ASCELIA PHARMA

Advancing
Orphan Oncology

HALF-YEAR REPORT 2023

January – June 2023

Re-evaluation required after intra-reader inconsistency in scoring of images from phase 3 study SPARKLE

SIGNIFICANT EVENTS IN Q2 2023

- Hepatic impairment study accepted for presentation at major radiology and liver conferences
- Ascelia Pharma presented Orviglance hepatic impairment data and hosted a Q&A with liver imaging experts at the 2023 ESGAR annual meeting

SIGNIFICANT EVENTS AFTER THE PERIOD

- Re-evaluation required after intra-reader inconsistency in scoring of images from phase 3 study SPARKLE
- Clarification that the images were not read and scored properly

Our confidence in positive Phase 3 result and belief in the potential of Orviglance are unchanged, but the timeline is changed

KEY RATIOS GROUP

	Q2 (Apr-Jun)		H1 (Jan-Jun)	
	2023	2022	**2023**	2022
OPERATING RESULT (SEKm)				
	-41.8	-32.7	**-78,5**	-65.2
EARNINGS PER SHARE (SEK)				
	-1.19	-0.68	**-2.30**	-1.54
CASH FLOW FROM OPERATIONS (SEKm)				
	-42.3	-32.7	**-79.8**	-60.1
LIQUID ASSETS INCL. MARKETABLE SECURITIES (SEKm)				
	70.5	208.9	**70.5**	208.9

CEO STATEMENT

This year, our focus has been on completing SPARKLE, the pivotal Phase 3 study for our first-in class magnetic resonance imaging (MRI) contrast agent Orviglance®. We successfully completed patient enrollment in March. In early August, we found that a high "intra-reader variability" in the image scoring by independent radiologists prevented us from evaluating the efficacy data to generate results from the SPARKLE study. As per FDA guidance, intra-reader variability is determined by the variance in ratings of a pre-defined number of patient images evaluated twice by the same reader at different time points. Due to this finding, we will unfortunately have to conduct a new evaluation of the images with independent readers before we can generate results from SPARKLE study. Although the planned re-evaluation does not require new or additional patient recruitment or clinical data, this is a regrettable setback for our timelines. Preparations for the re-evaluation are already underway, and we will communicate the timeline and financial implications for this mid-September. Most importantly, our confidence in the potential for Orviglance is unchanged and we are dedicated to making the product available for the patients in need of a gadolinium free liver imaging agent.

Reaching results for Phase 3 SPARKLE study. We completed the global multi-center SPARKLE study in early March 2023 with MRI data from 85 patients. Since then, the MRI images were evaluated by three independent radiologists, in accordance with regulatory guidance. During the data generation process, we identified a high level of inconsistency in the image scoring by some individual readers, commonly known as high "intra-reader variability". This occurs when a reader reports significantly different scores for the same image when seen at a different time point. The intra-reader variability analysis was specified in the clinical trial protocol and adheres to FDA guidance to industry. The finding means that data from SPARKLE cannot be reported based on this reading. The patient recruitment and collection and transfer of MR images to the central database is still validated, and therefore, we do not see a need to perform a new clinical study.

Our confidence in positive Phase 3 data and belief in the potential of Orviglance are unchanged and we are fully committed and focused on successfully completing the clinical development and pursuing regulatory submissions and approvals for Orviglance.

All efforts and resources of Ascelia Pharma will now be focused on planning and executing a new analysis of the images from SPARKLE. This includes a dialogue with the US Food and Drug Administration (FDA). As a consequence, activities not related to the new analysis will be postponed, and cost-saving initiatives will be taken. In mid-September, we will communicate a timeline and financial implications in order to complete the new analysis.

Completing clinical development and bringing Orviglance to market. In March, we hosted one of our virtual investor updates, where we presented more details about the SPARKLE study, as well as the launch strategy for Orviglance.

Orviglance addresses a well-defined unmet medical need. Our in-depth market research and launch preparations point to an attractive commercial potential as we see an annual global addressable market of USD 800 million with 100,000 pro-

”The unexpected and unfortunate outcome of the readout of the SPARKLE study does not change our confidence in Orviglance, nor the significant global medical need for a safe contrast agent for patients with impaired kidney function.”

cedures in the target patient population in the US alone. We continue our activities towards obtaining regulatory approval of Orviglance and making it available for cancer patients in need of liver imaging with kidney disease for whom the use of gadolinium-based products may be medically inadvisable. This is a key part of our mission, by offering better treatment options, to improve the life of people living with rare cancer conditions.

Interest for Orviglance in the medical community. In the second quarter, we continued to see strong interest for Orviglance within the scientific and medical community. In June, data from our Hepatic Impairment Study were presented at two key radiology and liver conferences – the European Society of Gastrointestinal and Abdominal Radiology (ESGAR) Annual Meeting and the European Association for the Study of the Liver (EASL) Congress.

