;388:310-8.
DOI: 10.1056/NEJMoa2209226
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ABSTRACT

BACKGROUND

Efanesoctocog alfa provides high sustained factor VIII activity by overcoming the von Willebrand factor–imposed half-life ceiling. The efficacy, safety, and pharmacokinetics of efanesoctocog alfa for prophylaxis and treatment of bleeding episodes in previously treated patients with severe hemophilia A are unclear.

METHODS

We conducted a phase 3 study involving patients 12 years of age or older with severe hemophilia A. In group A, patients received once-weekly prophylaxis with efanesoctocog alfa (50 IU per kilogram of body weight) for 52 weeks. In group B, patients received on-demand treatment with efanesoctocog alfa for 26 weeks, followed by once-weekly prophylaxis with efanesoctocog alfa for 26 weeks. The primary end point was the mean annualized bleeding rate in group A; the key secondary end point was an intrapatient comparison of the annualized bleeding rate during prophylaxis in group A with the rate during prestudy factor VIII prophylaxis. Additional end points included treatment of bleeding episodes, safety, pharmacokinetics, and changes in physical health, pain, and joint health.

RESULTS

In group A (133 patients), the median annualized bleeding rate was 0 (interquartile range, 0 to 1.04), and the estimated mean annualized bleeding rate was 0.71 (95% confidence interval [CI], 0.52 to 0.97). The mean annualized bleeding rate decreased from 2.96 (95% CI, 2.00 to 4.37) to 0.69 (95% CI, 0.43 to 1.11), a finding that showed superiority over prestudy factor VIII prophylaxis (P<0.001). A total of 26 patients were enrolled in group B. In the overall population, nearly all bleeding episodes (97%) resolved with one injection of efanesoctocog alfa. Weekly prophylaxis with efanesoctocog alfa provided mean factor VIII activity of more than 40 IU per deciliter for the majority of the week and of 15 IU per deciliter at day 7. Prophylaxis with efanesoctocog alfa for 52 weeks (group A) improved physical health (P<0.001), pain intensity (P=0.03), and joint health (P=0.01). In the overall study population, efanesoctocog alfa had an acceptable side-effect profile, and the development of inhibitors to factor VIII was not detected.

CONCLUSIONS

In patients with severe hemophilia A, once-weekly efanesoctocog alfa provided superior bleeding prevention to prestudy prophylaxis, normal to near-normal factor VIII activity, and improvements in physical health, pain, and joint health. (Funded by Sanofi and Sobi; XTEND-1 ClinicalTrials.gov number, NCT04161495.)

Another Victory for Patients with Hemophilia

Cindy Leissinger, M.D.

Congenital hemophilia A is a rare bleeding disorder caused by a mutation in the gene encoding factor VIII, resulting in a deficiency of factor VIII activity. Severe hemophilia (factor VIII activity level, <1%) is characterized by repetitive bleeding into joints beginning in early childhood and poses a major risk of life-threatening hemorrhage. Moderate hemophilia (factor VIII activity level, 1 to 5%) is associated with less frequent joint and soft-tissue bleeding related to mild trauma. Replacement therapy with the use of factor VIII concentrates restores hemostasis by raising levels of factor VIII activity and is effective in the treatment of acute bleeding. Unfortunately, even prompt treatment of joint hemorrhage is not sufficient to prevent the inevitable development of chronic hemophilic arthropathy, a painful joint condition associated with mobility impairment and other physical disabilities.

The only way to effectively preserve joint health is the near-complete prevention of joint bleeding. Nilsson and colleagues first reported the long-term benefits of regular infusions of factor VIII in the prevention of hemarthroses in patients with severe hemophilia.[1] Reasoning that patients with moderate hemophilia do not have spontaneous hemarthroses (and do not have as many hemarthroses as those with severe hemophilia), they administered factor VIII (which has a circulating half-life of approximately 12 hours) three times weekly to maintain trough factor VIII levels greater than 1 to 2%. A subsequent prospective randomized trial involving young children with severe hemophilia A showed that factor VIII prophylaxis reduced both joint bleeding and early joint disease.[2] The administration of factor VIII three times a week became widely accepted as a way to reduce bleeding with acceptable cost and convenience. Over time, however, it became clear that simply maintaining trough levels above 1 to 2% could not eliminate all joint bleeding and consequent joint disease, an observation that was supported by the results of a study of hemarthroses rates among children with various severities of hemophilia that showed that joint bleeding approached 0 only in children with baseline factor VIII levels above 12%.[3]

