ASCELIA PHARMA

Advancing Orphan Oncology

HALF-YEAR REPORT 2022

January – June 2022

Strong results from Orviglance Food Effect Study

SIGNIFICANT EVENTS IN Q2 2022

- Food Effect Study shows strong liver imaging enhancement with Orviglance both with light meal and fasting condition
- Orviglance comparison study to gadolinium presented at ESGAR conference
- US Patent and Trademark Office issued a notice of allowance for a second Oncoral patent application
- Déspina Georgiadou Hedin appointed as new CFO replacing Kristian Borbos

SIGNIFICANT EVENTS AFTER THE PERIOD

- Orviglance Food Effect Study accepted as an oral presentation at the world's largest radiology conference, RSNA

"In Q2, we presented results showing strong liver image enhancement with Orviglance both with light meal and fasting condition"

KEY RATIOS GROUP

	Q2 (Apr-Jun)		H1 (Jan-Jun)	
	2022	2021	**2022**	2021
OPERATING RESULTS (SEKm)				
	-32.7	-32.3	**-65.2**	-66.1
EARNINGS PER SHARE (SEK)				
	-0.68	-1.02	**-1.54**	-2.03
CASH FLOW FROM OPERATIONS (SEKm)				
	-32.7	-30.6	**-60.1**	-53.6
LIQUID ASSETS INCL. MARKETABLE SECURITIES (SEKm)				
	208.9	319.0	**208.9**	319.0

CEO COMMENTS

In the last couple of months, we have completed two clinical studies – Hepatic Impairment Study and Food Effect Study – that have run in parallel with the pivotal clinical study SPARKLE with our investigational contrast agent Orviglance®. This is a solid step forward in our preparations for regulatory submission and approval of Orviglance.

Orviglance Phase 3 program. In May, we reported positive final results from the Food Effect Study. The data showed that the intake of a light meal prior to Orviglance administration provides similar liver MRI enhancement compared to a fasting condition. In line with previous studies, the data also confirmed robust liver enhancement after Orviglance administration compared to an MRI image without a contrast agent. We are dedicated to improving the lives of patients with rare cancer conditions and this result will make the use of Orviglance even more convenient for the patient. This is a small but important step forward. After the end of the quarter, we received information that the results from the Food Effect Study will be presented orally at the RSNA conference in Chicago in November 2022.

The Hepatic Study has completed enrolment in the first half of the year. We will share more of the results in the third quarter this year.

Alongside these two studies, we continue our efforts in the pivotal clinical study SPARKLE. Hospitals have been added during the first half of 2022 to compensate for the suspension of Russian sites, communicated in March, and we continue to provide support to study investigators at all active hospitals to enroll patients.

Continued strong scientific interest for Orviglance. We continue to see a strong interest for Orviglance in the scientific community. In June, at the annual ESGAR conference in Lisbon, Portugal, we presented results from the study where Orviglance was compared to a gadolinium-based contrast agent to a well-attended scientific session.

The positive reactions to Orviglance are very encouraging, and the results from all our clinical studies so far confirm that Orviglance provides safe and effective enhancement of the liver.

Second US patent strengthens value of Oncoral. At the end of May, we received our second notice of allowance for a US patent for our novel oral chemotherapy drug candidate Oncoral which further strengthens our intellectual property. Our strong belief in Oncoral is unchanged. However, as our clinical development team is fully focused on SPARKLE, we will initiate patient enrollment in the Oncoral Phase 2 study when we are able to do this without impacting SPARKLE.

Déspina Georgiadou Hedin new CFO. I would also like to welcome Déspina Georgiadou Hedin as our new Chief Financial Officer (CFO). Déspina has a strong background in finance, most recently as CFO at Bioglan and she will take up her new position in September. I and the rest of the Ascelia Pharma team look forward to working with Déspina and I am confident she will contribute strongly to Ascelia Pharma's growth journey ahead. I would also like to thank our departing CFO Kristian Borbos who over the last 5 years has played an essential role in building Ascelia Pharma to where we are today and I wish him success in his new role.

Solid financial position. We have a solid balance sheet and closed the second quarter with 209 MSEK in cash, which will take us into H2 2023. The liquidity position will primarily be used for the ongoing Phase 3 program with Orviglance and market launch preparations.

Looking ahead. Our prime focus in 2022 is unchanged – to complete the clinical Phase 3 program for Orviglance and continue preparations for commercialization. I look forward to updating you on our achievements as we grow Ascelia Pharma.

