ASCELIA PHARMA

Advancing Orphan Oncology

HALF-YEAR REPORT 2021

January – June 2021

Preparing Oncoral for the next level

SIGNIFICANT EVENTS IN Q2 2021

- EGM approval of the directed new share issue
- Issuance and repurchase of C-shares for share saving program

SIGNIFICANT EVENTS AFTER THE PERIOD

- Covid-19 effect extends recruitment period for SPARKLE study with up to 6 months into H1 2022 (previously H2 2021)
- Abstract for Orviglance comparison study to gadolinium accepted as an oral paper presentation at the world's largest radiology conference RSNA
- FDA conditionally accepted Orviglance® as the brand name for Mangoral

"We are excited to move our second drug candidate Oncoral forward and expect to start Phase 2 later this year according to plan

KEY RATIOS GROUP

	Q2 (Apr-Jun)		H1 (Jan-Jun)	
	2021	2020	**2021**	2020
RÖRELSERESULTAT (MSEK)				
	-32.3	-28.6	**-66.1**	-49.3
VINST PER AKTIE (SEK)				
	-0.99	-1.31	**-1.99**	-2.02
KASSAFLÖDE FRÅN DEN LÖPANDE VERKSAMHETEN (MSEK)				
	-30.6	-20.7	**-53.6**	-39.1
LIKVIDA MEDEL INKL. KORTFRISTIGA PLACERINGAR (MSEK)				
	319.0	144.9	**319.0**	144.9

CEO COMMENTS

In the second quarter we continued to make progress in the clinical development program and the commercial preparations for Orviglance® (former working name Mangoral), our diagnostic agent currently in Phase 3. We continue to significantly expand the organization, primarily in roles that are important to transform Ascelia Pharma to a commercial stage company.

Updated timelines for the SPARKLE study with Orviglance. Despite the progress, the Covid-19 pandemic continues to substantially impact healthcare systems globally, including the conduct of clinical trials. Especially in the US, an important country in the SPARKLE study, the increasing infection rates are impacting clinical study activities and therein the recruitment pace. In this context, the timelines for the expected completion of patient enrollment could be extended to first half of 2022 (previously H2 2021). We are responding to the Covid-19 impact by increasing the number of countries and clinics recruiting patients into the study, with the hope to finish the recruitment according to our new timelines.

Taking Oncoral to the next level. With encouraging Phase 1 data, we have prepared the next steps of clinical development of Oncoral together with our distinguished Advisory Board. The planned Phase 2 study, which is expected to commence in H2-2021, will address metastatic gastric cancer, which is a serious disease with significant unmet medical need for novel safe and effective therapies. With Oncoral, we have the opportunity to develop a novel oral chemotherapy. Oncoral has potential to offer both better efficacy with improved safety following the daily dosing at home compared to intravenous high-dose infusions at the hospital.

The Phase 2 study in around 100 patients will be a randomized controlled multicenter study of Oncoral added to Standard of Care, compared to Standard of Care alone. For subsequent development, there is also potential for label expansion to other solid tumor indications where irinotecan has proved efficacious.

Growing the organization. In parallel with the solid development of our clinical pipeline, Ascelia Pharma continues to grow, and recently, we have expanded the company with several important new positions, including Directors for Marketing, Business Development and Medical Affairs. This signals that we take firm steps towards commercialization. Earlier in the year, we also opened a US office in Woodbridge, NJ, with an important proximity to the pharma and biotech community and competences in the area. This is a central part of preparing for Orviglance market launch on the important US market, where we plan to set up our own commercial operations and sales team.

Solid financial position. We have a strong balance sheet with 319 MSEK in cash at Q2-2021, which will take us well into 2023. The strong liquidity position will be used for the ongoing Phase 3 program for Orviglance and the market launch preparations as well as Oncoral's Phase 2 clinical program.

Looking ahead. Our focus is on the development program of Orviglance and the preparations to make it available to patients in need, and to initiate the clinical Phase 2 for Oncoral. We work constantly to create shareholder value, and the development in the first six months gives us assurance that 2021 will continue be a busy and interesting year for Ascelia Pharma.

