



ASCELIA PHARMA

Share ticker: ACE
Nasdaq Stockholm (small cap)

PRESENTATION OF Q2-2020 REPORT

APRIL-JUNE 2020

Present from Ascelia Pharma:

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CMO Carl Bjartmar | CCO Julie Waras Brogren

Webcast:

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<https://tv.streamfabriken.com/ascelia-pharma-q2-2020>

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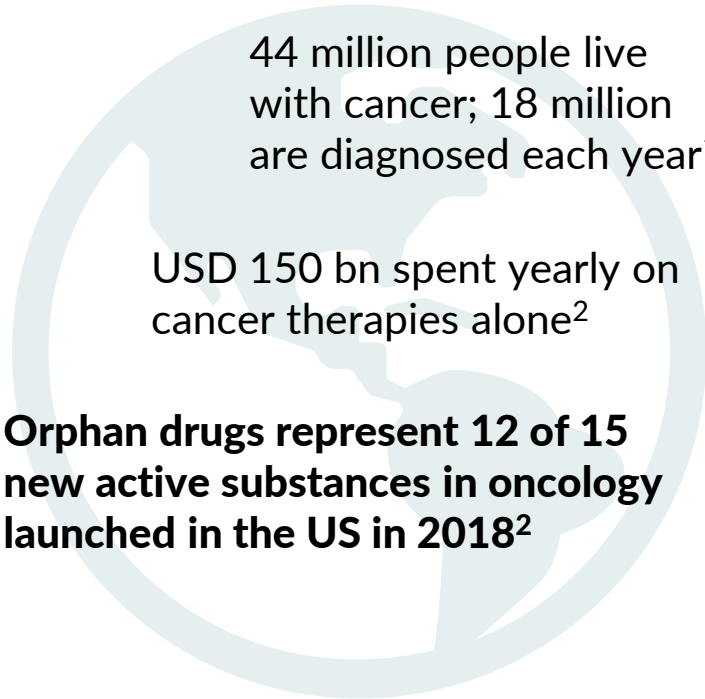
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ASCELIA PHARMA: ADVANCING ORPHAN ONCOLOGY

A global health burden



44 million people live with cancer; 18 million are diagnosed each year¹

USD 150 bn spent yearly on cancer therapies alone²

Orphan drugs represent 12 of 15 new active substances in oncology launched in the US in 2018²

Dedicated to unmet needs in orphan oncology

Drugs with a clear development and market pathway

- Advancing liver imaging with orphan MRI contrast agent with no competition (in ongoing Phase 3)
- Advancing chemotherapy with novel tablet for gastric cancer (Phase 2 ready)

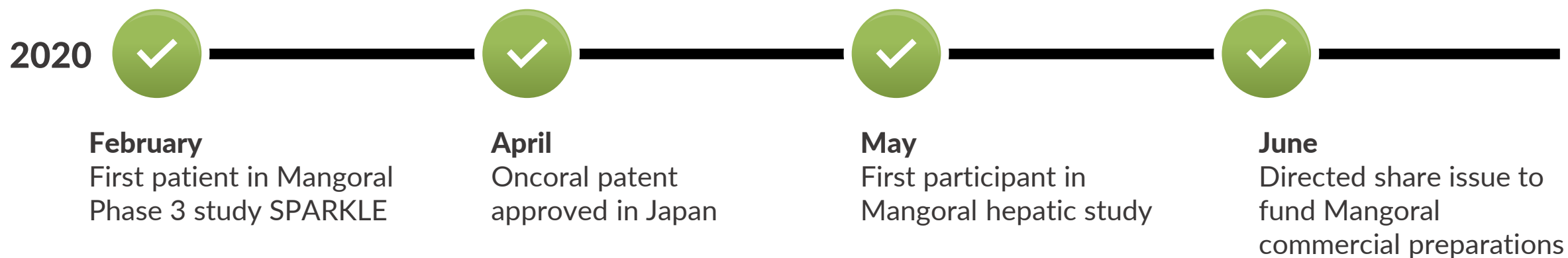
Capabilities to bring new compounds to market

- World class cross-functional team
- Headquartered in Malmö, Sweden
- Listed on NASDAQ STOCKHOLM in 2019 (ticker: ACE)
- Solid financial position

