ASCELIA PHARMA

Advancing Orphan Oncology

FULL-YEAR REPORT 2021

January – December 2021

Strong data for Orviglance vs. a liver-specific gadolinium contrast agent

SIGNIFICANT EVENTS IN Q4 2021

- Food Effect Study with Orviglance successfully completed
- FDA approves Investigational New Drug (IND) application for Oncoral clinical development
- Presentation at RSNA of results from Orviglance comparison study to gadolinium

NO SIGNIFICANT EVENTS AFTER THE PERIOD

"In Q4, we presented final results from the re-read study showing further evidence of the diagnostic value Orviglance can offer to patients and physicians"

KEY RATIOS GROUP

	Q4 (Oct-Dec)		FY (Jan-Dec)	
	2021	2020	**2021**	2020
OPERATING RESULT (SEKm)	**-39.2**	-27.9	**-137.9**	-93.4
EARNINGS PER SHARE (SEK)	**-1.01**	-1.25	**-3.82**	-3.76
CASH FLOW FROM OPERATIONS (SEKm)	**-32.2**	-27.6	**-116.6**	-85.5
LIQUID ASSETS INCL. MARKETABLE SECURITIES (SEKm)	**261.6**	184.7	**261.6**	184.7

CEO COMMENTS

As we now put a busy year behind us, I believe that, despite the effects from the continuing Covid-19 pandemic, we made good progress across our clinical portfolio. Not least in the fourth quarter, when we, among other things, completed the Food Effect study with our diagnostic drug candidate Orviglance®. In December, we presented strong results from a comparison study to gadolinium. Also, the FDA accepted our Investigational New Drug (IND) application for the upcoming global Phase 2 clinical study in gastric cancer with Oncoral in combination with Taiho Oncology's LONSURF®

SPARKLE Phase 3 study with Orviglance. The Covid-19 pandemic impacts healthcare systems and clinical study activities and has also affected the recruitment pace in the ongoing SPARKLE trial. We have responded to the Covid-19 impact by increasing the number of countries and clinics recruiting patients into the study. We have also recently amended the study protocol to include patients on hemodialysis and patients with moderate hepatic impairment. Our aim and expectation is to complete recruitment to SPARKLE in H1 2022.

Food effect study with Orviglance successfully completed. An important part of our pivotal clinical program with Orviglance are the two complementary studies – Food Effect Study and Hepatic Impairment Study – that run in parallel with SPARKLE. In October, we announced that the last patient visit was completed in the Food Effect Study to evaluate the effect of food intake on the absorption of Orviglance.

Preliminary data indicate that Orviglance has been well tolerated in the Food Effect Study. Final results are expected in Q1 2022. A potential removal of the current fasting requirement could further improve the convenience and ease the administration of Orviglance in clinical practice.

Results from the Orviglance comparison study to gadolinium presented at RSNA 2021. In December, we presented results from the study in which Orviglance was compared against a liver-specific gadolinium-based contrast agent at the world's largest radiology conference, RSNA, in Chicago, Illinois.

The comparison study showed that MRI with Orviglance was as effective as the gadolinium contrast agent gadobenate dimeglumine (Multihance) for visualization of lesions and number of detected lesions in the liver. In fact, 2 out of 3 readers reporting higher scores for Orviglance. We also saw that MRI with Orviglance provides improved efficacy in terms of lesion detection and visualization compared to MRI without contrast agent.

The study provides robust evidence of the diagnostic value that Orviglance can offer once available to patients and physicians. Orviglance is being developed to address the unmet medical need of patients with poor kidney function who require liver imaging, and it is very encouraging that Orviglance is as effective as a gadolinium contrast agent on these important parameters.

FDA acceptance of Oncoral IND application. In December, the FDA approved our Investigational New Drug (IND) application for the upcoming global Phase 2 clinical study in gastric cancer. In the study, our daily oral chemotherapy candidate drug Oncoral will be combined with Taiho Oncology's LONSURF (trifluridine and tipiracil) film-coated tablets for oral use.

The clinical collaboration agreement with Taiho Oncology shows the potential for Oncoral to be part of a new treatment regimen for gastric cancer. We believe this investigational all-oral tablet combination has the potential to provide a significant treatment benefit to patients suffering from this very aggressive cancer form where there is a massive unmet need.

