ASCELIA PHARMA

Advancing Orphan Oncology

FULL-YEAR 2020 REPORT

January – December 2020

Mangoral shows high diagnostic value in new study

SIGNIFICANT EVENTS IN Q4 2020

- Upgraded estimate of the addressable market for Mangoral to $500-600 million annually (previously $350-500 million)
- New study showing that Mangoral's lesion vizualisation is as effective as gadolinium
- US patent for second-generation Mangoral

SIGNIFICANT EVENTS AFTER THE PERIOD

- Presentation of clinical development plan for Oncoral

"The strong results from the re-read study demonstrates the value Mangoral can provide to patients"

KEY RATIOS GROUP

	Q4 (Oct-Dec)		FY (Jan-Dec)	
	2020	2019	**2020**	2019
OPERATING RESULT (SEKm)	**-27.9**	-22.9	**-93.4**	-63.0
EARNINGS PER SHARE (SEK)	**-1.25**	-1.16	**-3.76**	-3.02
CASH FLOW FROM OPERATIONS (SEKm)	**-27.6**	-16.8	**-85.5**	-54.3
LIQUID ASSETS INCL. MARKETABLE SECURITIES (SEKm)	**184.7**	184.2	**184.7**	184.2

CEO COMMENTS

In 2020, despite the ongoing Covid-19 pandemic, we continued to advance the clinical development program and commercial preparations of our novel Phase 3 contrast agent Mangoral. In the fourth quarter alone, we:

- Upgraded our estimate of the addressable market for Mangoral to $500-600 million annually
- Showed in a study that Mangoral is as effective as gadolinium contrast agent for visualization of focal liver lesions
- Obtained US patent for second generation Mangoral

The further clinical development of Mangoral is of course central to the growth of Ascelia Pharma, and early in the year, we enrolled the first patient in the global pivotal Phase 3 study SPARKLE. We also started the recruitment of patients for the hepatic impairment study, where the results could enable the use of Mangoral also in patients with an impaired liver function.

Re-study confirms Mangoral's efficacy. In December, we announced top line results from a re-read study demonstrating that Mangoral is as effective as the liver-specific gadolinium-based contrast agent Multihance for visualization of focal liver lesions. In the study, three independent radiologists reviewed all images, which also compared Mangoral to liver MRI without a contrast agent – the standard of care in Mangoral's target population. The result from this comparison clearly showed that Mangoral provides improved lesion detection and lesion visualization, and the endpoint of this evaluation is similar to the primary endpoint in SPARKLE.

We are very pleased with the results of this blinded re-read study as it provides a robust evidence of the diagnostic value that Mangoral offers and the clear unmet medical need it fills. The re-read study further strengthens the data package to the regulatory authorities.

Raising market estimate. At our Capital Markets Day in October, we raised our estimate of the addressable market for Mangoral to $500-600 million annually in key markets (previously $350-500 million). The upgraded estimate is primarily driven by procedure volume that we have identified by analyzing new real-world data from actual medical procedures as well as further insights from payers and reimbursement experts in key markets.

New patent to 2040. In December, we received a new US patent covering a second-generation formulation of Mangoral. The new patent further improves the unique value proposition of the Mangoral franchise and provides patent protection until year 2040 in the US. The new patent will add significant value and is a result of our focus on developing novel and better medicinal products for patients in need. We expect the patent to be obtained in other countries over the next few years and this will further expand the global value of the Mangoral franchise.

Oncoral Phase 2. We continue to advance Oncoral with preparations for Phase 2 clinical study. Oncoral is our oral chemotherapy tablet formulation of irinotecan for the treatment of gastric cancer. With Oncoral, we have the opportunity to develop a novel oral chemotherapy with the potential to offer both efficacy and safety benefits to cancer patients. The planned Phase 2 study, developed together with our distinguished Advisory Board, is expected to commence in H2 2021. For subsequent development, there is potential for expansion into other solid tumor indications where irinotecan has also proved efficacious.

Fully financed Phase 3 program. We continue to have a solid financial position, and at the end of the year, we had SEK 185 million in liquid assets. This cash position will take us into 2022 and consequently beyond the clinical milestone with topline Phase 3 data from SPARKLE, expected in H2-2021.

Covid-19. We are carefully monitoring the development of the pandemic. We take every precaution to ensure both that our organization and those working on our trials are safe and well, and that our clinical programs continue according to plan.

Looking ahead. Our focus is on the ongoing SPARKLE study, the preparations to make Mangoral available to patients in need, and to initiate the clinical Phase 2 for Oncoral. We work constantly to create stakeholder value, and the development in 2020 underlines the progress we have made.

