



Half-Year Report 2024

January – June 2024

Orviglance® Completes Clinical Development with Successful Phase 3 Study

KEY EVENTS IN Q2 2024

- SPARKLE image reading completed with expected headline results first half of May 2024
- Ascelia Pharma draws down SEK 15 million second tranche under existing loan
- Primary endpoint successfully met with strong headline results in Orviglance phase 3 study
- Bulletin from the Annual General Meeting in Ascelia Pharma AB on 6 May 2024
- Ascelia Pharma hosts Investor Update: Bringing Orviglance to Patients

KEY EVENTS AFTER THE PERIOD

- Ascelia Pharma carries out a Rights Issue of units of approximately SEK 105 million to fully finance the NDA submission for Orviglance
- Notice of Extraordinary General Meeting in Ascelia Pharma 14 August
- Bulletin from the Extraordinary General Meeting in Ascelia Pharma 14 August

“We have met a major milestone with the successful results from our Orviglance Phase 3 study. We look forward to meeting the regulatory milestones ahead and to progress commercial partnering on our journey to making Orviglance available to patients”.

KEY RATIOS GROUP

	Q2 (Apr-Jun)		H1 (Jan-Jun)	
	2024	2023	2024	2023
OPERATING RESULT (SEKm)				
	-11.3	-41.8	-28.0	-78.5
EARNINGS PER SHARE (SEK)				
	-0.39	-1.19	-0.89	-2.30
CASH FLOW FROM OPERATIONS (SEKm)				
	-12.0	-42.3	-27.0	-79.8
LIQUID ASSETS (SEKm)				
	29.8	70.5	29.8	70.5

CEO STATEMENT



Positive Orvigance Phase 3 headline results. As announced on 2 May 2024, the pivotal Phase 3 study for Orvigance, SPARKLE successfully met the primary endpoint and demonstrated that the company's magnetic resonance imaging (MRI) contrast agent, Orvigance significantly improved visualization of focal liver lesions compared to unenhanced MRI. The results had high statistical significance (P values <0.001) for all three readers and the reliability of the data was strong and conclusive for all three readers – this includes an acceptable level of variability.

Common adverse events in this vulnerable patient population were in line with previous studies with Orvigance, such as mild-to moderate nausea. No serious adverse drug reactions were observed.

In May 2024, we announced strong positive headline results from our pivotal Phase 3 study, SPARKLE, with Orvigance. The results showed that Orvigance significantly improved the visualization of focal liver lesions, successfully meeting the primary endpoint with statistical significance for all three readers (<0.001).

The successful Phase 3 data reinforce our confidence in the regulatory and commercial path ahead for Orvigance and mark the completion of clinical development for Orvigance. We will now focus on bringing Orvigance through the regulatory submission and approval process with a submission of the New Drug Application (NDA) to the US Food and Drug Administration (FDA) expected by mid 2025. We also continue to advance the dialogue with potential commercialization partners to launch Orvigance and make it available to patients who need high-quality liver imaging without gadolinium-related safety risk.

On 10 July, we announced the launch of a rights issue of approximately SEK 105 million, secured to SEK 70 million. This financing improves our financial position and strengthens our ability to obtain an attractive agreement with commercialization partners. It also ensures that we can complete all activities for the NDA submission mid 2025 with high quality. I am pleased that the financing allows all our shareholders to take part in the significant value creation opportunities ahead.

Completion of Orvigance clinical development. With the positive headline results for SPARKLE, clinical development of Orvigance has been successfully completed with consistent positive efficacy and safety data from nine clinical studies with a total of 286 patients and healthy volunteers. In the global multi-center Phase 3 SPARKLE study, 85 patients with known or suspected focal liver lesions and severely impaired kidney function were successfully completed with MRI data.

The strong results reinforce our confidence in the market potential and path to market for Orvigance. We will now focus on bringing Orvigance through the regulatory submission and approval process. We expect to submit the NDA file to the FDA by mid-2025 to obtain regulatory approval.

In parallel, we continue to advance the dialogues with potential commercialization partners to make Orvigance available to patients who need high-quality liver imaging without the safety risks associated with gadolinium.

Recognition in the scientific community. We were pleased to see the publication of a review article on Orvigance in the journal *Investigative Radiology* in the issue "A new era in MR contrast media" published in January 2024. The scientific review article, titled *Oral manganese chloride tetrahydrate, a novel magnetic resonance liver imaging agent for patients with renal impairment: efficacy, safety and clinical implication*, reviews and discusses liver imaging in patients with severely impaired kidney function and the development of Orvigance and its potential role in clinical practice.

”Following the positive Phase 3 results for Orviglance in May, the announced financing strengthens our ability to obtain an attractive agreement with commercialization partners and ensures that we have a solid financial position to complete all activities for the NDA”.

The acceptance of this publication in one of the leading journals in radiology demonstrates that the scientific community sees a need for novel contrast agents without gadolinium.

Strategy to commercialize with partners. Orviglance addresses a well-defined unmet medical need representing an annual global addressable market of USD 800 million, with 100,000 procedures in the target patient population in the US alone.

Our strategy is to launch with commercialization partners. This approach enables us to leverage established commercialization capabilities with a low investment requirement for launch. A focused, ambitious launch plan, built on advanced market insights, is in place. Our focus in 2024 is to create value by progressing the dialogue with potential partners and ensuring Orviglance launch readiness when approved.

Strengthened financial position. On 10 July, we launched a rights issue of units, consisting of ordinary shares and warrants, of approximately SEK 105 million before costs. The subscription period runs from 20 August to 3 September and is covered to SEK 70 million by subscription undertakings and guarantee commitments. The financing ensures that we have a solid financial position, which will strengthen our ability to obtain an attractive agreement with commercialization partners. It also ensures that we can complete all activities for the NDA submission by mid-2025 with high quality. The financing provides a cash runway past the NDA filing mid 2025.

A transformative 2024 ahead. With positive headline results from SPARKLE, we are excited to advance Orviglance to the registration phase and make it available for patients together with a partner. I look forward to sharing our continued progress and other opportunities for growing Ascelia Pharma in 2024 and beyond.