Achieving trough factor VIII levels above 12% with currently available factor VIII products given on an acceptable prophylaxis administration schedule is not possible. Despite the recent introduction of "extended half-life" factor VIII products, the extension has been limited by the natural half-life of von Willebrand factor (VWF), because factor VIII is stabilized by binding to VWF in the circulation. This "ceiling" effect has limited the half-life extension of factor VIII to approximately 18 hours. Although these products can achieve reasonable prophylaxis with fewer infusions (typically twice weekly) and may also allow for higher trough levels of factor VIII than standard half-life factor VIII if given more frequently, they are still unable to achieve consistent trough levels above 12%.

Efanesoctocog alfa is the first recombinant factor VIII product designed to overcome the half-life "ceiling."[4] It has a unique structure that is stabilized in circulation by the attachment of a portion of the VWF molecule (the D′D3 domain), which decouples the natural binding of factor VIII to VWF. In addition, it is fused to a dimeric Fc domain as well as two hydrophilic polypeptides that extend its half-life to approximately 47 hours by steric shielding. Results from the phase 3 study that are reported in this issue of the *Journal* by von Drygalski et al.[5] showed a mean factor VIII trough level of 15% and a median annualized bleeding rate of 0 among patients receiving efanesoctocog alfa once weekly.

Although hemophilia is a rare disease, the burden of treatment for patients and society has been disproportionately high owing to the intense nature of therapy and its cost. In recent years, many new therapies have been approved or are under review or in late-stage clinical trials. These diverse approaches to promote hemostasis include a factor VIII mimetic (emicizumab) that can prevent bleeding when given as a subcutaneous injection as infrequently as once monthly,[6] a small interfering RNA (fitusiran) that blocks

- Publication of XTEND-1 phase 3 study in The New England Journal of Medicine
- Very supportive editorial: "*In a crowded field of transformative therapies for hemophilia, efanesoctocog alfa stands out as a winner — a major therapeutic advance that achieves highly protective factor VIII levels with a once-weekly infusion.*"
- **H1 2023** XTEND-Kids phase 3 study data readout
- **H2 2023** EU regulatory submission

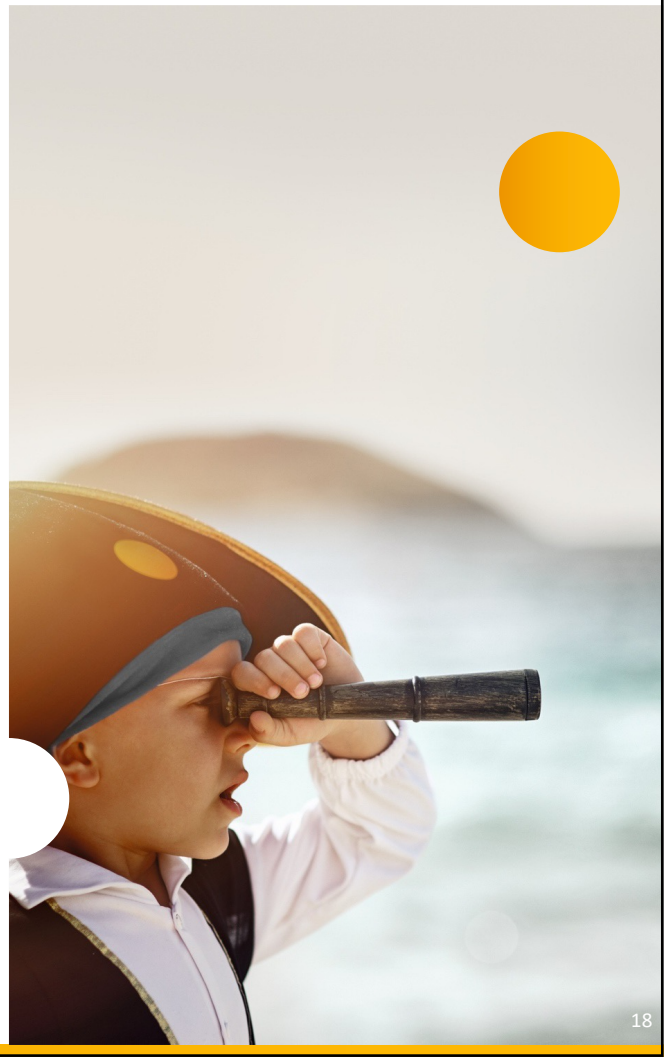
Source: The New England Journal of Medicine.