At ESGAR, we also hosted a Q&A session with two experts in liver imaging, Dr. Nikolaos Kartalis of Department of Radiology Huddinge, Karolinska University Hospital, and Dr. Alessandro Furlan of Radiology, Abdominal Imaging Division of University of Pittsburg Medical Center. We were pleased to chair this debate with two of the leading experts on liver imaging, and to hear their perspective of the target patient population and their unmet needs.

Financial position. Our development requires access to liquidity. We have a solid balance sheet and ended the second quarter with SEK 70.5 million in cash and cash equivalents. The cash and cash equivalents will primarily be used on planning and executing a re-evaluation of the images from SPARKLE. This includes a dialogue with the FDA. As a consequence, activities not related to the re-evaluation will be postponed and cost-saving initiatives will be taken.

This means we are prioritizing the re-evaluation activities and will implement cost reductions in other areas in the company which will affect progress there. Our ambition is that our available capital is sufficient to complete the re-evaluation. In mid-September we will communicate the timeline for the re-evaluation activity and the financial runway. Following the re-evaluation process, additional capital must be secured to continue operations and value creation.

Unchanged opportunities. The unexpected and unfortunate outcome preventing us from obtaining a readout of the efficacy data from the SPARKLE does not change our confidence in Orviglance, nor does it change the global medical need a liver imaging contrast agent without gadolinium. It does, however, change our timelines and time to market of Orviglance. As such, I will look forward to updating you on our plans going forward and to continue our efforts to allow Orviglance to reach patients in need.

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.

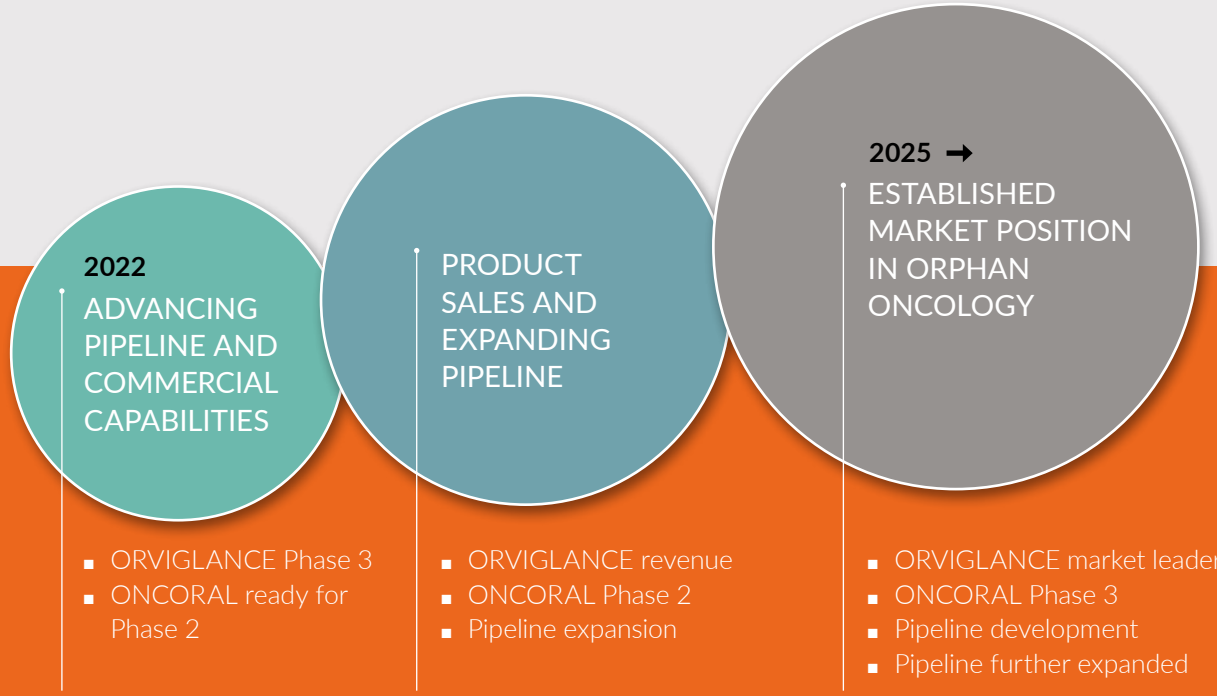
OUR VISION

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 the company and building value



OUR PIPELINE

ORVIGLANCE

Diagnostic drug for liver magnetic resonance imaging (MRI) in ongoing Phase 3

Orviglance is our novel non-gadolinium diagnostic drug (contrast agent) to be used in MRI-scans of the liver. Orviglance is developed to improve the visualization of focal liver lesions (liver metastases and primary liver cancer) in patients with impaired kidneys at risk of severe side-effects from the gadolinium contrast agents currently on the market. Orviglance characteristics:

