

ASCELIA PHARMA

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WEBCAST:

4 November 2021, 10:00AM CET

Link webcast:

[Ascelia Pharma Q3 Report 2021
\(streamfabriken.com\)](https://streamfabriken.com)

Dial-in teleconference:

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PRESENTATION OF Q3-2021 REPORT

Present from Ascelia Pharma:

CEO Magnus Corfitzen | CFO Kristian Borbos
CMO Carl Bjartmar | CCO Julie Waras Brogren

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INVESTMENT HIGHLIGHTS



TO IMPROVE THE LIFE OF PEOPLE LIVING
WITH CANCER BY OFFERING BETTER
TREATMENT OPTIONS

ADVANCING ORPHAN ONCOLOGY

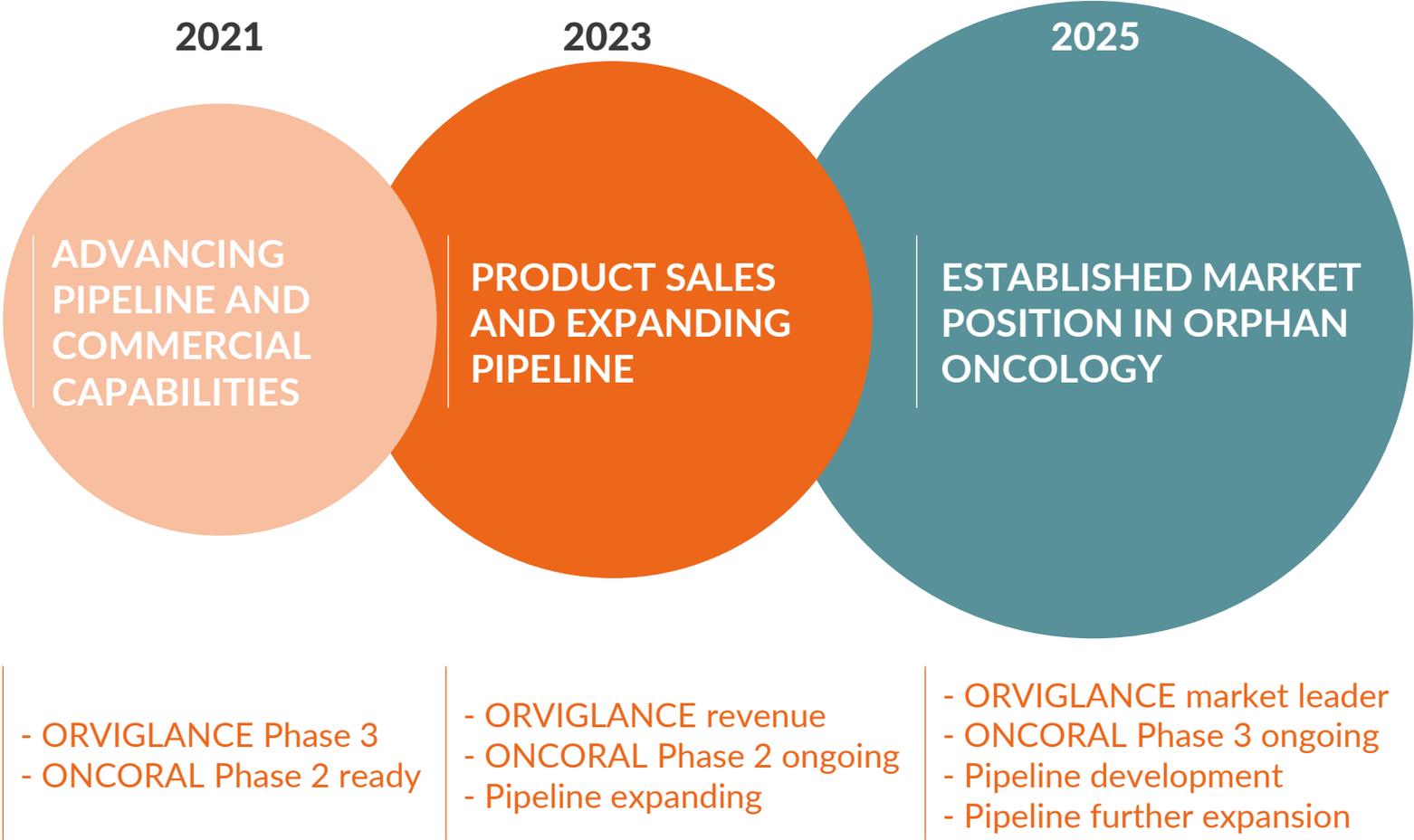
- Identify, develop and commercialize novel drugs that address unmet needs in rare cancers
- Two drugs in advanced clinical development
 - **ORVIGLANCE (MANGORAL)** – in global Phase 3; FDA Orphan Drug Designation; U.S. launch expected H2 2023
 - **ONCORAL** – starting Phase 2 in Q4 2021*

BUILDING GLOBAL CAPABILITIES

- Financed well into 2023
- Based in Malmö (Sweden) & Woodbridge, NJ (US)
- Listed on NASDAQ Stockholm (Ticker: ACE)

*Expected timing for study start approval (IND approval)