Magnus Corfitzen,
CEO

ADVANCING ORPHAN ONCOLOGY

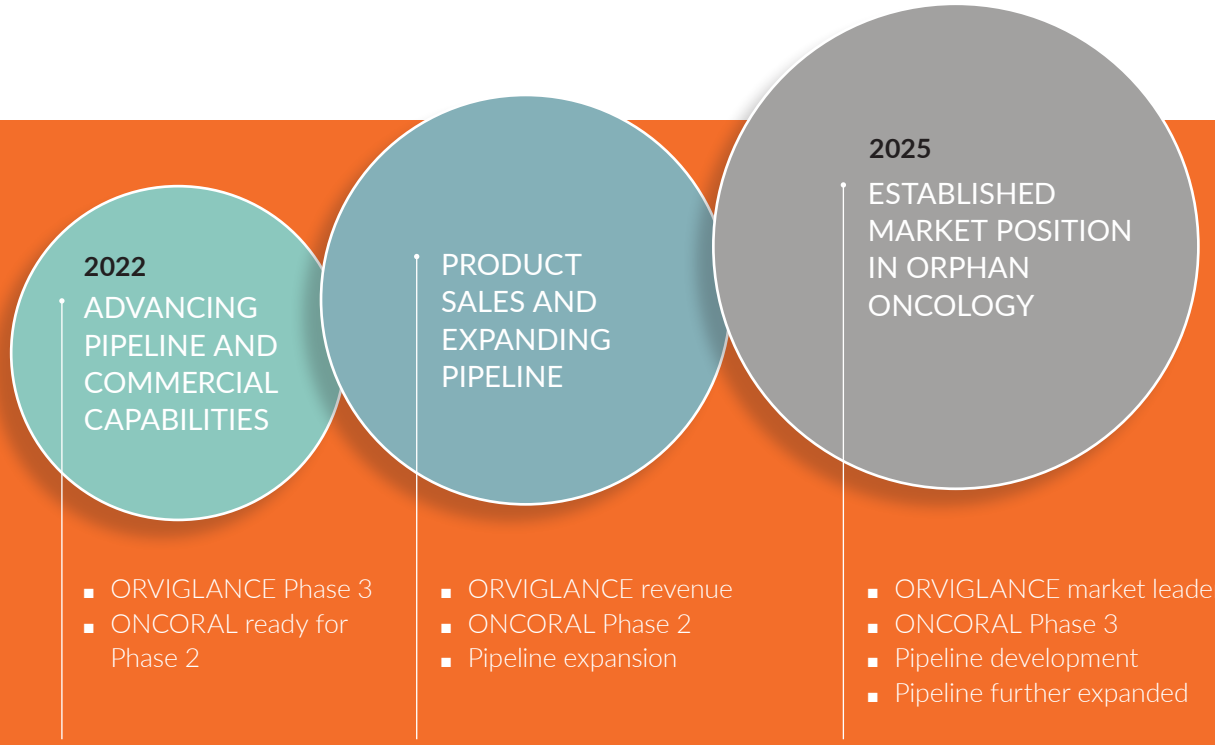
OUR VISION

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 (Mangoral)
Diagnostic drug for liver 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:

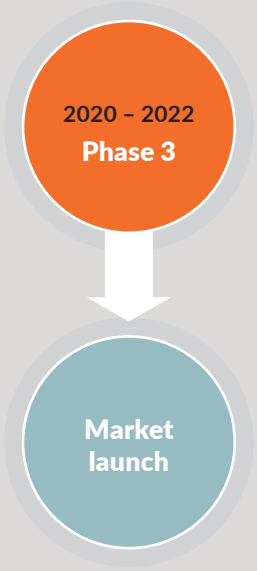
- Manganese-based diagnostic drug with Orphan Drug Designation (FDA)
- The only late-stage gadolinium-free agent
- $500-600 million annual addressable market

ONCORAL
Tablet chemotherapy ready for Phase 2

Oncoral is our novel oral chemotherapy tablet developed initially for the treatment of gastric cancer. Irinotecan chemotherapy 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
- Phase 2 in gastric cancer; potential to expand into other cancer forms

Expected timelines



Orviglance
Visualization of focal liver lesions
(liver metastases, primary liver cancer)

Oncoral
Gastric cancer treatment
and expansion potential to 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% to 46% 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 used in 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 increase the absorption of manganese from the small intestine into the portal liver vein. From there the manganese is transported to the liver where it is taken up by and retained in the normal liver cells, also known as the hepatocytes. The high manganese uptake causes the liver parenchyma to appear bright on MR images. As liver metastases are not liver cells, they do not take up manganese and consequently metastases appear dark on MR images. With Orviglance, liver metastases are consequently easier to identify due to this contrast effect.

