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Q1 REPORT (JUL-SEP 2019) FISCAL YEAR 2019/2020

AUDIO CONFERENCE 8 NOVEMBER 2019, AT 10:00 CET

Present from Ascelia Pharma:

CEO Magnus Corfitzen | CFO Kristian Borbos | CMO Carl Bjartmar | Head of IR Mikael Widell

Direct link audiocast:

<https://tv.streamfabriken.com/ascelia-pharma-q1-2019-2020>

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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)

KEY EVENTS IN THE PERIOD

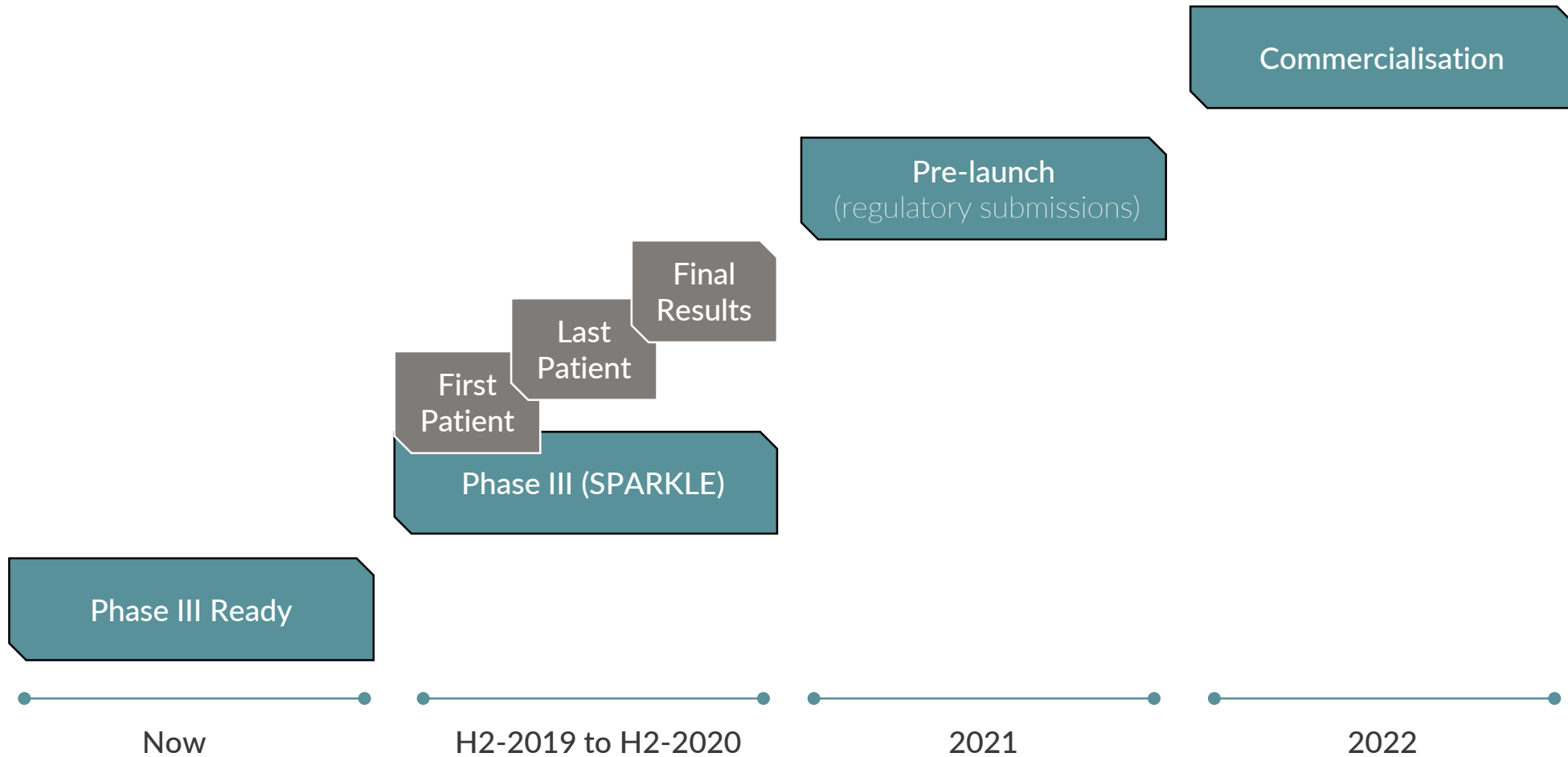
Summary of key events in Fiscal Q1 2019/2020