BUILDING VALUE



RECENT KEY EVENTS

Key events Q3-2021

- Aug** FDA conditionally accepted Orvigance® as the brand name for Mangoral
- Aug** Abstract for Orvigance comparison study to gadolinium accepted as an oral paper presentation at the world's largest radiology conference RSNA
- Aug** Guidance for expected recruitment completion for the SPARKLE study moved to H1 2022 (previously H2 2021)
- Sep** Clinical collaboration agreement with Taiho Oncology Inc. for the development of Oncoral in combination with LONSURF®

Key events after the quarter

- Oct** Food Effect Study with Orvigance successfully completed



ONCORAL – CLINICAL COLLABORATION WITH TAIHO ONCOLOGY

DEVELOPMENT OF ONCORAL IN COMBINATION WITH LONSURF®

- Clinical Phase 2 collaboration with Taiho Oncology Inc. (part of the Otsuka Group)
- Taiho Oncology will supply Lonsurf as well as provide scientific expertise for the study
- Depending on the results, the collaboration may be extended for further development
- Ascelia Pharma retains full development and commercialization rights to Oncoral

Clinical collaboration with



LONSURF is approved for treatment of metastatic gastric cancer and metastatic colorectal cancer

ORVIGLANCE – FOOD EFFECT STUDY SUCCESSFULLY COMPLETED

Last Patient Last Visit in Food Effect Study (part of the registration package for Orviglance)

- Crossover study in 24 healthy volunteers in fasting condition versus two fed conditions (snack or full meal)
- Study objectives included food effects on Orviglance PK, PD and safety profile
 - Data will provide guidance on fasting requirements before Orviglance administration
- Preliminary data indicate that Orviglance was well tolerated in the study – final results expected late 2021/early 2022
- A potential removal of the current fasting requirement could further improve the convenience and ease the administration of Orviglance in clinical practice



PORTFOLIO

ORVIGLANCE (MANGORAL)

Liver diagnostic drug in ongoing Phase 3

ONCORAL

Daily oral chemotherapy ready for Phase 2

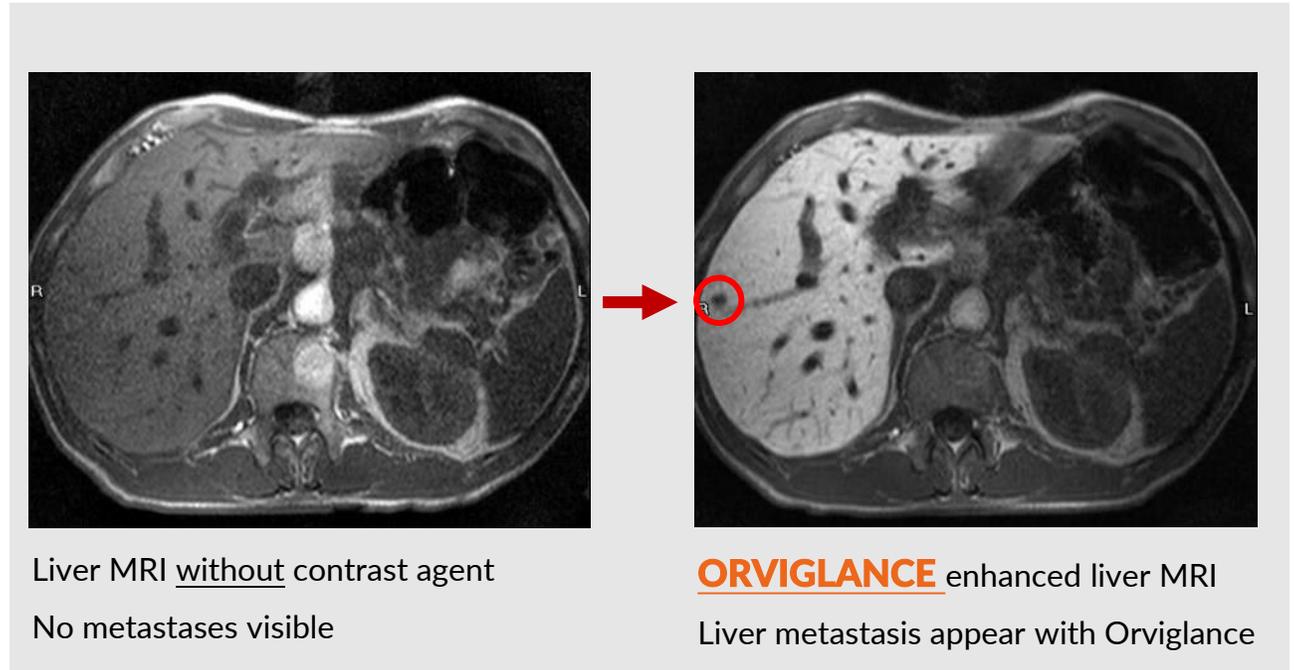
ORVIGLANCE – PHASE 3 LIVER MRI CONTRAST AGENT

NOVEL LIVER MRI CONTRAST AGENT

- Diagnostic drug for use in liver MRI scan to detect cancer
- Targeting patients at risk of potentially fatal side-effect from the current contrast agents on the market
- \$500-600 million addressable market with Orviglance as the only gadolinium-free agent

SOLID PROGRESS

- Strong clinical Phase 2 results (p-values <0.0001)
- Ongoing Global Phase 3 study
- Orphan Drug Designation from FDA



ORVIGLANCE PHASE 1 & 2 RESULTS (6 STUDIES)