Magnus Corfitzen
CEO

ABOUT ASCELIA PHARMA

- 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 – Orviglance (Mangoral) and Oncoral – currently in clinical development
- Global headquarter in Malmö, Sweden, and shares listed on Nasdaq Stockholm (ticker: ACE)

ORVIGLANCE (MANGORAL): Diagnostic drug for liver MRI in Phase 3

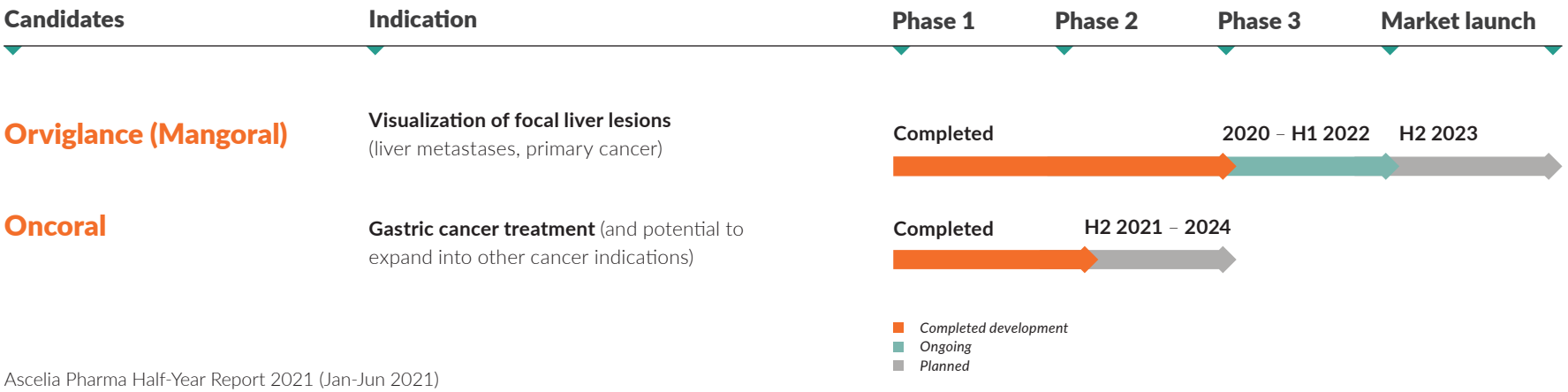
Orviglance is our novel non-gadolinium diagnostic drug (contrast agent) to be used in MRI-scans of the liver. Orviglance is developed to improve the visualization of focal liver lesions (liver metastases) in patients with impaired kidneys that are at risk of severe side-effects from the gadolinium contrast 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: Tablet chemotherapy ready for Phase 2

Oncoral is our novel oral chemotherapy tablet developed initialy 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 for both ongoing and planned development could be delayed in 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 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). 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

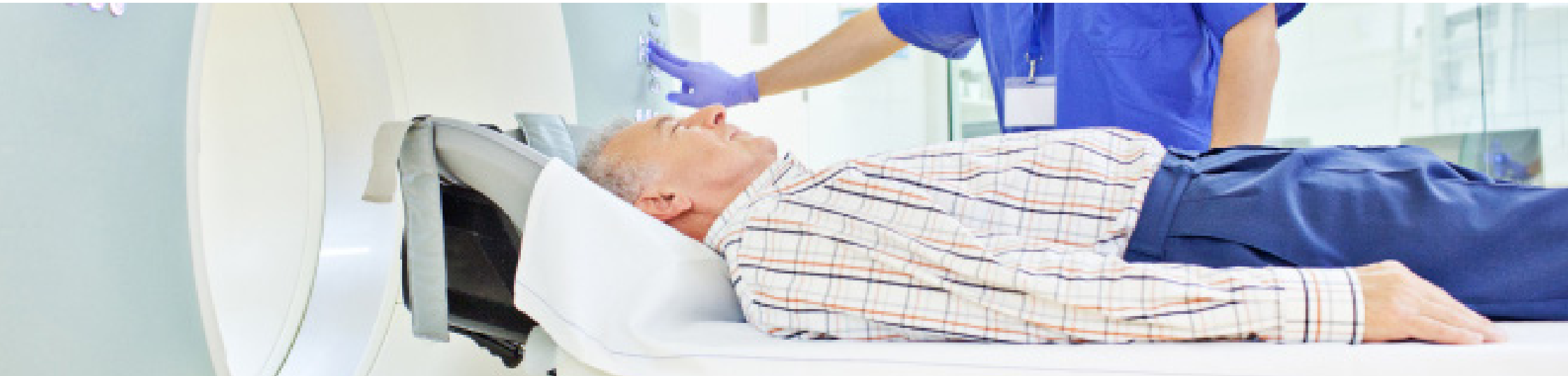
Orviglance is an orally administrated contrast agent used in MRI of the liver. It is based on the chemical element manganese, which is a natural trace element in the body. Orviglance also contains L-Alanine and Vitamin D3 to increase the absorption of manganese from the small intestine into the portal 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 August 2021, FDA conditionally accepted Orviglance as the proposed brand name for manganese chloride tetrahydrate (Mangoral).