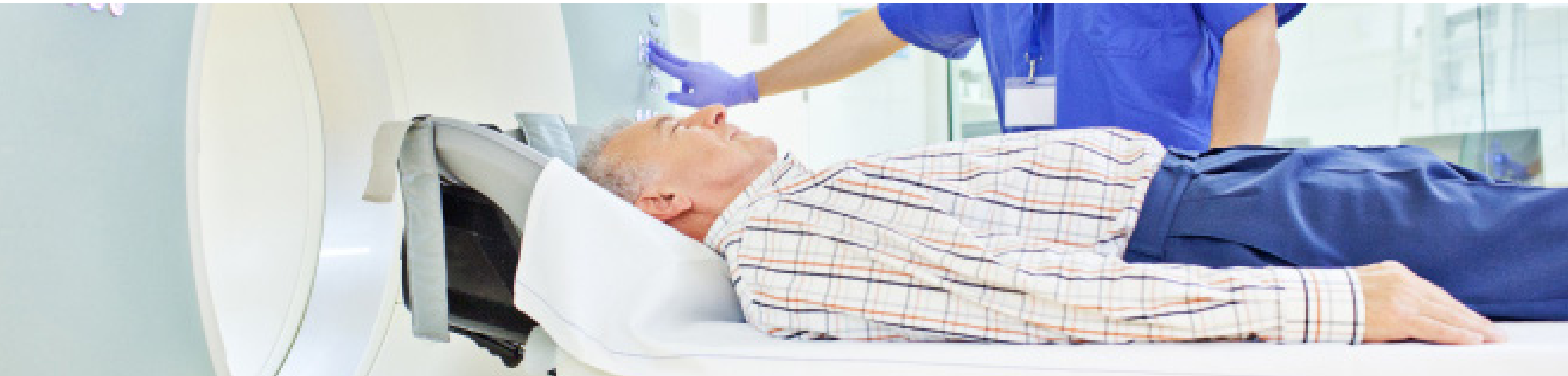
Latest development

In August 2022, the results of the Orviglance Food Effect Study have been accepted as an oral presentation at RSNA.

In May 2022, results from the Food Effect Study was published. The results showed intake of a light meal prior to Orviglance administration provides similar liver MRI enhancement compared to a fasting condition.

In March 2022, results from an independent market research with 270 healthcare professionals in the US was announced. The results showed, among other things, that 84% of healthcare professionals will likely use Orviglance for MRI scans of patients with cancer in the liver and reduced kidney function.

In March 2022, last patient visit was completed in Hepatic Impairment Study. Results are expected in Q3 2022.



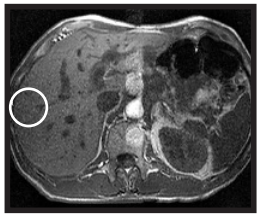
Patients referred for liver MRI scan

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

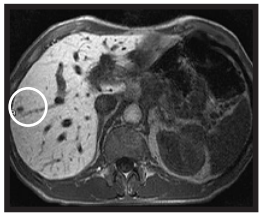


TOMORROW

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 impaired kidney function

Addressable market of $500-600 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 conducted clinical trials show that Orviglance is a safe and effective contrast agent 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 $500-600 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 market exclusivity for a number of years after market approval (seven years in the US and ten years in the EU/EEA). For orphan drugs in general, the time to approval is also usually shorter and the proportion of orphan drugs that are approved is higher than for non-orphan drugs.

ONGOING PHASE 3 STUDY (SPARKLE)

The ongoing pivotal Phase 3 study SPARKLE is a global multicentre study in up to 200 patients. The strong results in the Phase 1 and Phase 2, both in terms of safety and efficacy, studies provide a solid foundation for the ongoing Phase 3 program. This is underpinned by the high degree of similarity between the primary endpoints in Phase 2 and Phase 3, and since the Phase 3 study comparator for Orviglance is MRI with no contrast agent. In addition, the follow-up time is less than a week, compared to months or years for the typical Phase 3 oncology study.

Orviglance's clinical Phase 3 study (based on Phase 3 protocol meeting with FDA and EMA)

NUMBER OF PATIENTS	**Global ongoing study in up to 200 patients**
ENDPOINT	**Lesion visualisation** • 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**
RANDOMISATION	**No – each patient at 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 underpin that Orviglance significantly improves MRI performance.