Mangoral

- Detailed preparations including site selection and manufacturing ahead of the start of the Phase III study for Mangoral (named SPARKLE)
- This global pivotal study will be conducted at 30-35 leading hospitals/sites in Europe, the US and South Korea

MANGORAL[®] – RAPIDLY APPROACHING THE MARKET



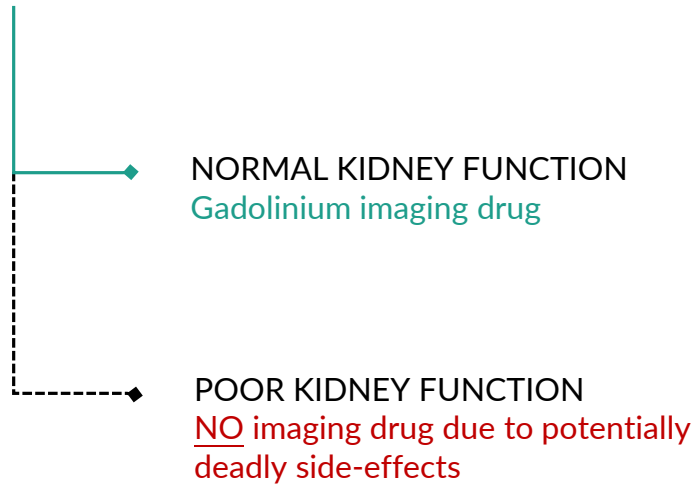


MANGORAL

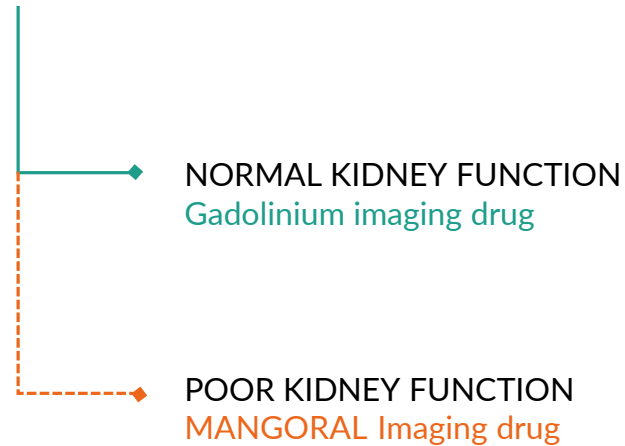


PATIENTS REFERRED FOR LIVER MRI SCAN

TODAY



TOMORROW



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

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

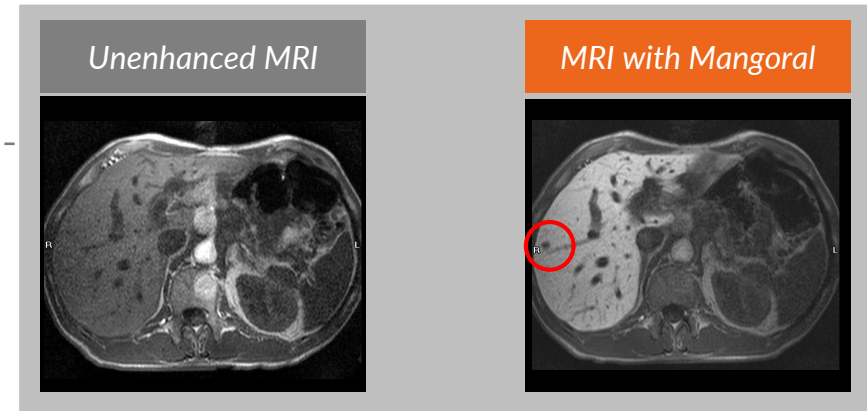
Blinded read study

- 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 $p\text{-value} < 0.0001$ which demonstrate significant improvements in MRI imaging

MANGORAL PHASE III STUDY (SPARKLE)

Mangoral global pivotal registration-enabling study design – based on Phase III protocol meetings with FDA and EMA

Number of patients	Up to 200 patients at 30-35 hospitals
Endpoint 	Lesion visualisation <ul style="list-style-type: none">• Lesion border delineation• Lesion contrast compared to liver background
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



VS.