Sources

- 1) <https://canceratlas.cancer.org/the-burden/the-burden-of-cancer/> (2018 figures)
- 2) Global Oncology Trends 2019, IQVIA (2018 figures)

SIGNIFICANT PROGRESS IN 2020 DESPITE COVID-19



CLINICAL STAGE PORTFOLIO ADDRESSING CLEAR UNMET NEEDS

Drug candidate	Indication	Phase 1	Phase 2	Phase 3	Filing	Launch
Mangoral <ul style="list-style-type: none">Only <u>non</u>-gadolinium imaging drugNo competing drugs\$350-500M market with upside potentialDe-risked Phase 3 clinical programOrphan Drug Designation	Visualization of focal liver lesions <ul style="list-style-type: none">Liver metastasesPrimary liver cancerBenign lesions	✓	✓	2020 – H2-2021	H1-2022	Q4-2022 – H1-2023
Oncoral <ul style="list-style-type: none">Novel tablet chemotherapy formulationPhase 1 completed with promising resultsGastric cancer is an Orphan indication	Treatment of gastric cancer	✓	2021 – 2023	Strong case for development and commercialization partnering after Phase 2		



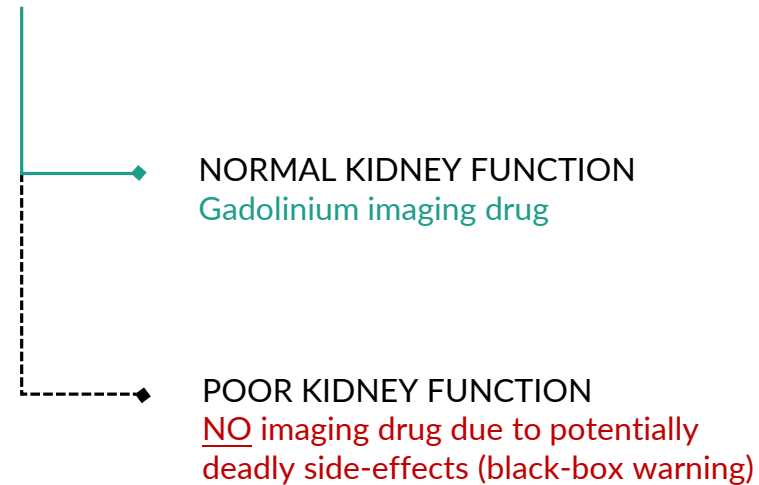
OUR CLINICAL PORTFOLIO

MANGORAL: LIVER CONTRAST AGENT IN PHASE 3

ONCORAL: CHEMOTHERAPY TABLET READY FOR PHASE 2

MANGORAL – MANGANESE BASED LIVER CONTRAST AGENT

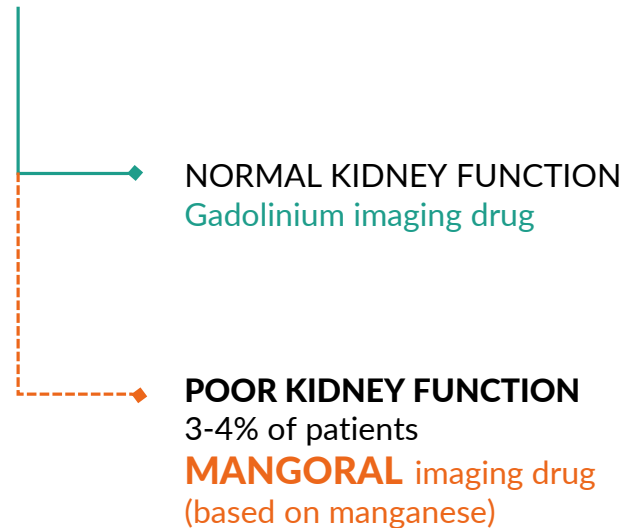
TODAY



WARNING: NEPHROGENIC SYSTEMIC FIBROSIS (NSF)
See full prescribing information for complete boxed warning.
Gadolinium-based contrast agents (GBCAs) increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of GBCAs in these patients unless the diagnostic information is essential and not available with non-contrasted MRI or other modalities.

- The risk for NSF appears highest among patients with:
 - Chronic, severe kidney disease (GFR < 30 mL/min/1.73m²), or
 - Acute kidney injury.
- Screen patients for acute kidney injury and other conditions that may reduce renal function.
- For patients at risk for chronically reduced renal function (for example, age >60 years, hypertension or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing (5.1).