Consistent strong efficacy readout and safety profile

Blind read study of all images vs. unenhanced MRI

(178 persons)

- Significantly improved MRI
- 33% more lesions
- **Lesion visualization**
Delineation (border sharpness): **p-value <0.0001**
Conspicuity (contrast vs. background): **p-value <0.0001**

Re-read study vs. gadolinium contrast agent (GBCA)

(20 patients)

- ORVIGLANCE lesion visualization as effective as GBCA
(2 out of 3 readers favoured Orviglance)

Proceed into Phase 3

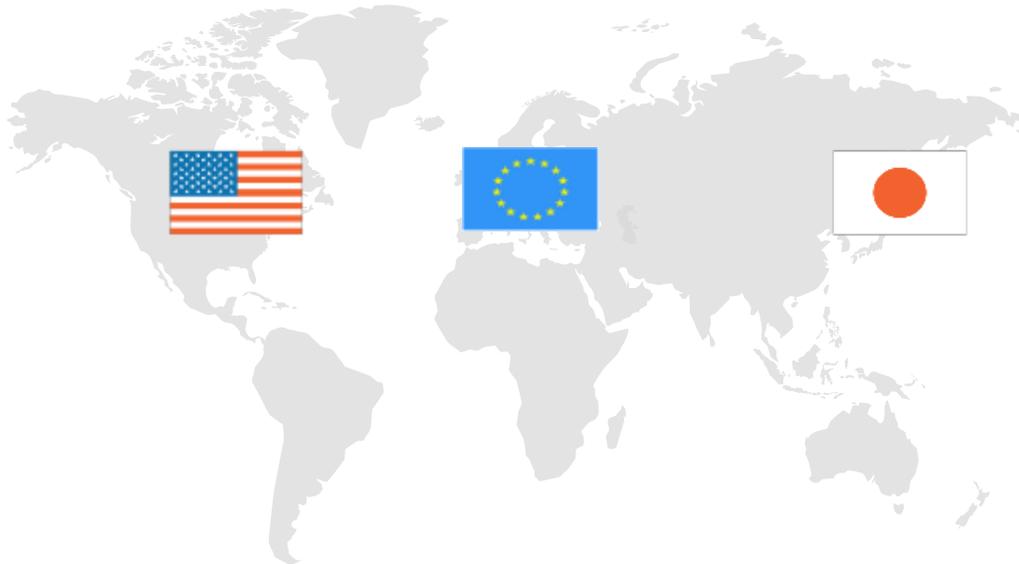
ORVIGLANCE ONGOING PHASE 3 STUDY – SPARKLE

Patients 	<ul style="list-style-type: none">• Global study, 200 patients• Known or suspected focal liver lesions and severe renal impairment• No randomization – each patient as own control	Status update: US, Europe, Latin America 40+ sites increasing to over 50 sites
Comparator 	Unenhanced MRI + ORVIGLANCE MRI vs. Unenhanced MRI	Internal control so not randomized
Endpoint 	Lesion visualization <ul style="list-style-type: none">• Lesion border delineation• Conspicuity	Same endpoints as Phase 2
Follow-up 	Less than a week	Expected pivotal study patient enrollment: H1 2022

ORVIGLANCE MARKET \$500-600 MILLION ANNUALLY

\$500-600M ADDRESSABLE MARKET IN US, EU AND JAPAN

- Ascelia Pharma to commercialize in the U.S
- RoW commercialization with partners