Magnus Corfitzen
CEO

ADVANCING ORPHAN ONCOLOGY

OUR VALUES

FOCUS

We are devoted to improving the lives of patients and creating values for our stakeholders.

COURAGE

We work tirelessly and follow our convictions even when it means changing status quo.

INTEGRITY

We build powerful relationship with mutual respect and adhere to the high ethical standards of our industry.

OUR VISION

To be a leader in identifying, developing and commercializing novel drugs that address unmet needs of people with rare cancer conditions.

OUR BASE

Our headquarter is in Malmö, Sweden, and our US base is in New Jersey.

The shares in the company are listed on NASDAQ Stockholm (ticker: ACE).

Building Ascelia Pharma and building value

ADVANCING PIPELINE AND COMMERCIAL CAPABILITIES

- Orviglance in registration phase
- Oncoral Phase 2 ready

PRODUCT LAUNCH AND EXPANDING PIPELINE

- Orviglance revenue
- Oncoral Phase 2
- Pipeline expansion

ESTABLISHED MARKET POSITION IN ORPHAN ONCOLOGY

- Orviglance market leader
- Oncoral Phase 3
- Pipeline development
- Pipeline further expanded

OUR PIPELINE

ORVIGLANCE

Diagnostic drug for liver MRI in registration phase

Orviglance is our first-in-class non-gadolinium diagnostic drug (contrast agent) to be used for magnetic resonance imaging (MRI) of the liver. Orviglance is developed to improve the visualization of focal liver lesions (liver metastases and primary liver cancer) in patients with impaired kidney function at risk of severe side-effects from the gadolinium contrast agents currently on the market.

- First-in-class manganese-based diagnostic drug with FDA Orphan Drug Designation
- \$800 million global annual addressable market
- Clinical development completed, incl. pivotal Phase 3, with consistent positive efficacy and safety data from nine clinical studies with 286 patients and healthy volunteers

ONCORAL

Daily tablet chemotherapy ready for Phase 2

Oncoral is our novel oral irinotecan chemotherapy tablet developed initially for the treatment of gastric cancer. The potential anti-tumor effect of irinotecan is well established.

- Oral daily dosing of irinotecan chemotherapy
- Potential for better efficacy and safety by frequent low dosing
- Ready for Phase 2 in gastric cancer; potential to expand into other cancers



ORVIGLANCE ADDRESSES UNMET NEEDS FOR LIVER MRI IN PATIENTS WITH KIDNEY IMPAIRMENT

Orviglance aims to be the standard of care liver MRI contrast agent for patients also suffering from severe kidney impairment. These patients are at risk of severe side-effects from using gadolinium-based contrast agents.

\$800 million global annual addressable market

The target group for Orviglance is patients who need liver imaging and have severely impaired kidney function. This patient group is at risk of serious, and potentially fatal, side effects from using the currently available contrast agents. These contrast agents, which are based on the heavy-metal gadolinium, carry Black Box warnings for patients with severely reduced kidney function.

The completed clinical trials show that Orviglance improve the diagnostic performance of MRI and offers a significantly better alternative than unenhanced MRI (i.e., MRI without contrast agent). Consequently, Orviglance fills a significant unmet medical need to

improve the diagnosis, and subsequently, the treatment of liver metastases and primary liver cancer.

The immediate addressable market for Orviglance is estimated at \$800 million yearly and Orviglance is expected to be the only gadolinium-free product on the market for this patient segment.

Orphan Drug Designation

Orviglance has received Orphan Drug Designation from the FDA. One major advantage of orphan drug status is, among other things, that orphan drugs can obtain longer market exclusivity after market approval.

Early detection of liver metastases is key.

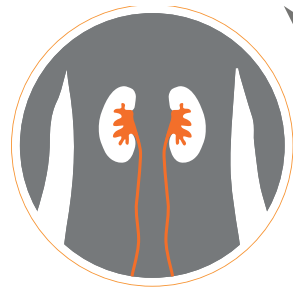
Orviglance is a contrast agent used in MRIs to improve the visualization of focal liver lesions (liver metastases and primary tumors). The liver is the second most common organ for metastasis after the lymph nodes. Detecting liver metastases at an early stage is crucial for determining the right treatment method and the patient's chances of survival. Studies show that the five-year survival rate can increase from 6 percent to 46 percent if liver metastases can be removed surgically. An accurate MR scan using contrast agents is therefore critical to evaluate the possibility for surgical resection, but also for monitoring of treatment effect and surveillance for recurrence of the disease.

Suspected cancer in the liver

Test kidney function

MRI contrast agent decision

Liver MRI scan

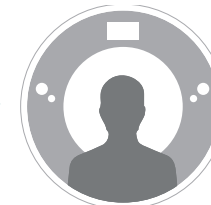


A) Healthy kidneys

MRI with gadolinium contrast agent

B) Poor kidneys

- All gadolinium contrast agents have regulatory Black Box warnings
- Risk of severe and potentially fatal side-effect (NSF - Nephrogenic Systemic Fibrosis)



Solution
MRI with
ORVIGLANCE

ORVIGLANCE CLINICAL DEVELOPMENT COMPLETED

Orphan liver MRI contrast agent in registration phase

How Orviglance works

Orviglance is an orally administered contrast agent developed for use with MRI of the liver. It is based on the chemical element manganese, which is a natural trace element in the body. Orviglance also contains L-Alanine and Vitamin D3 to enhance the function of manganese as a contrast agent. After having been absorbed from the small intestine, the manganese is transported to the liver where it is taken up by and retained in the normal liver cells. The high manganese uptake causes the normal liver tissue to appear bright on MR images. Metastases and tumor cells do not take up manganese to the same extent as normal liver tissue and therefore appear dark on MR images. Liver metastases are easier to identify due to this contrast effect by Orviglance.