TOMORROW



Mangoral aims to be the only standard of care liver MRI imaging drug for patients with impaired kidney function



280,000

patients with impaired kidney function in major markets

MANGORAL – DE-RISKED PHASE 3 STUDY

Strong data package for Mangoral






Six phase 1 and 2 clinical studies completed

Consistent strong efficacy readout and safety profile

Blind read study of all imaging data presented at major conferences

- The study with 178 persons further underlined that Mangoral significantly improves MRI performance
- 33% more lesions were detected after Mangoral enhanced MRI
- **Mangoral significantly improved lesion visualisation**
Delineation: p-value <0.0001
Conspicuity: p-value <0.0001

Phase 3 registration-enabling study (study ongoing)

Number of patients	Global study in up to 200 patients
Endpoint 	Lesion visualization <ul style="list-style-type: none">• Lesion border delineation (border sharpness of lesions)• Conspicuity (lesion contrast compared to liver background)
Comparator 	Unenhanced MRI + Mangoral MRI vs. Unenhanced MRI
Follow-up 	72 hours
Randomisation 	No – each patient at his/her own control
Validation 	Phase 3 program has been discussed with FDA and EMA

ONCORAL – NOVEL IRINOTECAN TABLET READY FOR PHASE 2

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

With promising Phase 1 results, we are now preparing for Phase 2

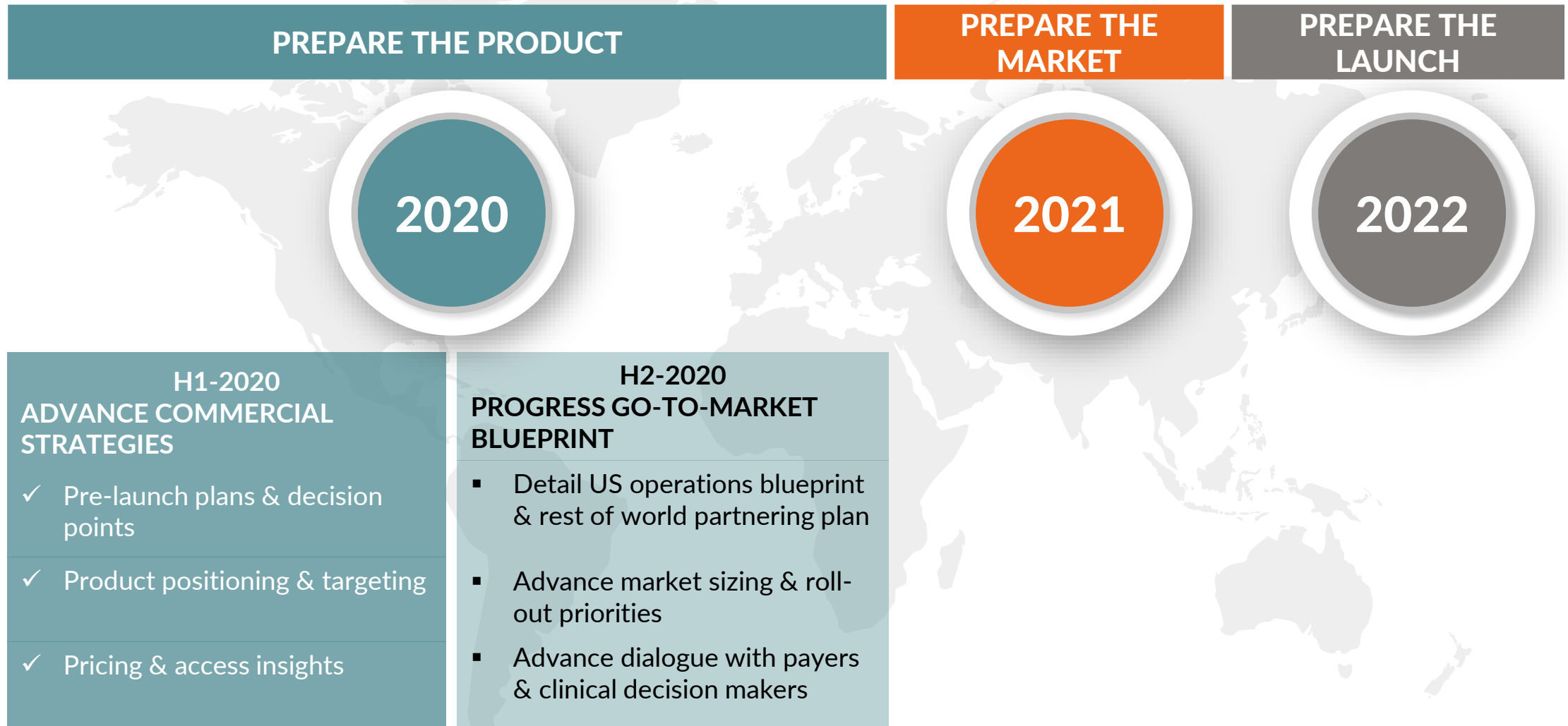
A man and a woman are standing in a grassy park. The man is holding a yellow bicycle with a wicker basket. They are both looking towards the right. The background is filled with trees and a bright, hazy sky. A semi-transparent white shape is overlaid on the left side of the image, containing the text.