DRIVERS

- Patients with suspected 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

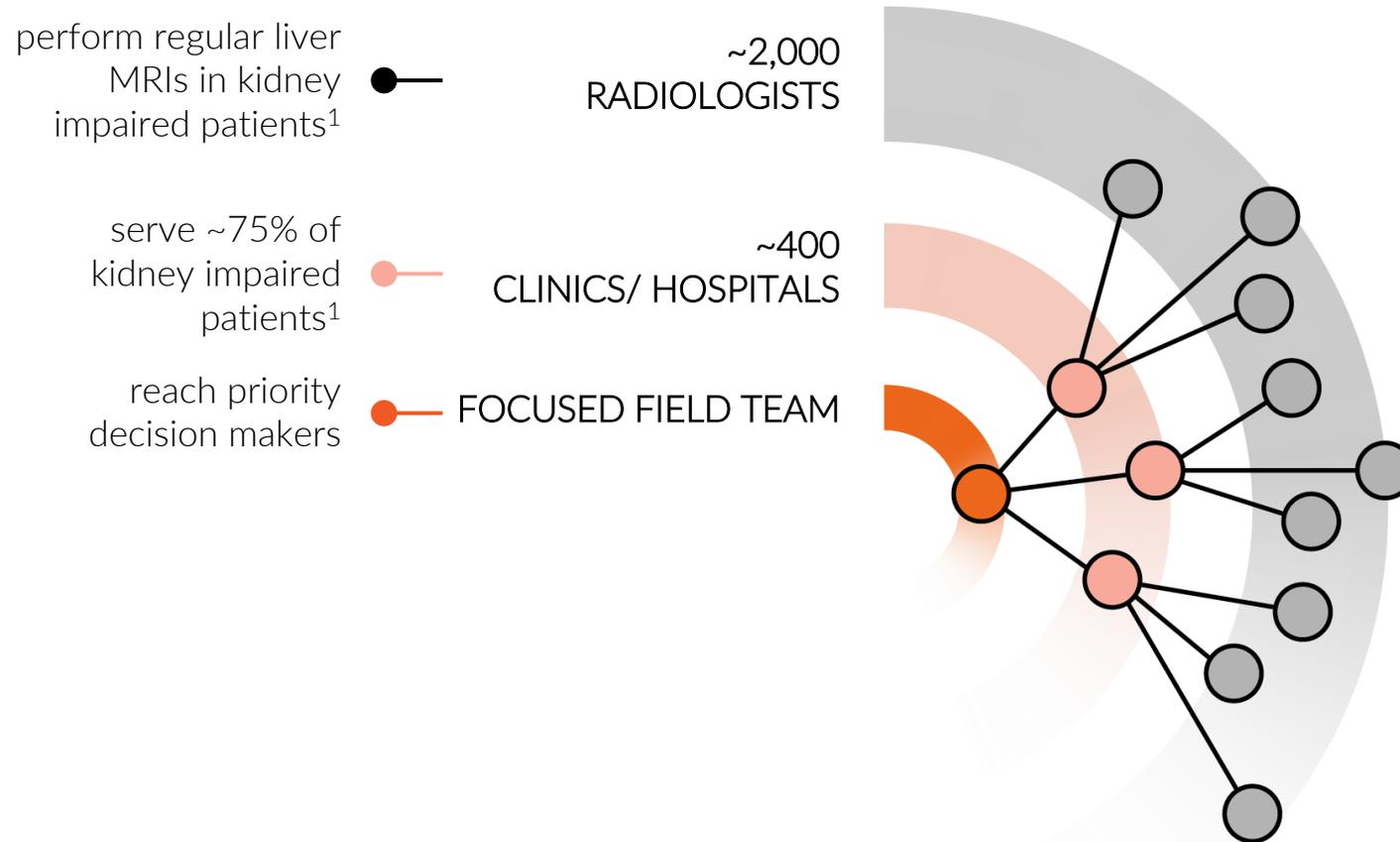
- Other markets, e.g., China
- Annual growth of 4-5%

Sources:

1) Market research with Decision Resources Group, 2020

2) Market research and analyses with Revenue Reimbursement Solutions and Charles River Associates, 2020

CAPTURING US MARKET VALUE WITH ASCELIA'S TEAM



BUILDING ASCELIA U.S. TEAM

New Jersey office (up to 40 FTEs at launch)

Cambrex manufacturing partner

BUILDING OUT U.S. FOOTPRINT

SPARKLE Phase 3 study 13+ US Sites including Yale, Stanford, Mass. General, UCLA Medical Center

Sources:

1) Market research with Decision Resources Group, 2020



PORTFOLIO

ORVIGLANCE (MANGORAL)

Liver contrast agent in ongoing Phase 3

ONCORAL

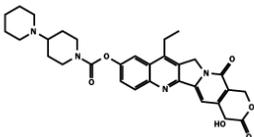
Daily oral chemotherapy ready for Phase 2

