Devyser Diagnostics AB (publ) Year-end report, January to December 2024



Strong sales growth and a positive operating result

Quarter from October to December 2024

- Net sales amounted to SEK 64.2 million (45.4), corresponding to a 41.5 percent increase. Adjusted for exchange rate fluctuations, net sales increased by 40.8 percent.
- Gross profit totaled SEK 54.2 million (40.0), corresponding to a gross margin of 84.4 percent (88.1).
- Operating profit (EBIT) amounted to SEK 0.7 million (-18.5).
- Profit after tax totaled SEK -3.2 million (-13.1).
- Earnings per share before and after dilution amounted to SEK -0.19 (-0.80).
- Cash flow from operating activities stood at SEK -1.4 million (-13.8).

Important events during the quarter

Devyser presented new innovations and research Devyser is continuing to invest in product development. At ASHI 2024, the foremost transplantation conference in the US, held at the end of October, six posters and one abstract were presented showcasing new, innovative Devyser products and the clinical results achieved from using them. These showed, among other things, the advantages offered by our products compared with the competition.

Devyser terminated its liquidity guarantee agreement In October, Devyser announced that its liquidity guarantee agreement with Carnegie Investment Bank would end on November 29, 2024. Devyser believes that current trading of the share and its liquidity are at good levels and that there is therefore no real need for a liquidity guarantee.

Expanded collaboration with Thermo Fisher

In addition to the commercial terms of the collaboration agreement with Thermo Fisher, the companies have now also agreed on the plan to apply for FDA approval for Devyser's product for the detection of cell-free DNA in the blood of kidney transplant patients. This addition to the agreement will significantly increase Devyser's chances of obtaining FDA approval quickly and cost effectively, as it means gaining access to Thermo Fisher's regulatory resources. As an FDAapproved product does not yet exist, FDA approval could potentially completely transform kidney transplant monitoring in the US. It would give patients access to faster test results.

The period from January to December 2024

- Net sales amounted to SEK 216.9 million (169.3), corresponding to a 28.1 percent increase. Adjusted for exchange rate fluctuations, net sales increased by 28.3 percent.
- Gross profit totaled SEK 172.7 million (144.7), corresponding to a gross margin of 79.6 percent (85.5).
- Operating profit (EBIT) amounted to SEK -58.3 million (-58.9).
- Profit after tax totaled SEK -61.5 million (-53.6).
- Earnings per share before and after dilution amounted to SEK -3.75 (-3.31).
- Cash flow from operating activities stood at SEK -46.8 million (-69.7).
- The Board is not proposing a dividend for 2024.

Regulatory approval of Devyser Compact in China

Devyser has reached a significant regulatory milestone with its first market registration with China's National Medical Products Administration (NMPA) for Devyser Compact, an IVDR-certified genetic test for the detection of chromosomal abnormalities in fetuses. Rapid prenatal detection is a Class III product in China. The regulatory approval enables Devyser to market Devyser Compact in China, and also lays the foundations for future regulatory approvals.

Devyser obtained Class D IVDR approval for RHD

In December, Devyser obtained IVDR approval for its product for the non-invasive screening of fetal RHD. This is the first approval of a Class D product; this is the highest risk class under the new, more comprehensive regulation, which entered into force in May 2022.

The share and new share issues

Three new share issues were carried out during the quarter in connection with the exercising of employee stock options. The issues raised SEK 3.9 million for the company.

Important events after the end of the quarter

CEO Fredrik Alpsten left Devyser and Board member Fredrik Dahl was appointed as Devyser's new acting CEO Fredrik Alpsten and Devyser's Board of Directors reached an agreement in January whereby he would leave his position as CEO of Devyser.

Devyser's Board of Directors has begun the recruitment of a new CEO. Fredrik Dahl, who has a PhD in Molecular Medicine, is currently a Board member and is well acquainted with the company, has been appointed as acting CEO. Fredrik Dahl has extensive international experience in various management roles at global research and diagnostics companies.

Important events during the period from January to December 2024

IVD development agreement with Illumina Inc.

In early January, a contract was signed with Illumina for IVD (in vitro diagnostics) development. This was to enable US and European regulatory registrations of Devyser's NGS tests on MiSeqDx, Illumina's FDA-regulated and CE-IVD-marked sequencing instrument.

Devyser Genomic Laboratories signed its first commercial contract

Devyser Genomic Laboratories, Devyser's US-based CLIA-certified laboratory, signed its first commercial contract in mid-January with UKbased diagnostics company Cyted. The contract's term is initially two years, and revenues are estimated to total approximately SEK 25.0 million, of which up to around SEK 6.0 million in 2024.

Regulatory approvals

In April, Devyser was granted IVDR approval for its Advyser Solid Organs software, which is used with the One Lambda Devyser Accept cfDNA product for post-transplant monitoring. This is Devyser's first software to be given IVDR approval under the new, more comprehensive regulation that came into force in May 2022.

Devyser reached a significant regulatory milestone in October with its first market registration with China's National Medical Products Administration (NMPA) for Devyser Compact, an IVDR-certified genetic test for the detection of chromosomal abnormalities in fetuses. The approval allows Devyser to market Devyser Compact in China, and paves the way for future regulatory clearances.

In December, Devyser obtained Class D IVDR approval for its product for the non-invasive screening of fetal RHD. This is the first approval of a Class D product; this is the highest risk class under the new, more comprehensive regulation, which entered into force in May 2022.

Devyser won a record-breaking tender in Italy

In June, Devyser was awarded a five-year extension agreement with the Tuscany region of Italy for ten of its products. Devyser was also awarded the transplant part of the tender through its distribution partner. The indicative order value for Devyser is estimated at approximately SEK 12 to 15 million annually, of which around half from new sales and half from extensions of existing contracts.

Devyser won a tender in Italy worth up to SEK 5.9 million In July, Devyser also won a tender with its NGS test for cystic fibrosis, Devyser CFTR. The contract with Policlinico Milano is for three years with

Devyser CFTR. The contract with Policlinico Milano is for three years with the possibility of a one-year extension. The estimated order value is up to SEK 5.9 million.