Magnus Corfitzen
CEO

ASCELIA PHARMA

Improving the life of people with rare oncology-related conditions

Ascelia Pharma in short

Ascelia Pharma is a biotech company focused on orphan oncology treatments. We develop and commercialize novel drugs that address unmet medical needs and have a clear development and market pathway. Two drug candidates – Mangoral and Oncoral – are in clinical development. Global headquarters is in Malmö, Sweden.

Mangoral is a novel contrast agent for MR-scans and is currently in ongoing Phase 3 clinical studies. Mangoral is developed to improve the visualisation of focal liver lesions (incl. liver metastases) in patient with impaired kidneys that are at risk of serious side effects from the currently available class of gadolinium-based contrast agents.

Oncoral is a novel daily irinotecan chemotherapy tablet initially developed for the treatment of gastric cancer. Oncoral is ready to start Phase 2.

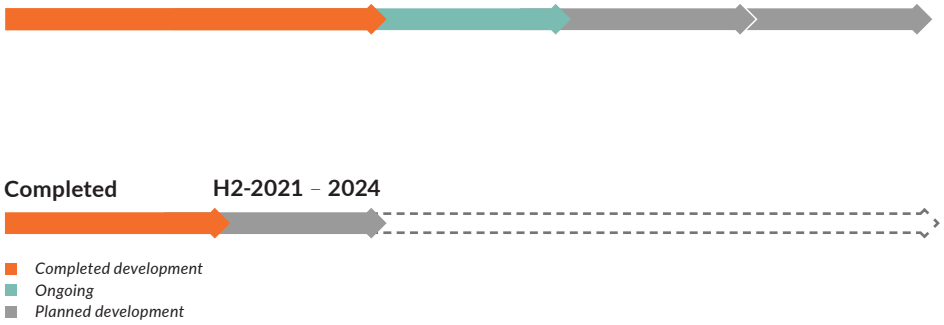
Strategy

Identify, acquire, develop and monetise drugs with:

- Unmet medical need
- Niche/orphan indication
- Known mode of action
- De-risked development plan
- Potential for global leadership

Ascelia Pharma is listed on Nasdaq Stockholm (ticker: ACE). For more information, please visit www.ascelia.com

Candidates	Indication	Phase 1	Phase 2	Phase 3	Filing	Market launch
Mangoral® • Novel imaging drug with Orphan Drug Designation • No competing products • $500-600 million adressable market • Ongoing Phase 3 clinical program	**Visualisation of Focal Liver Lesions** Liver metastases Primary liver cancer Benign lesions	Completed		2020 – H2-2021	H1-2022	Q4 2022 – H1-2023
Oncoral • Oral daily dosing of irinotecan chemotherapy • Potential for better patient outcomes and safety • Ready to start Phase 2 in gastric cancer	**Treatment of Gastric Cancer** Treatment of other solid cancers (label expansion)	Completed	H2-2021 – 2024			



Note: Timelines incorporate the currently assessed impact from Covid-19. An extended Covid-19 situation may further affect timelines.

MANGORAL®

Liver MRI contrast contrast agent in the final clinical Phase

Detecting liver metastases early is essential for survival

Ascelia Pharma's lead drug candidate, Mangoral, is a contrast agent used in Magnetic Resonance Imaging (MRI) to improve the visualization of focal liver lesions (liver metastases). 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 Mangoral works

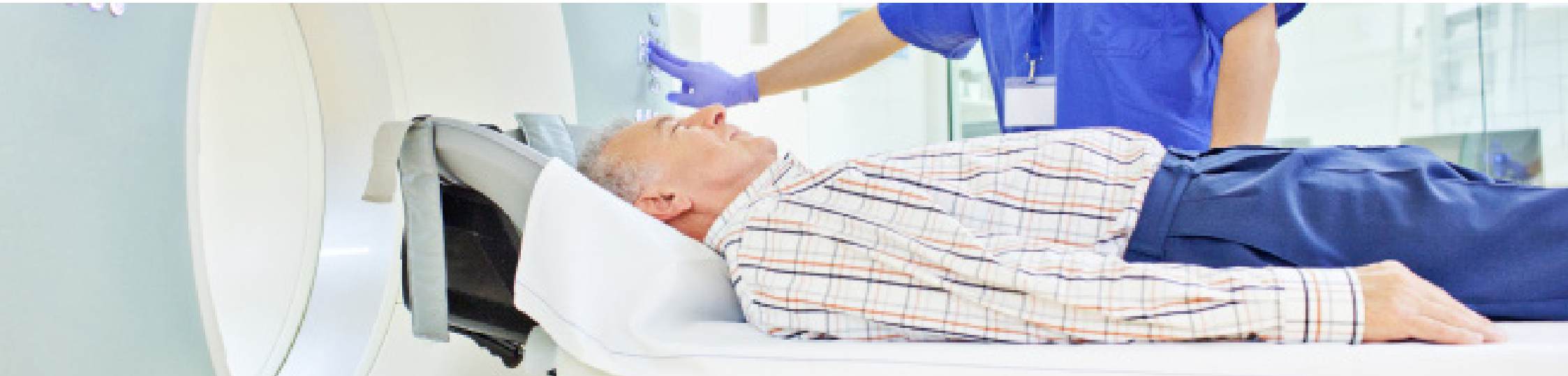
Mangoral is an orally administrated contrast agent used in MRI of the liver. It is based on the chemical element manganese, which is a natural trace element in the body. Mangoral also contains L-Alanine and Vitamin D3 to increase the absorption of manganese from the small intestine into the portal liver 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 Mangoral, liver metastases are consequently easier to identify due to this contrast effect.

