Q4 REPORT (APR-JUN 2019)
FISCAL YEAR 2018/2019

AUDIO CONFERENCE 22 AUGUST 2019, AT 09:00 CET

Present from Ascelia Pharma:
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ASCELIA PHARMA IN BRIEF

Orphan oncology-dedicated drug development company

We develop drugs which target unmet medical needs, have an established mode of action and a relatively low development risk

Mangoral®

Phase III ready novel liver MRI contrast agent with no competition

Oncoral

Phase II ready novel tablet chemotherapy for gastric cancer

Founded in 2000 and headquartered in Malmö, Sweden

Listed on Nasdaq Stockholm in 2019 (ticker: ACE)

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KEY EVENTS IN THE PERIOD

Summary of key events in Q4

Mangoral

- Supportive feedback from EMA on the phase III program for Mangoral

Oncoral

- Encouraging results from the Phase I combination study with Oncoral and oral capecitabine published in the journal Cancer Chemotherapy and Pharmacology

- Filing of a patent application for next generation Mangoral product

- Raised SEK 22 million in utilised IPO overallotment

SELECTED UPCOMING KEY EVENTS IN 2019 AND 2020

	H2-2019	2020
Mangoral	Phase III: First Patent First Visit	Phase III: Last Patent Last Visit (H2-2020) Final study results (H2-2020 / early 2021)
Oncoral	Phase II preparations	Phase II study

ASCELIA PHARMA HIGHLIGHTS AND PIPELINE

Mangoral

- Novel imaging drug with Orphan Drug Designation (FDA)
- No competing products
- $350-500M market with substantial upside potential
- De-risked Phase 3 clinical program starting in H2-2019

Oncoral

- Novel tablet chemotherapy formulation
- Gastric cancer is an Orphan indication
- Phase I clinical study completed
- Recent acquisition of comparable product >$1 billion

Candidate	Indication	Phase I	Phase II	Phase III	Rights
Mangoral 	**Visualization of Focal Liver Lesions** • *Liver metastases* • *Primary liver cancer* • *Benign lesions*	Completed		2019-2020	Wholly-owned
Oncoral 	**Treatment of Gastric cancer**	Completed	2020-2022		Wholly-owned
	Treatment of other solid cancers *(label expansion)*				

Completed development Planned development

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MANGORAL

PATIENTS REFERRED FOR LIVER MRI SCAN

TODAY

- NORMAL KIDNEY FUNCTION
  Gadolinium imaging drug
- POOR KIDNEY FUNCTION
  NO imaging drug due to potentially deadly side-effects

TOMORROW

- NORMAL KIDNEY FUNCTION
  Gadolinium imaging drug
- POOR KIDNEY FUNCTION
  MANGORAL Imaging drug

Mangoral aims to be the new gold standard liver MRI imaging drug for patients with impaired kidney function

280,000
patients with impaired kidney function in major markets

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MANGORAL STRONG CLINICAL RESULTS AND KEY BENEFITS

MANGORAL PROFILE AND KEY ADVANTAGES

Mangoral is based on manganese – a natural trace element in the body

FDA Orphan Drug Designation

Strong enhancement of liver on MRI – metastases do not take up manganese and appear darker on the MRI

No risk of Nephrogenic Systemic Fibrosis

Limited systemic exposure and good safety profile

No competing drug

Provides ease of use for patients and clinicians alike

STRONG CLINICAL RESULTS

Six Phase I and Phase II trials completed

- The clinical trials have shown strong clinical efficacy without any safety concerns

Blinded read study

- The study with 178 subjects further underlined that Mangoral significantly improves MRI performance
- 33% more lesions were detected after Mangoral enhanced MRI
- Parameters incl. lesion visualization (conspicuity) and delineation had p-value<0.0001 which demonstrate significant improvements in MRI imaging