[1] The above mentioned results stem from of a blinded-read study, which comprised all imaging data including Phase 1 and Phase 2 data. The blinded-read results have been presented at major radiology conferences

ADDRESSABLE MARKET OF $500-600 MILLION

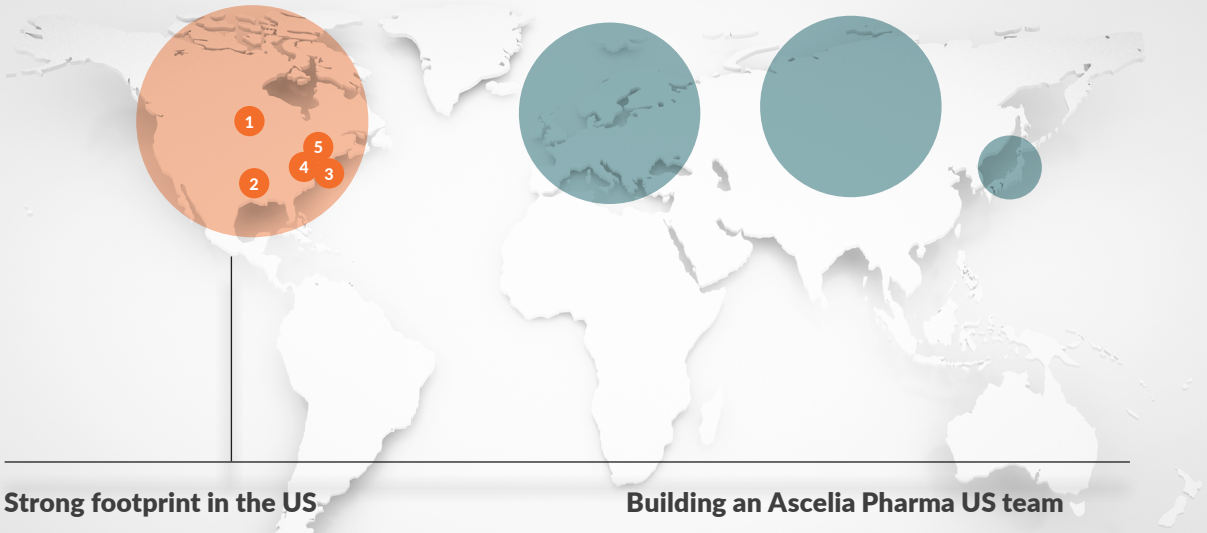
$500-600M annual addresable market in US, EU and Japan

Market estimate based on:

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

Upsides

- Other markets, e.g., China
- Annual growth of 4-5%



Value maximizing go-to-market

US	**Ascelia Pharma to drive commercialization**	
EU	**Ascelia Pharma global synergies**	**Commercial partner**
Japan		**Commercial partner**
Other		**Commercial partner**

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% 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 – IRINOTECAN 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.

Proven anti-cancer effect

The active pharmaceutical ingredient (API) in Oncoral is irinotecan, which has an established and proven effect in killing cancer cells. Irinotecan is 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 irinotecan

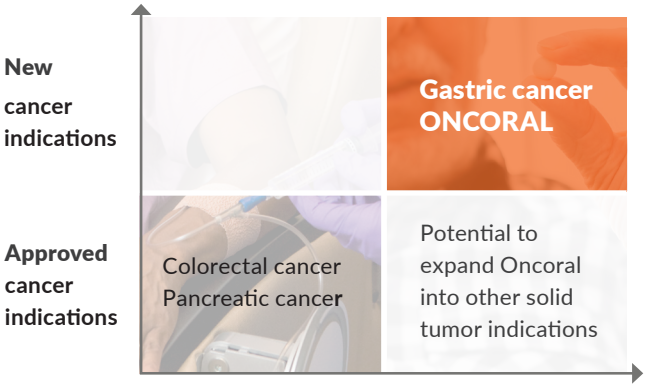
Oncoral is a new patented oral tablet formulation of irinotecan. Oncoral enables a secure and efficient release and absorption of irinotecan from the gastro-intestinal tract after oral administration with a high conversion rate of irinotecan to the active metabolite SN-38, which has a high anti-tumor activity. Oncoral has the potential to be combined with other chemotherapies and targeted cancer drugs and enable an all oral chemo combination.

Latest development

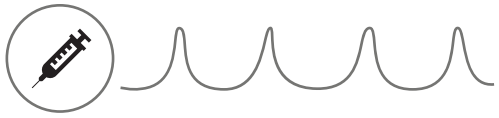
In H1 2022, both the Spanish and the UK regulatory authorities approved the study start of Phase 2. For the US, the corresponding approval (IND) was obtained in December 2021.

In May 2022, the US Patent and Trademark Office (USPTO) informed that they had issued a notice of allowance for a second Oncoral patent application covering the method of use of Oncoral.