Latest development

In December, a new US patent was granted for second-generation formulation of Mangoral. With the new patent, the protection rights are further strengthened until year 2040 in the US.

In December, results was announced from a blinded-read study where Mangoral was compared against a gadolinium-based liver specific contrast agent. The results showed that Mangoral was as effective as the gadolinium agent for visualization of focal liver lesions. The results also showed that Mangoral-enhanced MRI provides improved diagnostic efficacy compared to MRI without a contrast agent.

In October 2020, the estimate of the addressable market in the US, EU and Japan for Mangoral was increased to $500-600 million (previously $350-500M). Ascelia Pharma sees a strong case for building in-house commercial operations in the US.



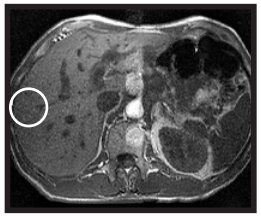
Patients referred for liver MRI scan

TODAY

NORMAL KIDNEY
Gadolinium imaging drug

POOR KIDNEY FUNCTION
NO imaging drug

No liver metastasis visible

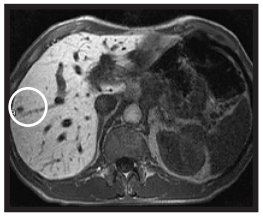


TOMORROW

NORMAL KIDNEY
Gadolinium imaging drug

POOR KIDNEY FUNCTION
MANGORAL® Imaging drug

Liver metastasis visible with Mangoral



Mangoral 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 Mangoral is patients with impaired kidney function who, due to the risk of serious, and potentially fatal, side effects cannot use today's heavy-metal gadolinium-based contrast agents. The conducted clinical trials show that Mangoral is a safe and effective contrast agent and offers a significantly better alternative than unenhanced MRI (i.e. MRI without contrast agent), which is the standard of care today for Mangoral's patient population. Consequently, Mangoral fills a significant unmet medical need to improve the diagnosis, and subsequently, the treatment of liver metastases.

The immediate addressable market for Mangoral is estimated at $500-600 million yearly and Mangoral is expected to be the only product on the market in its segment.

Mangoral has Orphan Drug Designation

Mangoral 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 ordinary drugs.

MANGORAL – PHASE 3 PIVOTAL STUDY (SPARKLE)

The ongoing pivotal Phase 3 study SPARKLE is a global multicentre study in up to 200 patients. Topline results from the study are expected in H2-2021. 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 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.

Mangoral'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 + Mangoral 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 Mangoral 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

ONCORAL

Chemotherapy treatment in tablet form, ready for Phase 2

A daily tablet chemotherapy formulation initially developed to treat gastric cancer

Oncoral is a novel daily irinotecan chemotherapy in development. Irinotecan chemotherapy has an established potent anti-tumor effect – even in difficult to treat cancers. Oncoral is a daily irinotecan tablet with the potential to offer better patient outcomes with improved safety following the daily dosing at home compared to intravenous high-dose infusions at the hospital. The market for gastric cancer is growing rapidly with an estimated yearly growth rate towards year 2022 of 14% (source GlobalData) and the market is expected to surpass USD 4 billion by 2022.