Successful clinical development

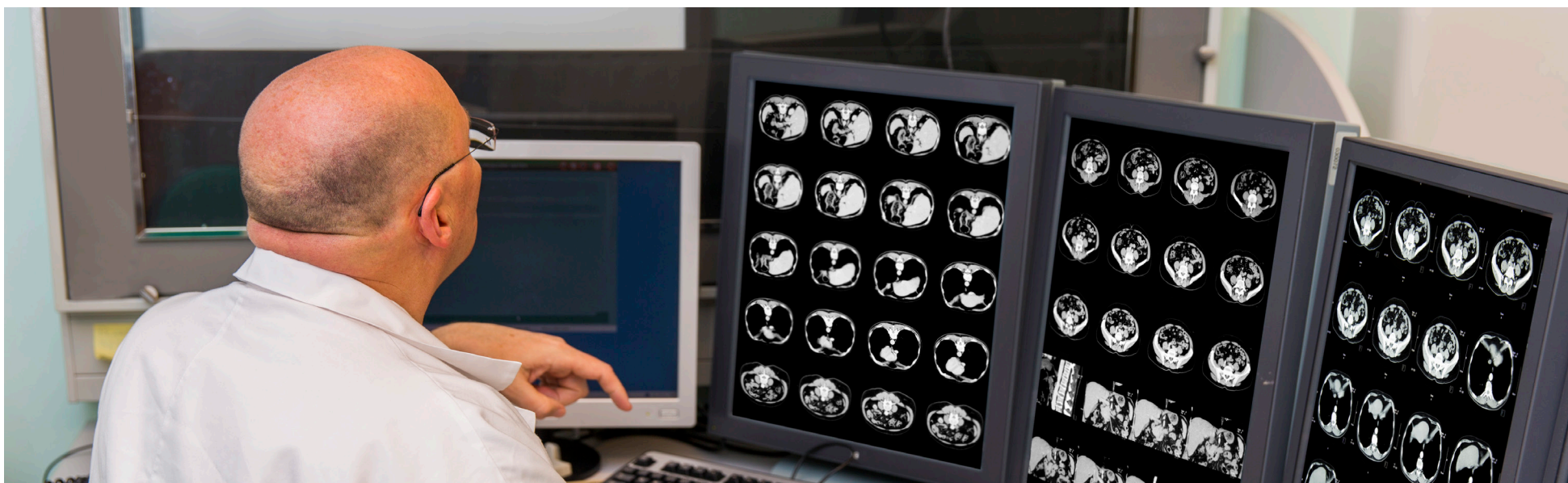
Clinical development of Orviglance has been completed with consistent positive efficacy and safety data from nine studies with 286 patients and healthy volunteers.

The pivotal Phase 3 study for Orviglance, SPARKLE successfully met the primary endpoint and demonstrated that Orviglance significantly improved visualization of focal liver lesions compared to unenhanced MRI. The results had high statistical significance (P values <0.001) for all three readers and the reliability of the data was strong and conclusive for all three readers, including an acceptable level of variability.

Common adverse events in this vulnerable patient population were in line with previous studies with Orviglance, such as mild-to moderate nausea. No serious adverse drug reactions were observed.

Advanced to registration phase

Submission of the NDA file to the FDA is expected by mid-2025. Key required steps during the NDA preparations include the Full Clinical Study Report early Q4 2024 and conclusions from an FDA pre-submission meeting by Q1 2025.



PHASE 3 SUCCESSFULLY COMPLETED

Phase 3 primary endpoint met

The pivotal Phase 3 study, SPARKLE, successfully met the primary endpoint and demonstrated that Orviglance significantly improved the visualization of focal liver lesions compared to MRI without contrast, unenhanced MRI. The results for all three readers were highly statistically significant (P values <0.001).

Common adverse events in this vulnerable patient population were in line with previous studies with Orviglance, such as mild- to moderate nausea. No serious adverse drug reactions were observed.

Designed to support regulatory approval

The pivotal Phase 3 study (SPARKLE) is a global multicentre study, which has been completed with 85 enrolled patients with suspected or known focal liver lesions and severely impaired kidney function.

The evaluation of the primary endpoint was independently carried out by three blinded, independent radiologists (readers), in accordance with regulatory guidance to the industry. The readers assessed changes of visualization of liver lesions with and without Orviglance, as well as other secondary efficacy endpoints.

Following an unacceptably high intra-reader variability in the first image scoring by readers mid-2023, a new evaluation of the images with new readers was successfully completed with the announced positive headline results and acceptable variability in May 2024, in line with the planned timeline.

The Phase 3 study was designed in accordance with industry standards, regulatory guidance for imaging agent development and based on discussions with regulatory agencies. The study aims to support a regulatory filing and approval for use of Orviglance for liver imaging in patients where the use of gadolinium may be medically inadvisable.

Orviglance clinical Phase 3 study

NUMBER OF PATIENTS	Global study with 85 patients
PRIMARY ENDPOINT	Lesion visualization <ul style="list-style-type: none"> ■ Border delineation (border sharpness of lesions) ■ Lesion contrast (conspicuity compared to liver background)
COMPARATOR	Unenhanced MRI + Orviglance MRI vs. Unenhanced MRI
EVALUATION	Centralized evaluation by 3 radiologists
RANDOMIZATION	None – each patient their own control
FOLLOW-UP	Less than a week

Strong positive Phase 3 headline results

Visualization of focal liver lesions with Orviglance (CMRI) vs. unenhanced MRI was strongly superior with statistical significance for all three readers (<0.001)

Results from both variables show that Orviglance significantly improves MRI performance



Orviglance advances to registration phase

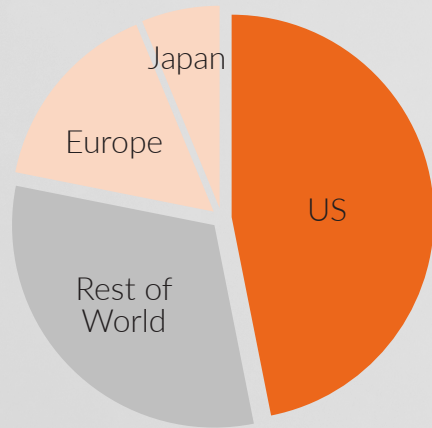
Submission of the NDA file to the FDA is expected by mid-2025

ANNUAL ADDRESSABLE MARKET OF \$800 MILLION

Clear and attractive addressable market

Orviglance addresses a well-defined unmet medical need representing an attractive commercial potential with an annual global addressable market of \$800 million. This estimate is based on:

- Patients with primary liver cancer or liver metastases and severe kidney impairment (~4 percent)
- Actual imaging procedures (real-world data)¹
- Payer and expert input (+75 stakeholders)²



Unique opportunity to address an unmet need

Orviglance addresses an attractive market opportunity by offering contrast enhanced liver imaging for cancer patients with poor kidney function

- not associated with gadolinium safety risks for patients with poor kidney function
- addressing the increasing demand for alternatives to toxic gadolinium

90 percent of health care professionals are concerned by safety issues related to gadolinium contrast agents including NSF. In fact, according to market research, 16 percent of healthcare providers have experienced gadolinium-induced NSF³.