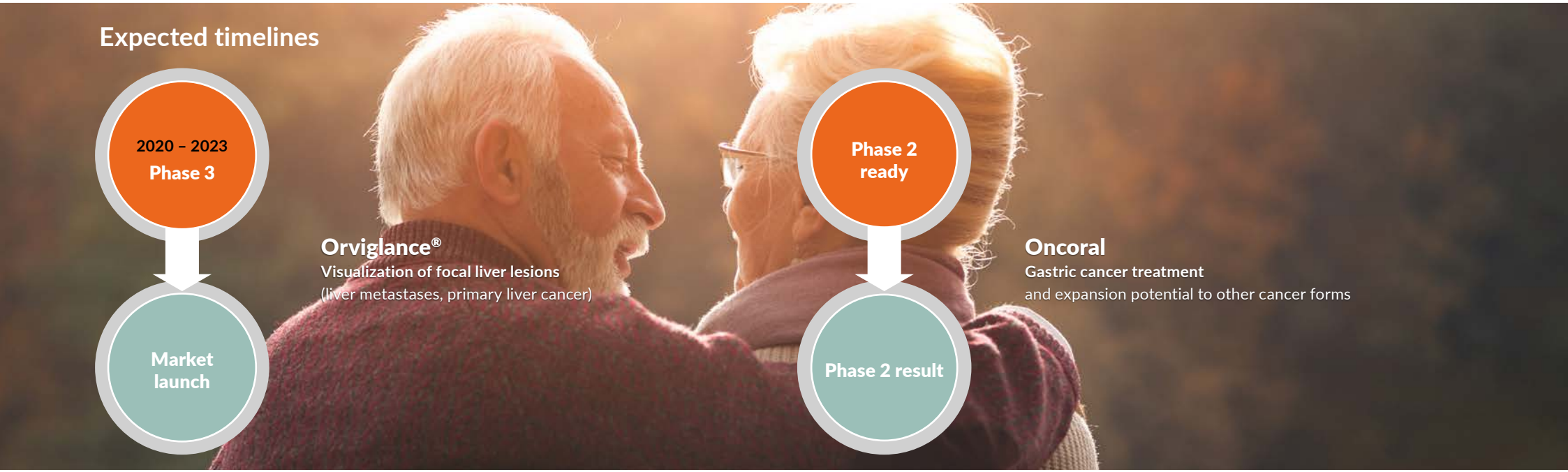
- Manganese-based diagnostic drug with Orphan Drug Designation (FDA)
- The only late-stage gadolinium-free agent
- $800 million annual global addressable market of which $500-600 million is related in US, Europe & Japan

ONCORAL

Tablet chemotherapy ready for Phase 2

Oncoral is our novel oral irinotecan chemotherapy tablet developed initially for the treatment of gastric cancer. Irinotecan has an established potent anti-tumor effect. Oncoral characteristics:

- 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 cancer forms



ORVIGLANCE

Liver MRI contrast agent in the final clinical Phase

Detecting liver metastases early is essential for survival

Ascelia Pharma's lead drug candidate, Orviglance, is a contrast agent used in Magnetic Resonance Imaging (MRI) 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.

How Orviglance works

Orviglance is an orally administrated 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. With Orviglance, liver metastases are consequently easier to identify due to this contrast effect.

Latest development

The phase 3 study, SPARKLE has completed enrollment with 85 patients. The evaluation of the primary endpoint was independently carried out by three blinded radiologists (readers), who assessed both changes of visualization of liver lesions with and without Orviglance (the primary endpoint), as well as other secondary efficacy endpoints.

During the evaluation of the reading result a very high, and unexpected, intra-reader (within reader) variability in the assessment of the primary efficacy variables were detected for some of the readers, making the readout-data unreliable. All images will be re-evaluated before a reliable conclusion of the efficacy of Orviglance can be made. Common adverse events in the SPARKLE study were in line with previous studies with Orviglance, such as mild to moderate nausea. No drug related serious adverse reactions were reported.

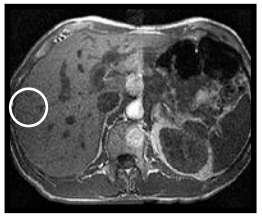
Patients referred for liver MRI scan

TODAY

NORMAL KIDNEY
Gadolinium imaging drug

POOR KIDNEY FUNCTION
All gadolinium contrast agents have regulatory Black Box warnings

MRI scan without contrast agent:
No liver metastasis visible

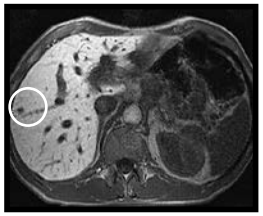


TOMORROW

NORMAL KIDNEY
Gadolinium imaging drug

POOR KIDNEY FUNCTION
ORVIGLANCE imaging drug

MRI scan with Orviglance:
Liver metastasis becomes visible



Orviglance aims to be the standard liver MRI contrast agent in patients with severely impaired kidney function

Annual global addressable market of $800 million

The target group for Orviglance is patients with 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 all are based on the heavy-metal gadolinium, carry Black Box warnings for patients with severely reduced kidney function.