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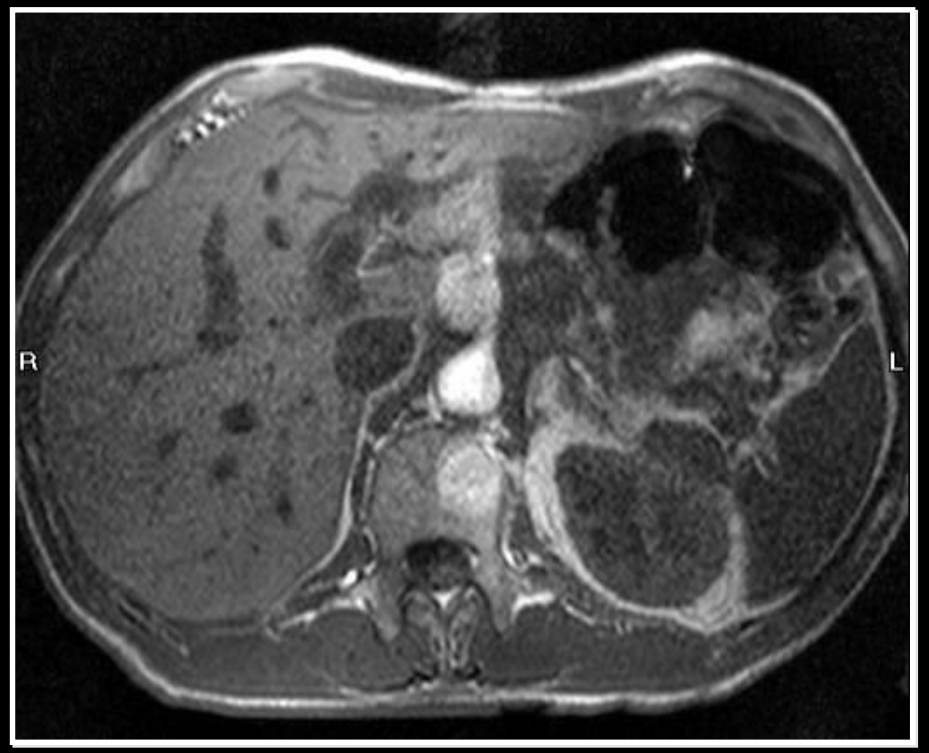
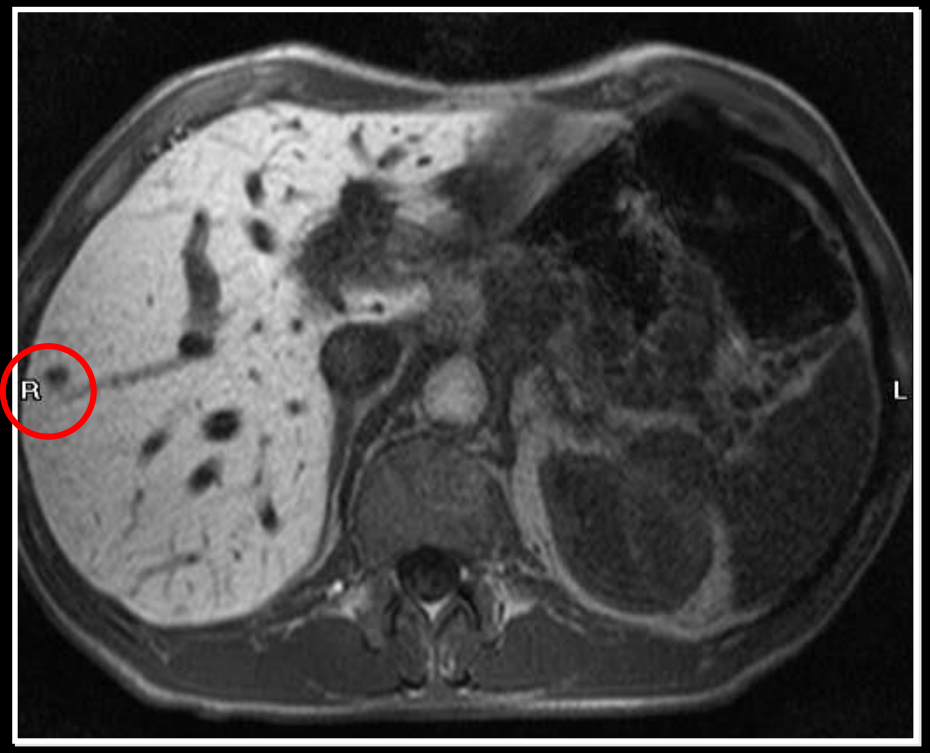
MANGORAL MAKES A REAL DIFFERENCE

PATIENT EXAMPLE FROM PHASE II STUDY



Unenhanced liver MRI

(standard of care today in target patient population)