The Phase 2 study will include around 100 patients with metastatic gastric cancer and first patient visit is expected in Q2/Q3 2022. The initial portion of the planned global study will be conducted at hospitals in Europe, whereas the subsequent randomized part will also include US sites.

Solid financial position. We have a solid balance sheet and closed the year with 262 MSEK in cash, which will take us into 2023. The liquidity position will be used for the ongoing Phase 3 program for Orviglance and the market launch preparations as well as Oncoral's clinical development program.

Looking ahead. Our focus in 2022 is on the pivotal study for Orviglance and the commercial preparations, and to initiate upcoming clinical studies with Oncoral. We work constantly to create shareholder value, and I look forward to updating you on the progress of Ascelia Pharma.

Magnus Corfitzen,
CEO

ADVANCING ORPHAN ONCOLOGY

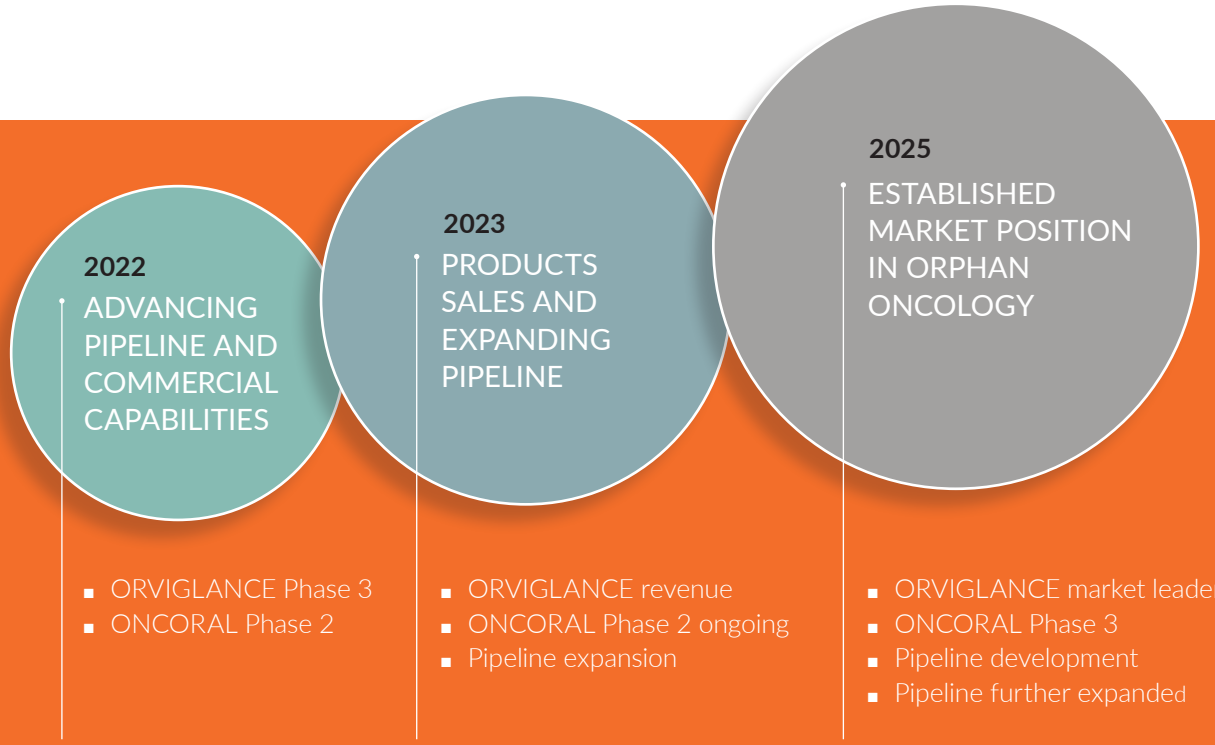
OUR VISION

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

OUR BASE

Our headquarter is in Malmö, Sweden, and our US base is in Woodbridge, NJ. 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 (metastases and primary cancer) in patients with impaired kidneys that are 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 gadolinium-free agent
- $500-600 million annual addressable market

ONCORAL
Daily chemotherapy starting Phase 2

Oncoral is our novel oral chemotherapy tablet developed initialy for the treatment of gastric cancer. It is based on the substance irinotecan, which 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

** Timelines reflect current expections, which could be extended and influenced by a prolonged Covid-19 situation*

MANGORAL BECOMES ORVIGLANCE

Orviglance® is the brand name for manganese chloride tetrahydrate (previous working name Mangoral)

Mangoral

Brand name approved by FDA

In August 2021, the U.S. Food and Drug Administration (FDA) conditionally accepted Orviglance* as the proposed brand name for manganese chloride tetrahydrate (Mangoral). The name Orviglance was developed in accordance with FDA's guidance for the submission and evaluation of proprietary names and the name selection included a research study of healthcare practitioners across the U.S. to ensure accurate prescription and safety interpretation of the name.