IMPROVING IRINOTECAN EFFICACY and TOLERABILITY

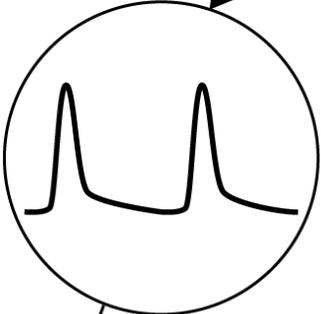
Irinotecan intravenous bolus dosing

ONCORAL – irinotecan oral daily dosing

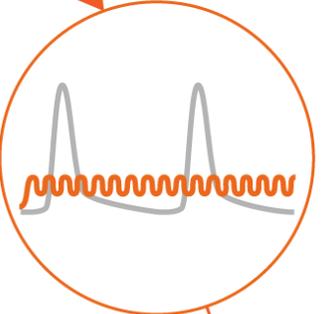
irinotecan



High-dose IV infusion every 3 weeks



Oncoral low-dosing daily tablet

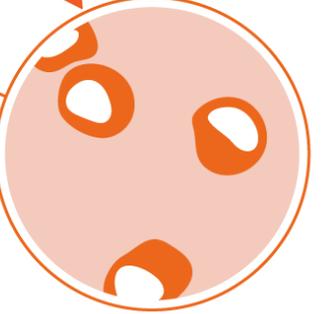


Serious side-effects limit efficacy



Tumor cells

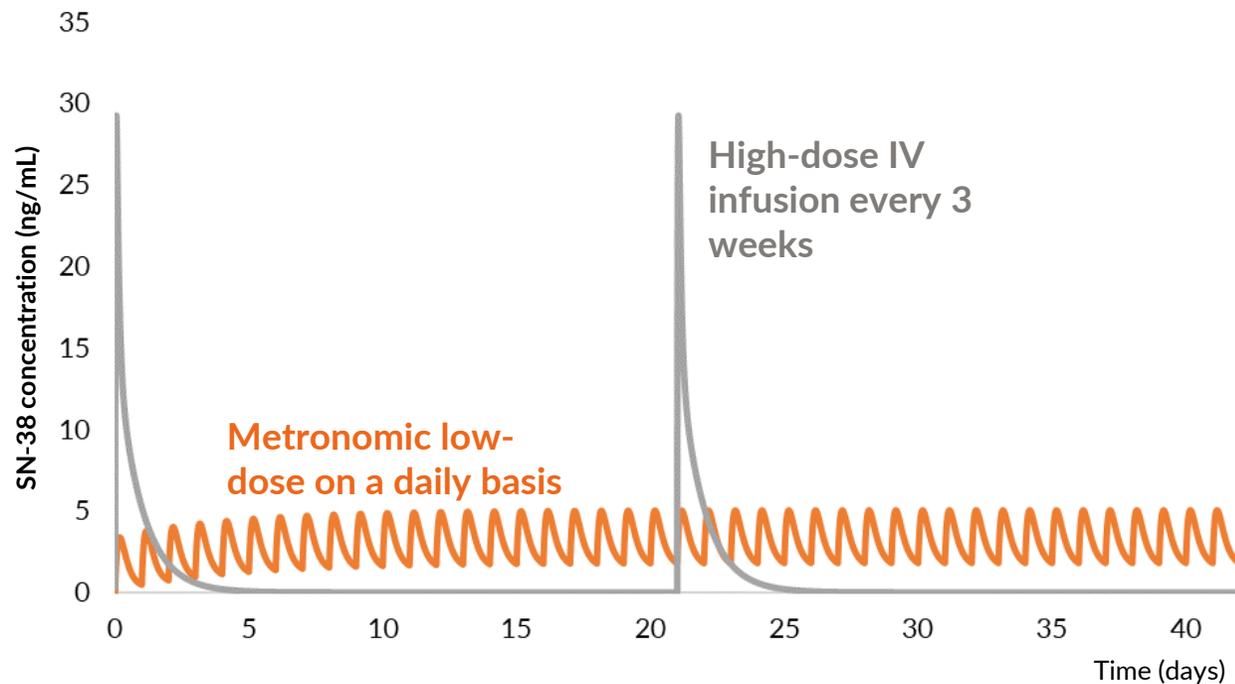
Potential for improved efficacy with reduced side-effects



Tumor cells

ONCORAL PHASE 1 RESULTS

PLASMA LEVELS OF IRINOTECAN



Source: Simulation of Oncoral vs. IV Camptosar performed by Pkxpert AB

Oncoral Phase 1 results

- Well tolerated, no unexpected side-effects
- Hematological toxicities mild-moderate (grade 1 or 2)⁴
- Efficacy: Stable disease even in patients previously treated with IV irinotecan

Infrequent high-dose IV irinotecan

Gastrointestinal and hematological side effects, ~30% severe or life-threatening (grade 3 or 4)¹

Frequent (metronomic) low-dose irinotecan

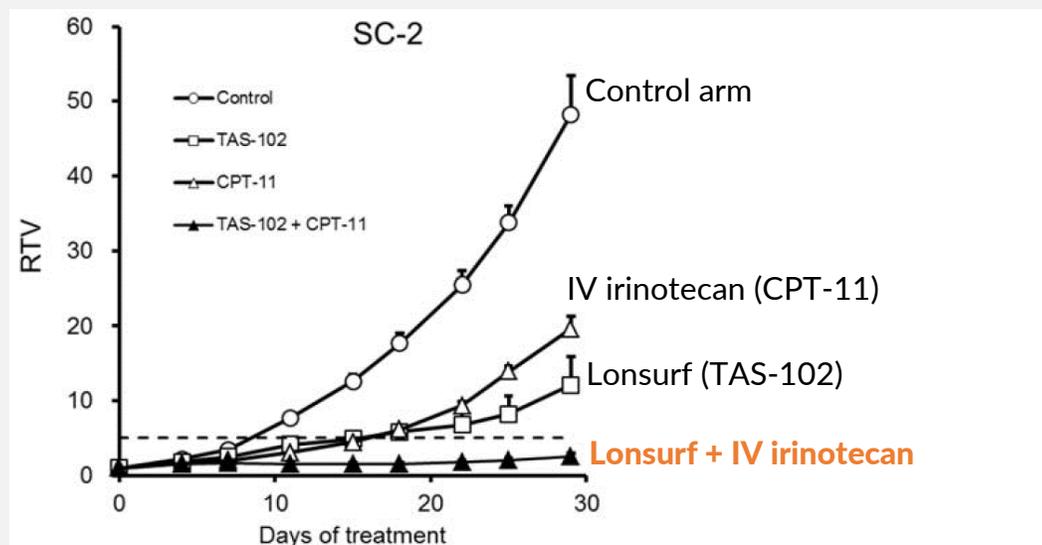
- Several studies show improved tolerability^{2,3}
- Daily dosing – adjust quickly if acute toxicity

ONCORAL PHASE 2 IN GASTRIC CANCER

STRONG RATIONALE FOR GASTRIC CANCER

- Clinical guidelines support efficacy of irinotecan
- Potential for Orphan Drug Designation
- Potential for synergistic effect between Lonsurf and irinotecan

Efficacy study in an animal model of gastric cancer¹ (Relative Tumor Volume, RTV)



STUDY DESIGN (ALL-ORAL COMBINATION STUDY)

Patients



- Around 100 patients
- Metastatic gastric cancer
- Randomized controlled, multicenter, multinational study

Comparator



Oncoral + Lonsurf
vs.
Lonsurf

Endpoints



Primary: Progression Free Survival
Secondary: Response rate, PK, Safety and Overall Survival data in a follow up analysis

