

ASCELIA PHARMA

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PRESENTATION OF Q4-2022 REPORT

Presenters from Ascelia Pharma:

CEO Magnus Corfitzen | Deputy CEO & CCO Julie Waras Brogren
CSO Andreas Norlin | CFO Déspina Georgiadou Hedin

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ASCELIA PHARMA – COMPANY HIGHLIGHTS



*IMPROVING 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** – in global Phase 3; FDA Orphan Drug Designation
 - **ONCORAL** – ready for Phase 2

BUILDING GLOBAL CAPABILITIES

- Based in Malmö (Sweden), US affiliate in New Jersey (US)
- Solid balance sheet and financed into Q4 2023
- Listed on NASDAQ Stockholm (Ticker: ACE)

RECENT KEY EVENTS

Key events in Q4-2022

- New strong Orvigance data support successful SPARKLE completion with substantially fewer patients
- Ascelia Pharma expands management team to prepare for commercialization
- Presentation at the RSNA congress of results from Orvigance food effect study showing strong liver enhancement both with light meal and in fasting condition
- 65 patients have completed SPARKLE at the end of 2022

Key events after Q4-2022

- 71 patients have completed the SPARKLE study by January 27, 2023





PORTFOLIO

ORVIGLANCE

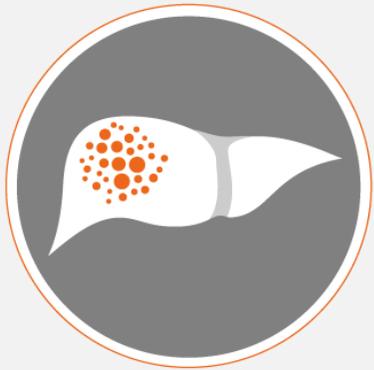
Liver diagnostic drug in ongoing Phase 3

ONCORAL

Daily oral chemotherapy ready for Phase 2

ORVIGLANCE – FILLING AN UNMET NEED IN LIVER MRI

Liver metastases
critical in cancer care



Liver metastases are common
in many cancer types and often
the cause of mortality¹⁻³

- Colorectal cancer, metastatic breast cancer, gastric cancer

Contrast enhanced MRI
is gold standard



Contrast enhanced MRI

- Detection and visualization
- Surgery or drug treatment planning
- Post-treatment surveillance

A role for Orviglance
in patients with kidney impairment



Healthy kidneys

MRI with gadolinium contrast agent

Severe kidney impairment

- All gadolinium contrast agents have regulatory Black Box warnings
- Risk of severe side effects, incl. Nephrogenic Systemic Fibrosis

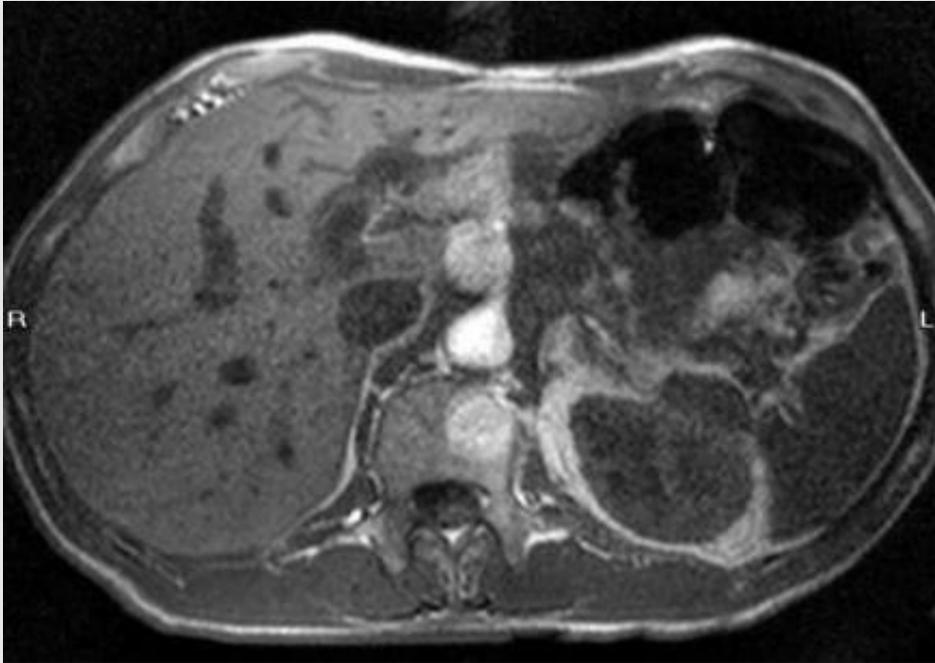
Orviglance

aims to be the liver imaging option without gadolinium-related safety risks for cancer patients with poor kidney function