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

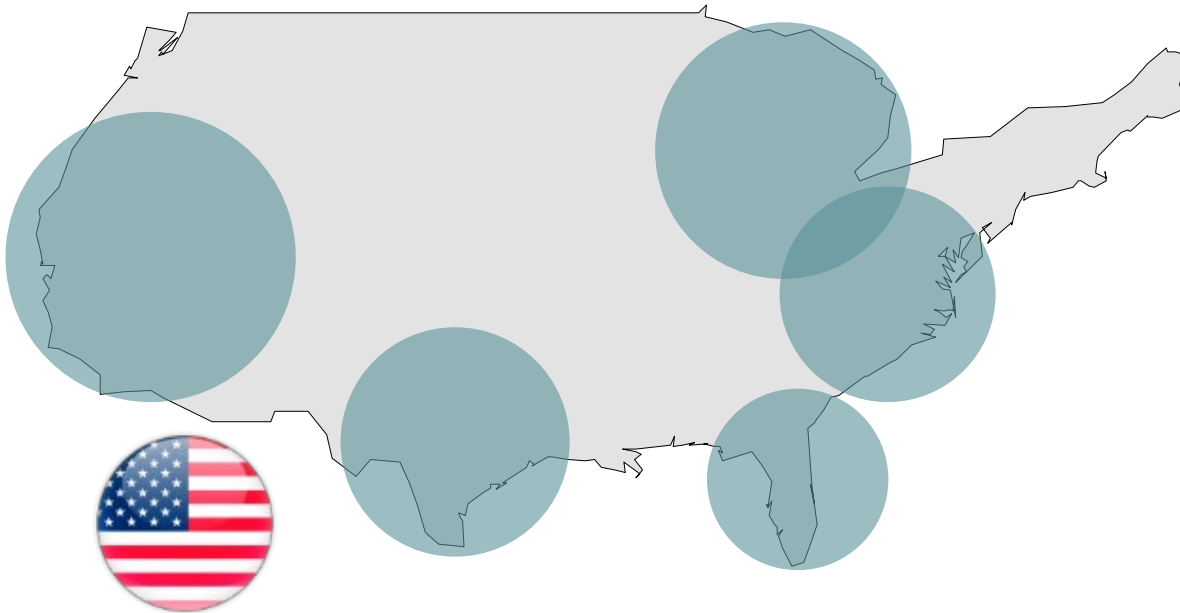
Detailed epidemiology analysis by geography, age groups and primary disease

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

MANGORAL COMMERCIAL STRATEGY FOR A 2022 SALES LAUNCH

10-20 Sales Reps sufficient for penetration in concentrated regions



- Ascelia Pharma's sales activities 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 III clinical study to finalise commercial strategy and prepare launch
- No recent innovation in the MRI space has enabled Mangoral to attract major attention. This will be utilised in the pre-marketing phase
- Go-to-market in Europe is being evaluated
- Find commercial partners in Japan, South Korea and Rest of World