Study period

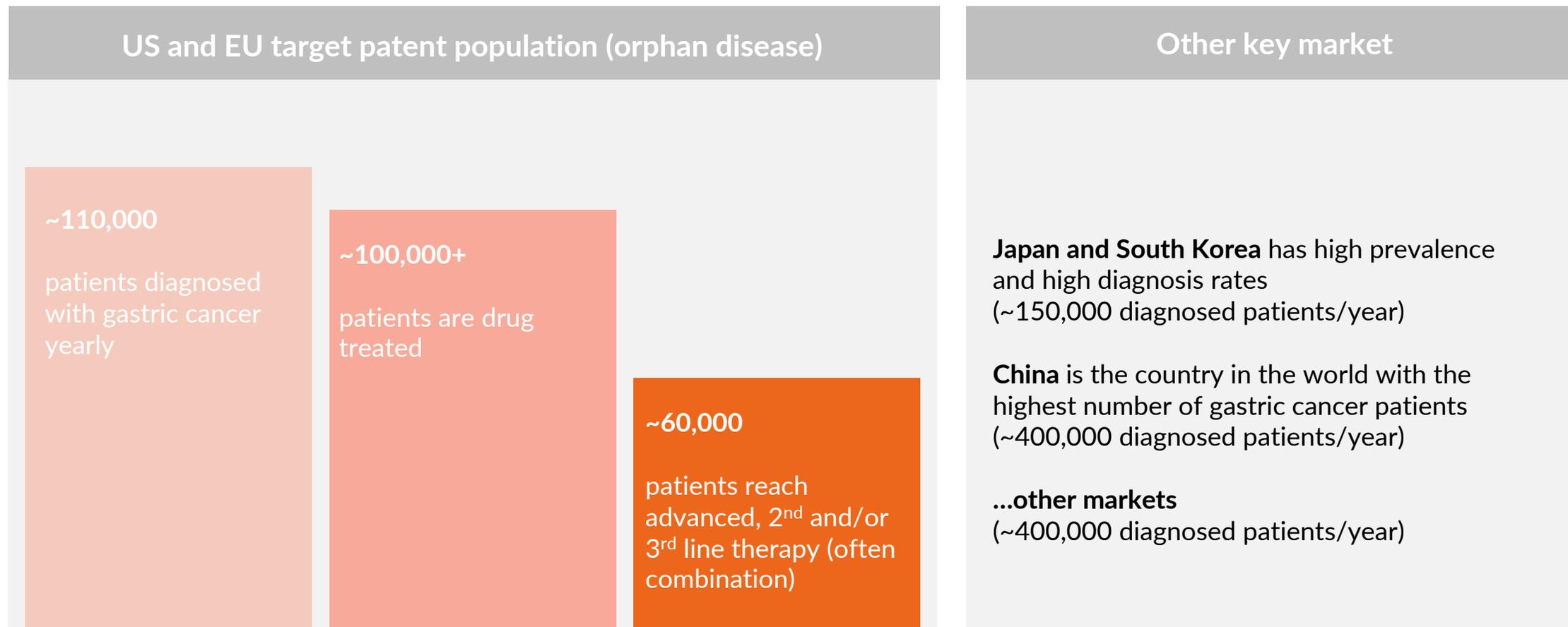


Q4 2021* - 2024

*Expected timing for study start approval (IND approval)

1: Nukatsuka et al: Combination Chemotherapy Using TAS-102 and Irinotecan Hydrochloride, ANTICANCER RESEARCH 35: 1437-1446 (2015)