Mangoral enhanced liver MRI

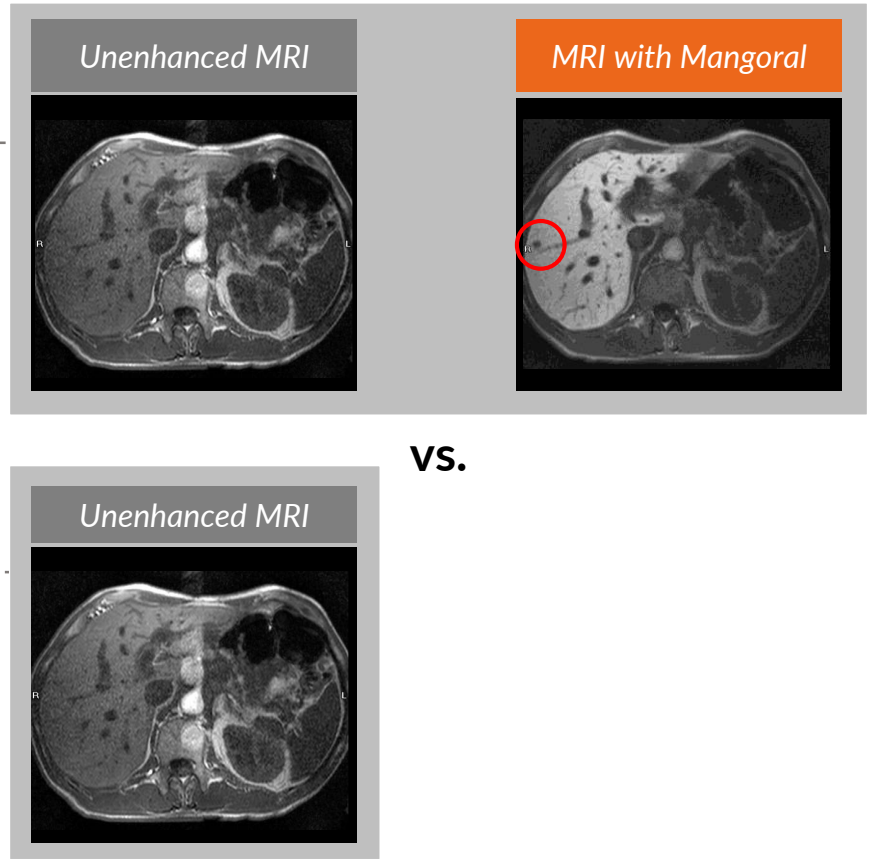
A liver metastasis now appear

Source: Patient with colorectal cancer. (Study CMC-P002)

MANGORAL PHASE III STARTING IN H2-2019

Mangoral clinical phase III study design – based on Phase III protocol meeting with FDA and EMA

Number of patients	Up to 200 patients
Endpoint	Lesion visualisation • No. of lesions visualised • Semi-quantitative and Semi-qualitative parameters
Comparator	Unenhanced MRI + Mangoral MRI *vs.* Unenhanced MRI
Evaluation	Centralised evaluation by 3 radiologists
Randomisation	**No** – each patient will be in both study arms
Follow-up	72 hours



MANGORAL IS THE ONLY PRODUCT IN A $350-500M MARKET

Overview of Mangoral's addressable market

280,000 patients having risk of cancer in the liver and poor kidney function

Mangoral useful for diagnosis, monitoring and surveillance

$1,500 - $3,000 per dose of Mangoral based on Value-based-pricing

$350-500 million addressable market for Mangoral

Source

Detailed epidemiology analysis by geography, age groups and primary disease

Use of liver MRI today and clinical guidelines

>25 interviews with payors/health insurers in US and EU and analysis of value provided by Mangoral

Note: 280,000 is estimated relevant patient population with cancer in USA, Europe and Japan

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NEXT GENERATION MANGORAL PRODUCT (LIFE CYCLE MANAGEMENT) - NEW PATENT APPLICATION TO EXTEND RIGHTS TO YEAR 2040

- In June 2019, a patent application was filed for an improved formulation of Mangoral
- Upon grant, the new patent would further improve the unique value proposition to the Mangoral franchise and extend the intellectual property protection rights until year 2040

US

- **Mangoral has Orphan Drug Designation** in the US
- **7 years of market exclusivity** after market authorisation
- 6 months extension can be obtained if a paediatric indication obtains market authorisation within seven years

EU

- Upon marketing authorisation, Mangoral is expected to be protected by 8+2 years of data exclusivity and market protection
- 10 years of market exclusivity if Mangoral obtains Orphan Drug Designation with a possible two year extension if certain criteria are met

Japan

- **Ten years of market exclusivity** if Mangoral obtains Orphan Drug Designation in Japan
- Orphan Drug Designation will be discussed with the Japanese health authorities, PMDA, during the course of the phase III clinical development and applied for at the time of NDA submission

New patent application to extend exclusivity to year 2040 – significant value impact, if granted