Pipeline news flow increasing

Anticipated major upcoming pipeline news flow

H1 2023	H2 2023	2024
efanesoctocog alfa – haemophilia A: regulatory decision (US)	**efanesoctocog alfa** – haemophilia A: regulatory submission (EU)	**Doptelet** – ITP: regulatory submission (JP)
efanesoctocog alfa – haemophilia A (paediatric): XTEND-Kids phase 3 study data readout	**Doptelet** – ITP: regulatory decision (CN)	**Aspaveli/Empaveli** – IC-MPGN[7] and C3G[8]: VALIANT phase 3 study data readout
Doptelet – CLD[1]: regulatory decision (JP)	**Aspaveli/Empaveli** – ALS[4]: MERIDIAN phase 2 study data readout (by Apellis in mid-2023)	**Kineret** – Still's disease: regulatory decision (CN)
Empaveli – PNH: regulatory decision (JP)	**Aspaveli/Empaveli** – TA-TMA[5]: phase 2 study data readout	
Gamifant – MAS[2] in rheumatological diseases: EMERALD phase 3 study data readout (Still´s disease cohort)	**Kineret** – FMF[6]: regulatory decision (CN)	
SEL-212 – CRG[3]: phase 3 studies data readout	**Gamifant** – MAS in rheumatological diseases: regulatory submission (Still´s disease cohort) (US)	
	SEL-212 – CRG: regulatory submission (US)	
	nirsevimab – RSV prevention: regulatory decision (US) (by AstraZeneca/Sanofi)	

1. Chronic liver disease 2. Macrophage activation syndrome 3. Chronic refractory gout 4. Amyotrophic lateral sclerosis 5. Transplant-associated thrombotic microangiopathy after allogenic haematopoietic stem cell transplantation 6. Familial Mediterranean fever 7. Immune-complex membranoproliferative glomerulonephritis 8. C3 glomerulopathy. Status as of 7 February 2023.



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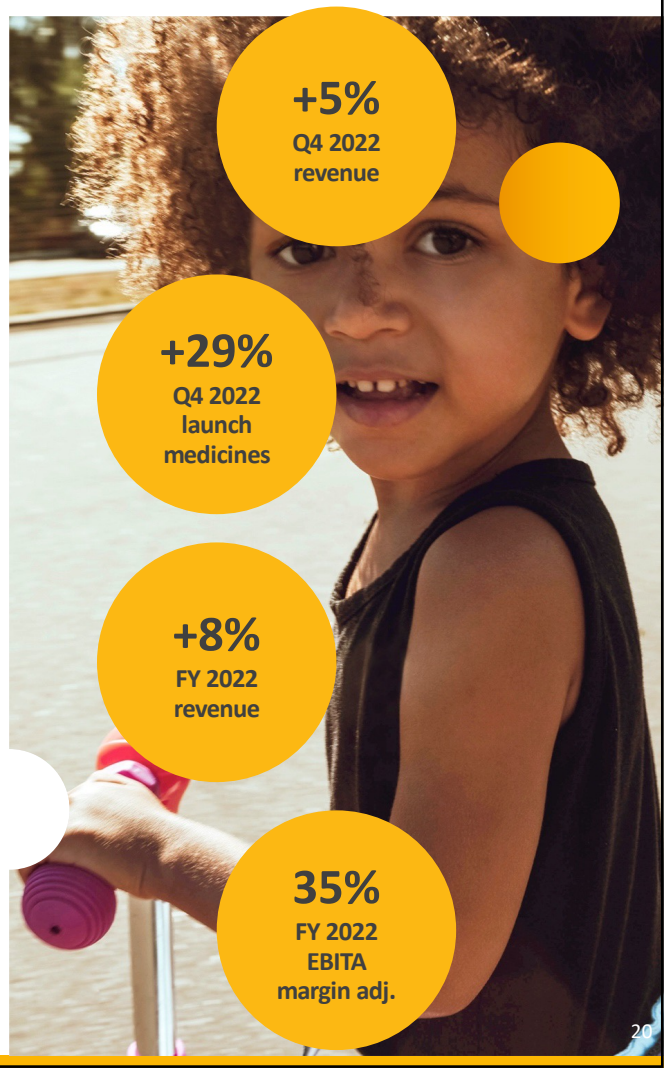
- **News flow** to increase in 2023