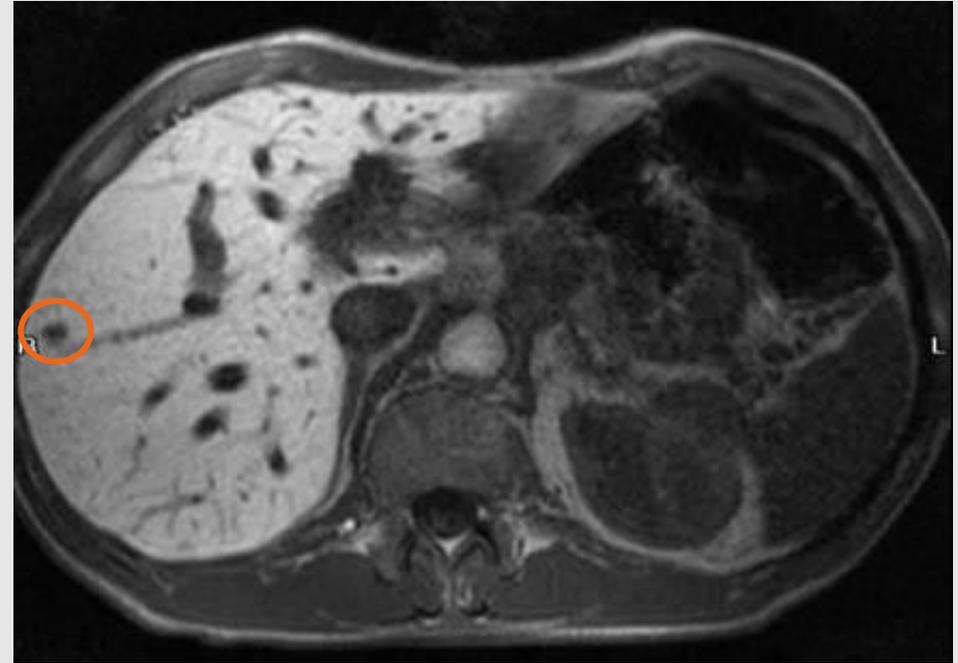
1) Riihimäki, M. *et al.* Patterns of metastasis in colon and rectal cancer. *Sci. Rep.* 6, 29765; doi: 10.1038/srep29765 (2016); *Journal of Pathology*, 2014, 232:23-31
2) Guy diSibio and Samuel W. French (2008) Metastatic Patterns of Cancers: Results From a Large Autopsy Study. *Archives of Pathology & Laboratory Medicine*: June 2008, Vol. 132, No. 6, pp. 931-939
3) Rahbari *et al.* Metastatic Spread Emerging From Liver Metastases of Colorectal Cancer: Does the Seed Leave the Soil Again? *Annals of Surgery*; February 2016 - Volume 263 - Issue 2 - p 345-352

STRONG LIVER ENHANCEMENT WITH ORVIGLANCE

PATIENT EXAMPLE FROM PHASE 2 STUDY



UNENHANCED liver MRI (without contrast agent)



ORVIGLANCE contrast enhanced liver MRI

Liver metastasis appear with Orviglance

EIGHT COMPLETED CLINICAL STUDIES

- Data presented at major radiology conferences

Phase 1 & 2	Completed (6 studies)	BLINDED READ STUDY Safety and efficacy vs. unenhanced in all phase 1 and 2 images (6 studies, including 178 persons and compassionate use)	Consistent positive results, incl. 33% more lesions Delineation (border sharpness) and conspicuity (contrast vs. background): p-value <0.0001
		ORVIGLANCE VS. GADOLINIUM CONTRAST AGENT Orviglance vs. gadolinium (Multihance) and vs. unenhanced (20 persons crossover with 3 independent readers)	Number of lesions (3 of 3 higher) Smaller lesion detection (3 of 3 higher) Delineation and conspicuity (2 of 3 higher)
Phase 3 Program	Completed (1 study)	FOOD EFFECT STUDY Evaluates the effect of food intake on absorption and signal intensity (23 healthy volunteers)	Strong liver enhancement both in fasting condition and with light meal, support intake of light meal
	Completed (1 study)	HEPATIC IMPAIRMENT STUDY Evaluates the effect of liver impairment on the safety, pharmacokinetics and pharmacodynamics	Well tolerated in patients with liver impairment Confirms excretion primarily via the liver and not the kidney
	Ongoing (1 study)	SPARKLE PHASE 3 PIVOTAL STUDY Evaluates the safety and efficacy in target patient population (enrollment not yet completed)	71 of 80 patients completed 27 Jan, 2023 Completion expected Feb-Mar 2023