Brand name also approved by EMA

Orviglance has earlier also received an invented name approval from the European Medicines Agency (EMA).

**Trademark is registered in Europe and several other markets and submitted for registration in the US.*

ORVIGLANCE (MANGORAL)

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.

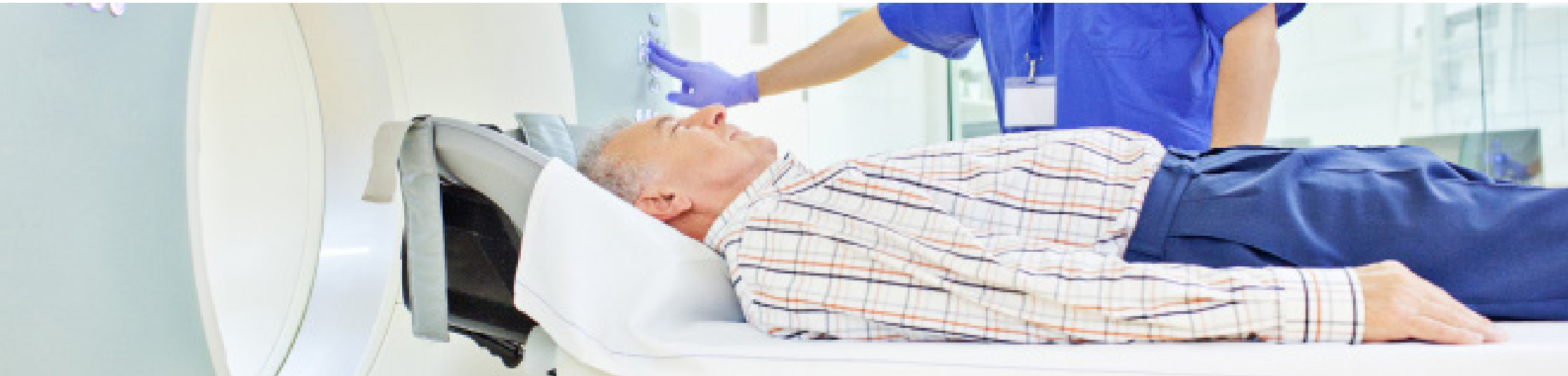
How Orviglance (Mangoral) works

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 December 2021, results was presented from the study where Orviglance was compared against a gadolinium-based contrast agent (Multihance) The results showed that a higher number of liver lesions was detected by all three independent readers for Orviglance compared to gadolinium. All three readers were also able to see smaller lesions with Orviglance compared to gadolinium. With respect to lesion border delineation and lesion contrast to liver, 2 out of 3 readers reported higher scores to Orviglance.

In October 2021, last patient visit was completed in the Food Effect Study. Preliminary data indicate that Orviglance has been well tolerated in the study. Final results of the Food Effect Study are expected in Q1-2022.



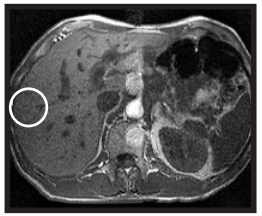
Patients referred for liver MRI scan

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

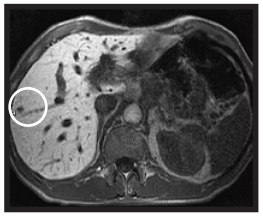


TOMORROW

NORMAL KIDNEY
Gadolinium imaging drug

POOR KIDNEY FUNCTION
ORVIGLANCE (MANGORAL) imaging drug

MRI scan with Orviglance:
Liver metastasis visible



Orviglance aims to be the standard of care liver MRI imaging drug for patients where gadolinium-based contrast agents may be medically inadvisable or cannot be administered

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 (Mangoral) 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 (Mangoral) 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 (Mangoral) 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 $500-600M