In the US alone real-world data shows that 100,000 abdominal imaging procedures are performed every year in 50,000 patients that fall under the black-box warning for gadolinium contrast agents, which is about 4 percent of the cancer patient population undergoing abdominal imaging.

“

Our commercialization strategy is to launch through partners, supporting our ambition to secure the optimal balance between future revenues and investment required. Our focus in 2024 is therefore to continue the ongoing dialogue with potential partners and to ensure that Orviglance is ready for launch when approved”, says Julie Waras Brogren, Deputy CEO

Partnering strategy

The go-to-market strategy for Orviglance is to launch with commercialization partners. This approach enables Ascelia Pharma to leverage established commercialization capabilities and maintain a low investment requirement for launch.

The focus of Ascelia Pharma is to create value by ensuring launch readiness and collaboration with a partner by preparing for optimal adoption by key stakeholders at launch.

UNIQUE OPPORTUNITY

Give people with cancer in the liver and poor kidney function
ACCESS TO SAFE AND EFFECTIVE IMAGING
to live healthier and longer lives

CLEAR AMBITION

Be the STANDARD OF CARE liver imaging choice
for cancer patients with poor kidney function

FOCUSED, AMBITIOUS STRATEGY

Ensure OPTIMAL LABEL, timely SUPPLY and launch READINESS
Drive EARLY ADOPTION AND PREFERENCE by decision
makers with focused efforts and a strong value proposition

1) Ascelia Pharma market research on real-world volumes with DRG (2020)

2) Market access research and analyses with Charles River Associates (2020), Triangle (2022)

and Trinity (2022), incl. 75 stakeholder and expert interactions. Final pricing and access strategy subject to Phase 3 data and payer evidence

3) Ascelia Pharma market research with Two Labs including 254 US HCPs (2022).

POTENTIAL BENEFITS OF DAILY DOSING

Oncoral is a novel daily irinotecan chemotherapy in development. Irinotecan chemotherapy has an established potent anti-tumor effect. Oncoral is a daily irinotecan tablet with the potential to offer better efficacy with improved safety following the daily dosing at home compared to intravenous high-dose infusions at the hospital.

Proven anti-cancer effect

The active substance in Oncoral is irinotecan, which has an established and proven effect in killing cancer cells. Irinotecan is a so-called antineoplastic agent that after metabolic activation inhibits the enzyme topoisomerase 1, thereby inducing cancer cell death via the prevention of their DNA replication. Irinotecan is converted by carboxylesterases, primarily in the liver, to the active metabolite SN-38 which is 100–1,000 more potent than irinotecan in killing tumor cells.

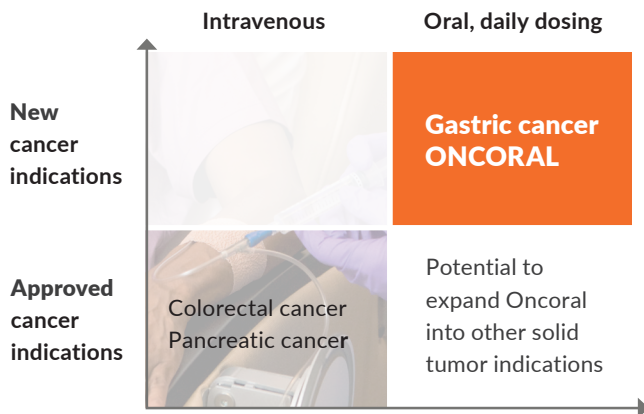
Potential to be the first oral version of irinotecan

Oncoral is a new patented oral tablet formulation of irinotecan, which enables a reliable release and efficient absorption of irinotecan from the gastro intestinal tract after oral administration. With oral administration, irinotecan can be given with low daily doses. This is very different from the current standard of giving a high intravenous doses every third week.

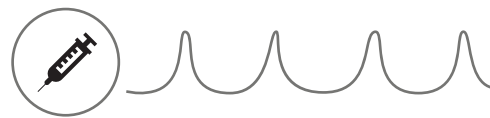
All-oral chemo combination

Oncoral has the potential to be combined with other chemotherapies and targeted cancer drugs and enable an all oral combination chemotherapy option with improved clinical outcomes.

ONCORAL – a novel formulation of irinotecan



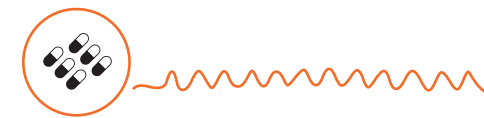
TODAY – Intravenous bolus infusions



Infrequent high-dose IV irinotecan

- Gastrointestinal and hematological side effects
- Dose limiting toxicity: 30 percent severe or life-threatening (grade 3 or 4)

TOMORROW – Oncoral oral daily dosing



Potential – Frequent low-dose irinotecan

- Improved efficacy driven by pharmacokinetic profile
- Improved tolerability due to lower peak exposure with less severe side effects and manageable toxicity with flexible dosing

PHASE 2 STUDY DESIGN AND COLLABORATION

Phase 2 study design

PATIENTS	<ul style="list-style-type: none">■ Around 100 patients■ Metastatic gastric cancer
COMPARATOR	Oncoral + Lonsurf vs. Lonsurf
ENDPOINTS	Primary: Progression Free Survival Secondary: Response rate, Pharmacokinetics, Safety and Overall Survival data in a follow up analysis
STUDY PERIOD	2 - 2½ years, study start pending

Clinical collaboration with Taiho Oncology

- Clinical Phase 2 collaboration with Taiho Oncology Inc. (part of Otsuka Group)
- Taiho Oncology Inc. will supply Lonsurf and provide scientific expertise
- The collaboration may be extended for further development
- Ascelia Pharma retains full development and commercialization rights



FINANCIAL OVERVIEW Q2 (APR-JUN 2024)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales in Q2 (Apr-Jun 2024) amounted to SEK 0 (SEK 0). Ascelia Pharma does not expect to recognize revenue before products have been launched on the market. Other operating income totalled SEK 10 thousand (SEK 0.4 million). The income refers to exchange rate gains.