Devyser expanded its collaboration with Thermo Fisher Scientific

In June, Devyser expanded its exclusive collaboration and distribution agreement with Thermo Fisher Scientific. The agreement gives Thermo Fisher exclusive rights to market Devyser's NGS products for posttransplant monitoring worldwide under combined trademarks. This is an extension of the previous agreement whereby Thermo Fisher had exclusive rights to market these products in North America, Europe, Brazil and Saudi Arabia.

In addition to the commercial terms of the collaboration agreement with Thermo Fisher, an agreement was also concluded on the securing of FDA approval for Devyser's product for the detection of cell-free DNA in the blood of kidney transplant patients. This addition to the agreement will significantly increase Devyser's chances of obtaining FDA approval quickly and cost effectively, as it means gaining access to Thermo Fisher's regulatory resources.

Devyser presented new innovations and research

At ASHI 2024, the leading transplantation conference in the US held in October, Devyser presented six posters and one abstract showcasing innovative products and their clinical impact. These showed, among other things, the advantages offered by our products compared with the competition.

The Board and management

The management team was expanded in February when it was joined by CSO Michael Uhlin. The latter has extensive experience in the global life sciences sector and has long been engaged in translational research and development. COO Göran Rydin left Devyser in the fall.

In January 2025, CEO Fredrik Alpsten left his position and Board member Fredrik Dahl was appointed as the new acting CEO of Devyser until the recruitment of a new CEO. This means that the management team now consists of Fredrik Dahl, acting CEO, Sabina Berlin, CFO, Theis Kipling, CCO, Michael Uhlin, CSO, and Camilla Wiberg, CHRO.

At the Annual General Meeting in May, Mia Arnhult, Lars Höckenström, Fredrik Dahl and Pia Gideon were re-elected as Board members. Thomas Eklund was elected as a new member of the Board. Mia Arnhult was reelected as Chair of the Board.

The share and new share issues

Eight new share issues were carried out during the period from January to December in connection with the exercising of warrants and employee stock options. The issues raised a total of SEK 23.6 million for the company. The Annual General Meeting in May decided to introduce a new employee stock option plan. See Note 2 on page 15.

In November, the liquidity guarantee agreement with Carnegie Investment Bank was terminated. Devyser believes that current trading of the share and its liquidity are at good levels and that there is therefore no real need for a liquidity guarantee.

Performance measures	Oct - Dec 2024	Oct - Dec 2023	Jan - Dec 2024	Jan - Dec 2023
Net sales, SEK million	64.2	45.4	216.9	169.3
Sales growth, %	41.5	32.7	28.1	33.7
Gross margin, %	84.4	88.1	79.6	85.5
EBITDA, SEK million	8.0	-14.2	-30.6	-45.8
EBITDA margin, %	12.4	Neg	Neg	Neg
Operating profit/loss (EBIT), SEK million	0.7	-18.5	-58.3	-58.9
Operating margin (EBIT margin), %	1.1	Neg	Neg	Neg
Profit/loss after tax, SEK million	-3.2	-13.1	-61.5	-53.6
Cash flow from operating activities, SEK million	-1.4	-13.8	-46.8	-69.7
Cash and cash equivalents, SEK million	144.5	262.9	144.5	262.9
Net cash (-)/Net debt (+), SEK million	-85.4	-188.2	-85.4	-188.2
Equity ratio, %	73.7	75.5	73.7	75.5
Return on equity, %	Neg	Neg	Neg	Neg
Average no. of employees	121	111	119	102

See page 16 for definitions of the performance measures.

A word from the CEO

I am pleased to have taken over as the new acting CEO of Devyser Diagnostics as of January 16, 2025 and look forward to working with the Devyser team to drive the company forward until a new, permanent CEO is hired. At the same time, I will also continue to be a member of the company's Board. My top priority is now to update and clarify our strategy as we transition our business towards profitability.

Fourth quarter - strong growth and figures in the black

Net sales increased during the fourth quarter by 41.5 percent to SEK 64.2 million, compared with the corresponding quarter of 2023. The growth and strong performance are a result of robust development in every geographical market and several large orders from Thermo Fisher.

The gross margin for the quarter amounted to 84.4 percent, up from 72.3 percent in Q3 2024. The same performance measure for the full-year 2024 amounted to 79.6 percent (85.5), a decrease linked to costs related to the validation of the new production facility, while the fourth quarter showed that we are once again above the target set of 80 percent.

The big financial news for the quarter is the positive operating result of SEK 0.7 million (-18.5), achieved through efficiency improvements implemented during the third quarter and a large inventory build-up order from Thermo Fisher. On the other hand, a non-recurring item related to a retroactive payback levy in Italy was deducted from operating profit during the quarter. The decision of 2022 has been appealed by many affected parties but, in 2024, an Italian court ruled that the retroactive levy is not unconstitutional and will have to be paid in the coming years. Devyser therefore made provisions in the fourth quarter of 2024 for estimated retroactive costs totaling SEK 6.2 million for the period 2015-2024 under Selling expenses.

Cash flow from operating activities amounted to SEK -1.4 million for the quarter, an improvement on SEK -13.8 million in the corresponding quarter of 2023.

Regulatory approvals and an extended cooperation agreement

During the quarter, we announced our intention to secure FDA approval for our NGS test for post-kidney transplant monitoring. We are working with Thermo Fisher to secure US regulatory approval, leveraging their extensive expertise to navigate complex approval processes. We are confident that this collaboration will pave the way for an effective and successful launch of our product in the US market.

Similarly, during the fourth quarter, we were able to secure regulatory approval in China for the Devyser Compact product, which means that we can now market the product in the country. The approval from the Chinese Medicines Agency, NMAP, also paves the way for future regulatory approvals. The Chinese market has great potential moving forward, although it will not be the main focus in the near future, and this is an important first step into that market.

Clarified strategic focus

Devyser is well-positioned for continued growth with a strong focus on profitability. Our tried and tested business model, built on providing high-quality IVD-approved tests to genetic testing laboratories and transplant centers, has proved capable of delivering good results and opportunities for further growth. By clarifying the strategy as one in which profitability is both a driving force and guides our decisions, in future we will focus on more clearly defined customer segments and work on refining the product portfolio to target specific product lines that have the highest potential.