Benefits to both patients and healthcare systems

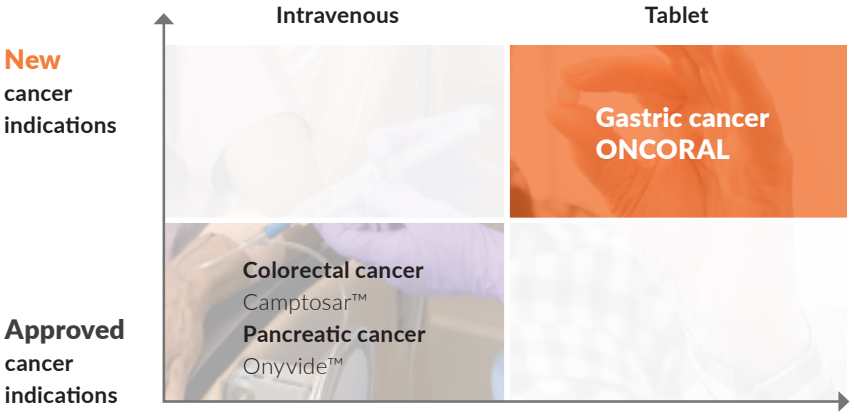
Treatment with currently available intravenous (IV) irinotecan infusions is often a trade-off between efficacy and tolerability for the patient, leading to sub-optimal outcomes for many cancer types, and toxicity related dose-reductions or discontinuations.

Oncoral is a daily irinotecan tablet with the potential to offer better patient outcomes with improved safety. Daily dosing can potentially improve efficacy driven by a more favorable, dosing-related, pharmacokinetic and pharmacodynamic profile. A continuous, low dose regimen also has the potential to reduce the severity of adverse events and infections.

Latest development

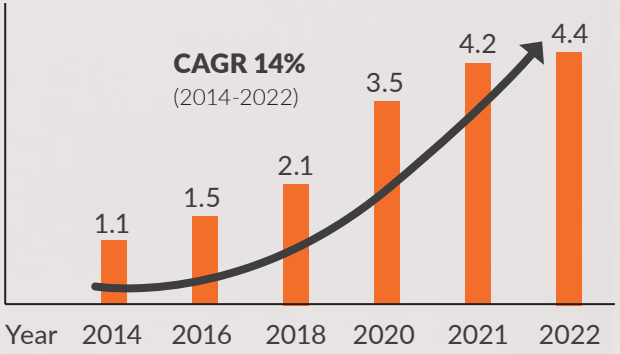
In January 2021, the development plan for Oncoral was presented. The planned Phase 2 study is expected to commence in H2 2021 (provided additional financing is obtained). The study will address metastatic gastric cancer, which is a serious disease with large unmet medical need for novel safe and effective therapies.

Oncoral - a novel formulation of irinotecan



- Significant unmet medical need in gastric cancer
- Gastric cancer is an orphan indication
- Irinotecan approved in Japan in gastric cancer
- Strong interest from oncologists

Global gastric cancer market (USDbn)



(Source GlobalData)

Preparing for Phase 2 studies

The Phase 2 study will be a randomized controlled multicenter study of Oncoral added to Standard of Care, compared to Standard of Care alone. The primary endpoint will be progression-free survival, which is standard for an oncology Phase 2 study. Secondary endpoints will include response rate, overall survival, pharmacokinetics, safety, and tolerability.

The development of Oncoral is supported by a Scientific Advisory Board of leading oncologists, who all share the company's view that Oncoral, a daily tablet formulation of irinotecan, would be a valuable additional treatment option for cancer patients, especially in later disease stages.

For subsequent development, there is potential for label expansion into other solid tumor indications where irinotecan has also proved efficacious.

Study start is expected in H2-2021 (completion of Oncoral's Phase 2 study will, however, require additional financing).

Advantages of oral tablet chemotherapy vs. intravenous

Patients

- Tablets can be swallowed at home instead of intravenous administrationat the hospital
- Sense of control over treatment and less interference with daily activities
- No risk of medical complications and pain from medical intravenous lines
- Less travel to hospital/clinic
- Enables fine tuning of individual dosing

Clinicians

- Better utilisation of hospital stay for patient-centered care
- Intravenous facilities can be prioritised for targeted therapies instead
- Less risk of adverse effects from intravenous chemotherapy (e.g. hospital-acquired infection or leakage of infused cytostatic from vasculature to surrounding tissue)

Payers

- All-oral chemotherapeutic regimens reduces the need to spend hospital resources on more expensive intravenous administration
- Less risk of hospital-acquired infections (which leads to a need for additional treatment), leading to reduced costs
- Less need for handling of side effects mainly associated with intravenous administration of chemotherapy, leading to overall reduced costs

FINANCIAL OVERVIEW: Q4-2020 (OCT–DEC 2020)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales in Q4 (Oct-Dec 2020) amounted to SEK 0 (SEK 0). Ascelia Pharma does not expect to recognise revenue before products have been launched on the market. Other operating income totalled SEK 237 thousand (SEK 115 thousand).