Research and development costs (R&D)

R&D costs for the Group in Q2 were SEK 7.5 million (SEK 31.2 million). The cost decrease of SEK 22.1 million reflects completion of SPARKLE patient recruitment activities and previous communicated cost-cutting initiatives.

Commercial preparation costs

During Q2, no costs related to commercial preparations was recognized (SEK 5.9 million). In Q2 a positive result of SEK 0.7 million was recognized related to cost savings for employees.

Administration costs

Administration costs for the Group in Q2 amounted to SEK 4.5 million (SEK 5.1 million). The decreased costs compared to the same period last year, primarily relates to a decrease in recognized costs for employee incentive programs.

Operating results (EBIT)

The operating result in Q2 amounted to SEK -11.3 million (SEK -41.8 million). The decreased loss mainly reflects the implemented cost-cutting initiatives with focus to complete the NDA.

Net Profit/Loss for the period

The Group's net loss in Q2 amounted to SEK -13.3 million (SEK -40.3 million). During the quarter, net financial costs of SEK -1.9 million was recognized which mainly reflects interest expenses related to loans. The net loss corresponds to a loss per share, before and after dilution, of SEK -0.39 (SEK -1.19).

CASH FLOW

Cash flow from operating activities before changes in working capital in Q2 amounted to SEK -14.6 million (SEK -40.6 million). The decreased outflow mainly reflects the initiated cost-cutting initiatives. Changes in working capital for the quarter totalled an inflow of SEK 2.6 million (outflow of SEK -1.7 million). The inflow primarily reflects the increase in accounts payables. Cash flow from investing activities in Q2 amounted to SEK 0 (SEK 0). Cash flow from financing activities amounted to an inflow of SEK 15.1 million (outflow of SEK -0.3 million), which reflects the new loans during the quarter.

FINANCIAL POSITION

On the closing date, equity amounted to SEK 47.7 million, compared with SEK 74.3 million per 31 December 2023 and SEK 105.7 million per 30 June 2023. The decrease since 31 December 2023 reflects the net loss incurred. Liquid assets on the closing date amounted to SEK 29.8 million, compared to SEK 21.9 million per 31 December 2023 and SEK 70.5 million per 30 June 2023. The increase in liquid assets reflects loans received during the quarter.

Financial key ratios for the Group	Q2 (April-June)	
	2024	2023
Operating result (SEK 000')	-11,328	-41,791
Net result (SEK 000')	-13,271	-40,251
Earnings per share (SEK)	-0.39	-1.19
Weighted avg. number of shares	33,757,746	33,722,762
R&D costs/operating costs (%)	63%	74%
Cash flow used in operating activities (SEK 000')	-11,966	-42,303
Equity (SEK 000')	47,687	105,675
Liquid assets incl. marketable securities (SEK 000')	29,775	70,500

FINANCIAL OVERVIEW H1 (JAN–JUN 2024)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales in H1 (Jan-Jun 2024) amounted to SEK 0 (SEK 0). Ascelia Pharma does not expect to recognize revenue before products have been launched on the market. Other operating income totalled SEK 370 thousand (SEK 736 thousand). The income refers to exchange rate gains.

Research and development costs (R&D)

R&D costs for the Group during the first half of the year amounted to SEK 18.3 million (SEK 60.8 million). The cost decrease reflects the completion of SPARKLE patient recruitment activities and previous communicated cost-cutting initiatives.

Commercial preparation costs

During H1, a positive result of SEK 0.7 million (SEK -8.8 million) was recognized related to employee cost savings.

Administration costs

Administration costs for the Group in H1 amounted to SEK 10.8 million (SEK 9.4 million). The cost increase reflects an increase in recognized costs for employee incentive programs.

Operating results (EBIT)

The operating result in H1 2024 amounted to SEK -28.0 million (SEK -78.5 million). The decreased loss mainly reflects the implemented cost-cutting initiatives with focus to complete the NDA.

Net Profit/Loss for the period

The Group's net loss in H1 amounted to SEK -30.0 million (SEK -77.5 million). In the period, net financial loss of SEK -1.9 million was recognized, which mainly reflects interest expenses related to loans. The net loss corresponds to a loss per share, before and after dilution, of SEK -0.89 (SEK -2.30).

CASH FLOW

Cash flow from operating activities before changes in working capital in H1 amounted to SEK -26.0 million (SEK -76.2 million). The decreased outflow reflects the lower level of activities due to the implemented cost-cutting initiatives in 2023. Changes in working capital in the period totalled an outflow of SEK -1.0 million (outflow of SEK -3.6 million). The outflow in primarily reflects the increase in current receivables. Cash flow from investing acti-

vities in H1 amounted to SEK 0 (SEK 0). Cash flow from financing activities totalled an inflow of SEK 34.0 million (outflow of SEK -0.5 million), which reflects loans received in H1 2024.

FINANCIAL POSITION

On the closing date, equity amounted to SEK 47.7 million, compared with SEK 74.3 million per 31 December 2023 and SEK 105.7 million per 30 June 2023. The decrease since 31 December 2023 and 30 June 2023 reflects the net loss incurred. Liquid assets on the closing date amounted to SEK 29.8 million, compared to SEK 21.9 million per 31 December 2023 and 70.5 million per 30 June 2023. The increase in liquid assets reflects the loans received.

The financing announced on 4 February 2024 consists of loan and convertible financing of SEK 35 million, of which the last SEK 15 million under the loan facility was drawn down on 18 April 2024.