> "Exciting opportunities lie ahead for Devyser to continue its growth journey while focusing on profitability."

Outlook

Devyser is well placed to become a leading player in the genetic diagnostics market. The company has a strong portfolio of products and a motivated team who are experts in their fields. By making major investments we have laid the foundations for increased growth, based on the cornerstones of efficiency and profitability. I am confident about the challenges awaiting us and optimistic about the future.

Stockholm, February 13, 2025 Fredrik Dahl, interim CEO



Group development, January to December 2024

Net sales

Net sales for the period from January to December 2024 amounted to SEK 216.9 million (169.3), corresponding to an increase of 28.1 percent. Adjusted for exchange rate fluctuations, the increase was 28.3 percent. The increase was driven by higher direct sales and distributor sales.

Net sales for the fourth quarter of 2024 amounted to SEK 64.2 million (45.4), corresponding to an increase of 41.5 percent. Adjusted for exchange rate fluctuations, the increase was 40.8 percent.

There are no major seasonal variations in the company's sales.

Gross profit

Gross profit for the period from January to December 2024 totaled SEK 172.7 million (144.7). Gross profit for the fourth quarter totaled SEK 54.2 million (40.0).

The gross margin for the period from January to December 2024 amounted to 79.6 percent, compared with 85.5 percent for the same period of the previous year. For the fourth guarter, the gross margin amounted to 84.4 percent, compared with 88.1 percent for the same quarter of last year. The lower gross margin is mainly attributable to moving costs and the planned curtailment of production in connection with the relocating of the business to new premises.

The cost of goods sold includes the direct production overheads for products sold, the amortization of capitalized development expenses, the overhead expenses for the production department, and personnel expenses for the department's employees.

The amortization of capitalized development expenses amounted to SEK 4.8 million (3.1) for the period from January to December 2024, and SEK 1.2 million (1.1) during the fourth quarter of 2024.

Operating expenses

Operating expenses for the period from January to December 2024 amounted to SEK 236.2 million (201.3), and for the fourth guarter to SEK 59.0 million (55.0). The increased costs are primarily due to new recruitment in sales, development and administration as part of the company's growth strategy, costs for the implementation of a new ERP system and CRM system, the cost of two rents (due to the amortization

of right-of-use assets for both the old and new premises), incentive program costs, and the payback levy in Italy of SEK 6.2 million (see Note 5 on page 15).

Total research and development costs during the period from January to December 2024 amounted to SEK 73.7 million (54.7), of which SEK 30.6 million (16.9) was capitalized and SEK 43.1 million (37.8) was expensed. During the fourth quarter of 2024, total research and development costs amounted to SEK 20.2 million (15.6), of which SEK 10.9 million (4.4) was capitalized and SEK 9.3 million (11.2) was expensed.

The expensed research and development costs mainly comprise employee and consultant-related costs attributable to the R&D department's non-capitalizable project phases. The capitalized expenses include costs for development projects related to products not yet completed.

For the period from January to December 2024, other operating income and expenses, mainly consisting of exchange gains/losses on current assets and current liabilities, amounted to SEK 5.3 million (-2.3) net, and amounted to SEK 5.5 million (-3.4) net for the fourth quarter.

Operating profit/loss

Operating profit for the period from January to December 2024 totaled SEK -58.3 million (-58.9). For the fourth guarter, operating profit stood at SEK 0.7 million (-18.5). The operating result for both 2024 and 2023 is mainly attributable to investments in an expanded sales force, new products and an increased production capacity.

Net financial items

Net financial items for the period from January to December 2024 totaled SEK 0.7 million (4.5). For the fourth guarter, net financial items stood at SEK -1.2 million (2.3).

Profit/loss

Profit before tax for the period from January to December 2024 was SEK -57.6 million (-54.4), and profit after tax was SEK -61.5 million (-53.6). For the fourth guarter, profit before tax was SEK -0.5 million (-16.2), and profit after tax was SEK -3.2 million (-13.1). See Note 4 on page 15.



Sales by region, SEK million	Oct - Dec 2024	Oct - Dec 2023	Change, %	Jan - Dec 2024	Jan - Dec 2023	Change, %
EMEA	54.0	40.6	32.8	192.0	149.4	28.5
Asia-Pacific	1.5	1.8	-16.2	7.0	6.1	15.8
North and South America	8.7	3.0	194.0	17.9	13.8	30.2
Total	64.2	45.4	41.5	216.9	169.3	28.1
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Sales by sales channel, SEK million	Oct - Dec 2024	Oct - Dec 2023	Change, %	Jan - Dec 2024	Jan - Dec 2023	Change, %
Direct sales	26.1	33.9	-23.1	140.7	130.8	7.5
Distributor sales	38.1	11.5	232.5	76.2	38.4	98.3
Total	64.2	45.4	41.5	216.9	169.3	28.1

Cash flow and cash position

For the period from January to December 2024, the cash flow from operating activities after changes in working capital was SEK -46.8 million (-69.7). For the fourth quarter of 2024, the cash flow from operating activities amounted to SEK -1.4 million (-13.8). During the period, eight new issues of a total of 269,645 shares were completed in connection with the exercising of warrants and employee stock options issued to employees, which brought in SEK 23.6 million for the company. Cash and cash equivalents as of December 31, 2024 amounted to SEK 144.5 million (262.9).

Investments

Total net investments came to SEK 76.9 million (32.0), including capitalized development expenses of SEK 39.2 million (17.0), SEK 20.3 million (1.7) related to the move to the new premises in Årsta and investments in an increased production capacity. The Group has no investment commitments.

Assets

As of December 31, 2024, intangible assets amounted to SEK 102.0 million (56.1). Intangible non-current assets consist of capitalized development costs for Devyser's products, other intangible assets and consolidated goodwill. Capitalized development expenses are amortized on a straight-line basis over their estimated useful lives, which vary from four to ten years.

The amortization of capitalized development expenses attributable to the products developed by Devyser is recognized in

Group cost of goods sold and in the Parent Company's research and development costs.