- **2023 outlook** solid with continued growth

Continued performance:	**2022 outlook fully met** **2023 outlook solid with continued growth**

Change at constant exchange rates.
1. Launch medicines include Doptelet (outside China), Aspaveli and Gamifant.




sobi
Q&A

Appendix: Q4 2022 sustainability performance

Highlights in Q4 2022

- Milestones toward increased access
  - European Commission approval of Zynlonta (loncastuximab tesirine)
  - US Food and Drug Administration Emergency Use Authorisation for use of Kineret to treat COVID-19 related pneumonia
- Raising awareness and supporting patients
  - Launch of new digital platform, my-PNH.com with information and tools to increase understanding of PNH
  - Sharing knowledge
  - Presented results at the 64th ASH Annual Meeting and Exposition and at the European Haemophilia Consortium 2022 Conference

Sobi sustainability priorities

Maintain commitment to patients

- Access to treatment
- Patient centricity & engagement
- Patient and product safety
- Ethical marketing & sales
- Transparent & ethical & R&D

Always act responsibly

- An inclusive and diverse workplace that grows people
- Safe, healthy and fair working conditions
- Reduction of environmental footprint
- Responsible sourcing
- Compliance & corruption prevention

Commitment to the UN Global Compact. Contribution to the 2030 Agenda, the UN Sustainable Development Goals and the Paris Agreement.

Highlights in Q4 2022

- Making progress on DEI
  - A company-wide initiative on diversity, equity and inclusion was launched
- DJSI membership
  - For the first time, Sobi qualified as a constituent of the Dow Jones Sustainability Indices
  - Sobi joins DJSI Europe as one of eight companies within Pharmaceuticals, Biotechnology & Life Sciences

Member of
Dow Jones Sustainability Indices
Powered by the S&P Global CSA

Appendix: items affecting comparability (IAC)

SEK M	Q4 2022	IAC	Q4 2022 adjusted	Q4 2021	FY 2022	IAC	FY 2022 adjusted	FY 2021
Total revenue	5,991		5,991	4,896	18,790		18,790	15,529
Cost of goods sold[i]	-1,308	—	-1,308	-1,016	-4,776	-363	-4,413	-3,484
Gross profit	4,683	—	4,683	3,880	14,014	-363	14,377	12,045
Gross margin	78 %		78 %	79 %	75 %		77 %	78 %
Selling and administrative expenses[ii,iii,iiii]	-2,120	—	-2,120	-1,824	-7,847	-210	-7,636	-6,294
Research and development expenses[ii,iiii]	-643		-643	-554	-2,354	-102	-2,252	-1,994
Operating expenses	-2,763	—	-2,763	-2,378	-10,201	-312	-9,889	-8,288
Other operating income/expenses	-4		-4	23	-1		-1	-24
Operating profit (EBIT)	1,916	—	1,916	1,525	3,813	-675	4,488	3,733
Plus amortisation and impairment of intangible assets	539		539	477	2,117		2,117	1,841
EBITA	2,455	—	2,455	2,002	5,930	-675	6,605	5,575
EBITA margin	41 %		41 %	41 %	32 %		35 %	36 %

This is non-IFRS financial information. For an IFRS income statement, please refer to the Consolidated statement of comprehensive income.