On 10 July 2024, after the closing of the quarter the Company announced a rights issue of units, consisting of ordinary shares and warrants, of approximately SEK 105 million before costs, secured to SEK 70 million by subscription undertakings and guarantee commitments. The Rights Issue is carried out to secure the resources required to finalize the Orvigance® NDA and to secure partnerships for the market launch of Orvigance®. Proceeds will also be used to repay part of the outstanding convertibles issued in February 2024 and to strengthen the working capital position and finance other administrative activities. The financing provides a cash runway past the NDA filing mid 2025.

Financials key ratios for the Group

	H1 (January-June)	
	2024	2023
Operating result (SEK 000')	-28,047	-78,498
Net result (SEK 000')	-29,965	-77,469
Earnings per share (SEK)	-0.89	-2.30
Weighted avg. number of shares	33,757,746	33,706,502
R&D costs/operating costs (%)	64%	77%
Cash flow used in operating activities (SEK 000')	-27,017	-79,834
Equity (SEK 000')	47,687	105,675
Liquid assets incl. marketable securities (SEK 000')	29,775	70,500

OTHER INFORMATION

Incentive programs

Ascelia Pharma has one outstanding employee option program as well as three share saving programs. If the terms of the option program are met at the time for utilization, the employees has the right to purchase shares at a pre-determined price. For the share-saving program, employees are entitled to receive matching and performance shares according to the terms of the program.

The Group recognizes share-based remuneration, which personnel may receive. A personnel cost is recognized, together with a corresponding increase in equity, distributed over the vesting period. Social security costs are revalued at fair value. Further information about the incentive programs can be found in the Annual Report 2023 on pages 67-69.

In case all outstanding incentive programs per 30 June 2024 are exercised in full, a total of 3.2 million common shares will be issued (including hedge for future payment of social security charges). This corresponds to an aggregate maximum dilution of approximately 8.6 percent of Ascelia Pharma's share capital after full dilution (calculated on the number of common shares that will be added upon full exercise of all incentive programs).

Information about risks and uncertainties for the Group and the parent company

Ascelia Pharma continuously needs to secure financing to ensure continued development. This results in uncertainties regarding ongoing and future operations due to market challenges and financing needs. To strengthen the balance sheet and ensure continued operations, the Company has in July 2024 announced a new share issue. If the new issue is not completed as planned, it could negatively impact the Company's liquidity and ongoing operations. The Board is actively working to minimize these risks and ensure the success of the new share issue, and has successfully secured guarantees for a significant portion of the issue.

From an operational perspective, the Company is exposed to a number of risks and uncertainties which impact, or could impact, its business, operations, financial position, and result. The risks and uncertainties considered to have the highest impact on results are within clinical drug development, regulatory conditions, commercialization and licensing, intellectual property rights and other forms of protection, financing conditions, macroeconomic conditions including impact from pandemics, geopolitical effects, inflation and foreign exchange exposure.

The Group's overall strategy for risk management is to limit undesirable impact on its result and financial position, to the extent it is possible. The Group's risks and uncertainties are described in more detail in the Annual Report 2023 on pages 35-37.

Significant events after the end of the reporting period

On 10 July 2024, Ascelia Pharma announced the carrying out of a rights issue of units of approximately SEK 105 million, which was subsequently approved at the Extraordinary General Meeting on 14 August 2024. The financing is secured to SEK 70 million by subscription undertakings and guarantee commitments.

Auditor's review

This interim report has been reviewed by the company's auditor.

This interim report has been prepared in both Swedish and English versions. In the event of any differences between the translations and the Swedish original, the Swedish version shall prevail.

The Board and the CEO declare that this Interim report provides a true and fair overview of the company and the Group's operations, positions and earnings and describes the material risks and uncertainty factors faced by the Parent company and the companies within the Group.

Malmö, 14 August 2024
Ascelia Pharma AB (publ)

Peter Benson
Chairman

Lauren Barnes
Member of the board

Hans Maier
Member of the board

Niels Mengel
Member of the board

Helena Wennerström
Member of the board

Magnus Corfitzen
CEO

AUDITOR'S REPORT

Ascelia Pharma AB (publ), corporate identity number 556571-8797. To the Board of Directors of Ascelia Pharma AB (publ).

Introduction

We have reviewed the condensed interim financial information (interim report) of Ascelia Pharma AB (publ) as of 30 June 2024 and the six-month period then ended. The board of directors and the CEO are responsible for the preparation and presentation of the interim financial information in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of Review

We conducted our review in accordance with the International Standard on Review Engagements ISRE 2410, Review of Interim Report Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing, ISA, and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act, regarding the Group, and with the Swedish Annual Accounts Act, regarding the Parent Company.

Malmö, 14 August 2024
Öhrlings PricewaterhouseCoopers AB

Mikael Nilsson

Authorized Public Accountant

Consolidated Income Statement

SEK in thousands (unless otherwise stated)*	Q2 (Apr-Jun)		H1 (Jan-Jun)	
	2024	2023	2024	2023
Net sales	-	-	-	-
Gross profit/loss	-	-	-	-
Administrative costs	-4,536	-5,088	-10,763	-9,373
Research and development costs	-7,487	-31,212	-18,297	-60,831
Commercial preparation costs	714	-5,857	700	-8,753
Other operating income	10	425	370	736
Other operating costs	-30	-60	-57	-277
Operating result	-11,328	-41,791	-28,047	-78,498
Finance income	330	1,773	993	2,080
Finance costs	-2,275	-357	-2,941	-1,225
Net financial items	-1,945	1,415	-1,948	855
Loss before tax	-13,273	-40,376	-29,994	-77,643
Tax	2	125	29	174
Loss for the period	-13,271	-40,251	-29,965	-77,469
Attributable to:				
Owners of the Parent Company	-13,271	-40,251	-29,965	-77,469
Non-controlling interest	-	-	-	-
Earnings per share				
Before and after dilution (SEK)	-0.39	-1.19	-0.89	-2.30

Consolidated Statement of Comprehensive Income

SEK in thousands (unless otherwise stated)*	Q2 (Apr-Jun)		H1 (Jan-Jun)	
	2024	2023	2024	2023
Profit/loss for the period	-13,271	-40,251	-29,965	-77,469
Other comprehensive income				
Currency translation of subsidiaries**	10	262	-52	-391
Other comprehensive income for the period	10	262	-52	-391
Total comprehensive income for the period	-13,261	-39,989	-30,017	-77,860

* Some figures are rounded, so amounts might not always appear to match when added up.