During the period, Devyser moved to its new premises in Årsta in Stockholm. The lease was signed during the second quarter of 2023 and will run for seven years, with a four-year option. The asset's value is recognized in Right-of-use assets, and the related liability in Lease liabilities. The value of the total right-of-use assets as of December 31, 2024 was SEK 59.9 million (74.5).

Equity and liabilities

As of December 31, 2024, the Group's equity amounted to SEK 349.0 million (385.1), and the equity ratio was 73.7 percent (75.5).

As of December 31, 2024, interest-bearing liabilities amounted to SEK 59.1 million (74.8). Interest-bearing liabilities consist mainly of lease liabilities attributable to leases. Current non-interest-bearing liabilities totaled SEK 58.9 million (45.4).

Important events in the Parent Company

The deterioration in the Parent Company's profits is mainly due to the Group contribution to the subsidiary Devyser AB of SEK 82.9 million (68.4).

During the period from January to December 2024, eight new issues of a total of 269,645 shares were completed in connection with the exercising of warrants and employee stock options issued to employees, which brought in SEK 23.6 million for the company.

Performance measures by quarter	Oct - Dec 2024	Jul - Sep 2024	Apr - Jun 2024	Jan - Mar 2024	Oct - Dec 2023	Jul - Sep 2023	Apr - Jun 2023
Net sales, SEK million	64.2	48.7	53.2	50.7	45.4	46.7	37.7
Gross profit, SEK million	54.2	35.2	41.4	41.9	40.0	39.6	31.5
Gross margin, %	84.4	72.3	77.7	82.7	88.1	85.0	83.4
EBITDA, SEK million	8.0	-16.7	-16.3	-5.6	-14.2	-4.1	-11.1
EBITDA margin, %	12.4	Neg	Neg	Neg	Neg	Neg	Neg
Operating profit/loss (EBIT), SEK million	0.7	-23.7	-23.1	-12.2	-18.5	-7.8	-13.5
Operating margin (EBIT margin), %	1.1	Neg	Neg	Neg	Neg	Neg	Neg
Profit/loss after tax, SEK million	-3.2	-23.2	-22.9	-12.2	-13.1	-6.0	-14.6
Cash flow from operating activities, SEK million	-1.4	-12.9	-15.9	-16.5	-13.8	-13.9	-22.8
Average no. of employees	121	119	120	119	111	102	98

See page 16 for definitions of the performance measures.

Parent Company

Devyser Diagnostics AB (publ), Corporate Registration Number 556669-7834, is a Swedish limited company domiciled in Stockholm. The address of its head office is Bränningevägen 12, 120 54 Årsta, Sweden. Devyser Diagnostics AB has been listed on the Nasdaq First North Premier Growth Market since December 2021.

Receivables and liabilities in respect of Group companies primarily consist of amounts owed to the Swedish subsidiary Devyser AB and owed by the Italian subsidiary Devyser Italia S.r.I. The Parent Company's risks and uncertainties indirectly coincide with those of the Group.

Employees

From January to December 2024, the average number of Group employees was 119 (102), including 2 (2) Parent Company employees. The average number broken down by country was 85 (70) in Sweden, 16 (17) in Italy, 9 (7) in the United States, 3 (3) in Germany, 2 (2) in Belgium, 1 (1) in the United Kingdom, 1 (1) in Spain and 1 (1) in France. The average number of women employed by the Group was 73 (62) and the average number of men was 46 (40).

Market

Devyser sells genetic testing products to laboratories in more than 65 countries. The products include reagent kits and the related software. Sales are made primarily to routine diagnostic laboratories, partly through our own sales teams in selected markets and partly through distributors.

The products are used for complex DNA testing in the hereditary disease, oncology and transplant fields, to enable targeted cancer treatment, the diagnosis of a large number of genetic diseases, and transplant patient follow-up.

The market size for the company's products is large and, according to an external market survey conducted in 2021, should reach EUR 5.6 billion by 2026.

Related-party transactions

See Notes 2 and 3 on page 15 for a description of the related-party transactions.

Significant risks and uncertainties

The Group's activities are associated with a number of risks and uncertainties.

Russia's invasion of Ukraine and the war in Gaza have no direct impact on Devyser, as it has no or limited business activities in the countries concerned.

A possible recession could negatively affect future revenues. Devyser's sales are mainly in Euros and US dollars, meaning that the company is exposed to exchange rate fluctuations.

For more information, a detailed description of the company's risk exposure can be found in the 2023 Annual Report, pages 41-42, and in Note 15, pages 79-87. No changes are considered to have occurred since the Annual Report was published other than those described above.

The share and shareholders

As of December 31, 2024, Devyser Diagnostics AB had a total of 16,554,114 (16,284,469) shares and voting rights.

On the submission date of this report, the company had four outstanding incentive programs for employees and key personnel.

The existing and new incentive programs may currently increase the number of shares by 534,552 (see Note 2 on page 15).

The largest shareholders as of December 31, 2024 were:

Owner	Number of shares	Ownership, %
Rutger Arnhult via company	4,035,000	24.4
Nordnet Pensionsförsäkringar	1,593,091	9.6
Swedbank Robur	895,313	5.4
Fourth Swedish National Pension Fund	759,821	4.6
Åsa Riisberg via company	664,294	4.0
Premier Miton Investors	478,126	2.9
Deka Investments	420,200	2.5
Anders Hedrum, privately and via company	406,100	2.5
Berenberg Asset Management on behalf of Universal Investment funds	357,037	2.2
Protean Funds Scandinavia	347,499	2.1
Other shareholders, around 1,800	6,597,633	39.9
Total	16,554,114	100.0

Auditors' review

This report has not been reviewed by the company's auditors.

The Board of Directors and CEO certify that the interim report provides a true and fair overview of the operations, financial position and earnings of the Group and the Parent Company and describes the significant risks and uncertainties faced by the Parent Company and the companies included in the Group.