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**

PHARMACEUTICAL INGREDIENT 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

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

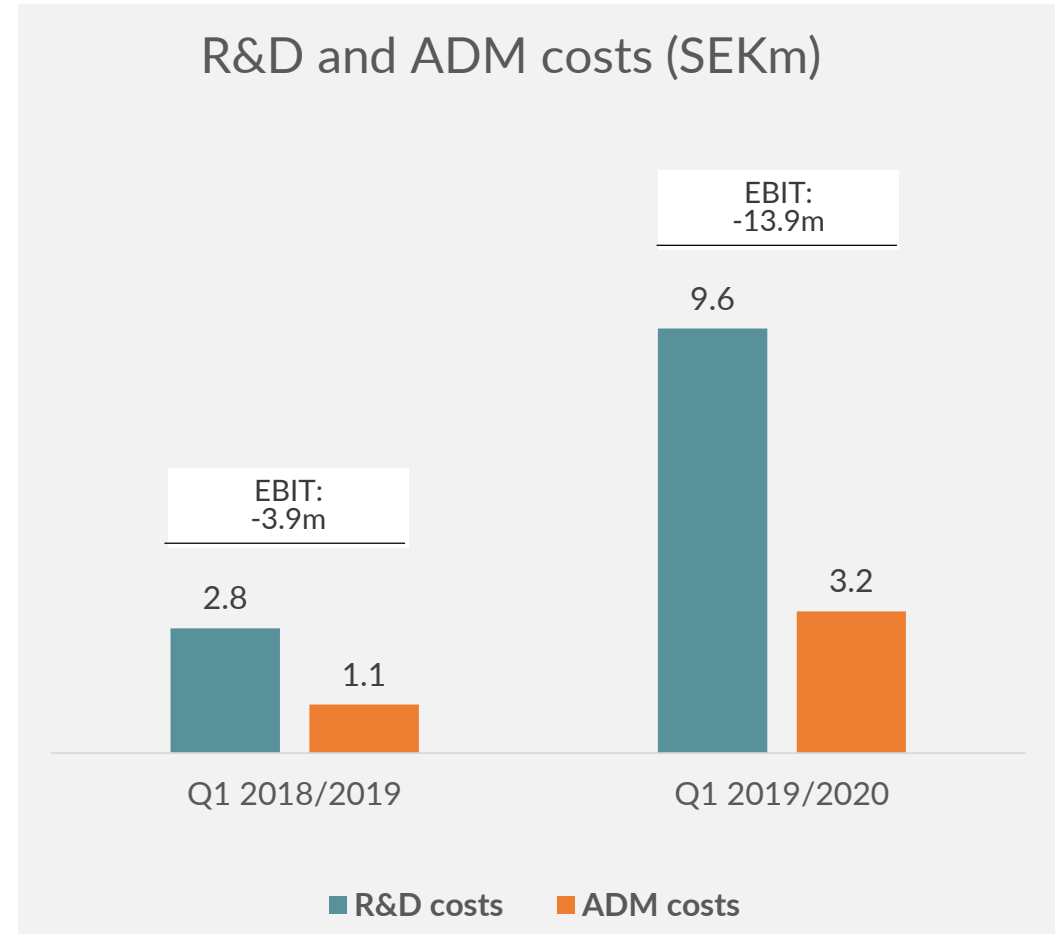
A scientist in a white lab coat and blue gloves is using a pipette to transfer a small amount of yellow liquid into a small glass vial. The