MANGORAL

PREPARING FOR COMMERCIALIZATION

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COMMERCIAL PREPARATIONS IN PROGRESS



OUTLOOK FOR MARKET OPTIMAL LAUNCH STRATEGY

Strong case for own US commercialization



US operations

- Field team of 10-20 FTEs can reach 3,500-5,000 healthcare professionals
- Target major hospitals with nephrology units and independent specialist clinics
- US capability to include commercial and cross-functional support team
- Local logistics and distribution partnerships

Optimal RoW uptake with partnering



Europe, Japan and RoW

- Roll-out according to market potential, pricing and access
- Leverage global synergies in pre-launch and launch
- Ascelia Pharma vs. partner roles evaluated to maximize value

FINANCIALS

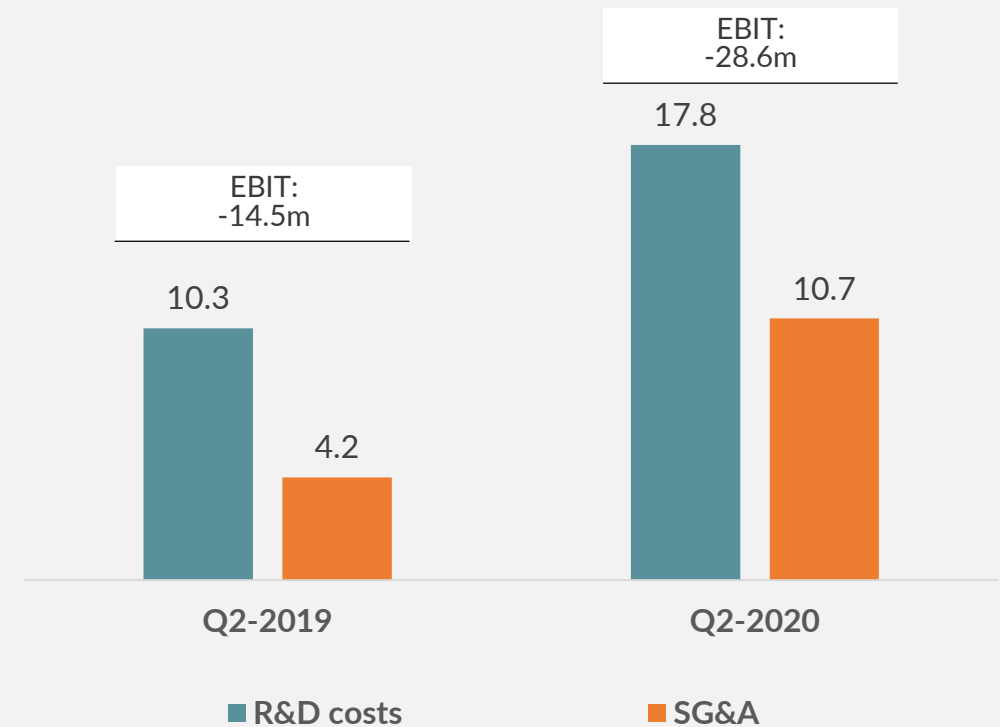
FINANCIAL HIGHLIGHTS – OPERATING RESULTS

Increased operating loss y/y mainly driven by higher R&D activity for Mangoral Phase 3 study:

- Preparing and opening of clinical study sites
- Manufacturing preparations
- Regulatory preparations

... And costs for commercial preparations for Mangoral (forming part of Selling, General & Administrative expenses)

Main operating costs and EBIT (SEKm)



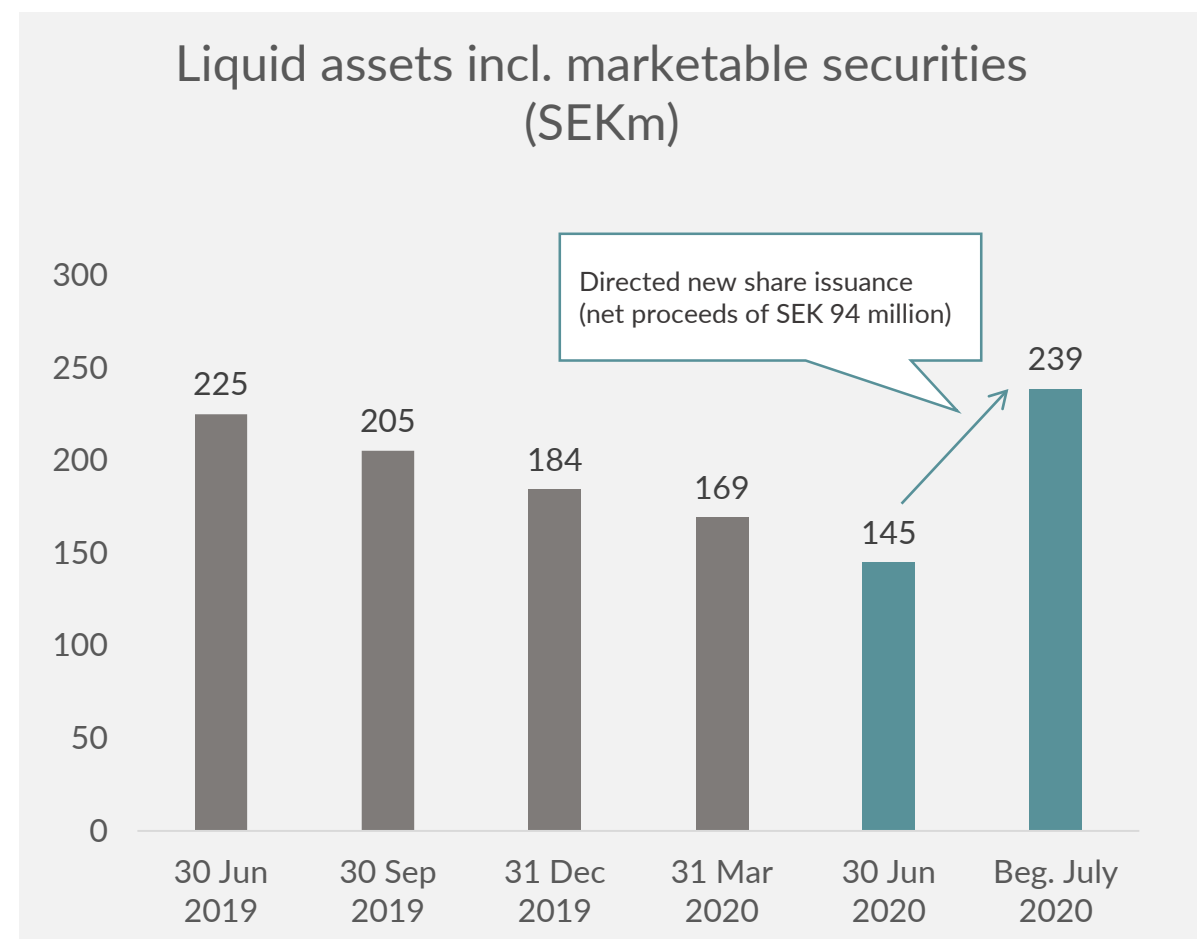
FINANCIAL HIGHLIGHTS – LIQUIDITY POSITION

Solid liquidity position:

- Liquid assets incl. marketable securities of SEK 145 million per 30 June 2020

Directed new share issuance at the end of June:

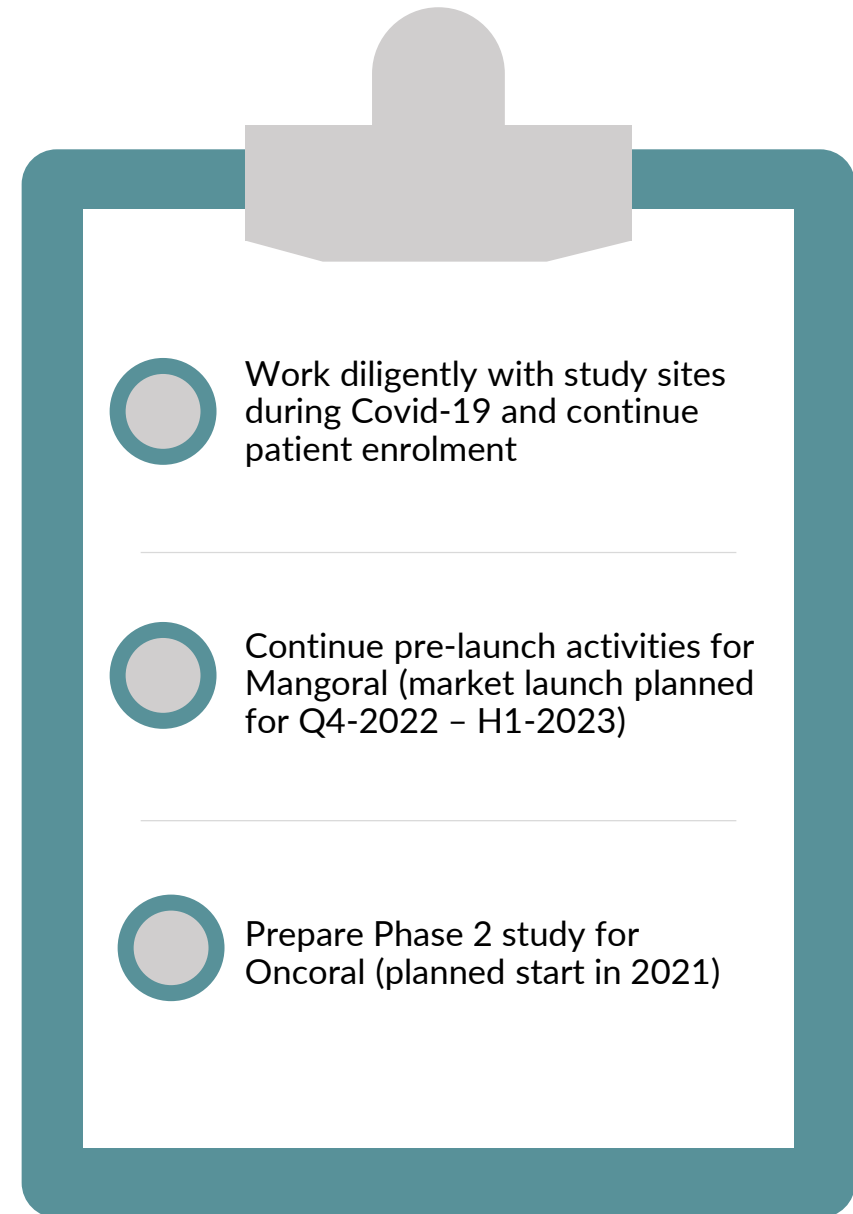
- Gross proceeds of SEK 99 million
- Highly acknowledged participated including:
 - Existing long-term shareholders AP4 and Handelsbanken Fonder
 - New investors including Healthinvest Partners, Länsförsäkringar Fondförvaltning, Unionen and OstVast Capital Management
- Proceeds received beginning of July taking the liquidity position to SEK 239 million





PRIORITIES 2020 AND SUMMARY

Priorities in H2-2020



ASCELIA PHARMA IN SUMMARY



Ascelia Pharma (ticker: ACE) – Advancing orphan oncology

- Drugs targeting unmet medical needs with a clear development and market pathway
- Solid financial position



Mangoral – Phase 3 non-gadolinium liver imaging drug

- \$350-500 million annual addressable market
- No competing drugs
- Ongoing Phase 3 program with high likelihood of success – study results expected in H2-2021
- Orphan Drug Designation



Oncoral – Phase 2 ready oral chemotherapy for gastric cancer

- Novel tablet formulation with significant patient and hospital benefits
- Effective molecule for killing cancer
- Promising Phase 1 results and preparing for Phase 2

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