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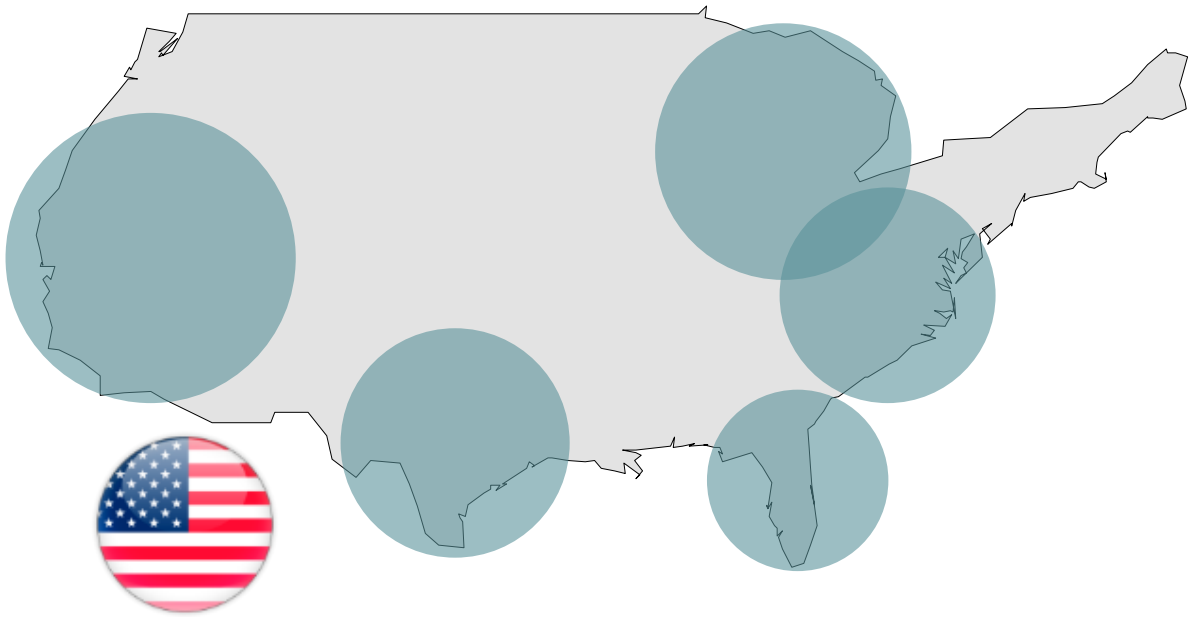
MANGORAL
COMMERCIAL STRATEGY FOR A 2022 SALES LAUNCH

10-20 Sales Reps sufficient for penetration in concentrated regions



- **Ascelia's sales force** will target **major hospitals** with nephrology units
- **10-20 sales reps in the US** sufficient for significant penetration
- **Reimbursement** expected shortly after sales launch
- **Chief Commercial Officer will be recruited during the Phase 3** clinical study to finalize commercial strategy and prepare launch
- **No recent innovation in the MRI space** Mangoral has attracted major attention. This will be utilized in the pre marketing phase
- Ascelia Pharma sales force in Europe being evaluated
- Find commercial partners in Japan, South Korea and China

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ONCORAL

ONCORAL – A NOVEL IRINOTECAN TABLET FOR ANTI-CANCER TREATMENT

NOVEL ORAL FORMULATION

Formulated as a **tablet** for convenient dosing and health-economic benefits

Promising safety potential of oral administration

Potential for **all-tablet chemo-combination**

PHARMACEAUTICAL INGRIEDIENT HAS PROVEN EFFECT

Irinotecan shown to be effective in **killing cancer cells**

Expected to be efficacious and safe **together** with other well-recognized anti-cancer drugs