New strong Orviglance data support successful SPARKLE completion with substantially fewer patients

Press Release 06 Dec 2022

Assumptions for original SPARKLE sample size estimate were conservative

New data with the same image reading methodology as in SPARKLE demonstrate

- Successful re-read study ($p < 0.009$) based on 20 patients for lesion visualization (primary endpoint in SPARKLE)
- Two to three times higher effect than originally assumed

Statistically significant results can be obtained with substantially fewer patients and strong likelihood of success, while maintaining conservative assumptions

We have thoroughly analyzed the new data and original assumptions with statisticians and regulatory experts to validate this important finding

Based on discussions with the FDA, Ascelia Pharma has decided to change the patient enrollment target of SPARKLE to 80 patients

As of 27 January, 71 patients were enrolled in SPARKLE.

Our confidence in SPARKLE outcomes and commercial potential remains strong as we prepare for the next steps for Orviglance and Ascelia Pharma

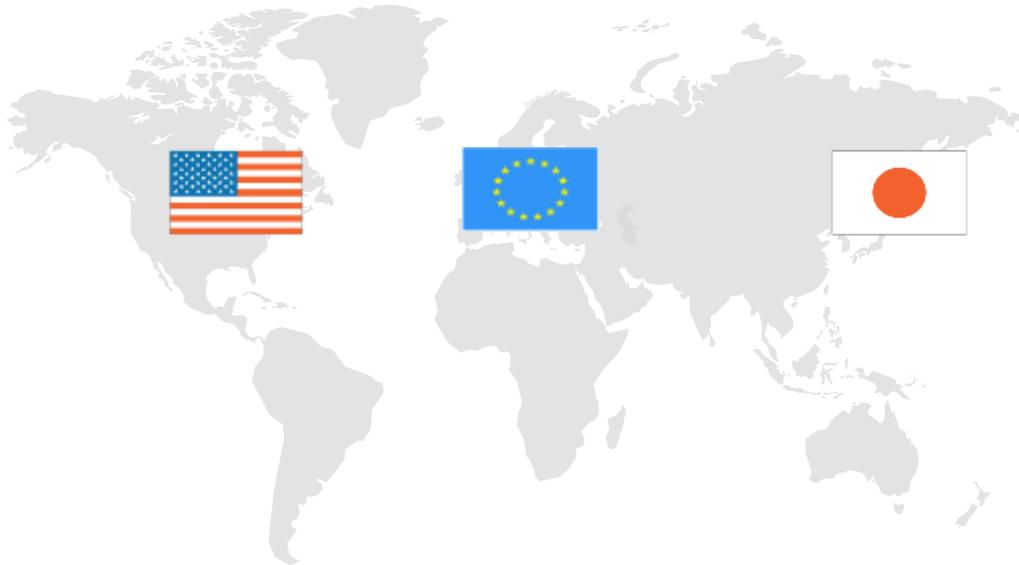


ASCELIA
PHARMA

ORVIGLANCE MARKET \$500-600 MILLION ANNUALLY

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

- Ascelia Pharma to commercialize in the US
- 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:

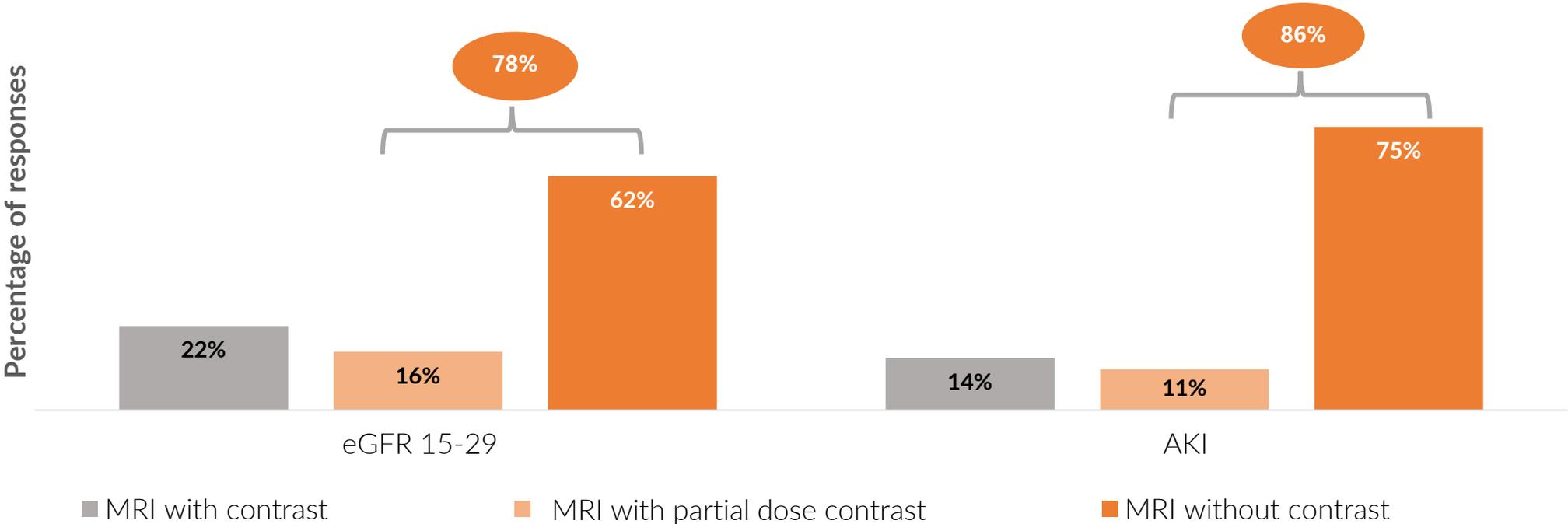
1) Ascelia Pharma market research with Decision Resources Group, 2020

2) Ascelia Pharma market research and analyses with Revenue Reimbursement Solutions and Charles River Associates, 2020