The clinical trials completed to date show that Orviglance has a potential to 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.

Orviglance has 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.

PHASE 3 STUDY (SPARKLE)

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 primary objective is to demonstrate an improved visualization of liver lesions compared to MRI without contrast, unenhanced MRI.

The primary endpoint of the SPARKLE study is similar to what was studied in the phase 1 and 2 studies. The strong results in the Phase 1 and Phase 2 studies, both in terms of safety and efficacy, provide a solid foundation for the ongoing Phase 3 program.

Orviglance clinical Phase 3 study

NUMBER OF PATIENTS	**Global study with 85 patients**
PRIMARY ENDPOINT	**Lesion visualization** ■ Lesions border delineation (border sharpness of lesions) ■ Conspicuity (lesion contrast compared to liver background)
COMPARATOR	**Unenhanced MRI + Orviglance MRI vs. Unenhanced MRI**
EVALUATION	**Centralised evaluation by 3 radiologists**
RANDOMIZATION	**None – each patient is his/her own control**
FOLLOW-UP	**Less than a week**

Strong support to Phase 3 endpoints from completed studies

The completed Phase 1 and Phase 2 studies have shown strong efficacy results regarding the endpoints that will be evaluated in the Phase 3 study. The completed studies, involving 178 persons in total[1], have showed a highly significant improvement compared to unenhanced MRI in:

- Delineation: p-value <0.0001
- Conspicuity: p-value <0.0001

Results from both variables show that Orviglance significantly improves MRI performance.

[1] The above mentioned results stem from of a blinded-read study, which comprised all imaging data from six phase 1 and 2 studies completed before start of the phase 3 program. The blinded-read results have been presented at major radiology conferences

GLOBAL ANNUAL ADDRESSABLE MARKET OF $800 MILLION ($500-600 MILLION US, EU & JAPAN)

$800 M global annual addressable market

Market estimate 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]

Go-to-market model

US	Ascelia Pharma led commercialization	
Rest of World	Ascelia Pharma strategy with global synergies	Partner led commercial operations

Strong footprint in the US

1. **SPARKLE Phase 3 Study** at leading US sites
2. **Hepatic Impairment Study** at Texas liver institute
3. **Ascelia Pharma Inc.** Office in New Jersey
4. **Manufacturing** at Cambrex (partner), NJ
5. **Imaging experts** RadMD, NY

Building an Ascelia Pharma US team

US team	**Around 40 FTEs at launch**
Clinics/ Hospitals	**Around 400 clinics and hospitals serve 75 percent of the target patient population[1]**

Sources:
1: Ascelia Pharma market research with Decision Resources Group, 2020
2: Ascelia Pharma market research and analyses with Revenue Reimbursement Solutions and Charles River Associates, 2020

ONCORAL CHEMOTHERAPY AS TABLET

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.

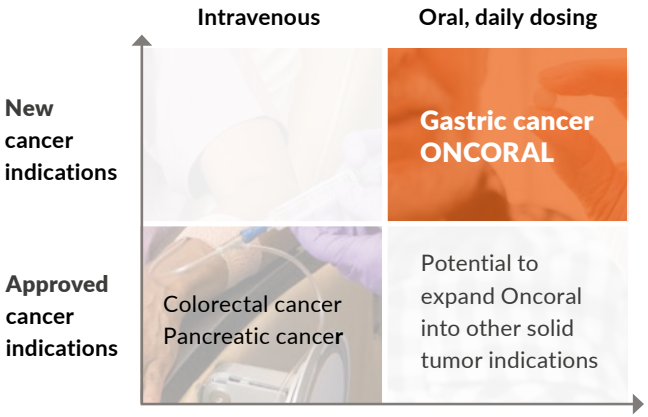
Anti-cancer effect is proven. The active pharmaceutical ingredient (API) in Oncoral is irinotecan, which has an established and proven effect in killing cancer cells. Irinotecan is a so-called anti-neoplastic agent that after metabolic activation inhibits the enzyme topoisomerase 1, thereby inducing 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 ofirinotecan. 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, iriontecan 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.

Latest development. A new patent covering the tablet composition of Oncoral, providing protection until 2035 plus potential extension in the US, received a positive Notice of Allowance from the United States Patent and Trademark Office (USPTO) in March 2023.

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	■ 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

Clinical collaboration with Taiho Oncology Inc.

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

TAIHO ONCOLOGY

LONSURF® is approved for treatment of metastatic gastric cancer and metastatic colorectal cancer

FINANCIAL OVERVIEW Q2 (APR-JUN 2023)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales in Q2 (Apr-Jun 2023) 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 425 thousand (SEK 260 thousand). The income refers to exchange rate gains.