In August 2021, the abstract for Orviglance comparison study to gadolinium was accepted as an oral paper presentation at the world's largest radiology conference RSNA.

In August 2021, Ascelia Pharma announced that due to Covid-19 the estimated timeline for completion of recruitment to the SPARKLE trial is extended into H1 2022.



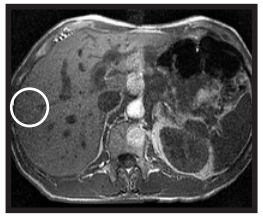
Patients referred for liver MRI scan

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

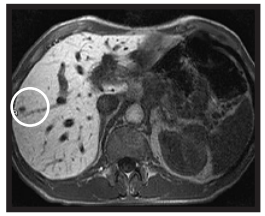


TOMORROW

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 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

- Large markets with mature clinical practices
- Clear regulatory and market access pathway
- Orviglance to be the only gadolinium-free product for this patient group

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

Sales team	**~20 full-time employees reach priority decision makers**
Clinics/ Hospitals	**Around 400 clinics and hospitals serve 75% of the kidney impairment patients[1]**

Sources:
1: Market research with Decision Resources Group, 2020
2: 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 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.

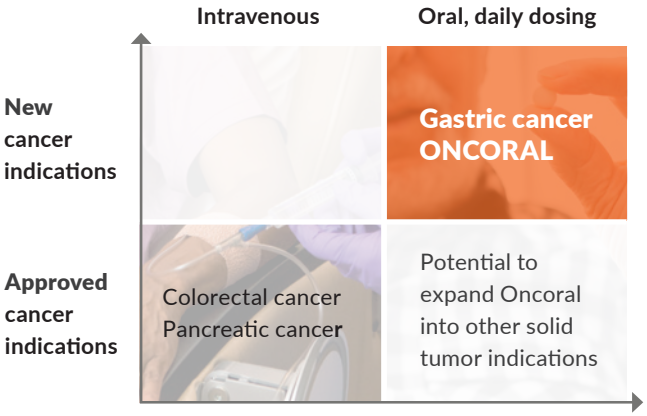
Potential to be the first oral irinotecan

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.

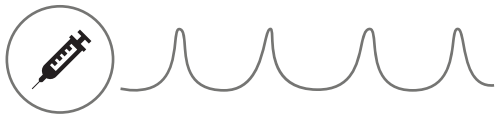
Latest development

During the second quarter, focus was on the preparations for the upcoming Phase 2 trial. Preparations included analysis of clinical study sites, choice of Contract Research Organization (CRO) to manage trial, manufacturing of clinical study material and regulatory documentation including the study protocol.

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 – STUDY IN PREPARATION

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 compelling Phase 2 data for further development and obtain solid data to design a Phase 3 study.

Phase 2 study design

TYPE OF STUDY	Randomized controlled, multicentre, multinational study: Oncoral + Standard of Care vs. Standard of Care
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	**H2-2021 - 2024**

FINANCIAL OVERVIEW: Q2-2021 (APR–JUN 2021)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales in Q2 (Apr-Jun 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 100 thousand (SEK 305 thousand).

Research and development costs (R&D)

R&D costs for the Group in Q2 were SEK 25.6 million (SEK 17.8 million). The cost increase of SEK 7.8 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 and regulatory work as well as increased costs for Oncoral Phase 2 preparations.