Research and development costs (R&D)

R&D costs for the Group in Q4 were SEK 22.0 million (SEK 17.3 million). The cost increase of SEK 4.7 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 Mangoral's Phase 3 clinical study as well as manufacturing preparations and regulatory work.

Commercial preparation costs

During the fourth quarter, costs for the commercial preparations of amounted to SEK 1.0 million (SEK 0). The costs increase compared with Q4-2019 reflects commercial preparations towards launching of Mangoral to the market.

Administration costs

Administration costs for the Group in Q4 amounted to SEK 4.9 million (SEK 5.2 million), which corresponds to a minor cost decrease y/y of 6%.

Operating results (EBIT)

The operating result in Q4 amounted to SEK -27.9 million (SEK -22.9 million). The increased loss reflects the overall higher level of R&D activities and commercial preparations in Q4-2020.

Net Profit/Loss for the period

The Group's net loss in Q4 amounted to SEK -35.9 million (SEK -27.1 million). In the current quarter, net finance costs increased and amounted to SEK 8.2 million due to weakening of EUR and USD vs. SEK. The weakening of USD and EUR translated into a decrease in the value of bank deposits in EUR and USD (a significant part of bank deposit is held in EUR and USD to match upcoming cash outflow in these currencies). The net loss corresponds to a loss per share, before and after dilution, of SEK -1.25 (SEK -1.16).

Financials key ratios for the Group	Q4 (October-December)	
	2020	2019
Operating result (SEK 000')	-27,880	-22,940
Net result (SEK 000')	-35,851	-27,133
Earnings per share (SEK)	-1.25	-1.16
Weighted avg. number of shares	28,697,234	23,488,908
R&D costs/operating costs (%)	78%	75%
Cash flow used in operating activities (SEK 000')	-27,553	-16,791
Equity (SEK 000')	236,056	237,062
Liquid assets incl. marketable securities (SEK 000')	184,686	184,227

CASH FLOW

Cash flow from operating activities before changes in working capital in Q4 amounted to SEK -22.5 million (SEK -22.3 million). The increased outflow primarily reflects the higher level of R&D activities and commercial preparations in the current quarter. Changes in working capital in the current quarter totalled an outflow of SEK 5.0 million (inflow of SEK 5.5 million). The outflow in the current quarter primarily reflects the increase in advance payments to major suppliers.

Cash flow from investing activities in Q4 amounted to an inflow of SEK 69.4 million (SEK 0), which reflects divestment of marketable securities.

Cash flow from financing activities totalled SEK 0.2 million (SEK 0) and reflects the amortisation of loans (leasing of cars and office).

FINANCIAL POSITION

On the closing date, equity amounted to SEK 236.1 million, compared with SEK 237.1 million per 31 December 2019. The slight decrease since 31 December 2019 reflects the net losses incurred, which outweighed the net proceeds from the share issuance received in the beginning of July 2020.

Liquid assets on the closing date amounted to SEK 184.7 million, which is largely unchanged compared to SEK 184.2 million per 31 December 2019. The cash outflow in 2020 from operations was counterbalanced by net proceeds from the aforementioned share issurance.

FINANCIAL OVERVIEW: FY-2020 (JAN–DEC 2020)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales in FY-2020 (Jan-Dec) amounted to SEK 0 (SEK 0). Ascelia Pharma does not expect to recognise revenue before products have been launched on the market. Other operating income totalled SEK 756 thousand (SEK 435 thousand).

Research and development costs (R&D)

R&D costs for the Group in FY-2020 were SEK 64.8 million (SEK 43.5 million). The cost increase of SEK 21.3 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 Mangoral's Phase 3 clinical study as well as manufacturing preparations and regulatory work.

Commercial preparation costs

In FY-2020, costs for the commercial preparations amounted to SEK 10.2 million (SEK 0). The costs increase compared with 2019 reflects commercial preparations towards launching of Mangoral to the market.

Administration costs

Administration costs for the Group in FY-2020 amounted to SEK 18.3 million (SEK 18.0 million), which corresponds to a y/y increase of 2%. Higher running costs for the organisation in FY-2020 were counterbalanced by IPO preparations costs that weighed on the results in 2019 (the IPO was in March 2019).

Operating results (EBIT)

The operating result in FY-2020 amounted to SEK -93.4 million (SEK -63.0 million). The increased loss reflects the overall higher level of R&D activities and commercial preparations in 2020.