** Will be classified to profit and loss when specific conditions are met

Consolidated Balance Sheet

	30 Jun	30 Jun	31 Dec
SEK in thousands*	2024	2023	2023
ASSETS			
Non-current assets			
Intangible assets	57,077	57,082	57,074
Tangible assets - Equipment	52	126	89
Right-of-use assets	541	1,512	973
Total non-current assets	57,670	58,721	58,135
Current assets			
Advance payments to suppliers	3,551	3,455	3,433
Current receivables			
Income tax receivables	1,517	3,523	1,981
Other receivables	578	2,030	480
Prepaid expenses and accrued income	1,866	1,067	1,188
Cash and bank balances	29,775	70,500	21,855
Total current assets	37,287	80,575	28,937
Total assets	94,957	139,296	87,072
EQUITY			
Share capital	34,871	34,871	34,871
Other paid-in capital	678,747	678,747	678,747
Reserve of exchange differences on translation	619	327	671
Loss brought forward (incl. net profit/loss for the period)	-666,550	-608,270	-639,962
Equity attributable to Parent Company shareholders	47,687	105,675	74,328
Total equity	47,687	105,675	74,328
LIABILITIES			
Long-term liabilities			
Long-term interest bearing liabilities	33,443	-	-
Lease liabilities	22	610	176
Total long-term liabilities	33,465	610	176
Current liabilities			
Accounts payable	2,668	6,497	1,525
Tax payable	1	-	-
Other liabilities	907	2,108	1,640
Current lease liabilities	604	961	884
Accrued expenses and deferred income	9,624	23,446	8,519
Total current liabilities	13,804	33,011	12,568
Total liabilities	47,269	33,621	12,744
Total equity and liabilities	94,957	139,296	87,072

* Some figures are rounded, so amounts might not always appear to match when added up.

Consolidated Statements of Changes in Equity

SEK in thousands*	H1 (Jan-Jun)		FY (Jan-Dec)
	2024	2023	2023
Equity at start of the period	74,328	180,859	180,859
Comprehensive income			
Profit/loss for the period	-29,965	-77,469	-109,288
Other comprehensive income	-52	327	-301
Total comprehensive income	-30,017	-77,142	-109,589
Transactions with shareholders			
New issue of C-shares	-	-	-
Repurchase of own shares C-shares	-	-	-
New issue of common shares	-	-	-
Common shares: Conversion from C-shares	-	-55	-89
C-shares: Resolution of C-shares	-	55	89
Issuance expenses	-429	-15	-30
Call option premium in relation to loan facility	1,433	-	-
Share based remuneration to employees	2,373	1,974	3,088
Total transactions with shareholders	3,377	1,959	3,058
Equity at end of the period	47,687	105,675	74,328

* Some figures are rounded, so amounts might not always appear to match when added up.

Consolidated Cash Flow Statement

SEK in thousands*	Q2 (Apr-Jun)		H1 (Jan-Jun)	
	2024	2023	2024	2023
Operating activities				
Operating result	-11,328	-41,791	-28,047	-78,498
Expensed share based remuneration	-1,547	1,050	3,477	2,022
Adjustment for items not included in cash flow	232	116	469	410
Interest received	21	327	35	361
Interest paid	-1,825	-30	-2,432	-66
Income tax paid/received	-148	-231	500	-439
Cash flow from operating activities before changes in working capital	-14,594	-40,559	-25,997	-76,209
Cash flow from changes in working capital				
Increase (-)/Decrease (+) of advance payments	-297	3	-119	1,903
Increase (-)/Decrease (+) of operating receivables	378	51	-1,310	-298
Increase (+)/Decrease (-) of accounts payable	1,575	-1,604	1,142	-9,381
Increase (+)/Decrease (-) of other liabilities	972	-193	-734	4,152
Change in working capital	2,628	-1,744	-1,020	-3,624
Cash flow used in operating activities	-11,966	-42,303	-27,017	-79,834
Investing activities				
Investment in equipment	-	-	-	-
Divestment of right-of-use assets	-	-	-	-
Cash flow from investing activities	-	-	-	-
Financing activities				
Transaction costs for issuance	-172	-15	-429	-15
Conversion from C-shares	-	-	-	-55
Resolution of C-shares	-	-	-	55
Convertible bond issue	-	-	1,433	-
New loans	15,485	-	33,443	-
Amortisation of loan (leasing)	-219	-238	-433	-466
Cash flow from financing activities	15,094	-253	34,014	-481
Cash flow for the period	3,128	-42,556	6,997	-80,315
Cash flow for the period	3,128	-42,556	6,997	-80,315
Cash and cash equivalents at start of period	26,542	111,371	21,855	149,555
Exchange rate differences in cash and cash equivalents	104	1,685	923	1,260
Cash and cash equivalents at end of period	29,775	70,500	29,775	70,500

* Some figures are rounded, so amounts might not always appear to match when added up.

Parent Company – Income Statement

SEK in thousands*	Q2 (Apr-Jun)		H1 (Jan-Jun)	
	2024	2023	2024	2023
Net sales	44	31	138	219
Gross profit/loss	44	31	138	219
Administrative costs	-4,496	-4,958	-10,661	-9,163
Research and development costs	-7,488	-30,882	-18,213	-60,353
Commercial preparation costs	714	-5,858	700	-8,760
Other operating income	3	449	3	463
Other operating costs	-1	-57	-29	-71
Operating result	-11,224	-41,275	-28,061	-77,666
Finance income	327	1,636	870	1,775
Finance costs	-2,256	-175	-2,898	-746
Result from other long-term receivables	1,050	60	1,797	785
Net financial costs	-879	1,520	-230	1,814
Loss before tax	-12,103	-39,755	-28,292	-75,851
Group contribution	-	-	-	-
Tax	-	-	-	-
Loss for the period	-12,103	-39,755	-28,292	-75,851

Parent Company – Statement of Comprehensive Income

SEK in thousands*	Q2 (Apr-Jun)		H1 (Jan-Jun)	
	2024	2023	2024	2023
Loss for the period	-12,103	-39,755	-28,292	-75,851
Other comprehensive income	-	-	-	-
Other comprehensive income for the period	-	-	-	-
Total comprehensive income for the period	-12,103	-39,755	-28,292	-75,851

* Some figures are rounded, so amounts might not always appear to match when added up.