Research and development costs (R&D)

R&D costs for the Group in Q2 were SEK 31.2 million (SEK 27.1 million). The cost increase of SEK 4.1 million reflects increased activity in the final stage of the phase 3 study.

Commercial preparation costs

During Q2, costs related to commercial preparations for Orviglance amounted to SEK 5.9 million (SEK 3.7 million). This reflects an increase in preparations for market launch.

Administration costs

Administration costs for the Group in Q2 amounted to SEK 5.1 million (SEK 2.0 million). The cost increase primarily reflects an increase in reported costs for incentive programs for employees.

Operating results (EBIT)

The operating result in Q2 amounted to SEK -41,8 million (SEK -32,7 million). The increased loss reflects the higher level of R&D and commercialization activities.

Net Profit/Loss for the period

The Group's net loss in Q2 amounted to SEK -40.3 million (SEK -22.8 million). In the current quarter, net financial income of SEK 1.4 million was recognized due to strengthening of USD against SEK, which translated into an increase in the value of bank deposits (a significant part of bank deposit is held in USD to match upcoming cash outflow in this currency). The net loss corresponds to a loss per share, before and after dilution, of SEK -1.19 (SEK -0.68).

CASH FLOW

Cash flow from operating activities before changes in working capital in Q2 amounted to SEK -40.6 million (SEK -33.9 million). The increased outflow reflects the higher level of R&D and commercial activities in current quarter. Changes in working capital in the current quarter totalled an outflow of SEK -1.7 million (inflow of SEK 1.2 million). The outflow in the current quarter reflects the decrease in accounts payable. Cash flow from investing activities in Q2 totalled to SEK 0 (SEK 0). Cash flow from financing activities amounted to an outflow of SEK -0.3 million (outflow of SEK -0.3 million), which mainly reflects amortization of lease liabilities.

FINANCIAL POSITION

On the closing date, equity amounted to SEK 105.7 million, compared with SEK 180.9 million per 31 December 2022 and SEK 257.3 million per 30 June 2022. The decrease since 31 December 2022 and 30 June 2022 reflects the net loss incurred. Liquid assets on the closing date amounted to SEK 70.5 million, compared to SEK 149.6 million per 31 December 2022 and 208.9 million per 30 June 2022. The decrease in liquid assets reflects the net loss incurred.

Financials key ratios for the Group	Q2 (April-June)	
	2023	2022
Operating result (SEK 000')	-41,791	-32,651
Net result (SEK 000')	-40,251	-22,807
Earnings per share (SEK)	-1.19	-0.68
Weighted avg. number of shares	33,722,762	33,668,262
R&D costs/operating costs (%)	74%	82%
Cash flow used in operating activities (SEK 000')	-42,303	-32,691
Equity (SEK 000')	105,675	257,315
Liquid assets incl. marketable securities (SEK 000')	70,500	208,861

FINANCIAL OVERVIEW: H1-2023 (JAN–JUN 2023)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales in H1 (Jan-Jun 2023) 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 736 thousand (SEK 395 thousand). The income refers to exchange rate gains.

Research and development costs (R&D)

R&D costs for the Group in H1 were SEK 60.8 million (SEK 51.4 million). The cost increase of SEK 9.4 million primarily reflects higher level of R&D activities.

Commercial preparation costs

During H1, costs related to commercial preparations for Orviglance amounted to SEK 8.8 million (SEK 7.9 million). The cost increase compared with H1 2023 reflects a step-up in market launch preparations.

Administration costs

Administration costs for the Group in H1 amounted to SEK 9.4 million (SEK 6.1 million). The cost increase primarily reflects an increase in recognized costs for employee incentive programs.

Operating results (EBIT)

The operating result in H1 2023 amounted to SEK -78.5 million (SEK -65.2 million). The increased loss mainly reflects the increased level of R&D activities and increased commercialization preparations.

Net Profit/Loss for the period

The Group's net loss in H1 amounted to SEK -77.5 million (SEK -51.9 million). In the current period, net financial income of SEK 0.9 million was recognized due to strengthening of USD against SEK, which translated into an increase in the value of bank deposits (a significant part of bank deposit is held in USD to match upcoming cash outflow in these currencies). The net loss corresponds to a loss per share, before and after dilution, of SEK -2.30 (SEK -1.54).