Net Profit/Loss for the period

The Group's net loss in FY-2020 amounted to SEK -98.7 million (SEK -66.0 million). In FY-2020, net finance costs increased and amounted to SEK 6.3 million due to weakening of EUR and USD against SEK, especially in Q4. This translated into a decrease in the value of bank deposits in EUR and USD since a significant part of bank deposit is in EUR and USD to match upcoming cash outflow in the currencies. The net loss corresponds to a loss per share, before and after dilution, of SEK -3.76 (SEK -3.02).

Financials key ratios for the Group	FY (January-December)	
	2020	2019
Operating result (SEK 000')	-93,428	-63,023
Net result (SEK 000')	-98,697	-66,036
Earnings per share (SEK)	-3.76	-3.02
Weighted avg. number of shares	26,270,854	21,835,326
R&D costs/operating costs (%)	69%	69%
Cash flow used in operating activities (SEK 000')	-85,527	-54,300
Equity (SEK 000')	236,056	237,062
Liquid assets incl. marketable securities (SEK 000')	184,686	184,227

CASH FLOW

Cash flow from operating activities before changes in working capital in FY-2020 amounted to SEK -84.8 million (SEK -59.7 million). The increased outflow primarily reflects the higher level of R&D activities and commercial preparations in the current period. Changes in working capital in the current period totalled an outflow of SEK 0.7 million (inflow of SEK 5.4 million).

Cash flow from investing activities amounted to an inflow of SEK 76.0 million and reflects divestment of marketable securities (SEK 75.0 million outflow in 2019 from investment in marketable securities).

Cash flow from financing activities totalled SEK 92.7 million and reflects the net proceeds from the new share issuance received in the beginning of July 2020. In 2019, there was an inflow of SEK 200.2 million from net proceeds received in the IPO.

FINANCIAL POSITION

On the closing date, equity amounted to SEK 236.1 million, compared with SEK 237.1 million per 31 December 2019. The slight decrease since 31 December 2019 reflects the net losses incurred, which outweighed the net proceeds from the share issuance received in the beginning of July 2020.

Liquid assets on the closing date amounted to SEK 184.7 million, which is largely unchanged compared to SEK 184.2 million per 31 December 2019. The cash outflow in 2020 from operations was counterbalanced by net proceeds from the aforementioned share issurance.

Other information

Incentive programs

Ascelia Pharma has two active employee options programs that include members of the management team and a share-saving programme for employees. If the terms of the option programs are met at the time for utilisation, the management team has the right to purchase shares at a pre-determined price. For the share-saving programme, employees are entitled to receive matching and performance shares according to terms of the programme.

The Group recognises share-based remuneration, which personnel may receive. A personnel cost is recognised, 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 programmes can be found in the Annual Report 2019 on pages 55-56.

In case all outstanding incentive programmes are exercised in full, a total of 2.2 million shares will be issued (including hedge for future payment of social security charges). This corresponds to an aggregate dilution of approximately 7.2% of Ascelia Pharma's share capital after full dilution (calculated on the number of shares that will be added upon full exercise of all outstanding incentive programmes.

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 potient 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 2019 on pages 27-29.

Significant events after the end of the reporting period

In January 2021, the development plan for Oncoral was announced. The planned Phase 2 study, which is expected to commence in H2 2021 provided additional financing is obtained, will address metastatic gastric cancer.

Auditor's review

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

Annual General Meeting (AGM) 2021

The AGM of Ascelia Pharma AB (publ) will be held on 5 May, 2021 at 2.00pm in Malmö, Sweden. 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, can 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 long-term 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, 16 February 2021
Ascelia Pharma AB (publ)

Consolidated Income Statement

	Q4 (Oct-Dec)		Full Year (Jan-Dec)	
SEK in thousands (unless otherwise stated)*	2020	2019	2020	2019
Net sales	–	–	–	–
Gross profit/loss	**–**	**–**	**–**	**–**
Administrative costs	-4,860	-5,178	-18,295	-17,986
Research and development costs	-21,970	-17,339	-64,764	-43,475
Commercial preparation costs	-1,014	–	-10,228	–
Other operating income	237	115	756	435
Other operating costs	-273	-539	-897	-1,997
Operating result	**-27,880**	**-22,941**	**-93,428**	**-63,023**
Finance income	114	348	11,800	1,583
Finance costs	-8,332	-4,611	-18,119	-4,891
Net financial items	**-8,218**	**-4,263**	**-6,319**	**-3,308**
Loss before tax	**-36,098**	**-27,204**	**-99,747**	**-66,331**
Tax	247	70	1,050	295
Loss for the period	**-35,851**	**-27,134**	**-98,697**	**-66,036**
Attributable to:				
Owners of the Parent Company	-35,851	-27,134	-98,697	-66,036
Non-controlling interest	–	–	–	–
Earnings per share				
Before and after dilution (SEK)	-1.25	-1.16	-3.76	-3.02