$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 Woodbridge, NJ
4. **Manufacturing** at Cambrex (partner), NJ
5. **Imaging experts** RadMD, NY

Building an Ascelia Pharma US team

US team	**Around 40 FTE at launch**
Clinics/ Hospitals	**Around 400 clinics and hospitals serve 75% of the kidney impairment patients[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

Oncoral is a novel daily irinotecan chemotherapy in development. Irinotecan chemotherapy has an established potent anti-tumor effect. Oncoral is a oral 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

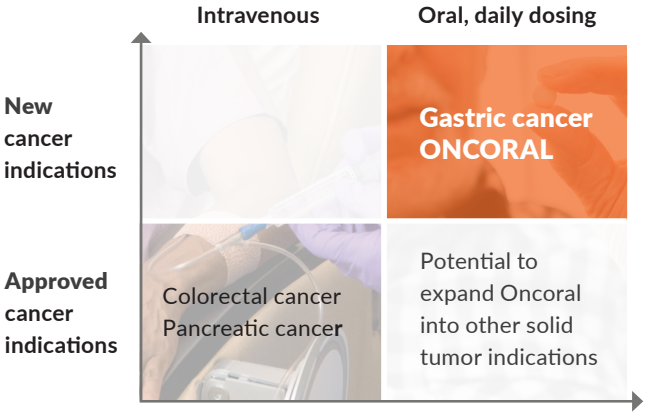
Oncoral is a patented oral tablet formulation of irinotecan. Oncoral enables a secure and efficient release and absorption of irinotecan from the gastro-intestinal tract after oral administration with a high conversion rate of irinotecan to the active metabolite SN-38, which has a high anti-tumor activity.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

Latest development

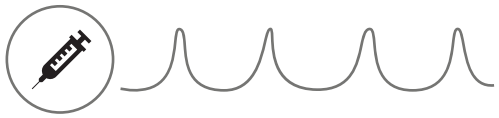
In December 2021, the FDA accepted the Investigational New Drug (IND) application for the upcoming global Phase 2 clinical study in gastric cancer.

In September 2021, a clinical collaboration agreement was signed with Taiho Oncology for the development of Oncoral in combination LONSURF. The collaboration concerns the upcoming Phase 2 clinical study in gastric cancer.

Oncoral – a novel formulation of irinotecan



TODAY – Intravenous bolus infusions



Infrequent high-dose IV irinotecan

- Gastrointestinal and hematological 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

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. Gastric cancer is chosen partly because of strategic reasons. 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 all, compelling Phase 2 data for further development and obtain solid data to 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**
STUDY PERIOD	**2022* - 2024**

**IND approved by the FDA in December 2021*

FINANCIAL OVERVIEW: Q4-2021 (OCT–DEC 2021)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales in Q4 (Oct-Dec 2021) 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 123 thousand (SEK 237 thousand).

Research and development costs (R&D)

R&D costs for the Group in Q4 were SEK 27.9 million (SEK 22.0 million). The cost increase of SEK 5.9 million underlines an overall higher activity level in Ascelia Pharma in the current quarter vis-à-vis corresponding quarter last year. This was driven by costs related to Orviglance Phase 3 clinical study and manufacturing preparations as well as increased costs for Oncoral Phase 2 preparations.

Commercial preparation costs

During Q4, costs related to commercial preparations amounted to SEK 6.1 million (SEK 1.0 million). The cost increase compared with Q4-2020 reflects preparations towards launching of Orviglance to the market.

Administration costs

Administration costs for the Group in Q4 amounted to SEK 5.3 million and largely unchanged compared to Q4 last year (SEK 4.9 million).

Operating results (EBIT)

The operating result in Q4 amounted to SEK -39.2 million (SEK -27.9 million). The increased loss reflects the overall higher level of R&D activities and manufacturing preparations in Q4-2021.

Net Profit/Loss for the period

The Group's net loss in Q4 amounted to SEK -35.1 million (SEK -35.9 million). In the current quarter, net financial income of SEK 3.0 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 -1.01 (SEK -1.25).