Commercial preparation costs

During Q2, costs related to commercial preparations of amounted to SEK 2.1 million (SEK 6.2 million). The higher costs in Q2-2020 reflects timing of purchase of external expert work and studies in that particular quarter.

Administration costs

Administration costs for the Group in Q2 amounted to SEK 4.6 million (SEK 4.5 million).

Operating results (EBIT)

The operating result in Q2 amounted to SEK -32.3 million (SEK -28.6 million). The increased loss reflects the overall higher level of R&D activities and manufacturing preparations in Q2-2021.

Net Profit/Loss for the period

The Group's net loss in Q2 amounted to SEK -33.5 million (SEK -31.4 million). In the current quarter, financial costs of SEK 1.9 million was recognized due to weakening of USD against SEK, which translated into a decrease in the value of bank deposits (a significant part of bank deposit is held in USD to match upcoming cash outflow in USD). The net loss corresponds to a loss per share, before and after dilution, of SEK -0.99 (SEK -1.31).

Financials key ratios for the Group	Q2 (April-June)	
	2021	2020
Operating result (SEK 000')	-32,312	-28,600
Net result (SEK 000')	-33,494	-31,442
Earnings per share (SEK)	-0.99	-1.31
Weighted avg. number of shares	33,796,617	23,999,453
R&D costs/operating costs (%)	79%	62%
Cash flow used in operating activities (SEK 000')	-30,636	-20,734
Equity (SEK 000')	367,882	283,688
Liquid assets incl. marketable securities (SEK 000')	319,014	144,864

CASH FLOW

Cash flow from operating activities before changes in working capital in Q2 amounted to SEK -30.1 million (SEK -28.1 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 outflow of SEK 0.6 million (inflow of SEK 7.4 million).

Cash flow from investing activities in Q2 totaled to SEK 0 (SEK 0.9 million). Cash flow from financing activities amounted to an inflow of SEK 186.2 million (SEK -174 thousand), which reflects net proceeds from the share issuance in the spring.

FINANCIAL POSITION

On the closing date, equity amounted to SEK 367.9 million, compared with SEK 236.1 million per 31 December 2020 and SEK 283.7 million per 30 June 2020. The increase since 31 December 2020 and 30 June 2020 reflects the issuance of shares, which outweighed the net losses incurred.

Liquid assets on the closing date amounted to SEK 319.0 million, compared to SEK 184.7 million per 31 December 2020 and SEK 144.9 million per 30 June 2020, which also is an effect of the share issuance.

FINANCIAL OVERVIEW: H1-2021 (JAN–JUN 2021)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales in H1 (Jan-Jun 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 127 thousand (SEK 666 thousand).

Research and development costs (R&D)

R&D costs for the Group in H1 were SEK 55.0 million (SEK 31.5 million). The cost increase of SEK 23.5 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 and regulatory work as well as increased costs for Oncoral Phase 2 preparations.

Commercial preparation costs

During H1, costs related to commercial preparations of amounted to SEK 3.1 million (SEK 8.0 million). The higher costs in H1-2020 reflects timing of purchase of external expert work and studies in primarily Q2-2020.

Administration costs

Administration costs for the Group in H1 amounted to SEK 7.7 million (SEK 9.8 million). The cost decrease is partially explained by high recruitment costs in Q1-2020.

Operating results (EBIT)

The operating result in H1 amounted to SEK -66.1 million (SEK -49.3 million). The increased loss reflects the overall higher level of R&D activities and manufacturing preparations in H1-2021.

Net Profit/Loss for the period

The Group's net loss in H1 amounted to SEK -62.3 million (SEK -48.2 million). In H1, net financial income of SEK 2.5 million was recognized due to strengthening of USD against SEK, which translated into an increase in the value of bank deposits in USD (a significant part of bank deposit is held in USD to match upcoming cash outflow in USD). The net loss corresponds to a loss per share, before and after dilution, of SEK -1.99 (SEK -2.02).