Stockholm, February 13, 2025 Devyser Diagnostics AB (publ)

Mia Arnhult Chair of the Board

Thomas Eklund Board member Lars Höckenström Board member

Pia Gideon Board member Fredrik Dahl Interim CEO and Board member

Consolidated income statement

SEK million	Oct - Dec 2024	Oct - Dec 2023	Jan - Dec 2024	Jan - Dec 2023
Net sales	64.2	45.4	216.9	169.3
Cost of goods sold	-10.0	-5.4	-44.2	-24.5
Gross profit	54.2	40.0	172.7	144.7
Other operating income	6.0	2.4	14.2	9.0
Selling expenses ¹	-41.1	-30.8	-141.8	-121.5
Administrative expenses	-8.6	-13.0	-51.3	-42.0
Research and development costs	-9.3	-11.2	-43.1	-37.8
Other operating expenses	-0.5	-5.8	-8.9	-11.4
Operating profit/loss	0.7	-18.5	-58.3	-58.9
Financial income	-0.4	2.1	4.2	5.3
Financial expenses	-0.8	0.1	-3.5	-0.8
Net financial items	-1.2	2.3	0.7	4.5
Profit/loss before tax	-0.5	-16.2	-57.6	-54.4
Tax ²	-2.7	3.1	-3.9	0.8
Profit/loss for the period	-3.2	-13.1	-61.5	-53.6
Earnings per share before dilution, SEK	-0.19	-0.80	-3.75	-3.31
Diluted earnings per share, SEK	-0.19	-0.80	-3.75	-3.31
Average no. of shares, before dilution	16,519,941	16,284,469	16,398,116	16,180,907
Average no. of shares, after dilution	16,618,045	17,155,807	16,443,870	17,052,245

Consolidated statement of comprehensive income

SEK million	Oct - Dec 2024	Oct - Dec 2023	Jan - Dec 2024	Jan - Dec 2023
Profit/loss for the period	-3.2	-13.1	-61.5	-53.6
Other comprehensive income for the period:				
Items that will not be reclassified to profit or loss	-	-	-	-
Items that will be reclassified to profit or loss				
Currency translation differences	-1.9	-0.3	-0.6	0.3
Other comprehensive income for the period	-1.9	-0.3	-0.6	0.3
Total comprehensive income for the period	-5.1	-13.4	-62.1	-53.2

Since there are no minority interests in the Group (no non-controlling interests), all earnings are wholly attributable to the owners of the Parent Company.

See Note 5 on page 15.
 See Note 4 on page 15.

Consolidated statement of financial position

SEK million	Dec 31, 2024	Dec 31, 2023
ASSETS		
Non-current assets		
Goodwill	7.0	6.7
Capitalized development expenses	78.6	43.9
Other intangible assets	16.4	5.4
Equipment, tools and plant	37.6	17.1
Right-of-use assets	59.9	74.5
Deferred tax assets ¹	21.8	20.6
Other non-current receivables	0.2	0.1
Total non-current assets	221.5	168.3
Current assets	20.0	<u> </u>
Inventories	30.2	20.6
Trade receivables	50.9	33.7
Current tax assets	2.9	1.9
Other receivables	10.7	9.7
Prepaid expenses and accrued income	13.0	13.0
Cash and cash equivalents	144.5	262.9
Total current assets	252.3	341.8
TOTAL ASSETS	473.8	510.1
EQUITY AND LIABILITIES		
EQUITY		
Share capital	1.0	0.9
Share premium	536.5	513.2
Translation reserve	0.6	1.2
Retained earnings, including profit/loss for the period	-189.0	-130.2
TOTAL EQUITY	349.0	385.1
LIABILITIES		
Non-current liabilities		
Borrowings	0.3	0.6
Lease liabilities	45.1	56.7
Deferred tax liabilities	0.1	0.2
Provisions ²	5.1	1.0
Other non-current liabilities	1.5	3.7
Total non-current liabilities	52.1	62.1
Current liabilities		
Borrowings	0.1	-
Lease liabilities	13.6	17.5
Trade payables	12.6	14.2
Current tax liabilities	2.5	0.3
Other liabilities	15.6	10.9
Accrued expenses and deferred income	25.8	20.0
Provisions ²	2.4	-
Total current liabilities	72.6	62.9
TOTAL EQUITY AND LIABILITIES	473.8	510.1

1) See Note 4 on page 15. 2) See Note 5 on page 15.

Consolidated statement of changes in equity

		Share	Translation	Retained earnings, including profit/loss for the	
SEK million	Share capital	premium	reserve	period	Total equity
Opening equity, Jan 1, 2023	0.9	507.6	0.8	-77.9	431.4
Comprehensive income					
Profit/loss for the period	-	-	-	-53.6	-53.6
Other comprehensive income for the period	-	-	0.3	-	0.3
Total comprehensive income	-	-	0.3	-53.6	-53.2
Shareholder transactions					
New share issues	0.0	5.6	-	-	5.6
Warrants	-	-0.0	-	-	-0.0
Employee stock options	-	-	-	1.3	1.3
Closing equity, Dec 31, 2023	0.9	513.2	1.2	-130.2	385.1
Opening equity, Jan 1, 2024	0.9	513.2	1.2	-130.2	385.1
Comprehensive income					
Profit/loss for the period	-	-	-	-61.5	-61.5
Other comprehensive income for the period	-	-	-0.6	-	-0.6
Total comprehensive income	-	-	-0.6	-61.5	-62.1
Shareholder transactions					
New share issues	0.0	23.6	-	0.0	23.6
New share issue expenses	-	-0.2	-	-	-0.2
Warrants	-	-0.0	-	-	-0.0
Employee stock options ¹	-	-	-	2.7	2.7
Closing equity, Dec 31, 2024	1.0	536.5	0.6	-189.0	349.0

1) The item employee stock options includes net share-based payments and the related deferred tax.