Consolidated Statement of Comprehensive Income

	Q4 (Oct-Dec)		Full Year (Jan-Dec)	
SEK in thousands (unless otherwise stated)*	2020	2019	2020	2019
Profit/loss for the period	**-35,851**	**-27,134**	**-98,697**	**-66,036**
Other comprehensive income				
Currency translation of subsidiaries**	-49	78	-5	93
Other comprehensive income for the period	**-49**	**78**	**-5**	**93**
Total comprehensive income for the period	**-35,900**	**-27,056**	**-98,702**	**-65,943**

* 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 2020	31 Dec 2019
ASSETS		
Intangible assets	57,061	57,065
Tangible assets		
Equipment	301	–
Right-of-use assets	1,688	212
Total fixed assets	**59,050**	**57,277**
Current assets		
Advance payments to suppliers	8,279	4,017
Current receivables		
Income tax receivables	1,748	736
Other receivables	857	686
Prepaid expenses and accrued income	754	3,283
Marketable securities	–	75,711
Cash and bank balances	184,686	108,516
Total current assets	**196,324**	**192,949**
Total assets	**255,374**	**250,226**
EQUITY		
Share capital	28,697	23,489
Other paid-in capital	493,731	405,061
Loss brought forward (incl. net profit/loss for the period)	-286,372	-191,488
Equity attributable to Parent Company shareholders	**236,056**	**237,062**
Total equity	**236,056**	**237,062**
LIABILITIES		
Long-term liabilities		
Leasing	956	96
Total long-term liabilities	**956**	**96**
Current liabilities		
Accounts payable	3,884	5,236
Tax payable	–	–
Other liabilities	1,494	1,138
Accrued expenses and deferred income	12,984	6,695
Total current liabilities	**18,362**	**13,069**
Total liabilities	**19,318**	**13,164**
Total equity and liabilities	**255,374**	**250,226**

* 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*	2020	2019
Equity at start of the period	**237,062**	**101,016**
Comprehensive income		
Profit/loss for the period	-98,697	-66,036
Other comprehensive income	-5	93
Total comprehensive income	**-98,702**	**-65,943**
Transactions with shareholders		
New issue of C-shares	511	–
Repurchase of own shares C-shares	-511	–
New issue of common shares	98,653	222,050
Issurance expenses	-5,286	-21,807
Share based remuneration to employees	4,329	1,746
Total transactions with shareholders	**97,696**	**201,989**
Equity at end of the period	**236,056**	**237,062**

* 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*	**2020**	**2019**	**2020**	**2019**
Operating activities				
Operating result	-27,880	-22,941	-93,428	-63,023
Expensed share based remuneration	4,886	1,437	7,873	3,297
Adjustment for items not included in cash flow	273	-756	870	37
Interest received	27	–	27	–
Interest paid	-21	–	-87	–
Income tax paid/received	201	–	-89	–
Cash flow from operating activities before changes in working capital	**-22,514**	**-22,260**	**-84,834**	**-59,689**
Cash flow from changes in working capital				
Increase (-)/Decrease (+) of advance payments	-4,263	2,622	-4,263	2,622
Increase (-)/Decrease (+) of operating receivables	1,045	-620	1,696	-6,406
Increase (+)/Decrease (-) of accounts payable	-942	1,544	-1,220	4,644
Increase (+)/Decrease (-) of other liabilities	-879	1,923	3,094	4,529
Change in working capital	-5,039	5,469	-693	5,389
Cash flow used in operating activities	**-27,553**	**-16,791**	**-85,527**	**-54,300**
Investing activities				
Investment in equipment	–	–	-397	–
Marketable securities/Other investments, net	69,388	–	76,388	-75,000
Cash flow from investing activities	**69,388**	**–**	**75,991**	**-75,000**
Financing activities				
Issuance proceeds	–	–	98,653	222,050
Issuance costs	–	–	-5,285	-21,808
Amortisation of loan (leasing)	-180	-30	-643	-60
Cash flow from financing activities	**-180**	**-30**	**92,725**	**200,182**
Cash flow for the period	**41,655**	**-16,821**	**83,189**	**70,882**
Cash flow for the period	41,655	-16,821	83,189	70,882
Cash and cash equivalents at start of period	151,438	129,814	108,516	42,111
Exchange rate differences in cash and cash equivalents	-8,407	-4,477	-7,019	-4,477
Cash and cash equivalents at end of period	**184,686**	**108,516**	**184,686**	**108,516**