Oncoral - a novel formulation of irinotecan



TODAY – Intravenous bolus infusions



Infrequent high-dose IV irinotecan

- Gastrointestinal and haematological side effects
- Side-effects: 30% severe or life-threatening (grade 3 or 4)

TOMORROW – Oncoral oral daily dosing

Potential – Frequent low-dose irinotecan

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

ONCORAL PHASE 2 STUDY DESIGN

Following an initial dose-finding part, the Phase 2 study will be a randomized controlled multicenter study. In the study, Oncoral will be added to LONSURF (trifluridine and tipiracil) film-coated tablets for oral use compared to LONSURF alone. The objectives of the planned Phase 2 study are several. First of all, to establish a clinical proof of concept in metastatic gastric cancer. There is a potential for Orphan Drug Designation in gastric cancer and also the clinical guidelines and clinical data support efficacy of irinotecan in gastric cancer. Then there is potential for subsequent label expansion into other solid tumor indications. Another objective is to generate, compelling Phase 2 data for further development and design a Phase 3 study.

Phase 2 study design (an all-oral combination study)

TYPE OF STUDY	Randomized controlled, multicentre, multinational study: Oncoral + LONSURF vs. LONSURF
ENDPOINTS	**Primary:** Progression Free Survival **Secondary:** Response rate, PK, Safety and Overall Survival data in a follow up analysis
NUMBER OF PATIENTS	**Approximately 100 patients**

FINANCIAL OVERVIEW: Q2-2022 (APR–JUN 2022)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales in Q2 (Apr-Jun 2022) 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 totaled SEK 260 thousand (SEK 100 thousand).

Research and development costs (R&D)

R&D costs for the Group in Q2 were SEK 27.1 million (SEK 25.6 million). The cost increase of SEK 1.4 million primarily reflects higher costs for Oncoral Phase 2 preparations in current quarter.

Commercial preparation costs

During Q2, costs related to commercial preparations for Orviglance amounted to SEK 3.7 million (SEK 2.1 million). The cost increase compared with Q2 2021 reflects a step-up in market launch preparations.

Administration costs

Administration costs for the Group in Q2 amounted to SEK 2.0 million (SEK 4.6 million). The cost decrease in the current quarter compared with Q2-2021 primarily reflects a decrease in recognized costs for employee incentive programs.

Operating results (EBIT)

The operating result in Q2 was largely unchanged y/y and amounted to SEK -32.7 million (SEK -32.3 million).

Net Profit/Loss for the period

The Group's net loss in Q2 amounted to SEK -22.8 million (SEK -33.5 million). In the current quarter, net financial income of SEK 8.9 million was recognized due to primarily 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 -0.68 (SEK -1.02).

Financials key ratios for the Group	Q2 (April-June)	
	2022	2021
Operating result (SEK 000')	-32,651	-32,312
Net result (SEK 000')	-22,807	-33,494
Earnings per share (SEK)	-0.68	-1.02
Weighted avg. number of shares	33,668,262	33,026,911
R&D costs/operating costs (%)	82%	79%
Cash flow used in operating activities (SEK 000')	-32,691	-30,636
Equity (SEK 000')	257,315	367,882
Liquid assets incl. marketable securities (SEK 000')	208,861	319,014

CASH FLOW

Cash flow from operating activities before changes in working capital in Q2 amounted to SEK -33.9 million (SEK -30.1 million). The increased outflow y/y primarily reflects the higher level of R&D activities and commercial preparations in current quarter. Changes in working capital in the current quarter totaled an inflow of SEK 1.2 million (outflow of SEK 0.6 million). The inflow in the current quarter primarily reflects the increase in accounts payable.

Cash flow from investing activities in Q2 totaled to SEK 0 (SEK -38 thousand). Cash flow from financing activities amounted to an outflow of SEK -0.3 million (inflow of SEK 186.2 million), which mainly reflects amortization of lease liabilities.

FINANCIAL POSITION

On the closing date, equity amounted to SEK 257.3 million, compared with SEK 307.8 million per 31 December 2021 and SEK 367.9 million per 30 June 2021. The decrease since 31 December 2021 and 30 June 2021 reflects the net losses incurred.

Liquid assets on the closing date amounted to SEK 208.9 million, compared to SEK 261.6 million per 31 December 2021 and SEK 319.0 million per 30 June 2021. The decrease since 31 December 2021 and 30 June 2021 reflects the net losses incurred.

FINANCIAL OVERVIEW: H1-2022 (JAN–JUN 2022)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales in H1 (Jan-Jun 2022) 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 totaled SEK 395 thousand (SEK 127 thousand).

Research and development costs (R&D)

R&D costs for the Group in H1 were SEK 51.4 million (SEK 55.0 million). The cost decrease of SEK 3.5 million primarily reflects timing of milestone payments for Orviglance Phase 3 study, which caused higher cost recognition in first quarter last year compared to the first quarter this year.