Consolidated cash flow statement

SEK million	Oct - Dec 2024	Oct - Dec 2023	Jan - Dec 2024	Jan - Dec 2023
Cash flow from operating activities				
Operating profit/loss ¹	0.7	-18.5	-58.3	-58.9
Adjustment for non-cash items				
- Depreciation, amortization and impairment	7.3	4.3	27.7	13.1
- Other non-cash items	6.0	0.2	9.3	2.0
Interest received	4.1	4.9	4.2	5.0
Interest paid	-0.8	-0.3	-3.5	-0.8
Income tax paid	-1.1	-3.7	-2.5	-8.6
Cash flow from operating activities before changes in working capital	16.2	-13.1	-23.1	-48.2
Cash flow from changes in working capital				
Increase (-)/Decrease (+) in inventories	-5.3	-5.0	-9.4	-10.5
Increase (-)/Decrease (+) in operating receivables	-16.2	-0.5	-20.2	-15.7
Increase (+)/Decrease (-) in operating payables	3.9	4.8	5.9	4.7
Cash flow from operating activities	-1.4	-13.8	-46.8	-69.7
Cash flow from investing activities				
Investments in intangible non-current assets	-20.0	-7.6	-51.1	-20.5
Investments in property, plant and equipment	-1.7	-2.1	-25.8	-11.5
Sale of property, plant and equipment	0.0	0.0	0.1	0.0
Cash flow from investing activities	-21.7	-9.7	-76.9	-32.0
Cash flow from financing activities				
New share issues	3.9	-0.0	23.6	5.6
New share issue expenses	-	-	-0.2	-
Warrant programs	-	-	-0.0	-0.0
Repayments of borrowings	-0.1	-0.1	-0.1	-0.1
Repayments of lease liabilities	-3.8	-1.8	-15.4	-5.7
Cash flow from financing activities	0.1	-1.8	7.8	-0.2
Cash flow for the period	-23.0	-25.3	-115.8	-102.0
Cash and cash equivalents at the beginning of the period	171.4	287.9	262.9	363.6
Exchange gains/losses on cash and cash equivalents	-3.8	0.3	-2.5	1.3
Cash and cash equivalents at the end of the period	144.5	262.9	144.5	262.9

1) See Note 5 on page 15.

Parent Company income statement

SEK million	Oct - Dec 2024	Oct - Dec 2023	Jan - Dec 2024	Jan - Dec 2023
Net sales	14.7	12.5	47.0	37.7
Cost of goods sold	-0.1	-0.1	-0.2	-0.2
Gross profit	14.7	12.5	46.8	37.5
Other operating income	-0.2	0.0	0.0	0.0
Selling expenses	-	-	-	-0.9
Administrative expenses	-3.4	-6.9	-21.0	-20.6
Research and development costs	-1.2	-1.1	-4.5	-3.1
Other operating expenses	0.0	-0.0	-0.0	-0.0
Operating profit/loss	9.9	4.4	21.3	12.9
Net interest and similar items	0.4	2.5	4.9	5.2
Profit/loss from financial items	0.4	2.5	4.9	5.2
Profit/loss after financial items	10.3	6.9	26.2	18.1
Appropriations	-82.9	-68.4	-82.9	-68.4
Profit/loss before tax	-72.6	-61.5	-56.6	-50.3
Tax ¹	0.0	2.0	0.3	2.1
Profit/loss for the period	-72.6	-59.5	-56.3	-48.2
Earnings per share before dilution, SEK	-4.39	-3.65	-3.44	-2.98
Diluted earnings per share, SEK	-4.39	-3.65	-3.44	-2.98
Average no. of shares, before dilution	16,519,941	16,284,469	16,398,116	16,180,907
Average no. of shares, after dilution	16,618,045	17,155,807	16,443,870	17,052,245

As there are no items of other comprehensive income, the Parent Company's earnings are the same as the comprehensive income.

1) See Note 4 on page 15.

Parent Company balance sheet

SEK million	Dec 31, 2024	Dec 31, 202
ASSETS		
Non-current assets		
Intangible assets		
Capitalized development expenses	70.5	43
Total intangible assets	70.5	43
Financial non-current assets	15(0	69
Investments in Group companies	156.0 20.5	20
Deferred tax assets ¹		
Total financial non-current assets Total non-current assets	176.4	89
	240.7	132
Current assets		
Amounts owed by Group companies	1.2	30
Current tax assets	0.5	(
Other receivables	0.4	(
Prepaid expenses and accrued income	0.8	(
Cash in hand and at bank	113.0	218 250
Total current assets	116.0	250
TOTAL ASSETS	362.9	383
EQUITY AND LIABILITIES		
EQUITY		
Share capital	1.0	(
Statutory reserve	3.7	3
Reserve for development expenses	70.8	43
Total restricted equity	75.5	48
Share premium reserve	532.7	507
Retained earnings	-206.2	-131
Profit/loss for the period	-56.3	-48
Total non-restricted equity	270.2	328
TOTAL EQUITY	345.7	376
LIABILITIES		
Non-current liabilities		
Provisions	1.2	1
Total non-current liabilities	1.2	1
Current liabilities		
Trade payables	0.4	(
Amounts owed to Group companies	10.7	(
Other liabilities	1.7	
Accrued expenses and deferred income	3.1	2
Total current liabilities	15.9	5

1) See Note 4 on page 15.

Changes in the Parent Company's equity

SEK million	Share capital	Reserve for development expenses	Reserves	Share premium reserve	Retained earnings	Profit/loss for the period	Total equity
Opening equity lon 1 2022	0.9	30.0	3.7	501.8	-69.2	-49.6	417.7
Opening equity, Jan 1, 2023	0.7				-07.2	- 47.0 -48.2	-48.2
Profit/loss for the period	-	-	-	-	-		-48.2
Appropriation of earnings	-	-	-	-	-49.6	49.6	-
Capitalization of development expenses	-	13.3	-	-	-13.3	-	-
New share issues	0.0	-	-	6.0	-0.4	-	5.6
Employee stock options	-	-	-	-	1.3	-	1.3
Warrants	-	-	-	-	-0.0	-	-0.0
Closing equity, Dec 31, 2023	0.9	43.3	3.7	507.8	-131.2	-48.2	376.3
Opening equity, Jan 1, 2024	0.9	43.3	3.7	507.8	-131.2	-48.2	376.3
Profit/loss for the period	-	-	-	-	-	-56.3	-56.3
Appropriation of earnings	-	-	-	-	-48.2	48.2	-
Capitalization of development expenses	-	27.5	-	-	-27.5	-	-
New share issues	0.0	-	-	25.2	-1.6	-	23.6
New share issue expenses	-	-	-	-0.2	-	-	-0.2
Employee stock options	-	-	-	-	2.4	-	2.4
Warrants	-	-	-	-	-0.0	-	-0.0
Closing equity, Dec 31, 2024	1.0	70.8	3.7	532.7	-206.2	-56.3	345.7