GASTRIC CANCER – A \$3BN+ MARKET OPPORTUNITY

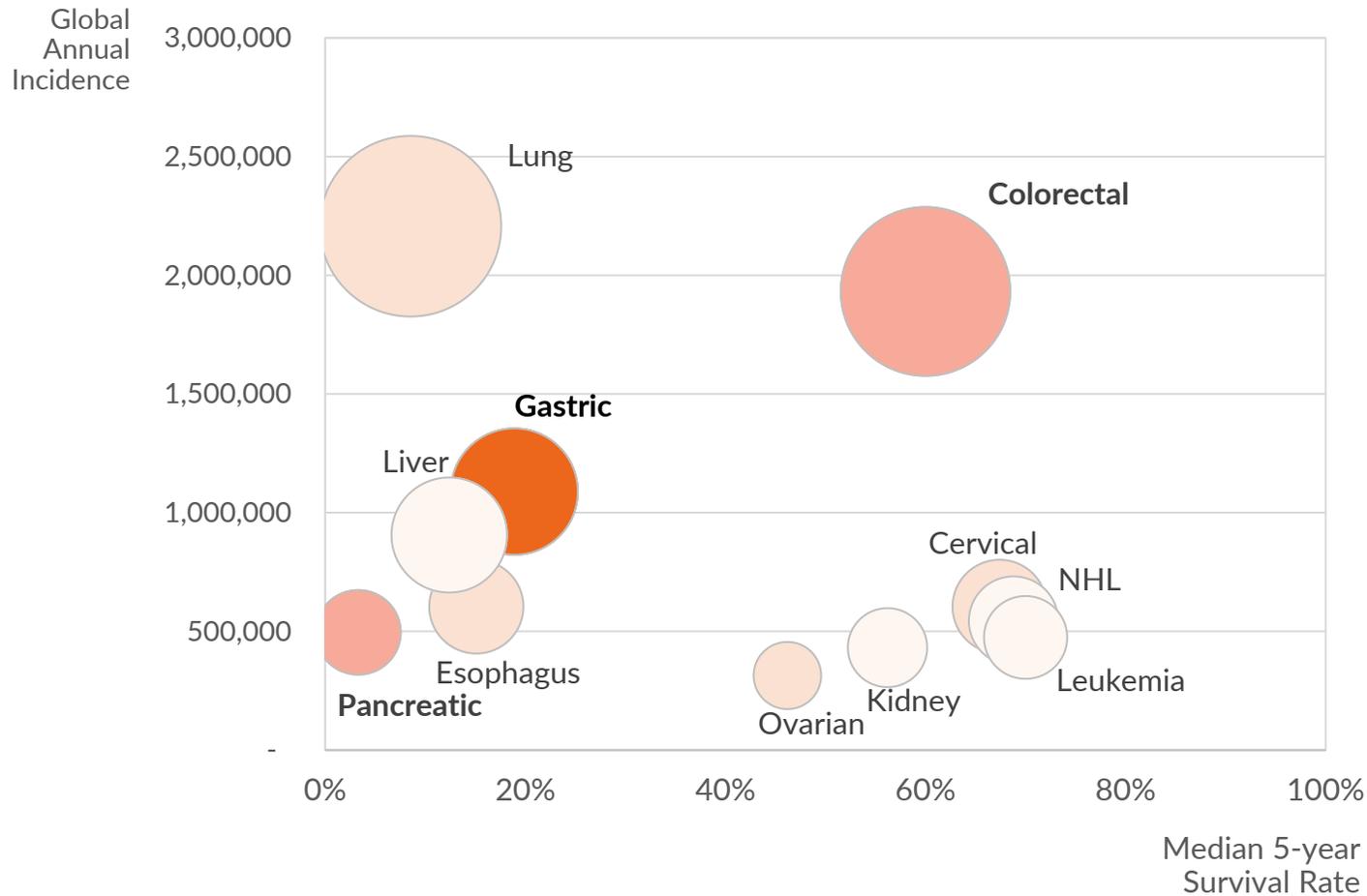


Sources:

International Agency for Research on Cancer (IARC, 2021, input from key opinion leaders and Ascelia analysis)
GlobalData - Gastric and Gastroesophageal Junction Adenocarcinoma – Global Drug Forecast and Market Analysis to 2024

HIGH VALUE OPPORTUNITY IN GASTRIC CANCER AND EXPANSION

POTENTIAL FOR ORAL, DAILY DOSING OF IRINOTECAN³



- **Current focus: Gastric cancer**
 - 3rd highest cancer deaths¹
 - Orphan opportunity (U.S. and EU)
 - \$3-4bn market²

- Approved indications for IV irinotecan infusions

- Indications for which IV irinotecan infusions are clinically demonstrated & NCCN recognized

- Indications for which IV irinotecan infusions are clinically demonstrated

1) International Agency for Research on Cancer (IARC, 2021)
 2) GlobalData - Gastric and Gastroesophageal Junction Adenocarcinoma – Global Drug Forecast and Market Analysis to 2024
 3) Globocan 2020, WHO, Cancer Research UK