Commercial preparation costs

During H1, costs related to commercial preparations for Orviglance amounted to SEK 7.9 million (SEK 3.1 million). The cost increase compared with H1 2021 reflects a step-up in market launch preparations.

Administration costs

Administration costs for the Group in H1 amounted to SEK 6.1 million (SEK 7.4 million). The cost decrease primarily reflects a decrease in recognized costs for employee incentive programs.

Operating results (EBIT)

The operating result in H1 amounted to SEK -65.2 million (SEK -66.1 million). The reduced loss reflects the timing effect with lower R&D costs in Q1-2022, which was partly counterbalanced by higher commercial preparation costs.

Net Profit/Loss for the period

The Group's net loss in H1 amounted to SEK -51.9 million (SEK -62.3 million). In the current period, net financial income of SEK 11.4 million was recognized due to primarily 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).

Financials key ratios for the Group	H1 (January-June)	
	2022	2021
Operating result (SEK 000')	-65,221	-66,052
Net result (SEK 000')	-51,882	-62,309
Earnings per share (SEK)	-1.54	-2.03
Weighted avg. number of shares	33,668,262	30,916,702
R&D costs/operating costs (%)	78%	83%
Cash flow used in operating activities (SEK 000')	-64,057	-53,584
Equity (SEK 000')	257,315	367,882
Liquid assets incl. marketable securities (SEK 000')	208,861	319,014

The net loss corresponds to a loss per share, before and after dilution, of SEK -1.54 (SEK -2.03).

CASH FLOW

Cash flow from operating activities before changes in working capital in H1 amounted to SEK -65.7 million (SEK -63.3 million). The increased outflow y/y primarily reflects the higher level of commercial preparation in the current period. Changes in working capital in the current quarter totaled an inflow of SEK 1.6 million (inflow of SEK 9.7 million). The inflow in the current period primarily reflects the increase in accounts payable.

Cash flow from investing activities in H1 totaled an outflow of SEK -64 thousand (SEK 0), which reflects a value loss in divestment of a leasing car. Cash flow from financing activities amounted to an outflow of SEK -0.6 million (inflow of SEK 185.4 million), which mainly reflects amortization of lease liabilities.

FINANCIAL POSITION

On the closing date, equity amounted to SEK 257.3 million, compared with SEK 307.8 million per 31 December 2021 and SEK 367.9 million per 30 June 2021. The decrease since 31 December 2021 and 30 June 2021 reflects the net losses incurred.

Liquid assets on the closing date amounted to SEK 208.9 million, compared to SEK 261.6 million per 31 December 2021 and SEK 319.0 million per 30 June 2021. The decrease since 31 December 2021 and 30 June 2021 reflects the net losses incurred.

Other information

Incentive programs

Ascelia Pharma has one outstanding employee option program that includes members of the management team and share-saving programs for employees. If the terms of the option program are met at the time for utilization, the management team 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 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 2021 on pages 67-68.

In case all outstanding incentive programs per 30 June 2022 (incl. a new share-saving program approved by the AGM in May 2022) are exercised in full, a total of 2.8 million common shares will be issued (including hedge for future payment of social security charges). This corresponds to an aggregate maximum dilution of approximately 7.7% 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 and 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 2021 on pages 34-36.

Siginificant events after the end of the reporting period

On 11 August 2022, it was annonced that the results Orviglance Food Effect Study have been accepted as an oral presentation at the world's largest radiology conference, RSNA.

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, 18 August 2022

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

René Spogárd
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 2022 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, 18 August 2022
Öhrlings PricewaterhouseCoopers AB

Carl Fogelberg
Authorized Public Accountant

Consolidated Income Statement

	Q2 (Apr-Jun)		H1 (Jan-Jun)	
*SEK in thousands (unless otherwise stated)**	2022	2021	2022	2021
Net sales	–	–	–	–
Gross profit/loss	**–**	**–**	**–**	**–**
Administrative costs	-2,009	-4,600	-6,132	-7,744
Research and development costs	-27,093	-25,644	-51,446	-54,988
Commercial preparation costs	-3,687	-2,145	-7,916	-3,080
Other operating income	260	100	395	127
Other operating costs	-122	-23	-122	-367
Operating result	**-32,651**	**-32,312**	**-65,221**	**-66,052**
Finance income	8,863	–	11,420	4,442
Finance costs	-11	-1,945	-26	-1,963
Net financial items	**8,852**	**-1,945**	**11,394**	**2,479**
Loss before tax	**-23,799**	**-34,257**	**-53,827**	**-63,573**
Tax	992	763	1,945	1,264
Loss for the period	**-22,807**	**-33,494**	**-51,882**	**-62,309**
Attributable to:				
Owners of the Parent Company	-22,807	-33,494	-51,882	-62,309
Non-controlling interest	–	–	–	–
Earnings per share				
Before and after dilution (SEK)	-0.68	-1.02	-1.54	-2.03