Parent Company cash flow

SEK million	Oct - Dec 2024	Oct - Dec 2023	Jan - Dec 2024	Jan - Dec 2023
Cash flow from operating activities				
Operating profit/loss	9.9	4.4	21.3	12.9
Adjustments for non-cash items				
- Depreciation, amortization and impairment	1.2	1.1	4.5	3.1
- Other non-cash items	0.0	0.5	1.9	0.7
Interest received	4.0	4.9	4.0	4.9
Interest paid	-	-0.0	-	-0.0
Tax paid	-0.1	-	-0.6	-
Cash flow from operating activities before changes in working capital	14.9	10.9	31.1	21.6
Cash flow from changes in working capital				
Increase (-)/Decrease (+) in operating receivables	49.2	-0.1	31.1	-16.8
Increase (+)/Decrease (-) in operating payables	-73.6	-7.6	-74.4	-6.4
Cash flow from operating activities	-9.5	3.1	-12.2	-1.6
Cash flow from investing activities				
Shareholder contributions	-85.0	-9.3	-85.0	-9.3
Investments in intangible non-current assets	-10.5	-3.9	-31.7	-16.4
Increase/decrease in financial non-current assets	82.5	-9.7	-	-83.7
Cash flow from investing activities	-13.0	-22.9	-116.7	-109.4
Cash flow from financing activities				
New share issues	3.9	-0.0	23.6	5.6
New share issue expenses	-	-	-0.2	-
Stock option plans	-	-	-0.0	-0.0
Cash flow from financing activities	3.9	-0.0	23.3	5.6
Cash flow for the period	-18.6	-19.8	-105.6	-105.5
Cash and cash equivalents at the beginning of the period	131.6	238.4	218.6	324.1
Cash and cash equivalents at the end of the period	113.0	218.6	113.0	218.6

Notes

Note 1 Accounting policies

The interim report for the Devyser Group has been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU. The Swedish Annual Accounts Act and RFR 1, Supplementary Accounting Rules for Groups, have also been applied.

The interim report for the Group has been prepared in accordance with IAS 34 Interim Financial Reporting. The Parent Company applies the Swedish Annual Accounts Act and RFR 2, Accounting for Legal Entities. Under RFR 2, the Parent Company is required to apply the same accounting policies as the Group, which means that IFRS should be applied as far as possible within the framework of the Swedish Annual Accounts Act, the Swedish Pension Obligations Protection Act and tax considerations.

New or amended IFRS standards and other IFRIC interpretations came into effect on January 1, 2024. None of the new standards affected the reporting of the Group or the Parent Company as of December 31, 2024.

All amounts are reported in millions of kronor (SEK million) unless otherwise stated. Figures in brackets refer to the previous year. The figures in tables and calculations may be rounded, meaning that the total amounts shown may not always be the exact sum of the rounded amounts.

For more information about the accounting policies, refer to the 2023 Annual Report.

Segment reporting

Devyser applies IFRS 8 Operating segments. Devyser's activities are currently focused on development and sales within a niche and uniform category of goods of a similar nature in the product area of diagnostic reagents, and only one segment is therefore reported, which is fully reflected in the Group's financial statements. All of its development activities are centered on the same common base product. The Group's strategic steering committee and highest decision-makers, consisting of the CEO and a number of other senior executives who together form the senior management, evaluate the Group's activities as a whole based on products and product development. Sales are monitored by geographic region, currently Europe, the Middle East and Africa (EMEA), Asia-Pacific, North and South America and other regions. Refer to the table on page 5.

Note 2 Incentive programs

Devyser has four outstanding incentive programs for employees and key personnel.

2021/2026 employee stock option plan

The total plan comprises 102,000 employee stock options, plus 32,048 options for the hedging of social security contributions. The options are granted free of charge. Each option entitles its holder to subscribe for one new share at SEK 87.06 per share until June 2026. The options are vested at a rate of one-third annually starting from the grant date, provided that the holder remains an employee.

As of December 31, 2024, a total of 30,534 options had been granted and not exercised. No members of the senior management hold any employee stock options under the plan.

2022/2026 employee stock option plan

The total plan comprises 250,000 employee stock options, plus 78,550 options for the hedging of social security contributions. The options are granted free of charge. Each option entitles its holder to subscribe for one new share at SEK 89.34 per share until June 2026. The options are vested at a rate of one-third annually starting from the grant date, provided that the holder remains an employee.

As of December 31, 2024, a total of 167,718 options had been granted and not exercised. Two members of the senior management together hold a total of 100,000 employee stock options.

2023/2027 employee stock option plan

The total plan comprises 200,000 employee stock options, plus 62,840 options for the hedging of social security contributions. The options are granted free of charge. Each option entitles its holder to subscribe for one new share at SEK 101.71 per share until June 2027. The options are vested at a rate of one-third annually starting from the grant date, provided that the holder remains an employee.

As of December 31, 2024, a total of 188,550 options had been granted and not exercised. Former CEO Fredrik Alpsten holds 50,000 options. Four members of the senior management together hold a total of 90,000 employee stock options.

2024/2028 employee stock option plan

The total plan comprises 200,000 employee stock options, plus 62,840 options for the hedging of social security contributions. The options are granted free of charge. Each option entitles its holder to subscribe for one new share at SEK 136.48 per share until June 2028. The options are vested at a rate of one-third annually starting from the grant date, provided that the holder remains an employee.

As of December 31, 2024, a total of 147,750 options had been granted and not exercised. Former CEO Fredrik Alpsten holds 50,000 options. Four members of the senior management together hold a total of 38,500 employee stock options.

Note 3 Related-party transactions

Related-party transactions arise in the normal course of business and are carried out at arm's length and market prices. In addition to customary transactions between Group companies and the remuneration of management and the Board, the following transactions with related parties took place during the period;

The Group purchased a software license from a company that is a related party of CFO Sabina Berlin. Expenses for the period from January to December 2024 amounted to SEK 30.0 thousand (30.0) and for the fourth quarter of 2024 to SEK 30.0 thousand (30.0). The transactions are considered to have been carried out at arm's length. See Note 2 on incentive programs.