Financials key ratios for the Group	Q4 (October-December)	
	2021	2020
Operating result (SEK 000')	-39,160	-27,880
Net result (SEK 000')	-35,073	-35,851
Earnings per share (SEK)	-1.01	-1.25
Weighted avg. number of shares	34,576,448	28,697,234
R&D costs/operating costs (%)	71%	78%
Cash flow used in operating activities (SEK 000')	-32,246	-27,553
Equity (SEK 000')	307,834	236,056
Liquid assets incl. marketable securities (SEK 000')	261,599	184,686

CASH FLOW

Cash flow from operating activities before changes in working capital in Q4 amounted to SEK -35.5 million (SEK -22.5 million). The increased outflow y/y primarily reflects the higher level of R&D activities and manufacturing preparations in the current quarter. Changes in working capital in the current quarter totaled an inflow of SEK 3.3 million (outflow of SEK 5.0 million). The inflow in the current quarter primarily reflects the decrease in advance payments to major suppliers, as well as increase in accrued expenses.

Cash flow from investing activities in Q4 totaled SEK 0 (inflow of SEK 69.4 million). Cash flow from financing activities amounted to an outflow of SEK 0.3 million (outflow of SEK 0.2 million), which reflects the amortization of loans (leasing of cars and office).

FINANCIAL POSITION

On the closing date, equity amounted to SEK 307.8 million, compared with SEK 236.1 million per 31 December 2020. The increase since 31 December 2020 reflects the issuance of new shares in the spring 2021, which outweighed the net losses incurred in 2021.

Liquid assets on the closing date amounted to SEK 261.6 million, compared to SEK 184.7 million per 31 December 2020, which also is an effect of the share issuance in the spring 2021.

FINANCIAL OVERVIEW: FY-2021 (JAN–DEC 2021)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales in FY-2021 (Jan-Dec) 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 317 thousand (SEK 756 thousand).

Research and development costs (R&D)

R&D costs for the Group in FY-2021 were SEK 107.6 million (SEK 64.8 million). The cost increase of SEK 42.8 million underlines an overall higher activity level in Ascelia Pharma in the current period vis-à-vis corresponding period last year. This was driven by costs related to Orviglance Phase 3 clinical study and manufacturing preparations as well as increased costs for Oncoral Phase 2 preparations.

Commercial preparation costs

In FY-2021, costs related to commercial preparations of amounted to SEK 13.2 million (SEK 10.2 million). The costs increase compared with 2020 reflects commercial preparations towards launching of Orviglance to the market.

Administration costs

Administration costs for the Group in FY-2021 amounted to SEK 17.1 million (SEK 18.3 million). The cost decrease is partially explained by high recruitment costs in Q1-2020.

Operating results (EBIT)

The operating result in FY-2021 amounted to SEK -137.9 million (SEK -93.4 million). The increased loss reflects the overall higher level of R&D activities and manufacturing preparations in 2021.

Net Profit/Loss for the period

The Group's net loss in FY-2021 amounted to SEK -125.9 million (SEK -98.7 million). In FY-2021, net financial income of SEK 8.4 million was recognized due to strengthening of USD, 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 -3.82 (SEK -3.76).

Financials key ratios for the Group	FY (January-December)	
	2021	2020
Operating result (SEK 000')	-137,948	-93,428
Net result (SEK 000')	-125,903	-98,697
Earnings per share (SEK)	-3.82	-3.76
Weighted avg. number of shares	32,959,110	26,270,854
R&D costs/operating costs (%)	78%	69%
Cash flow used in operating activities (SEK 000')	-116,559	-85,527
Equity (SEK 000')	307,834	236,056
Liquid assets incl. marketable securities (SEK 000')	261,599	184,686

CASH FLOW

Cash flow from operating activities before changes in working capital in FY-2021 amounted to SEK -130.0 million (SEK -84.8 million). The increased outflow y/y primarily reflects the higher level of R&D activities and manufacturing preparations in the current period. Changes in working capital in the current period totaled an inflow of SEK 13.5 million (outflow of SEK 0.7 million). The inflow in the current period primarily reflects increase in accrued expenses and accounts payable as well as decrease in advance payments to major suppliers.

Cash flow from investing activities in FY-2021 totaled SEK -38 thousand (inflow of SEK 76.0 million). Cash flow from financing activities amounted to an inflow of SEK 184.9 million (inflow of SEK 92.7 million), which reflects net proceeds from the share issuance in the spring 2021.

FINANCIAL POSITION

On the closing date, equity amounted to SEK 307.8 million, compared with SEK 236.1 million per 31 December 2020. The increase since 31 December 2020 reflects the issuance of new shares in the spring 2021, which outweighed the net losses incurred in 2021.