Consolidated Statement of Comprehensive Income

	Q2 (Apr-Jun)		H1 (Jan-Jun)	
*SEK in thousands (unless otherwise stated)**	2022	2021	2022	2021
Profit/loss for the period	**-22,807**	**-33,494**	**-51,882**	**-62,309**
Other comprehensive income				
Currency translation of subsidiaries**	257	-13	425	8
Other comprehensive income for the period	**257**	**-13**	**425**	**8**
Total comprehensive income for the period	**-22,550**	**-33,507**	**-51,457**	**-62,301**

* 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 2022	30 Jun 2021	31 Dec 2021
ASSETS			
Non-current assets			
Intangible assets	57,069	57,062	57,063
Tangible assets - Equipment	201	279	238
Right-of-use assets	828	2,121	1,581
Total non-current assets	**58,098**	**59,462**	**58,882**
Current assets			
Advance payments to suppliers	5,686	5,526	6,175
Current receivables			
Income tax receivables	6,970	3,362	4,395
Other receivables	1,902	1,766	1,165
Prepaid expenses and accrued income	1,571	595	1,277
Cash and bank balances	208,861	319,014	261,599
Total current assets	**224,990**	**330,263**	**274,611**
Total assets	**283,088**	**389,725**	**333,493**
EQUITY			
Share capital	34,871	34,576	34,576
Other paid-in capital	678,747	678,831	678,831
Reserve of exchange differences on translation	679	127	254
Loss brought forward (incl. net profit/loss for the period)	-456,982	-345,652	-405,827
Equity attributable to Parent Company shareholders	**257,315**	**367,882**	**307,834**
Total equity	**257,315**	**367,882**	**307,834**
LIABILITIES			
Long-term liabilities			
Leasing	204	1,094	553
Total long-term liabilities	**204**	**1,094**	**553**
Current liabilities			
Accounts payable	8,923	9,085	6,147
Tax payable	–	–	5
Other liabilities	1,403	1,031	1,509
Current lease liabilities	673	1,105	1,102
Accrued expenses and deferred income	14,570	9,528	16,343
Total current liabilities	**25,569**	**20,749**	**25,106**
Total liabilities	**25,773**	**21,843**	**25,659**
Total equity and liabilities	**283,088**	**389,725**	**333,493**

* 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**	2022	2021	2021
Equity at start of the period	**307,834**	**236,056**	**236,056**
Comprehensive income			
Profit/loss for the period	-51,882	-62,309	-125,903
Other comprehensive income	425	8	135
Total comprehensive income	**-51,457**	**-62,301**	**-125,768**
Transactions with shareholders			
New issue of C-shares	295	398	398
Repurchase of own shares C-shares	-295	-398	-398
New issue of common shares	–	200,000	200,000
Issuance expenses	-84	-13,271	-13,271
Redemption of warrants	–	3,853	3,853
Share based remuneration to employees	1,022	3,545	6,964
Total transactions with shareholders	**938**	**194,127**	**197,546**
Equity at end of the period	**257,315**	**367,882**	**307,834**

* 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**	**2022**	**2021**	**2022**	**2021**
Operating activities				
Operating result	-32,651	-32,312	-65,221	-66,052
Expensed share based remuneration	-1,254	2,201	-620	2,731
Adjustment for items not included in cash flow	268	222	600	438
Interest paid	-11	-19	-26	-36
Income tax paid/received	-208	-169	-437	-339
Cash flow from operating activities before changes in working capital	**-33,856**	**-30,077**	**-65,704**	**-63,258**
Cash flow from changes in working capital				
Increase (-)/Decrease (+) of advance payments	1,733	163	519	2,753
Increase (-)/Decrease (+) of operating receivables	-177	214	-1,345	-761
Increase (+)/Decrease (-) of accounts payable	3,976	2,127	2,718	5,199
Increase (+)/Decrease (-) of other liabilities	-4,367	-3,063	-245	2,483
Change in working capital	1,165	-559	1,647	9,674
Cash flow used in operating activities	**-32,691**	**-30,636**	**-64,057**	**-53,584**
Investing activities				
Investment in equipment	–	-38	–	-38
Divestment of right-of-use assets	–	–	-64	–
Cash flow from investing activities	**–**	**-38**	**-64**	**-38**
Financing activities				
Issuance proceeds	–	200,000	–	200,000
Issuance costs	-12	-12,680	-84	-13,271
Redemption of warrants net	–	-914	–	-914
Amortisation of loan (leasing)	-256	-204	-527	-400
Cash flow from financing activities	**-268**	**186,202**	**-611**	**185,415**
Cash flow for the period	**-32,959**	**155,528**	**-64,732**	**131,793**
Cash flow for the period	-32,959	155,528	-64,732	131,793
Cash and cash equivalents at start of period	232,603	165,422	261,599	184,686
Exchange rate differences in cash and cash equivalents	9,217	-1,936	11,994	2,535
Cash and cash equivalents at end of period	**208,861**	**319,014**	**208,861**	**319,014**