Financials key ratios for the Group	H1 (January-June)	
	2021	2020
Operating result (SEK 000')	-66,052	-49,256
Net result (SEK 000')	-62,309	-48,156
Earnings per share (SEK)	-1.99	-2.02
Weighted avg. number of shares	31,305,832	23,830,212
R&D costs/operating costs (%)	83%	63%
Cash flow used in operating activities (SEK 000')	-53,584	-39,089
Equity (SEK 000')	367,882	283,688
Liquid assets incl. marketable securities (SEK 000')	319,014	144,864

CASH FLOW

Cash flow from operating activities before changes in working capital in H1 amounted to SEK -63.3 million (SEK -47.9 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 9.7 million (inflow of SEK 8.8 million). The inflow in the current period primarily reflects the reduction in advance payments to major suppliers, as well as increase in accounts payable and accrued expenses.

Cash flow from investing activities in H1 totaled to SEK 0 (SEK 6.6 million). Cash flow from financing activities amounted to an inflow of SEK 185.4 million (SEK -0.3 million), which reflects net proceeds from the share issuance in the spring.

FINANCIAL POSITION

On the closing date, equity amounted to SEK 367.9 million, compared with SEK 236.1 million per 31 December 2020 and SEK 283.7 million per 30 June 2020. The increase since 31 December 2020 and 30 June 2020 reflects the issuance of shares, which outweighed the net losses incurred.

Liquid assets on the closing date amounted to SEK 319.0 million, compared to SEK 184.7 million per 31 December 2020 and SEK 144.9 million per 30 June 2020, which also is an effect of the share issuance.

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.

Significant events after the end of the reporting period

In August 2021, FDA conditionally accepted Orviglance as the proposed brand name for Mangoral.

In August 2021, the abstract for Orviglance comparison study to gadolinium was accepted as as an oral paper presentation at the world's largest radiology conference RSNA.

In August 2021, Ascelia Pharma announced that due to Covid-19 the estimated timeline for completion of recruitment to the SPARKLE trial is extended into H1 2022.

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, 19 August 2021

Peter Benson
Chairman

Lauren Barnes
Member of the board

Bo Jesper Hansen
Member of the board

Hans Maier
Member of the board

Niels Mengel
Member of the board

René Spogård
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 2021 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, 19 August 2021
Öhrlings PricewaterhouseCoopers AB

Carl Fogelberg
Authorized Public Accountant

Consolidated Income Statement

	Q2 (Apr-Jun)		H1 (Jan-Jun)	
*SEK in thousands (unless otherwise stated)**	2021	2020	2021	2020
Net sales	–	–	–	–
Gross profit/loss	**–**	**–**	**–**	**–**
Administrative costs	-4,600	-4,522	-7,744	-9,756
Research and development costs	-25,644	-17,799	-54,988	-31,479
Commercial preparation costs	-2,145	-6,167	-3,080	-7,981
Other operating income	100	305	127	666
Other operating costs	-23	-417	-367	-706
Operating result	**-32,312**	**-28,600**	**-66,052**	**-49,256**
Finance income	–	2,400	4,442	6,277
Finance costs	-1,945	-5,897	-1,963	-5,920
Net financial items	**-1,945**	**-3,497**	**2,479**	**357**
Loss before tax	**-34,257**	**-32,097**	**-63,573**	**-48,899**
Tax	763	655	1,264	743
Loss for the period	**-33,494**	**-31,442**	**-62,309**	**-48,156**
Attributable to:				
Owners of the Parent Company	-33,494	-31,442	-62,309	-48,156
Non-controlling interest	–	–	–	–
Earnings per share				
Before and after dilution (SEK)	-0.99	-1.31	-1.99	-2.02

Consolidated Statement of Comprehensive Income

	Q2 (Apr-Jun)		H1 (Jan-Jun)	
SEK in thousands (unless otherwise stated)*	2021	2020	2021	2020
Profit/loss for the period	**-33,494**	**-31,442**	**-62,309**	**-48,156**
Other comprehensive income				
Currency translation of subsidiaries**	-13	-123	8	57
Other comprehensive income for the period	**-13**	**-123**	**8**	**57**
Total comprehensive income for the period	**-33,507**	**-31,565**	**-62,301**	**-48,099**