Liquid assets on the closing date amounted to SEK 261.6 million, compared to SEK 184.7 million per 31 December 2020, which also is an effect of the share issuance in the spring 2021.

Other information

Incentive programs

Ascelia Pharma has one employee option program that includes members of the management team and share-saving programs for employees. If the terms of the option programs 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 2020 on pages 63-64.

In case all incentive programs are exercised in full, a total of 2.0 million common shares will be issued (including hedge for future payment of social security charges). This corresponds to an aggregate dilution of approximately 5.5% of Ascelia Pharma's share capital after full dilution (calculated on the number of 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 Covid-19 and foreign exchange exposure.

With respect to Covid-19, the outbreak influences many sectors and companies, including the healthcare industry and Ascelia Pharma. For most biotech companies in clinical development, the main operational impact is potential delays in clinical trials as sites reduce or stop of patient enrolment. Patients could also be hesitant to visit clinical sites for the tests. In addition to the operational impact, the funding environment is negatively influenced by Covid-19 pandemic, causing constraints to capital access.

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 2020 on pages 27-32.

No significant events after the end of the reporting period

Auditor's review

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

Annual General Meeting (AGM) 2022

The AGM of Ascelia Pharma AB (publ) will be held on 5 May, 2022. Shareholders wishing to have a matter discussed at the AGM should send their suggestion by e-mail to: kb@ascelia.com or by mail to:
ASCELIA PHARMA AB
Hyllie Boulevard 34
SE-215 32 Malmö

Suggestions to the AGM must reach the Board of Directors at least seven weeks prior to the meeting (17 March) or in good time for the matter, if necessary, to be included in the notice to the AGM.

Dividend

In accordance with Ascelia Pharma's dividend policy, no dividend is proposed and available financial resources is reinvested in the business to finance the company's long-term strategy. The Board of Directors' intention is not to propose a dividend to shareholders before the company is able to generate a longterm sustainable profitability and a long-term sustainable positive cash flow.

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.

Magnus Corfitzen
CEO

Malmö, 10 February 2022
Ascelia Pharma AB (publ)

Consolidated Income Statement

	Q4 (Oct-Dec)		Full Year (Jan-Dec)	
*SEK in thousands (unless otherwise stated)**	2021	2020	2021	2020
Net sales	–	–	–	–
Gross profit/loss	**–**	**–**	**–**	**–**
Administrative costs	-5,328	-4,860	-17,122	-18,295
Research and development costs	-27,900	-21,970	-107,574	-64,764
Commercial preparation costs	-6,055	-1,014	-13,201	-10,228
Other operating income	123	237	317	756
Other operating costs	–	-273	-368	-897
Operating result	**-39,160**	**-27,880**	**-137,948**	**-93,428**
Finance income	3,051	114	10,439	11,800
Finance costs	-24	-8,332	-2,014	-18,119
Net financial items	**3,027**	**-8,218**	**8,425**	**-6,319**
Loss before tax	**-36,133**	**-36,098**	**-129,523**	**-99,747**
Tax	1,060	247	3,620	1,050
Loss for the period	**-35,073**	**-35,851**	**-125,903**	**-98,697**
Attributable to:				
Owners of the Parent Company	-35,073	-35,851	-125,903	-98,697
Non-controlling interest	–	–	–	–
Earnings per share				
Before and after dilution (SEK)	-1.01	-1.25	-3.82	-3.76

Consolidated Statement of Comprehensive Income

	Q4 (Oct-Dec)		Full Year (Jan-Dec)	
*SEK in thousands (unless otherwise stated)**	2021	2020	2021	2020
Profit/loss for the period	**-35,073**	**-35,851**	**-125,903**	**-98,697**
Other comprehensive income				
Currency translation of subsidiaries**	66	-49	135	-5
Other comprehensive income for the period	**66**	**-49**	**135**	**-5**
Total comprehensive income for the period	**-35,007**	**-35,900**	**-125,768**	**-98,702**