Parent Company – Balance Sheet

	30 Jun	30 Jun	31 Dec
SEK in thousands*	2024	2023	2023
ASSETS			
Non-current assets			
Tangible assets			
Equipment	52	126	89
Financial assets			
Shares in affiliated companies	58,068	58,068	58,068
Other long-term receivables from group companies	37,303	36,052	35,874
Total non-current assets	95,423	94,247	94,032
Current assets			
Advance payments to suppliers	3,551	3,455	3,433
Current receivables			
Receivables from group companies	2,234	13,081	15,114
Income tax receivables	1,164	1,192	1,668
Other receivables	546	1,961	453
Prepaid expenses and accrued income	1,844	946	1,129
Cash and bank balances	29,303	58,205	8,199
Total current assets	38,642	78,840	29,996
Total assets	134,065	173,087	124,027
EQUITY			
Restricted equity			
Share capital	34,871	34,871	34,871
Non-restricted equity			
Other paid-in capital	678,747	678,747	678,747
Loss brought forward	-597,764	-496,678	-495,578
Loss for the period	-28,292	-75,851	-105,563
Total equity	87,563	141,089	112,477
LIABILITIES			
Long-term liabilities			
Long-term interest bearing liabilities	33,443	-	-
Total long-term liabilities	33,443	-	-
Current liabilities			
Accounts payable	2,609	6,537	1,489
Other liabilities	907	2,108	1,640
Accrued expenses and deferred income	9,544	23,353	8,422
Total current liabilities	13,060	31,998	11,551
Total equity and liabilities	134,065	173,087	124,027

* Some figures are rounded, so amounts might not always appear to match when added up.

Notes

General information

This interim report for the Group has been prepared according to IAS 34 Interim Financial Reporting and applicable rules in the Swedish Annual Accounts Act (ÅRL). The interim report for the parent company has been prepared according to the Swedish Annual Accounts Act chapter 9, Interim Reporting. The fair value of the debt component of a convertible bond is calculated using a discount rate which is based on the market rate for a debt with the same terms without the conversion right to shares. The amount is reported as debt at amortized cost until the debt is converted or matures. The conversion right is initially reported as the difference between the fair value of the entire compound financial instrument and the fair value of the debt component. The value of the conversion right is reported in equity. For the Group and the parent company, the same accounting principles and basis for calculations have been applied as in the recent Annual Report.

Fair value of financial instruments

The recognized value for other receivables, cash and cash equivalents, trade payables and other liabilities constitutes a reasonable approximation of fair value. Interest bearing liabilities are recognized at amortized cost which is considered an approximation of the fair value.

Purchases from related parties

No significant transactions with related parties have occurred during the period.

Use of non-international financial reporting standards (IFRS) performance measures

Reference is made in this interim report to alternative performance measures that are not defined according to IFRS. Ascelia Pharma considers these performance measures to be an important complement since they enable a better evaluation of the

company's economic trends. The company believes that these alternative performance measures give a better understanding of the company's financial development and that such key performance measures contain additional information to the investors to those performance measures already defined by IFRS. Furthermore, the key performance measures are widely used by the management in order to assess the financial development of the company. These financial key performance measures should not be viewed in isolation or be considered to substitute the key performance measures prepared by IFRS.

Furthermore, such key performance measures should not be compared to other key performance measures with similar names used by other companies. This is due to the fact that the above-mentioned key performance measures are not always defined identically by other companies. These alternative performance measures are described below.

Important estimations and judgements

Valuation of intangible assets

The recognized research and development project in progress is subject for management's impairment test. The most critical assumption, subject to evaluation by management, is whether the recognized intangible asset will generate future economic benefits that at a minimum correspond to the intangible asset's carrying amount. Management's assessment is that the expected future cash flows will be sufficient to cover the intangible asset's carrying amount and accordingly no impairment loss has been recognized.

Capitalization of development expenses

In H1 2024, the criteria for classifying R&D costs as an asset according to IAS 38 has not been met (capitalization of development expenses is normally done in connection with final regulatory approval). Hence, all R&D costs related to the development of the product candidates have been expensed.

Share-based incentive programs

Employee option programs

Ascelia Pharma has in total implemented three employee option programs with individual terms and conditions of which one program is active. The parameter, which have the largest impact on the value of the options, is the publicly traded share price.

In January 2023, the second option program was expired and the options were not exercised. In November 2023 a new option program was implemented.

The total recognized costs for the option programs including social security charges in H1 2024 were SEK 2.4 million.

Share saving programs

Ascelia Pharma has implemented five long-term incentive programs for employees in the form of performance-based share saving programs of which three are active. The parameter, which have the largest impact on the value of the programs, is the publicly traded share price.

The total recognized costs for the share saving programs including social security charges in H1 2024 were SEK 1.0 million.

Notes

Definitions of alternative performance measures

Alternative performance measures

Operating results (TSEK)

Definition

Profit before financial items and tax.

Aim

The performance measure shows the company's operational performance.

Research and development costs/Operating costs (%)

The research and development expenses in relation to total operating costs (consisting of the sum of administrative expenses, R&D, costs for commercial preparations and other operating expenses).

The performance measure is useful in order to understand how much of the operating costs that are related to research- and development expenses.

Reconciliation table for alternative performance measures for the Group

SEK in thousands*	Q2 (Apr-Jun)		H1 (Jan-Jun)	
	2024	2023	2024	2023
R&D costs	-7,487	-31,212	-18,297	-60,831
Administration costs	-4,536	-5,088	-10,763	-9,373
Commercial preparation costs	714	-5,857	700	-8,753
Other operating costs	-30	-60	-57	-277
Total operating costs	-11,339	-42,217	-28,417	-79,234
R&D costs/Operating costs (%)	66%	74%	64%	77%

Financial calendar

Interim report 9M 2024 (Jan-Sep):
Full-year report 2024 (Jan-Dec):

7 November 2024
7 February 2025

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