* 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 2021	30 Jun 2020	31 Dec 2020
ASSETS			
Intangible assets	57,062	57,066	57,061
Tangible assets			
Equipment	279	361	301
Right-of-use assets	2,121	1,842	1,688
Total fixed assets	**59,462**	**59,269**	**59,050**
Current assets			
Advance payments to suppliers	5,526	3,446	8,279
Current receivables			
Income tax receivables	3,362	1,593	1,748
Receivables from shareholders	–	98,653	–
Other receivables	1,766	677	857
Prepaid expenses and accrued income	595	772	754
Marketable securities	–	67,883	–
Cash and bank balances	319,014	76,981	184,686
Total current assets	**330,263**	**250,005**	**196,324**
Total assets	**389,725**	**309,274**	**255,374**
EQUITY			
Share capital	34,576	24,000	28,697
Other paid-in capital	678,831	498,577	493,731
Loss brought forward (incl. net profit/loss for the period)	-345,525	-238,889	-286,372
Equity attributable to Parent Company shareholders	**367,882**	**283,688**	**236,056**
Total equity	**367,882**	**283,688**	**236,056**
LIABILITIES			
Long-term liabilities			
Leasing	1,094	1,177	956
Total long-term liabilities	**1,094**	**1,177**	**956**
Current liabilities			
Accounts payable	9,085	5,282	3,884
Tax payable	–	1	–
Other liabilities	1,031	706	672
Current lease liabilites	1,105	716	822
Accrued expenses and deferred income	9,528	17,704	12,984
Total current liabilities	**20,749**	**24,409**	**18,362**
Total liabilities	**21,843**	**25,586**	**19,318**
Total equity and liabilities	**389,725**	**309,274**	**255,374**

* 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**	2021	2020	2020
Equity at start of the period	**236,056**	**237,062**	**237,062**
Comprehensive income			
Profit/loss for the period	-62,309	-48,156	-98,697
Other comprehensive income	8	57	-5
Total comprehensive income	**-62,301**	**-48,099**	**-98,702**
Transactions with shareholders			
New issue of C-shares	398	511	511
Repurchase of own shares C-shares	-398	-511	-511
Subscribed but not paid-up capital	–	93,516	–
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	3,545	1,209	4,329
Total transactions with shareholders	**194,127**	**94,725**	**97,696**
Equity at end of the period	**367,882**	**283,688**	**236,056**

* 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**	**2021**	**2020**	**2021**	**2020**
Operating activities				
Operating result	-32,312	-28,600	-66,052	-49,256
Expensed share based remuneration	2,201	604	2,731	1,209
Adjustment for items not included in cash flow	222	84	438	372
Interest paid	-19	-23	-36	-46
Income tax paid/received	-169	-197	-339	-197
Cash flow from operating activities before changes in working capital	**-30,077**	**-28,132**	**-63,258**	**-47,918**
Cash flow from changes in working capital				
Increase (-)/Decrease (+) of advance payments	163	571	2,753	273
Increase (-)/Decrease (+) of operating receivables	214	1,799	-761	3,206
Increase (+)/Decrease (-) of accounts payable	2,127	1,153	5,199	172
Increase (+)/Decrease (-) of other liabilities	-3,063	3,875	2,483	5,178
Change in working capital	-559	7,398	9,674	8,829
Cash flow used in operating activities	**-30,636**	**-20,734**	**-53,584**	**-39,089**
Investing activities				
Investment in equipment	-38	-65	-38	-397
Marketable securities/Other investments, net	–	1,000	–	7,000
Cash flow from investing activities	**-38**	**935**	**-38**	**6,603**
Financing activities				
Issuance proceeds	200,000	–	200,000	–
Issuance costs	-12,680	–	-13,271	–
Redemption of warrants net	-914	–	-914	–
Amortisation of loan (leasing)	-204	-174	-400	-288
Cash flow from financing activities	**186,202**	**-174**	**185,415**	**-288**
Cash flow for the period	**155,528**	**-19,973**	**131,793**	**-32,774**
Cash flow for the period	155,528	-19,973	131,793	-32,774
Cash and cash equivalents at start of period	165,422	102,815	184,686	108,516
Exchange rate differences in cash and cash equivalents	-1,936	-5,861	2,535	1,239
Cash and cash equivalents at end of period	**319,014**	**76,981**	**319,014**	**76,981**