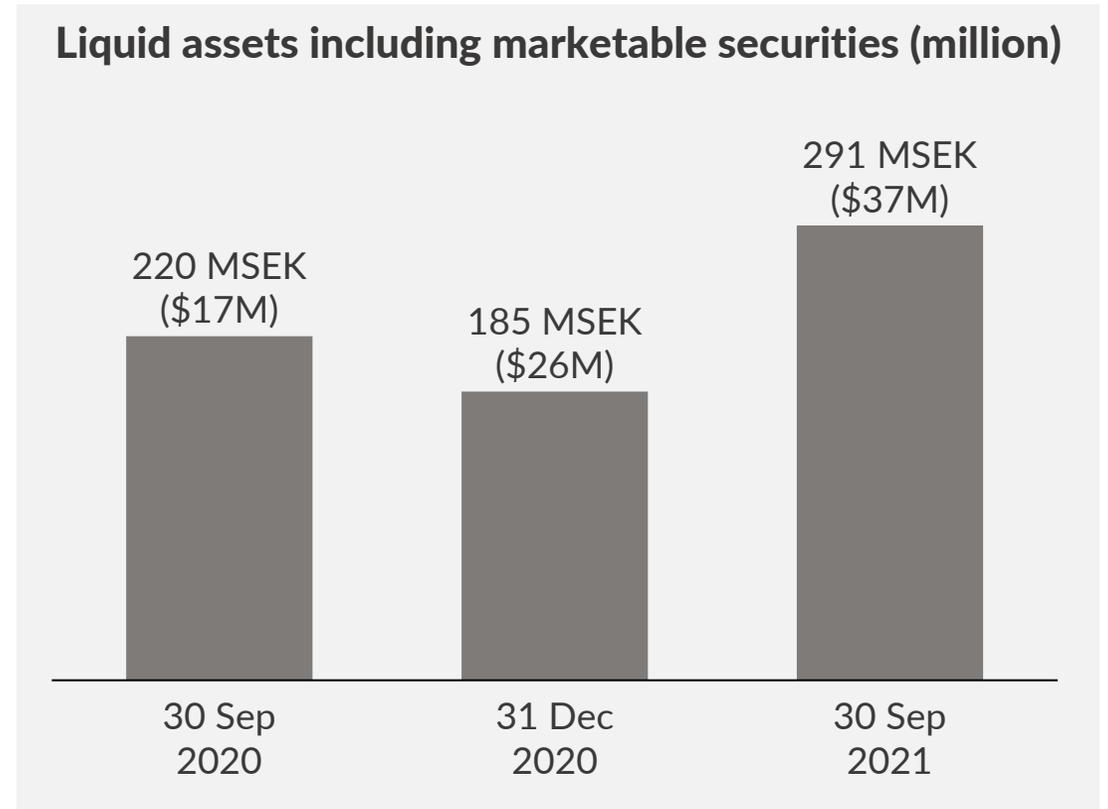
FINANCIALS AND PRIORITIES



FINANCIAL HIGHLIGHTS Q3 2021 – LIQUIDITY POSITION

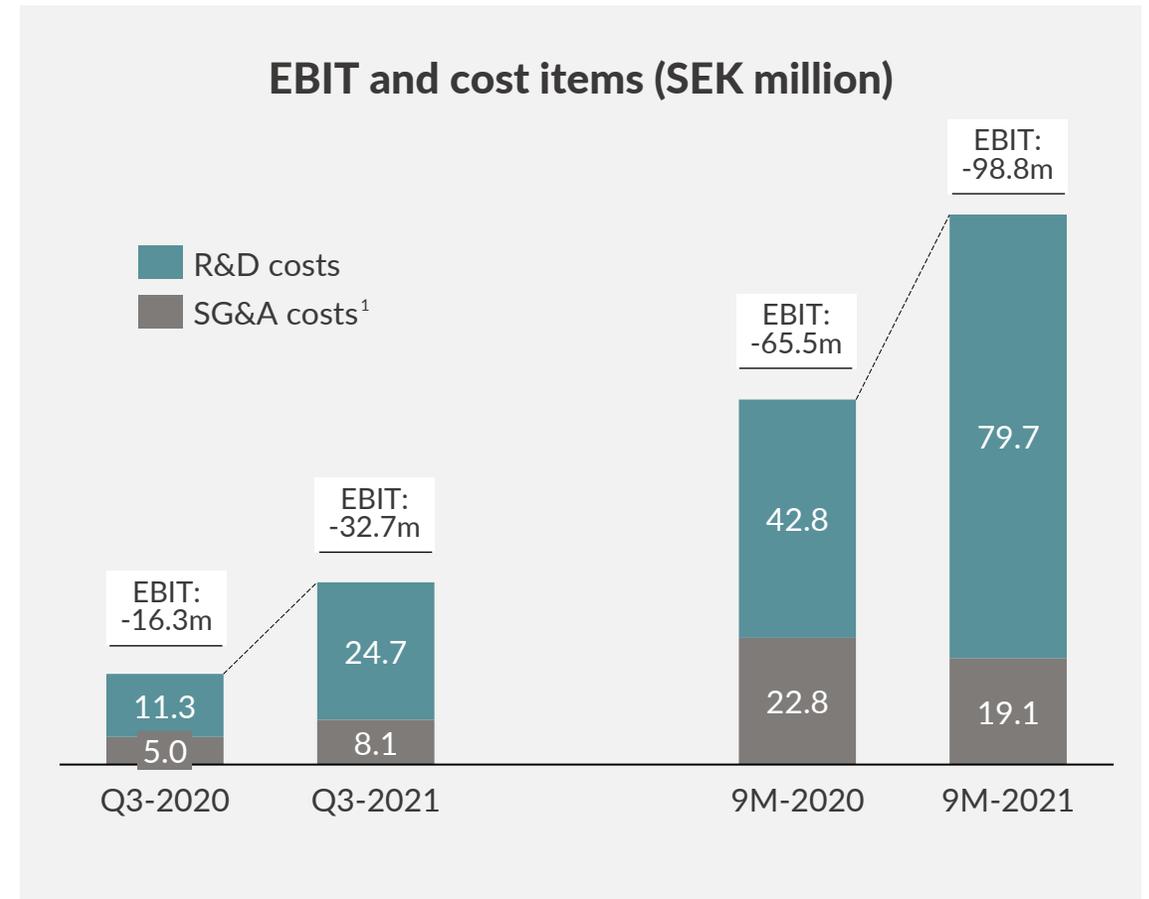
Solid liquidity position:

- Liquid assets of 291 MSEK (\$34 million) by 30 Sep 2021
- Quarterly burn rate in 9M 2021 of ~30 MSEK (\$3-4 million)
- Current cash position provides financing well into 2023



FINANCIAL HIGHLIGHTS Q3 2021 – OPERATING RESULTS

- Increased operating loss y/y mainly driven by higher R&D activity for Orviglance Phase 3 study:
 - Clinical development
 - Manufacturing preparations
- Also higher R&D costs y/y due to Oncoral Phase 2 preparations



Notes:

1) Other operating income and other operating costs added to SG&A



PRIORITIES AND KEY MILESTONES

- 1 Initiate Phase 2 study for Oncoral (study approval start, IND, expected Q4-2021)¹
- 2 Complete Orvigance Phase 3 patient enrollment (expected H1-2022)¹
- 3 Prepare Orvigance launch (planned for H2-2023)¹

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

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