* 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**	31 Dec 2021	31 Dec 2020
ASSETS		
Intangible assets	57,063	57,061
Tangible assets		
Equipment	238	301
Right-of-use assets	1,581	1,688
Total fixed assets	**58,882**	**59,050**
Current assets		
Advance payments to suppliers	6,175	8,279
Current receivables		
Income tax receivables	4,395	1,748
Other receivables	1,165	857
Prepaid expenses and accrued income	1,277	754
Cash and bank balances	261,599	184,686
Total current assets	**274,611**	**196,324**
Total assets	**333,493**	**255,374**
EQUITY		
Share capital	34,576	28,697
Other contributed capital	678,831	493,731
Reserve of exchange differences on translation	135	119
Loss brought forward (incl. net profit/loss for the period)	-405,708	-286,491
Equity attributable to Parent Company shareholders	**307,834**	**236,056**
Total equity	**307,834**	**236,056**
LIABILITIES		
Long-term liabilities		
Leasing	553	956
Total long-term liabilities	**553**	**956**
Current liabilities		
Accounts payable	6,147	3,884
Tax payable	5	–
Other liabilities	1,509	672
Current lease liabilites	1,102	822
Accrued expenses and deferred income	16,343	12,984
Total current liabilities	**25,106**	**18,362**
Total liabilities	**25,659**	**19,318**
Total equity and liabilities	**333,493**	**255,374**

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

Consolidated Statements of Changes in Equity

	Full Year (Jan-Dec)	
*SEK in thousands**	2021	2020
Equity at start of the period	**236,056**	**237,062**
Comprehensive income		
Profit/loss for the period	-125,903	-98,697
Other comprehensive income	135	-5
Total comprehensive income	**-125,768**	**-98,702**
Transactions with shareholders		
New issue of C-shares	398	511
Repurchase of own shares C-shares	-398	-511
New share issue with cach contribution	200,000	98,653
Issurance expenses	-13,271	-5,286
Redemption of warrants	3,853	–
Share based remuneration to employees	6,964	4,329
Total transactions with shareholders	**197,546**	**97,696**
Equity at end of the period	**307,834**	**236,056**

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

Consolidated Cash Flow Statement

	Q4 (Oct-Dec)		Full Year (Jan-Dec)	
*SEK in thousands**	**2021**	**2020**	**2021**	**2020**
Operating activities				
Operating result	-39,160	-27,880	-137,948	-93,428
Expensed share based remuneration	1,790	4,886	5,919	7,873
Adjustment for items not included in cash flow	321	273	1,045	870
Interest received	10	27	10	27
Interest paid	-19	-21	-77	-87
Income tax paid/received	1,559	201	1,020	-89
Cash flow from operating activities before changes in working capital	**-35,499**	**-22,514**	**-130,031**	**-84,834**
Cash flow from changes in working capital				
Increase (-)/Decrease (+) of advance payments	1,240	-4,263	2,110	-4,263
Increase (-)/Decrease (+) of operating receivables	81	1,045	-900	1,696
Increase (+)/Decrease (-) of accounts payable	-2,119	-942	2,258	-1,220
Increase (+)/Decrease (-) of other liabilities	4,051	-879	10,004	3,094
Change in working capital	3,253	-5,039	13,472	-693
Cash flow used in operating activities	**-32,246**	**-27,553**	**-116,559**	**-85,527**
Investing activities				
Investment in equipment	–	–	-38	-397
Marketable securities/Other investments, net	–	69,388	–	76,388
Cash flow from investing activities	**–**	**69,388**	**-38**	**75,991**
Financing activities				
Issuance proceeds	–	–	200,000	98,653
Issuance costs	–	–	-13,271	-5,285
Redemption of warrants net	–	–	-914	–
Amortisation of loan (leasing)	-273	-180	-944	-643
Cash flow from financing activities	**-273**	**-180**	**184,871**	**92,725**
Cash flow for the period	**-32,519**	**41,655**	**68,274**	**83,189**
Cash flow for the period	-32,519	41,655	68,274	83,189
Cash and cash equivalents at start of period	291,029	151,438	184,686	108,516
Exchange differences in cash and cash equivalents	3,089	-8,407	8,639	-7,019
Cash and cash equivalents at end of period	**261,599**	**184,686**	**261,599**	**184,686**