* 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**	2022	2021	2022	2021
Net sales	318	1,670	990	2,481
Gross profit/loss	**318**	**1,670**	**990**	**2,481**
Administrative costs	-1,930	-4,566	-6,024	-7,716
Research and development costs	-22,761	-23,204	-43,474	-50,943
Commercial preparation costs	-3,695	-2,145	-7,931	-3,089
Other operating income	–	100	57	100
Other operating costs	-122	–	-122	-344
Operating result	**-28,190**	**-28,145**	**-56,504**	**-59,511**
Finance income	8,319	–	10,759	4,442
Finance costs	–	-1,930	–	-1,930
Result from other long-term receivables	-243	229	458	788
Net financial costs	**8,076**	**-1,701**	**11,217**	**3,300**
Loss before tax	-20,114	-29,846	-45,287	-56,211
Group contribution	–	–	–	–
Tax	–	–	–	–
Loss for the period	**-20,114**	**-29,846**	**-45,287**	**-56,211**

Parent Company – Statement of Comprehensive Income

	Q2 (Apr-Jun)		H1 (Jan-Jun)	
*SEK in thousands**	2022	2021	2022	2021
Loss for the period	**-20,114**	**-29,846**	**-45,287**	**-56,211**
Other comprehensive income	–	–	–	–
Other comprehensive income for the period	**–**	**–**	**–**	**–**
Total comprehensive income for the period	**-20,114**	**-29,846**	**-45,287**	**-56,211**

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

Parent Company – Balance Sheet

*SEK in thousands**	30 Jun 2022	30 Jun 2021	31 Dec 2021
ASSETS			
Non-current assets			
Tangible assets			
Equipment	201	279	238
Financial assets			
Shares in affiliated companies	58,068	58,068	58,068
Other long-term receivables from group companies	37,242	12,981	36,620
Total non-current assets	**95,511**	**71,328**	**94,926**
Current assets			
Advance payments to suppliers	5,190	5,526	5,323
Current receivables			
Receivables from group companies	7,930	3,879	6,971
Income tax receivables	1,168	962	739
Other receivables	1,704	1,051	656
Prepaid expenses and accrued income	1,451	595	1,183
Cash and bank balances	197,935	317,306	246,311
Total current assets	**215,378**	**329,319**	**261,183**
Total assets	**310,889**	**400,647**	**356,109**
EQUITY			
Restricted equity			
Share capital	34,871	34,576	34,576
Non-restricted equity			
Other paid-in capital	678,747	678,831	678,831
Loss brought forward	-379,857	-274,714	-271,295
Loss for the period	-45,287	-56,211	-109,288
Total equity	**288,474**	**382,482**	**332,824**
LIABILITIES			
Current liabilities			
Accounts payable	6,467	7,783	5,700
Other liabilities	1,403	1,032	1,509
Accrued expenses and deferred income	14,545	9,350	16,076
Total current liabilities	**22,415**	**18,165**	**23,285**
Total equity and liabilities	**310,889**	**400,647**	**356,109**

* 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 2022, the owners of Solural ApS collectively owned 1.9% 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 2022, services for a value of around SEK 394 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 2022, 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, one program reached its exercise period and all options related to this program, 481,573 in total, were exercised into common shares.

For the outstanding option program, a gain of SEK 0.9 million including social security charges was recognized in H1 2022. The gain primarily reflects the decline is Ascelia Pharma's share price during the period resulting in a lower liability for social security charges.

Share saving programs

Ascelia Pharma has implemented three 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 2022 were SEK 0.3 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**	2022	2021	2022	2021
R&D costs	-27,093	-25,644	-51,446	-54,988
Administration costs	-2,009	-4,600	-6,132	-7,744
Commercial preparation costs	-3,687	-2,145	-7,916	-3,080
Other operating costs	-122	-23	-122	-367
Total operating costs	**-32,911**	**-32,412**	**-65,616**	**-66,179**
R&D costs/Operating costs (%)	**82%**	**79%**	**78%**	**83%**

Financial calendar

Interim report 9M 2022 (Jan-Sep): 4 November 2022
Full-year report 2022 (Jan-Dec): 10 February 2023

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