US PHYSICIANS PREFER UNENHANCED MRI FOR TARGET PATIENTS

78% PREFER MRI WITHOUT OR WITH PARTIAL DOSE CONTRAST FOR PATIENTS WITH LOW eGFR

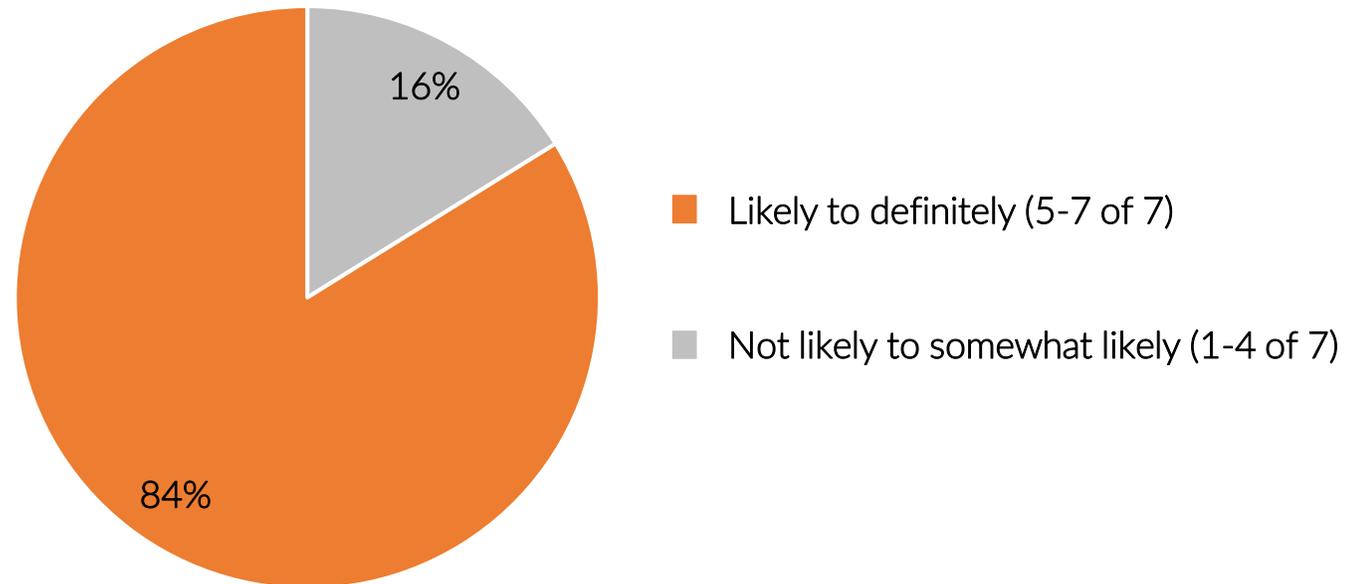
... EVEN MORE FOR AKI PATIENTS



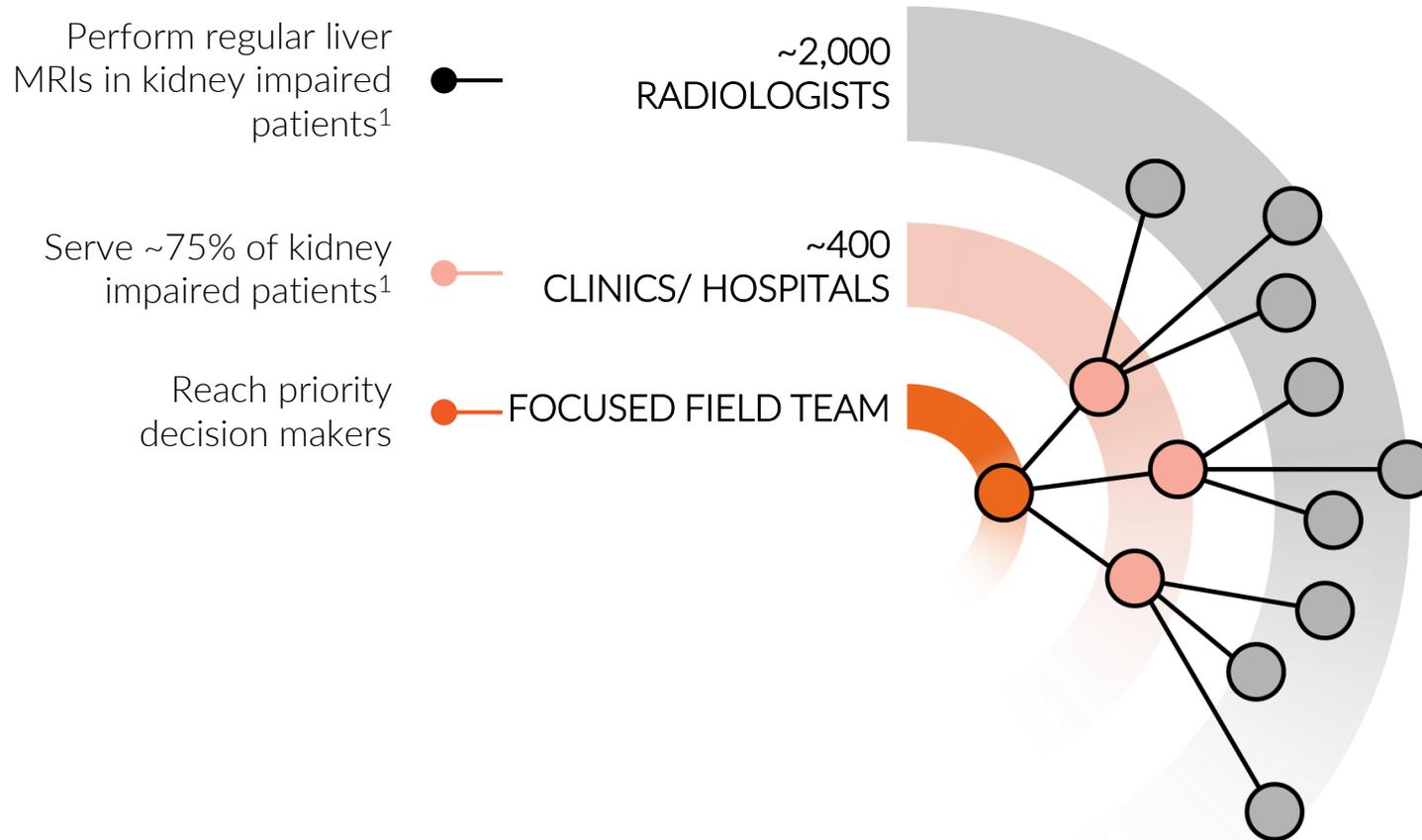
N=103 oncologist, nephrologist, and radiologist responses.
Q: Please assign priority to the imaging tests in the sequence or order in which you would recommend or perform them (shown as % split of first priority of MRI options)