Financials key ratios for the Group	H1 (January-June)	
	2023	2022
Operating result (SEK 000')	-78,498	-65,221
Net result (SEK 000')	-77,469	-51,882
Earnings per share (SEK)	-2.30	-1.54
Weighted avg. number of shares	33,706,502	33,668,262
R&D costs/operating costs (%)	77%	78%
Cash flow used in operating activities (SEK 000')	-79,834	-64,057
Equity (SEK 000')	105,675	257,315
Liquid assets incl. marketable securities (SEK 000')	70,500	208,861

CASH FLOW

Cash flow from operating activities before changes in working capital in H1 amounted to SEK -76.2 million (SEK -65.7 million). The increased outflow primarily reflects the higher level of R&D activities in the current period. Changes in working capital in the current period totalled an outflow of SEK -3.6 million (inflow of SEK 1.6 million). The outflow in the current period primarily reflects the decrease in accounts payable. Cash flow from investing activities in H1 totalled an outflow of SEK 0 (outflow of SEK -64 thousand). Cash flow from financing activities amounted to an outflow of SEK -0.5 million (outflow of SEK -0.6 million), which mainly reflects amortization of lease liabilities.

FINANCIAL POSITION

On the closing date, equity amounted to SEK 105.7 million, compared with SEK 180.9 million per 31 December 2022 and SEK 257.3 million per 30 June 2022. The decrease since 31 December 2022 and 30 June 2022 reflects the net loss incurred. Liquid assets on the closing date amounted to SEK 70.5 million, compared to SEK 149.6 million per 31 December 2022 and 208.9 million per 30 June 2022. The decrease in liquid assets reflects the net loss incurred.

OTHER INFORMATION

Incentive programs

In January 2023, the last option program was expired and the options were not exercised. Ascelia Pharma has outstanding share saving programs. The board of directors of Ascelia Pharma has during Q1 2023, in accordance with the provisions of LTI 2019, resolved to convert 54,500 series C shares for allotment of 54,500 ordinary shares to the participants in LTI 2019. For the share-saving program, employees are entitled to receive matching and performance shares according to 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 2022 on pages 70–72.

In case all outstanding incentive programs per 30 June 2023 are exercised in full, a total of 1.1 million common shares will be issued (including hedge for future payment of social security charges). This corresponds to an aggregate maximum dilution of approximately 3.4 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's activities and markets are exposed to a number of risks and uncertainties which impact, or could impact, the company's business, financial position and result. The risks and uncertainties, which Ascelia Pharma considers to have the largest impact on its results are 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.

Other information

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 2022 on pages 36–40.

Impact of the Ukraine crisis

Ascelia Pharma decided in March 2022 to suspend all clinical activities, including patient recruitment in Russia. Moving forward, we don't see any direct impact on the company.

Significant events after the end of the reporting period

Ascelia Pharma reported on August 8 2023, the need for a re-evaluation after intra-reader inconsistency in scoring of the collected images in the pivotal Phase 3 study SPARKLE with the liver imaging candidate drug Orviglance.

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, 17 August 2023
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 2023 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, 17 August 2023
Öhrlings PricewaterhouseCoopers AB

Carl Fogelberg
Authorized Public Accountant

Consolidated Income Statement

	Q2 (Apr-Jun)		H1 (Jan-Jun)	
*SEK in thousands (unless otherwise stated)**	**2023**	**2022**	**2023**	**2022**
Net sales	–	–	–	–
Gross profit/loss	**–**	**–**	–	–
Administrative costs	-5,088	-2,009	-9,373	-6,132
Research and development costs	-31,212	-27,093	-60,831	-51,446
Commercial preparation costs	-5,857	-3,687	-8,753	-7,916
Other operating income	425	260	736	395
Other operating costs	-60	-122	-277	-122
Operating result	**-41,791**	**-32,651**	**-78,498**	**-65,221**
Finance income	1,773	8,863	2,080	11,420
Finance costs	-357	-11	-1,225	-26
Net financial items	**1,415**	**8,852**	**855**	**11,394**
Loss before tax	**-40,376**	**-23,799**	**-77,643**	**-53,827**
Tax	125	992	174	1,945
Loss for the period	**-40,251**	**-22,807**	**-77,469**	**-51,882**
Attributable to:				
Owners of the Parent Company	-40,251	-22,807	-77,469	-51,882
Non-controlling interest	**–**	–	–	–
Earnings per share				
Before and after dilution (SEK)	-1.19	-0.68	-2.30	-1.54

Consolidated Statement of Comprehensive Income

	Q2 (Apr-Jun)		H1 (Jan-Jun)	
*SEK in thousands (unless otherwise stated)**	**2023**	**2022**	**2023**	**2022**
Profit/loss for the period	**-40,251**	**-22,807**	**-77,469**	**-51,882**
Other comprehensive income				
Currency translation of subsidiaries**	262	257	-391	425
Other comprehensive income for the period	**262**	**257**	**-391**	**425**
Total comprehensive income for the period	**-39,989**	**-22,550**	**-77,860**	**-51,457**