Note 4 Deferred tax

Within the Group, deferred tax is mainly recognized for accumulated losses, leases, share-based payments and endowment policies for which there are temporary differences that are grounds for the recognition of deferred tax.

The tax effects of loss carryforwards are taken into account only to the extent that there are convincing factors that suggest that these may be utilized in the foreseeable future. There are no time limits on any of the losses.

At year-end 2024, the Parent Company had carryforwards of unused tax losses of SEK 241.0 million (185.8), corresponding to deferred tax assets of SEK 49.6 million (38.3). After valuation, SEK 19.1 million (19.1) are recognized in deferred tax assets in the balance sheet.

Note 5 Provision due to retroactive payback levy

In 2022, the Italian Ministry of Health announced a retroactive payback levy based on sales in excess of budget to the National Health Service (NHS-SSN). The decision has been appealed by many affected parties but, in 2024, an Italian court ruled that the retroactive levy is not unconstitutional and will probably have to be paid in the coming years. Devyser therefore made provisions in the fourth quarter of 2024 for estimated retroactive costs totaling SEK 6.2 million for the period 2015-2024.

The provision is recognized in the consolidated statement of income and comprehensive income under Selling expenses and in the consolidated statement of financial position under Provisions.

Use of non-IFRS performance measures

The Devyser Group prepares its consolidated financial statements in accordance with IFRS. Only a few performance measures are defined in the IFRS standards. Devyser applies the Guidelines on Alternative Performance Measures (APMs) issued by the European Securities and Markets Authority (ESMA). To support the assessment of the Group's performance made by senior management and other stakeholders, Devyser uses some non-IFRS performance measures. Senior management believes that these measures make it easier to evaluate the performance of the Group.

Definitions of non-IFRS performance measures that are not provided elsewhere in this report are presented in the following table. The measures have been calculated using the actual financial statements, including IFRS 16.

	Oct - Dec 2024	Oct - Dec 2023	Jan - Dec 2024	Jan - Dec 2023
Gross margin (gross profit/net sales)				
Gross profit, SEK million	54.2	40.0	172.7	144.7
Net sales, SEK million	64.2	45.4	216.9	169.3
Gross margin, %	84.4	88.1	79.6	85.5
EBITDA margin (EBITDA/net sales)				
Operating profit/loss, SEK million	0.7	-18.5	-58.3	-58.9
Depreciation/amortization, SEK million	-7.3	-4.3	-27.7	-13.1
Net sales, SEK million	64.2	45.4	216.9	169.3
EBITDA margin, %	12.4	Neg	Neg	Neg
Operating margin (operating profit/net sales)				
Operating profit/loss, SEK million	0.7	-18.5	-58.3	-58.9
Net sales, SEK million	64.2	45.4	216.9	169.3
Operating margin, %	1.1	Neg	Neg	Neg
Return on equity (profit for the period/average equity)				
Profit/loss for the period, SEK million	-3.2	-13.1	-61.5	-53.6
Average equity, SEK million	349.0	391.6	367.1	408.3
Return on equity, %	Neg	Neg	Neg	Neg
Net cash/Net debt (interest-bearing liabilities - interest-bearing assets)				
Interest-bearing liabilities, SEK million	59.1	74.8	59.1	74.8
Interest-bearing assets, SEK million	144.5	262.9	144.5	262.9
Net cash (-)/Net debt (+), SEK million	-85.4	-188.2	-85.4	-188.2
Equity ratio (closing equity for the period/closing total assets for the period)				
Closing equity, SEK million	349.0	385.1	349.0	385.1
Closing total assets, SEK million	473.8	510.1	473.8	510.1
Equity ratio, %	73.7	75.5	73.7	75.5
Growth adjusted for exchange rate changes (((sales in currency for the period * (previous period's exchange rate - average exchange rate for the period in currency) + net sales)) - previous period's net sales)))/previous period's net sales)				
Net sales in EUR million	3.4	3.1	13.8	11.7
Net sales in USD million	1.9	0.5	3.8	1.8
Net sales in GBP million	0.2	0.1	0.5	0.5
Net sales, SEK million	64.2	45.4	216.9	169.3
Average exchange rate EUR/SEK	11.4949	11.4788	11.4456	11.4751
Average exchange rate USD/SEK	10.7775	10.6850	10.5870	10.6121
Average exchange rate GBP/SEK	13.8124	13.2396	13.5325	13.1954
Sales growth adjusted for exchange rate changes, %	40.8	27.5	28.3	24.9

About Devyser

Devyser develops, manufactures and sells diagnostic solutions and analysis services to clinical laboratories in more than 65 countries. Our products are used for advanced genetic testing in the fields of inherited diseases, oncology and transplantation. They provide the opportunity to tailor cancer treatments, diagnose a wide range of genetic diseases and follow up transplant patients. Devyser's products, and unique, patented solution, which requires only a single test tube, simplify genetic testing processes, improve sample throughput, minimize hands-on time and deliver rapid results. Our goal is for every patient to receive a correct diagnosis in the shortest possible time. Sustainability is a central part of Devyser's business model, and is a prerequisite for long-term value creation over time.

Devyser was founded in 2004 and is based in Stockholm, Sweden. The company has eight in-house sales offices in Europe and the US, as well as a CLIA laboratory in Atlanta, Georgia. In August 2022, Devyser's quality management system was IVDR certified. Devyser's shares are listed on the Nasdag First North Premier Growth Market Stockholm (ticker: DVYSR).

For more information, visit www.devyser.com.

The company's Certified Adviser is Redeye AB.

Contact

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All reports are published on the company's website: https://investors.devyser.com/en/reports-presentations

Financial calendar

May 8, 2024 May 14, 2024 July 23, 2024 October 30, 2024 February 13, 2025 April 2, 2025 May 14, 2025 July 22, 2025 November 5, 2025 February 12, 2026

Analysts covering the company

Ulrik Trattner, Carnegie Investment Bank Oscar Bergman, Redeye Johan Unnérus, Redeye Ludvig Lundgren, Nordea Filip Wiberg, Pareto Securities

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