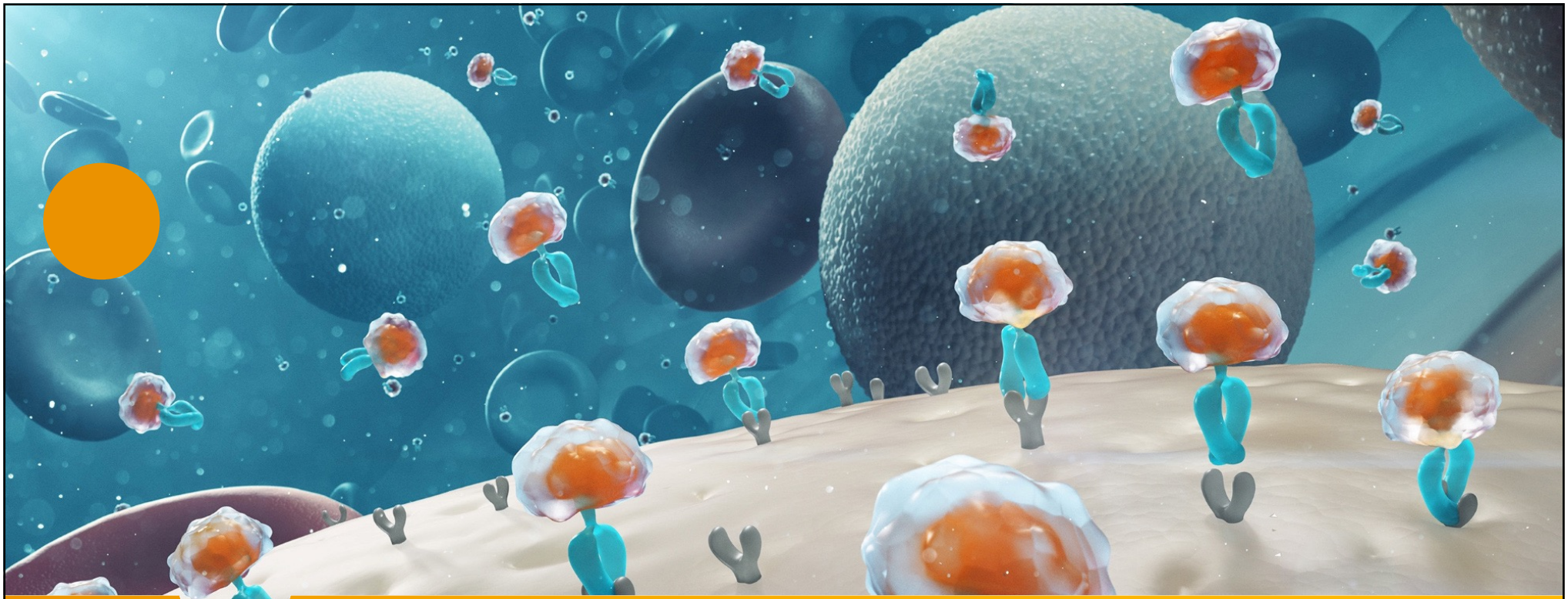
i) Full-year restructuring costs were SEK 363 M including impairment and accelerated depreciation of tangible assets of SEK 136 M following the decision to discontinue contract manufacturing for Pfizer. The process of downsizing the manufacturing facility started in the second half of 2022 with the last volumes anticipated to be delivered to Pfizer in the beginning of 2024.

ii) Full year refers to external expenses and restructuring costs of SEK 134 M related to structural efficiency programmes, whereof SEK 77 M were allocated to selling and administrative expenses and SEK 57 M were allocated to R&D expenses.

iii) Refers to provision for expected credit losses in Russia of SEK 106 M.

iv) Full-year restructuring costs were SEK 72 M including impairment of tangible assets of SEK 12 M followed by the decision in the first quarter to consolidate the Geneva site into Basel. SEK 27 M were allocated to selling and administrative expenses and SEK 45 M were allocated to R&D expenses.

Source: Sobi Q4 and FY 2022 report, page 3.



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