Orphan drug indication for gastric cancer by the FDA and EMA

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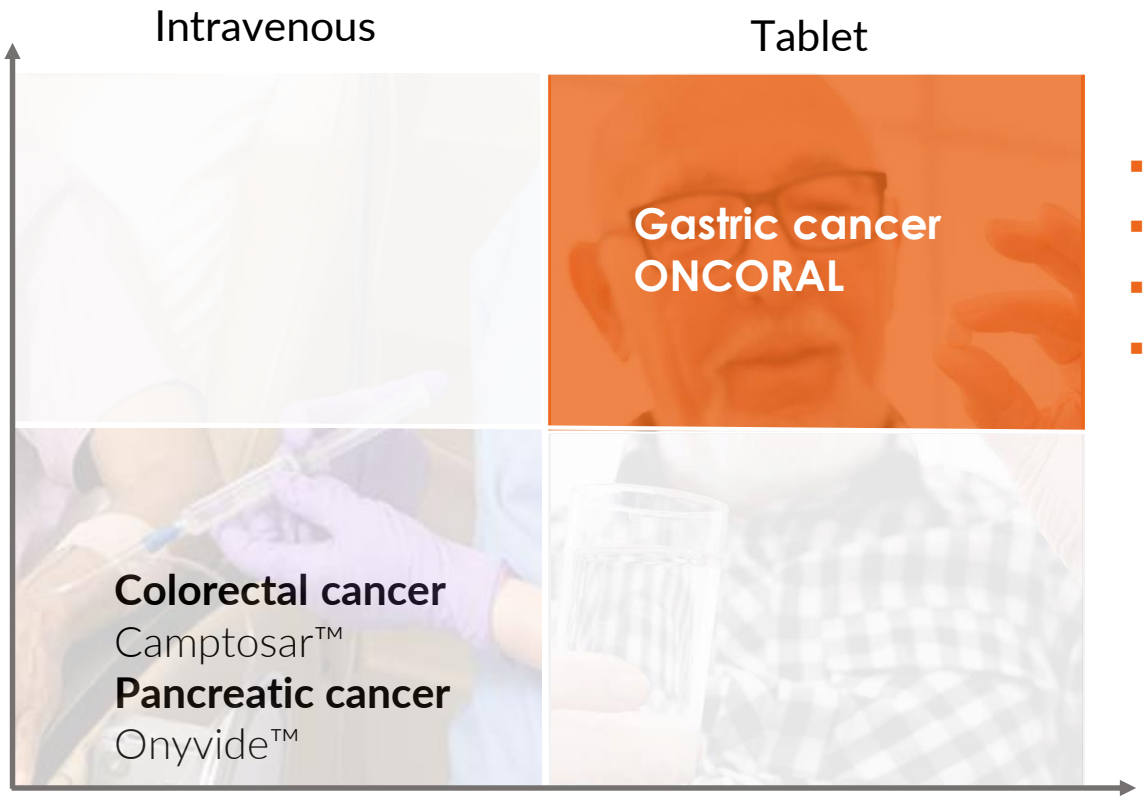
ONCORAL HIGHLY DIFFERENTIATED FROM OTHER IRINOTECAN PRODUCTS



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

ENCOURAGING ONCORAL PHASE I STUDY RESULTS

Phase 1 *single agent study* published in Jan 2019

Results showed that Oncoral was well tolerated; side effects were generally mild to moderate, manageable and similar in type to those observed with intravenous irinotecan

Hematological toxicities were few and all were mild to moderate

Pharmaco-Kinetic (PK) data showed consistent daily exposures during treatment at days 1 and 14 with no drug accumulation

The active metabolite, SN-38, interpatient variability was in the same range as after infusion of irinotecan

In this heavily pre-treated patient population, Oncoral indicated activity even among patients previously treated with irinotecan infusion

The study was presented at ESMO congress in October 2018

Phase 1 *combination study* published in April 2019

The combination of Oncoral with another oral chemotherapy, capecitabine, was encouraging which could enable an all-oral chemotherapy combination

The study data demonstrated reassuring tolerability of Oncoral together with capecitabine

The combination with capecitabine could become a more convenient and patient friendly treatment option compared to the intravenous formulations of these compounds

The encouraging tolerability profile justifies further clinical studies to assess the efficacy of this treatment regimen