* 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*	2020	2019	2020	2019
Net sales	383	191	768	365
Gross profit/loss	**383**	**191**	**768**	**365**
Administrative costs	-4,495	-5,126	-17,882	-17,784
Research and development costs	-21,326	-16,936	-60,573	-42,115
Commercial preparation costs	-1,005	–	-10,220	–
Other operating income	284	115	753	430
Other operating costs	-275	-527	-830	-1,985
Operating result	**-26,434**	**-22,283**	**-87,984**	**-61,088**
Finance income	114	422	11,800	1,962
Finance costs	-8,255	-4,610	-18,043	-4,935
Result from other long-term receivables	-251	–	157	–
Net financial costs	**-8,392**	**-4,188**	**-6,086**	**-2,973**
Loss before tax	-34,826	-26,471	-94,070	-64,062
Group contribution	–	–	–	-50
Tax	–	–	–	–
Loss for the period	**-34,826**	**-26,471**	**-94,070**	**-64,112**

Parent Company – Statement of Comprehensive Income

	Q4 (Oct-Dec)		Full Year (Jan-Dec)	
SEK in thousands*	2020	2019	2020	2019
Loss for the period	**-34,826**	**-26,471**	**-94,070**	**-64,112**
Other comprehensive income	–	–	–	–
Other comprehensive income for the period	**–**	**–**	**–**	**–**
Total comprehensive income for the period	**-34,826**	**-26,471**	**-94,070**	**-64,112**

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

Parent Company – Balance Sheet

SEK in thousands*	31 Dec 2020	31 Dec 2019
ASSETS		
Tangible assets		
Equipment	301	–
Right-of-use assets	–	212
Financial assets		
Shares in affiliated companies	58,068	58,068
Other long-term receivables	9,449	3,352
Total fixed assets	**67,818**	**61,632**
Current assets		
Advance payments to suppliers	8,279	4,017
Current receivables		
Receivables from affiliated companies	1,346	–
Income tax receivables	623	–
Other receivables	616	1,374
Prepaid expenses and accrued income	706	3,641
Marketable securities	–	75,711
Cash and bank balances	182,498	107,434
Total current assets	**194,068**	**192,177**
Total assets	**261,886**	**253,809**
EQUITY		
Restricted equity		
Share capital	28,697	23,489
Non-restricted equity		
Other paid-in capital	493,731	405,061
Loss brought forward	-183,792	-148,534
Loss for the period	-94,070	-39,077
Total equity	**244,566**	**240,939**
LIABILITIES		
Long-term liabilities		
Leasing	–	96
Total long-term liabilities	**–**	**96**
Current liabilities		
Accounts payable	3,733	5,104
Liabilities from affiliated companies	–	–
Other liabilities	673	1,163
Accrued expenses and deferred income	12,914	6,508
Total current liabilities	**17,320**	**12,774**
Total equity and liabilities	**261,886**	**253,809**

* 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 2020, the owners of Solural ApS collectively owned 2.5% 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 2020, services for a value of around SEK 1.8 million were acquired from Solural Pharma ApS.

In 2020, consulting services for a total value of around SEK 0.7 million was acquired from BGM Associates where Ascelia Pharma's board member Hans Maier is Managing Director.

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 2020, 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. The total recognised costs for the option programs including social security charges in 2020 were SEK 2.4 milion.

Share saving programs

Ascelia Pharma has implemented two long-term incentive programs for employees in the form of a performance-based share saving programme. The parameter, which have the largest impact on the value of the programme, is the publicly traded share price. The total recognised costs for the share saving programs including social security charges in 2020 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)	
	2020	2019	2020	2019
R&D costs (SEK 000')	-21,970	-17,339	-64,764	-43,475
Administration costs (SEK 000')	-4,860	-5,177	-18,295	-17,985
Commercial preparation costs (SEK 000')	-1,014	–	-10,228	–
Other operating costs (SEK 000')	-273	-539	-897	-1,997
Total operating costs (SEK 000')	**-28,117**	**-23,055**	**-94,184**	**-63,457**
R&D costs/Operating costs (%)	**78%**	**75%**	**69%**	**69%**

Financial calendar

Annual General Meeting 2021	5 May 2021
Interim report Q1-2021 (Jan-Mar):	12 May 2021
Half-year report H1-2021 (Jan-Jun):	19 August 2021
Interim report 9M-2021 (Jan-Sep):	4 November 2021
Full-year report 2021 (Jan-Dec):	10 February 2022

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