* 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

*SEK in thousands**	30 Jun 2023	30 Jun 2022	31 Dec 2022
ASSETS			
Non-current assets			
Intangible assets	57,082	57,069	57,074
Tangible assets - Equipment	126	201	163
Right-of-use assets	1,512	828	462
Total non-current assets	**58,721**	**58,098**	**57,700**
Current assets			
Advance payments to suppliers	3,455	5,686	5,359
Current receivables			
Income tax receivables	3,523	6,970	2,785
Other receivables	2,030	1,902	1,745
Prepaid expenses and accrued income	1,067	1,571	1,426
Cash and bank balances	70,500	208,861	149,555
Total current assets	**80,575**	**224,990**	**160,869**
Total assets	**139,296**	**283,088**	**218,569**
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	327	679	718
Loss brought forward (incl. net profit/loss for the period)	-608,270	-456,982	-533,478
Equity attributable to Parent Company shareholders	**105,675**	**257,315**	**180,859**
Total equity	**105,675**	**257,315**	**180,859**
LIABILITIES			
Long-term liabilities			
Leasing	610	204	193
Total long-term liabilities	**610**	**204**	**193**
Current liabilities			
Accounts payable	6,497	8,923	15,881
Tax payable	–	–	–
Other liabilities	2,108	1,403	1,688
Current lease liabilities	961	673	291
Accrued expenses and deferred income	23,446	14,570	19,657
Total current liabilities	**33,011**	**25,569**	**37,518**
Total liabilities	**33,621**	**25,773**	**37,711**
Total equity and liabilities	**139,296**	**283,088**	**218,569**

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

Consolidated Statements of Changes in Equity

	H1 (Jan-Jun)		FY (Jan-Dec)
*SEK in thousands**	2023	2022	2022
Equity at start of the period	**180,859**	**307,834**	**307,834**
Comprehensive income			
Profit/loss for the period	-77,469	-51,882	-131,223
Other comprehensive income	327	425	718
Total comprehensive income	**-77,142**	**-51,457**	**-130,505**
Transactions with shareholders			
New issue of C-shares	–	295	295
Repurchase of own shares C-shares	–	-295	-295
New issue of common shares	–	–	–
Common shares: Conversion from C-shares	-55	–	–
C-shares: Resolution of C-shares	55	–	–
Issuance expenses	-15	-84	-84
Redemption of warrants	–	–	–
Share based remuneration to employees	1,974	1,022	3,612
Total transactions with shareholders	**1,959**	**938**	**3,529**
Equity at end of the period	**105,675**	**257,315**	**180,859**

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

Consolidated Cash Flow Statement

	Q2 (Apr-Jun)		H1 (Jan-Jun)	
*SEK in thousands**	**2023**	**2022**	**2023**	**2022**
Operating activities				
Operating result	-41,791	-32,651	-78,498	-65,221
Expensed share based remuneration	1,050	-1,254	2,022	-620
Adjustment for items not included in cash flow	116	268	410	600
Interest received	327	–	361	–
Interest paid	-30	-11	-66	-26
Income tax paid/received	-231	-208	-439	-437
Cash flow from operating activities before changes in working capital	**-40,559**	**-33,856**	**-76,209**	**-65,704**
Cash flow from changes in working capital				
Increase (-)/Decrease (+) of advance payments	3	1,733	1,903	519
Increase (-)/Decrease (+) of operating receivables	51	-177	-298	-1,345
Increase (+)/Decrease (-) of accounts payable	-1,604	3,976	-9,381	2,718
Increase (+)/Decrease (-) of other liabilities	-193	-4,367	4,152	-245
Change in working capital	-1,744	1,165	-3,624	1,647
Cash flow used in operating activities	**-42,303**	**-32,691**	**-79,834**	**-64,057**
Investing activities				
Investment in equipment	–	–	–	–
Divestment of right-of-use assets	–	–	–	-64
Cash flow from investing activities	**–**	**–**	**–**	**-64**
Financing activities				
Issuance proceeds	–	–	–	–
Issuance costs	-15	-12	-15	-84
Conversion from C-shares	–	–	-55	–
Resolution of C-shares	–	–	55	–
Redemption of warrants net	–	–	–	–
Amortisation of loan (leasing)	-238	-256	-466	-527
Cash flow from financing activities	**-253**	**-268**	**-481**	**-611**
Cash flow for the period	**-42,556**	**-32,959**	**-80,315**	**-64,732**
Cash flow for the period	-42,556	-32,959	-80,315	-64,732
Cash and cash equivalents at start of period	111,371	232,603	149,555	261,599
Exchange rate differences in cash and cash equivalents	1,685	9,217	1,260	11,994
Cash and cash equivalents at end of period	**70,500**	**208,861**	**70,500**	**208,861**