background shows various laboratory equipment, including a flask with yellow liquid and a flask with blue liquid. The scene is lit with a cool blue light.

FINANCIALS

Q1 2019/2020 FINANCIAL HIGHLIGHTS – OPERATING RESULTS

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

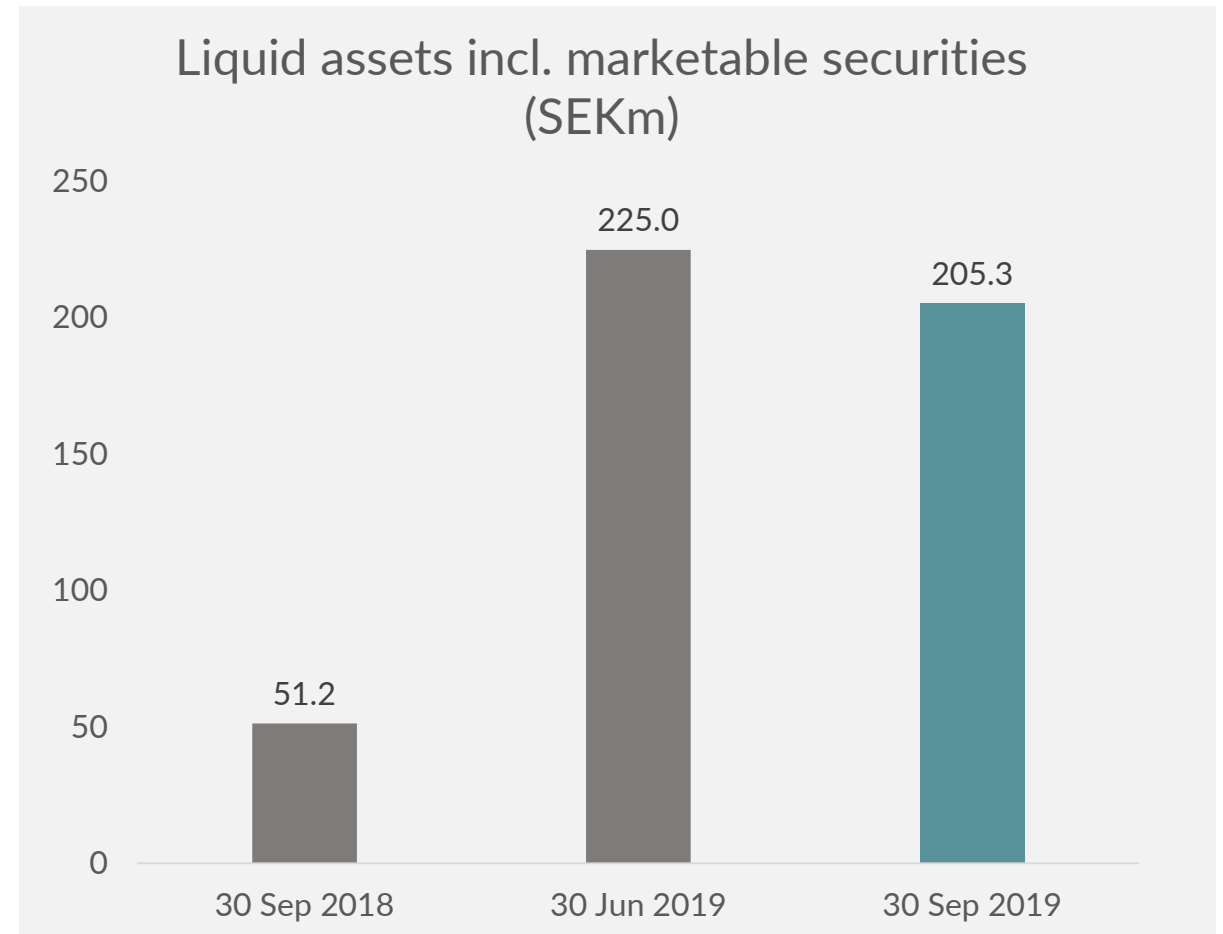
- Site selection
- Upscale of manufacturing