* 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**	**2021**	**2020**	**2021**	**2020**
Net sales	1,670	136	2,481	276
Gross profit/loss	**1,670**	**136**	**2,481**	**276**
Administrative costs	-4,566	-4,524	-7,716	-9,710
Research and development costs	-23,204	-15,362	-50,943	-28,103
Commercial preparation costs	-2,145	-6,193	-3,089	7,982
Other operating income	100	309	100	666
Other operating costs	–	-418	-344	-687
Operating result	**-28,145**	**-26,052**	**-59,511**	**-45,540**
Finance income	–	2,395	4,442	6,272
Finance costs	-1,930	-5,896	-1,930	-5,918
Result from other long-term receivables	229	-235	788	229
Net financial costs	**-1,701**	**-3,736**	**3,300**	**583**
Loss before tax	-29,846	-29,788	-56,211	-44,957
Group contribution	–	–	–	–
Tax	–	–	–	–
Loss for the period	**-29,846**	**-29,788**	**-56,211**	**-44,957**

Parent Company – Statement of Comprehensive Income

	Q2 (Apr-Jun)		H1 (Jan-Jun)	
*SEK in thousands**	**2021**	**2020**	**2021**	**2020**
Loss for the period	**-29,846**	**-29,788**	**-56,211**	**-44,957**
Other comprehensive income	–	–	–	–
Other comprehensive income for the period	**–**	**–**	**–**	**–**
Total comprehensive income for the period	**-29,846**	**-29,788**	**-56,211**	**-44,957**

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

Parent Company – Balance Sheet

*SEK in thousands**	30 Jun 2021	30 Jun 2020	31 Dec 2020
ASSETS			
Tangible assets			
Equipment	279	360	301
Right-of-use assets	–	1,842	–
Financial assets			
Shares in affiliated companies	58,068	58,068	58,068
Other long-term receivables	12,981	6,770	9,449
Total fixed assets	**71,328**	**67,040**	**67,818**
Current assets			
Advance payments to suppliers	5,526	3,446	8,279
Current receivables			
Receivables from affiliated companies	3,879	853	1,346
Income tax receivables	962	738	623
Receivables from shareholders	–	98,653	–
Other receivables	1,051	476	616
Prepaid expenses and accrued income	595	772	706
Marketable securities	–	67,883	–
Cash and bank balances	317,306	76,306	182,498
Total current assets	**329,319**	**249,127**	**194,068**
Total assets	**400,647**	**316,167**	**261,886**
EQUITY			
Restricted equity			
Share capital	34,576	23,999	28,697
Non-restricted equity			
Other paid-in capital	678,831	498,577	493,731
Loss brought forward	-274,714	-186,912	-183,792
Loss for the period	-56,211	-44,957	-94,070
Total equity	**382,482**	**290,707**	**244,566**
LIABILITIES			
Long-term liabilities			
Leasing	–	1,177	–
Total long-term liabilities	**–**	**1,177**	**–**
Current liabilities			
Accounts payable	7,783	5,160	3,733
Liabilities from affiliated companies	–	3	–
Other liabilities	1,032	1,422	673
Accrued expenses and deferred income	9,350	17,698	12,914
Total current liabilities	**18,165**	**24,283**	**17,320**
Total equity and liabilities	**400,647**	**316,167**	**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 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 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 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 2021, services for a value of around SEK 2.3 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 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 2021, 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 H1 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 recognized costs for both option programs including social security charges in H1 2021 were SEK 2.8 milion.

Share saving programs

Ascelia Pharma has implemented two 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 2021 were SEK 2.1 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**	2021	2020	2021	2020
R&D costs	-25,644	-17,799	-54,988	-31,479
Administration costs	-4,600	-4,522	-7,744	-9,756
Commercial preparation costs	-2,145	-6,167	-3,080	-7,981
Other operating costs	-23	-417	-367	-706
Total operating costs	**-32,412**	**-28,905**	**-66,179**	**-49,922**
R&D costs/Operating costs (%)	**79%**	**62%**	**83%**	**63%**

Financial calendar

Interim report 9M-2021 (Jan-Sep): 4 November 2021
Full-year report 2021 (Jan-Dec): 10 February 2022

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