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

Parent Company – Income Statement

	Q4 (Oct-Dec)		Full Year (Jan-Dec)	
*SEK in thousands**	2021	2020	2021	2020
Net sales	1 197	383	5 495	768
Gross profit/loss	**1 197**	**383**	**5 495**	**768**
Administrative costs	-5 189	-4 495	-16 901	-17 882
Research and development costs	-23 819	-21 326	-94 306	-60 573
Commercial preparation costs	-6 061	-1 005	-13 223	-10 220
Other operating income	105	284	241	753
Other operating costs	–	-275	-344	-830
Operating result	**-33 767**	**-26 434**	**-119 038**	**-87 984**
Finance income	2 731	114	9 830	11 800
Finance costs	-4	-8 257	-1 940	-18 043
Result from other long-term receivables	679	-251	1 860	157
Net financial costs	**3 406**	**-8 394**	**9 750**	**-6 086**
Loss before tax	-30 361	-34 828	-109 288	-94 070
Group contribution	–	–	–	–
Tax	–	–	–	–
Loss for the period	**-30 361**	**-34 828**	**-109 288**	**-94 070**

Parent Company – Statement of Comprehensive Income

	Q4 (Oct-Dec)		Full Year (Jan-Dec)	
*SEK in thousands**	2021	2020	2021	2020
Loss for the period	**-30,361**	**-34,828**	**-109,288**	**-94,070**
Other comprehensive income	–	–	–	–
Other comprehensive income for the period	**–**	**–**	**–**	**–**
Total comprehensive income for the period	**-30,361**	**-34,828**	**-109,288**	**-94,070**

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

Parent Company – Balance Sheet

*SEK in thousands**	31 Dec 2021	31 Dec 2020
ASSETS		
Tangible assets		
Equipment	238	301
Right-of-use assets	–	–
Financial assets		
Shares in affiliated companies	58,068	58,068
Other long-term receivables	36,620	9,449
Total fixed assets	**94,926**	**67,818**
Current assets		
Advance payments to suppliers	5,323	8,279
Current receivables		
Receivables from affiliated companies	6,971	1,346
Income tax receivables	739	623
Other receivables	656	616
Prepaid expenses and accrued income	1,183	706
Cash and bank balances	246,311	182,498
Total current assets	**261,183**	**194,068**
Total assets	**356,109**	**261,886**
EQUITY		
Restricted equity		
Share capital	34,576	28,697
Non-restricted equity		
Other contributed capital	678,831	493,731
Loss brought forward	-271,295	-183,792
Loss for the period	-109,288	-94,070
Total equity	**332,824**	**244,566**
LIABILITIES		
Long-term liabilities		
Leasing	–	–
Total long-term liabilities	**–**	**–**
Current liabilities		
Accounts payable	5,700	3,733
Other liabilities	1,509	673
Accrued expenses and deferred income	16,076	12,914
Total current liabilities	**23,285**	**17,320**
Total liabilities	**23,285**	**17,320**
Total equity and liabilities	**356,109**	**261,886**

* 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 recognised 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 31 December 2021, the owners of Solural ApS collectively owned 2.0% 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 commercialisation occurs through a sale or a outlicensing and SEK 12 million if commercialisation is carried out by Oncoral Pharma ApS or Ascelia Pharma AB itself.

Regardless the commercialisation 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 2021, services for a value of around SEK 3.7 million 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 recognised 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 recognised 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 recognised.

Capitalisation of development expenses

In 2021, the criteria for classifying R&D costs as an asset according to IAS 38 has not been met (capitalisation 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.

The total recognised costs for both option programs including social security charges in 2021 were SEK 2.7 milion.

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 recognised costs for the share saving programs including social security charges in 2021 were SEK 5.4 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

	Q4 (Oct-Dec)		Full Year (Jan-Dec)	
*SEK in thousands**	2021	2020	2021	2020
R&D costs	-27,900	-21,970	-107,574	-64,764
Administration costs	-5,328	-4,860	-17,122	-18,295
Commercial preparation costs	-6,055	-1,014	-13,201	-10,228
Other operating costs	–	-273	-368	-897
Total operating costs	**-39,283**	**-28,117**	**-138,265**	**-94,184**
R&D costs/Operating costs (%)	**71%**	**78%**	**78%**	**69%**

Financial calendar

Annual General Meeting 2022:	5 May 2022
Interim report Q1 2022 (Jan-Mar):	11 May 2022
Half-year report H1 2022 (Jan-Jun):	18 August 2022
Interim report 9M 2021 (Jan-Sep):	4 November 2022
Full-year report 2022 (Jan-Dec):	10 February 2023

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