Q1 2019/2020 FINANCIAL HIGHLIGHTS – LIQUIDITY POSITION

Continued strong liquidity:

- Liquid assets incl. marketable securities of SEK 205.3 million
- The liquidity position provides a fully financed Phase III program for Mangoral including some commercial preparations as well as financing to prepare the Phase II program for Oncoral

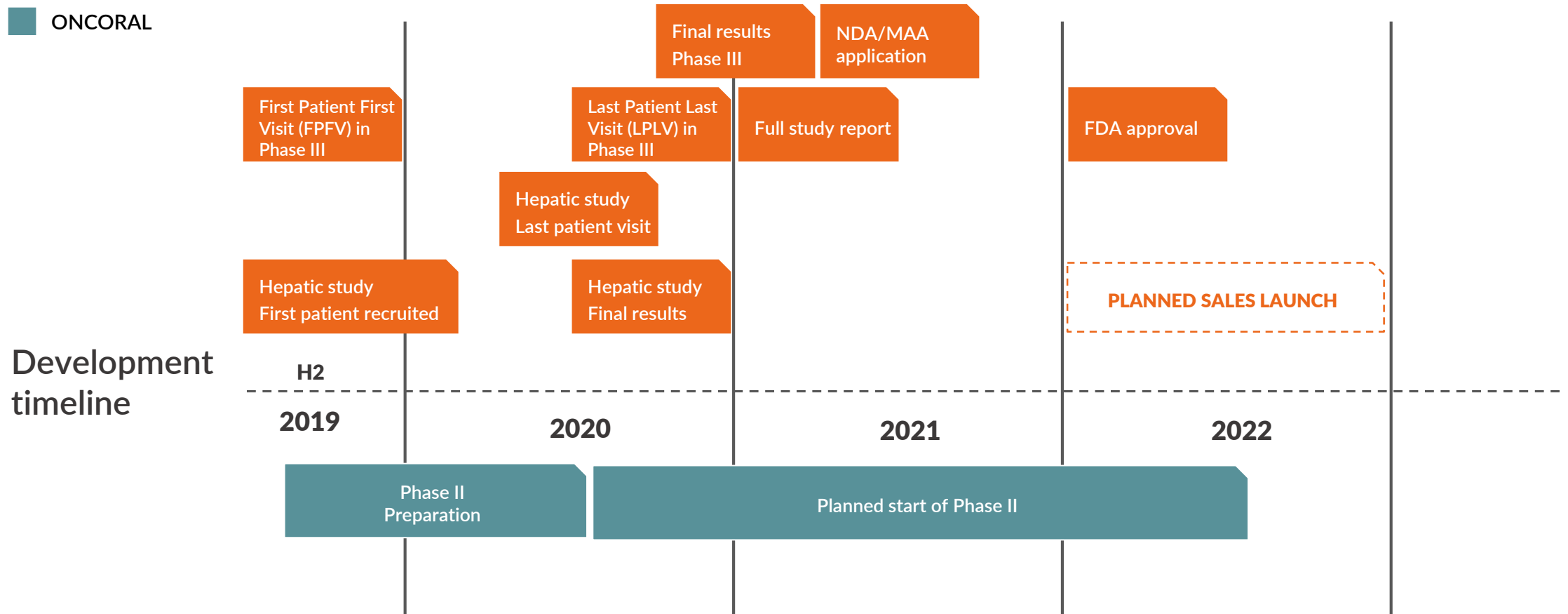


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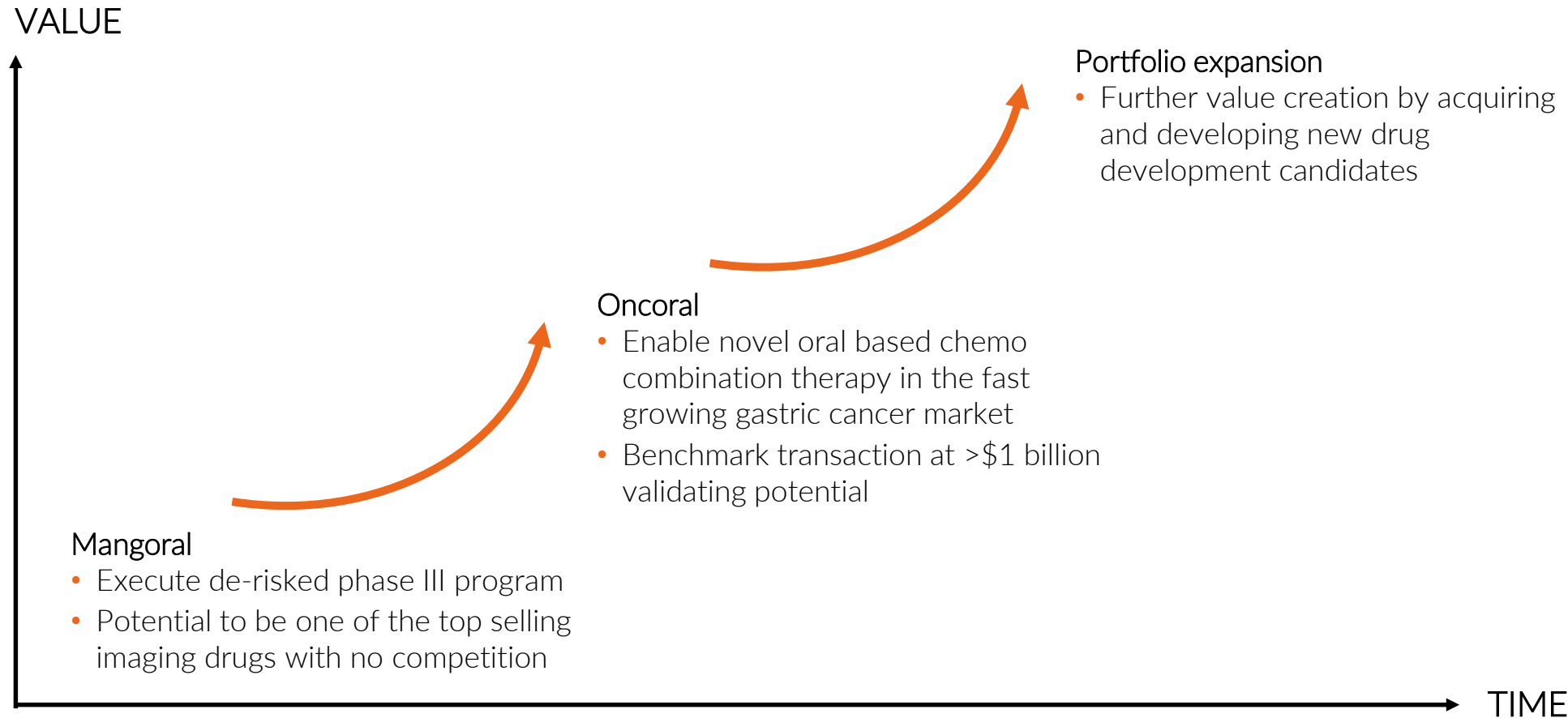
MILESTONES AND STRATEGIC OUTLOOK

SIGNIFICANT VALUE DRIVERS AHEAD

- MANGORAL
- ONCORAL



ASCELIA PHARMA STRATEGIC OUTLOOK



ASCELIA PHARMA

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