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

Parent Company – Income Statement

	Q2 (Apr-Jun)		H1 (Jan-Jun)	
*SEK in thousands**	**2023**	**2022**	**2023**	**2022**
Net sales	31	318	219	990
Gross profit/loss	**31**	**318**	**219**	**990**
Administrative costs	-4,958	-1,930	-9,163	-6,024
Research and development costs	-30,882	-22,761	-60,353	-43,474
Commercial preparation costs	-5,858	-3,695	-8,760	-7,931
Other operating income	449	–	463	57
Other operating costs	-57	-122	-71	-122
Operating result	**-41,275**	**-28,190**	**-77,666**	**-56,504**
Finance income	1,636	8,319	1,775	10,759
Finance costs	-175	–	-746	–
Result from other long-term receivables	60	-243	785	458
Net financial costs	**1,520**	**8,076**	**1,814**	**11,217**
Loss before tax	-39,755	-20,114	-75,851	-45,287
Group contribution	–	–	–	–
Tax	–	–	–	–
Loss for the period	**-39,755**	**-20,114**	**-75,851**	**-45,287**

Parent Company – Statement of Comprehensive Income

	Q2 (Apr-Jun)		H1 (Jan-Jun)	
*SEK in thousands**	**2023**	**2022**	**2023**	**2022**
Loss for the period	**-39,755**	**-20,114**	**-75,851**	**-45,287**
Other comprehensive income	–	–	–	–
Other comprehensive income for the period	**–**	**–**	–	–
Total comprehensive income for the period	**-39,755**	**-20,114**	**-75,851**	**-45,287**

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

Parent Company – Balance Sheet

*SEK in thousands**	30 Jun 2023	30 Jun 2022	31 Dec 2022
ASSETS			
Non-current assets			
Tangible assets			
Equipment	126	201	163
Financial assets			
Shares in affiliated companies	58,068	58,068	58,068
Other long-term receivables from group companies	36,052	37,242	38,486
Total non-current assets	**94,247**	**95,511**	**96,717**
Current assets			
Advance payments to suppliers	3,455	5,190	5,359
Current receivables			
Receivables from group companies	13,081	7,930	8,395
Income tax receivables	1,192	1,168	756
Other receivables	1,961	1,704	1,627
Prepaid expenses and accrued income	946	1,451	1,349
Cash and bank balances	58,205	197,935	137,879
Total current assets	**78,840**	**215,378**	**155,365**
Total assets	**173,087**	**310,889**	**252,082**
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	-496,678	-379,857	-377,266
Loss for the period	-75,851	-45,287	-121,371
Total equity	**141,089**	**288,474**	**214,982**
LIABILITIES			
Current liabilities			
Accounts payable	6,537	6,467	16,022
Other liabilities	2,108	1,403	1,688
Accrued expenses and deferred income	23,353	14,545	19,390
Total current liabilities	**31,998**	**22,415**	**37,101**
Total equity and liabilities	**173,087**	**310,889**	**252,082**

* 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. 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.

Related parties Purchases from related parties

Oncoral Pharma ApS has an agreement with Solural Pharma ApS according to which, Solural Pharma ApS provides development and manufacturing of clinical study material. The owners of Solural Pharma ApS are the founders of Oncoral Pharma ApS and are, after the sale of Oncoral Pharma ApS to Ascelia Pharma AB in 2017, shareholders in Ascelia Pharma AB. Per 30 June 2023, the owners of Solural ApS collectively owned 1.55 percent of the shares in Ascelia Pharma AB. In addition to payment for services performed, Solural Pharma ApS has the right to receive a bonus of maximum SEK 10 million if commercialization occurs through a sale or a outlicensing and SEK 12 million if commercialization is carried out by Oncoral Pharma ApS or Ascelia Pharma AB itself.

Regardless the commercialization method, Oncoral Pharma ApS has the right to, at any time, finally settle Solural Pharma ApS right for remuneration by payment of SEK 10 million. In H1 2023, services for a value of around SEK 280 thousand were acquired from Solural Pharma ApS.

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 2023, 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 implemented two employee option programs with individual terms and conditions. The parameter, which have the largest impact on the value of the options, is the publicly traded share price.

In 2021, the first program reached its exercise period and all options related to this program, 481,573 in total, were exercised into common shares.

In January 2023, the last option program was expired and the options were not exercised.

Share saving programs

Ascelia Pharma has implemented four long-term incentive programs for employees in the form of performance-based share saving programs. 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 2023 were SEK 2.0 million.

Notes

Definitions of alternative performance measures

Alternative performance measures	Definition	Aim
Operating results (TSEK)	Profit before financial items and tax.	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

	Q2 (Apr-Jun)		H1 (Jan-Jun)	
*SEK in thousands**	**2023**	**2022**	**2023**	**2022**
R&D costs	-31,212	-27,093	-60,831	-51,446
Administration costs	-5,088	-2,009	-9,373	-6,132
Commercial preparation costs	-5,857	-3,687	-8,753	-7,916
Other operating costs	-60	-122	-277	-122
Total operating costs	**-42,217**	**-32,911**	**-79,234**	**-65,616**
R&D costs/Operating costs (%)	**74%**	**82%**	**77%**	**78%**

Financial calendar

Interim report 9M 2023 (Jan-Sep):	8 November 2023
Full-year report 2023 (Jan-Dec):	9 February 2024

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