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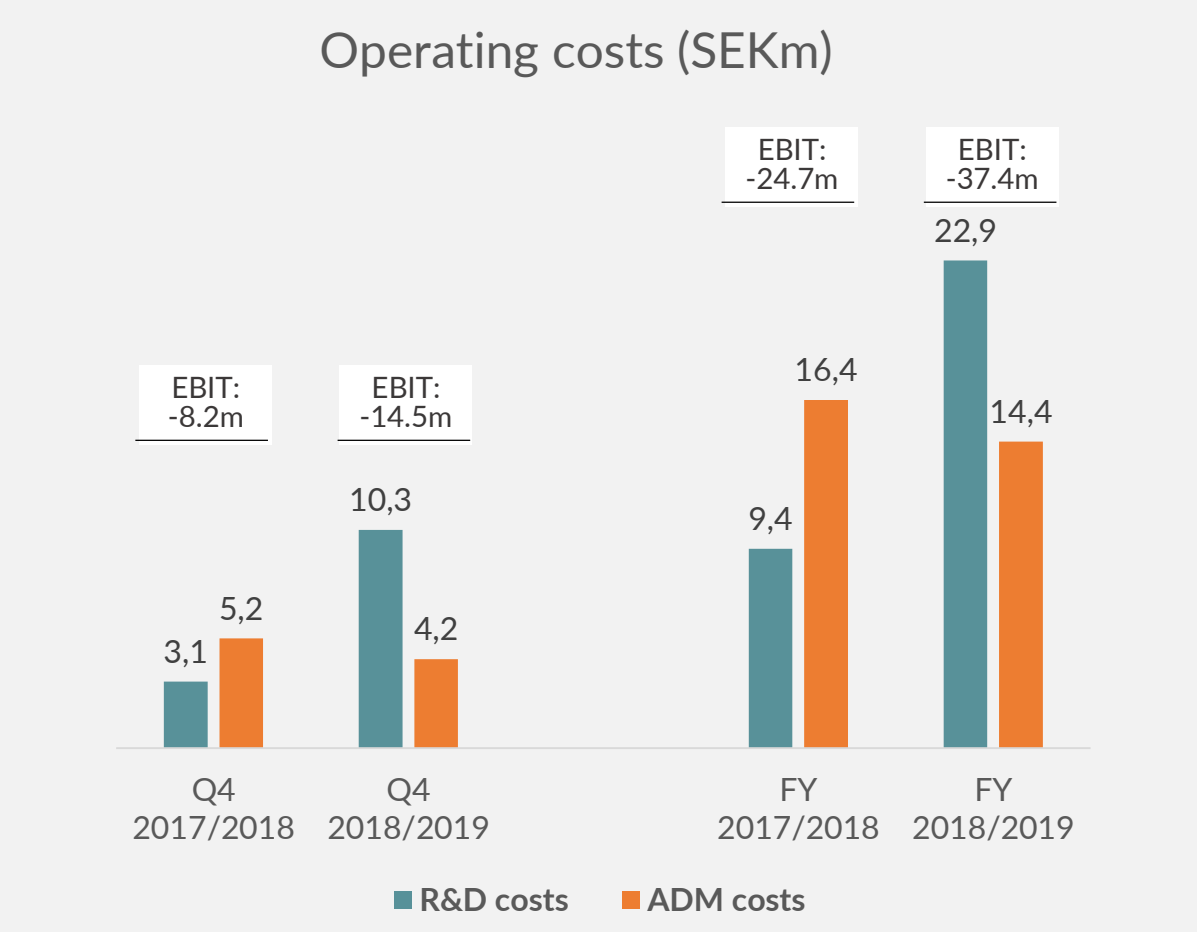
FINANCIALS

Q4 2018/2019 FINANCIAL HIGHLIGHTS – OPERATING RESULTS

Increased operating loss y/y driven by higher R&D activity for Mangoral Phase III preparations:

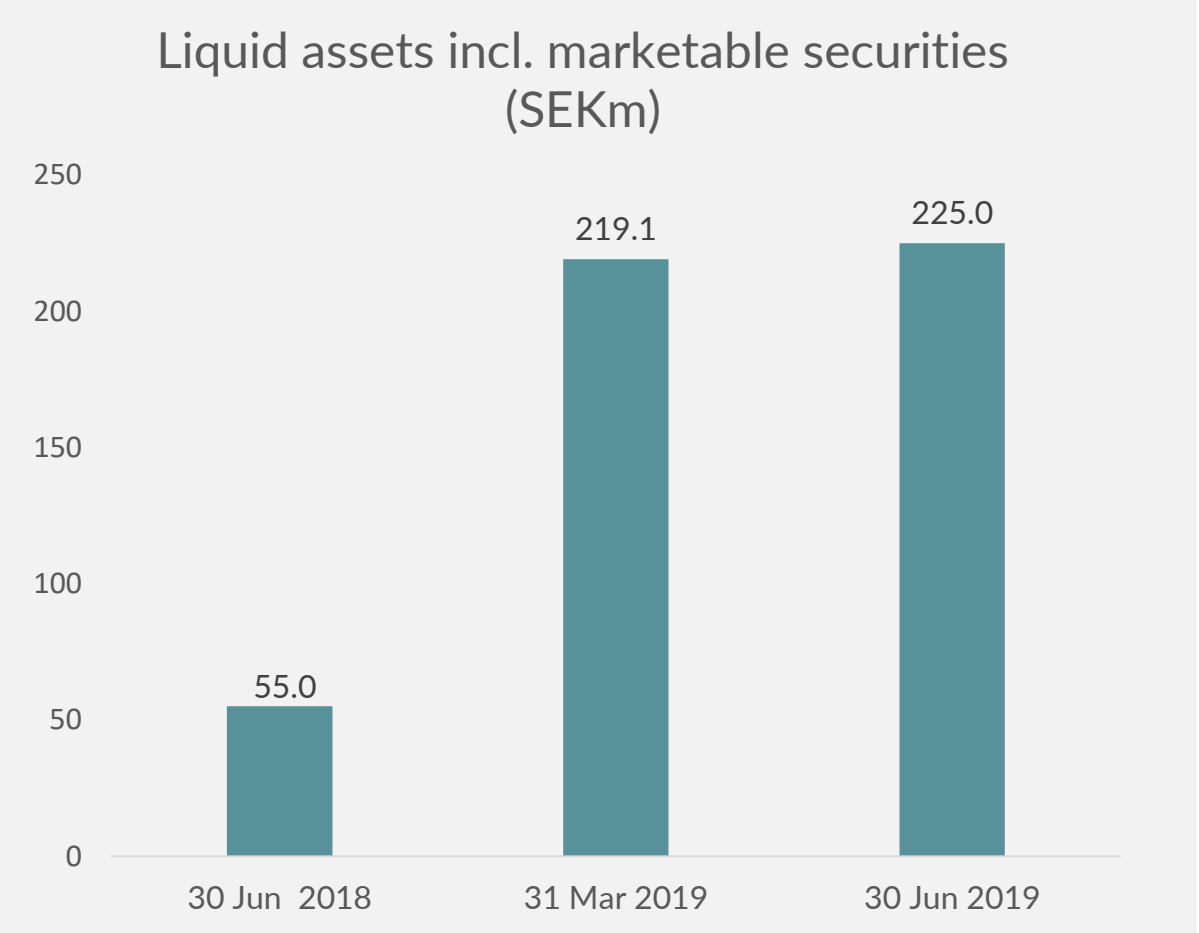
- Protocol finalisation
- Site selection
- Upscale of manufacturing



Q4 2018/2019 FINANCIAL HIGHLIGHTS – LIQUIDITY POSITION

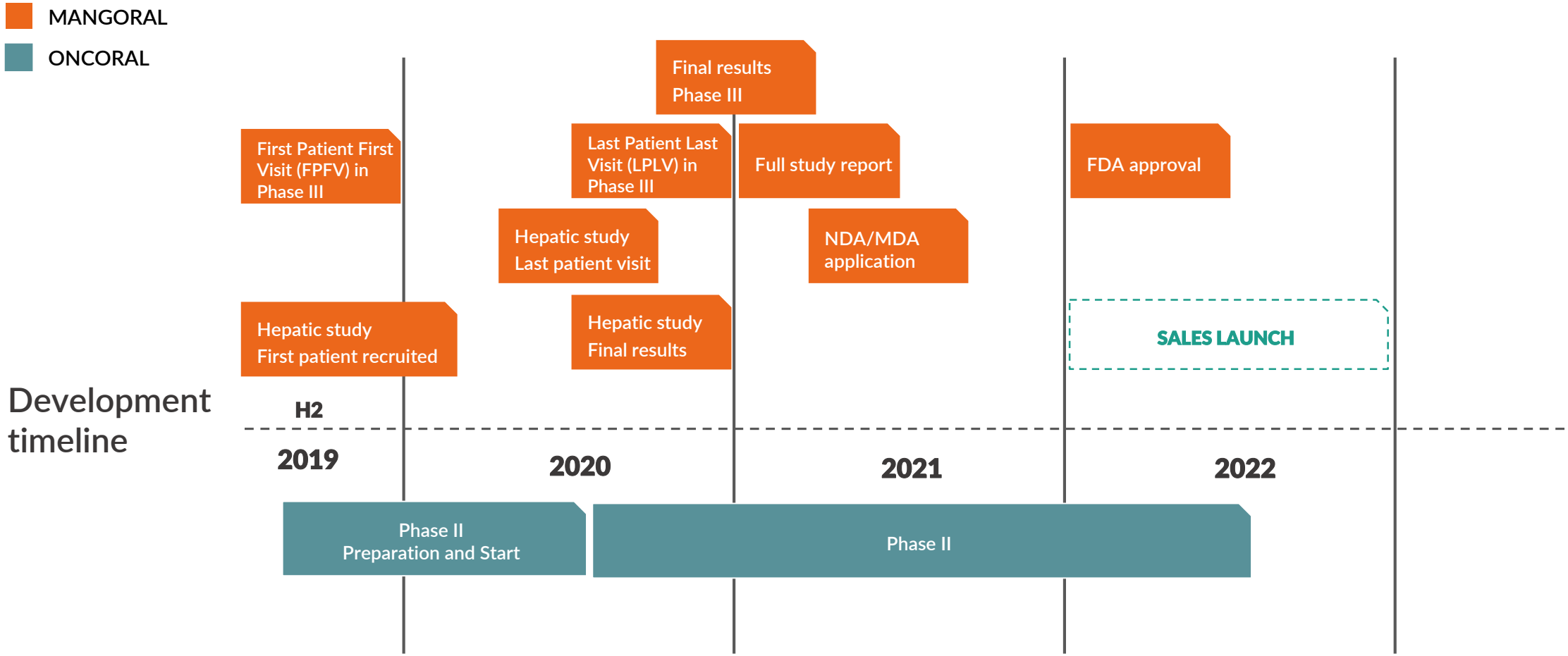
Continued strong liquidity:

- Liquid assets incl. marketable securities of SEK 225 million
- The liquidity position provides a fully financed Phase III program for Mangoral including commercial preparations as well as financing to prepare the Phase II program for Oncoral

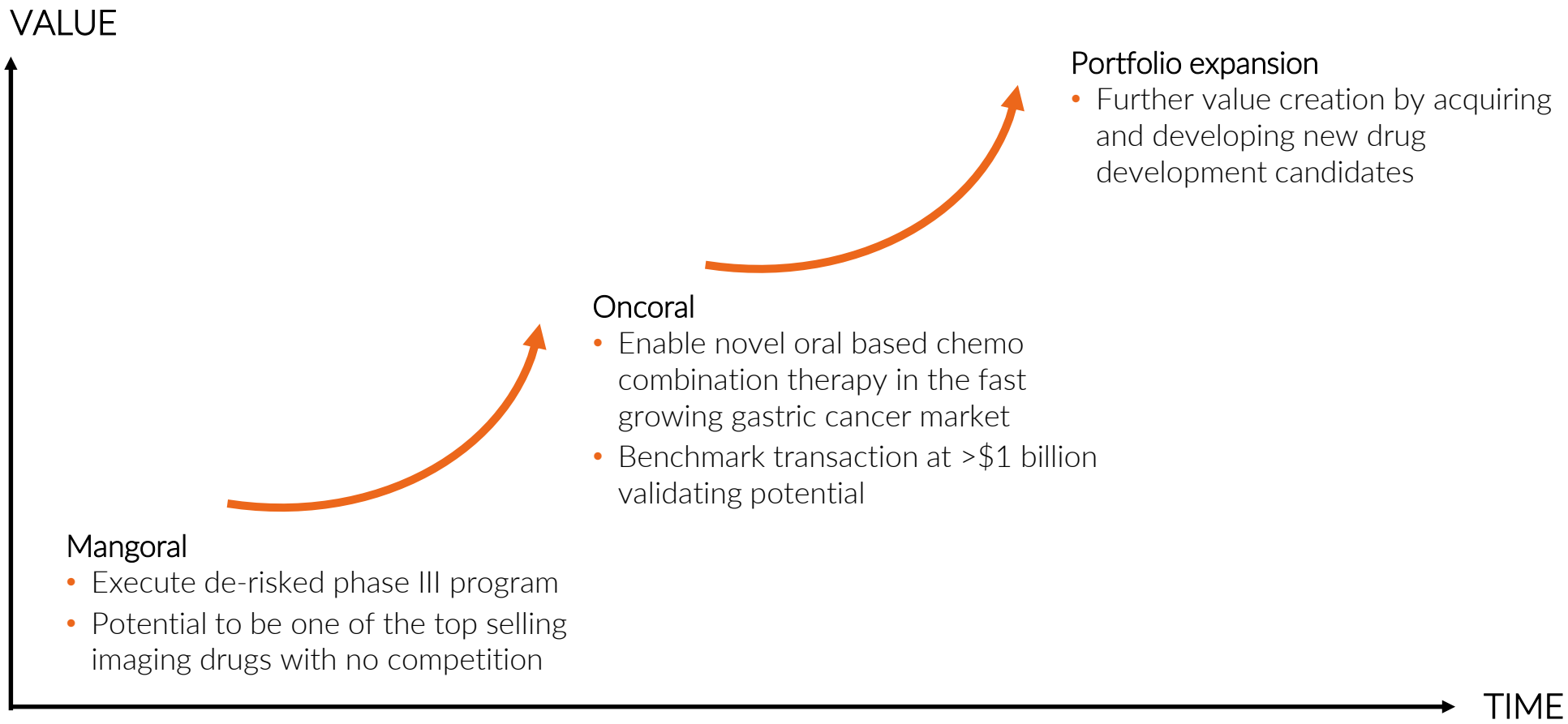


MILESTONES AND STRATEGIC OUTLOOK

SIGNIFICANT VALUE DRIVERS AHEAD



ASCELIA PHARMA STRATEGIC OUTLOOK



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