US PHYSICIANS SAY THEY WILL USE ORVIGLANCE

LIKELIHOOD OF USING ORVIGLANCE FOR TARGET PATIENTS



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 in New Jersey

BUILDING OUT U.S. FOOTPRINT

SPARKLE Phase 3 study at leading US Sites including Mayo Clinic, Mass. General, Stanford

Sources:

1) Ascelia Pharma analysis based on market research with Decision Resources Group, 2020



PORTFOLIO

ORVIGLANCE

Liver contrast agent in ongoing Phase 3

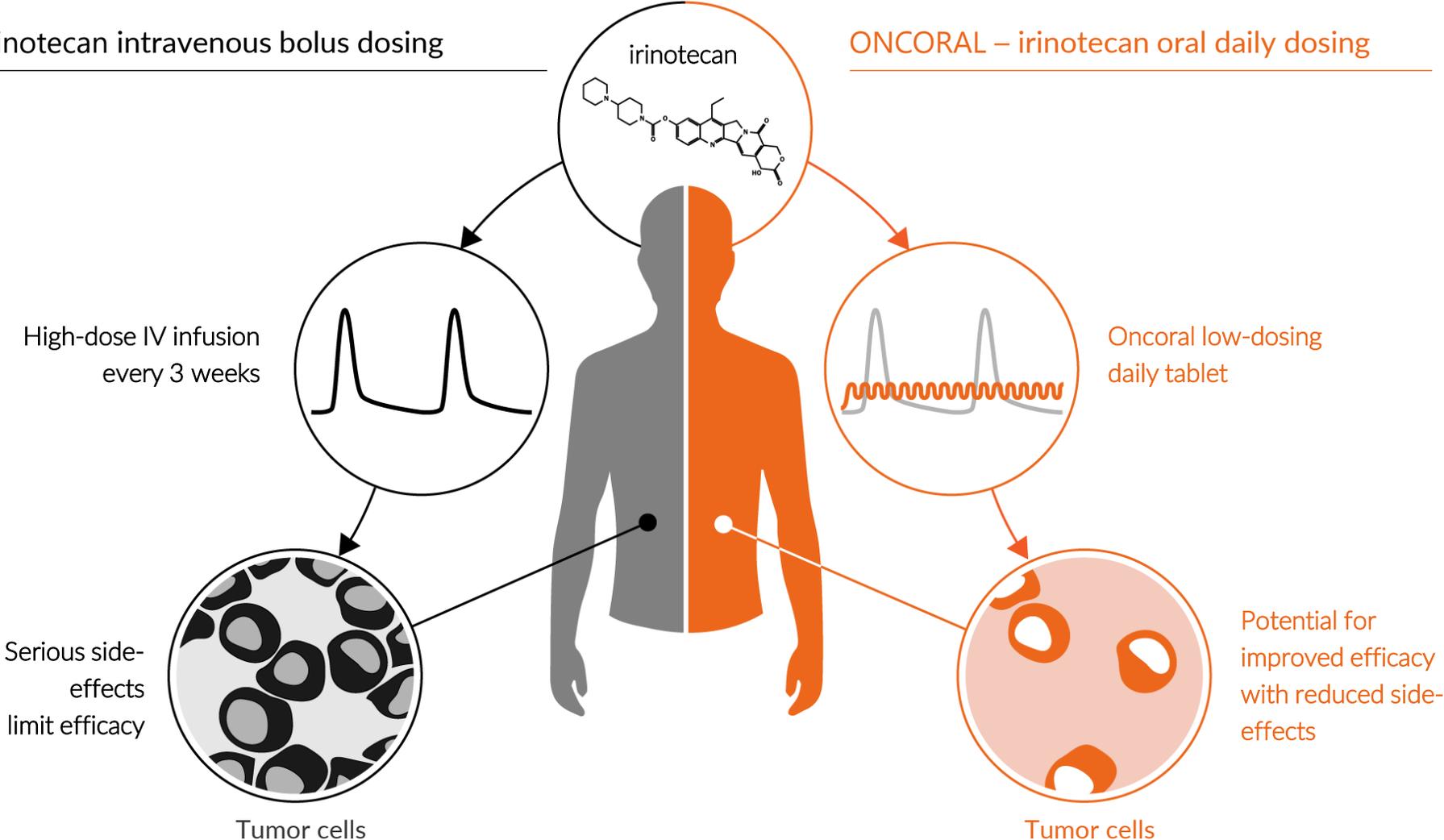
ONCORAL

Daily oral chemotherapy ready for Phase 2

IMPROVING IRINOTECAN EFFICACY and TOLERABILITY

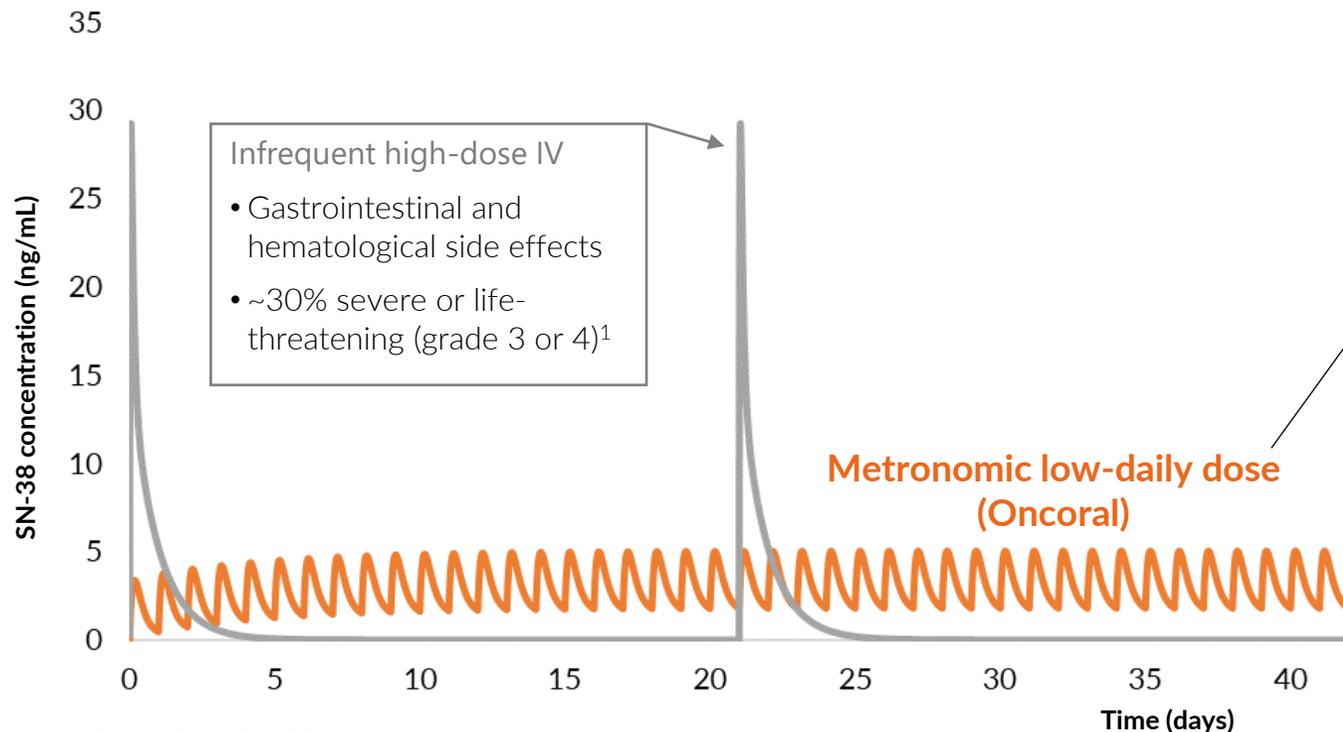
Irinotecan intravenous bolus dosing

ONCORAL – irinotecan oral daily dosing



ONCORAL PHASE 1: ENCOURAGING SAFETY PROFILE

PLASMA LEVELS OF IRINOTECAN



Source: Simulation of Oncoral vs. IV Camptosar

Frequent (metronomic) low-dose irinotecan

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

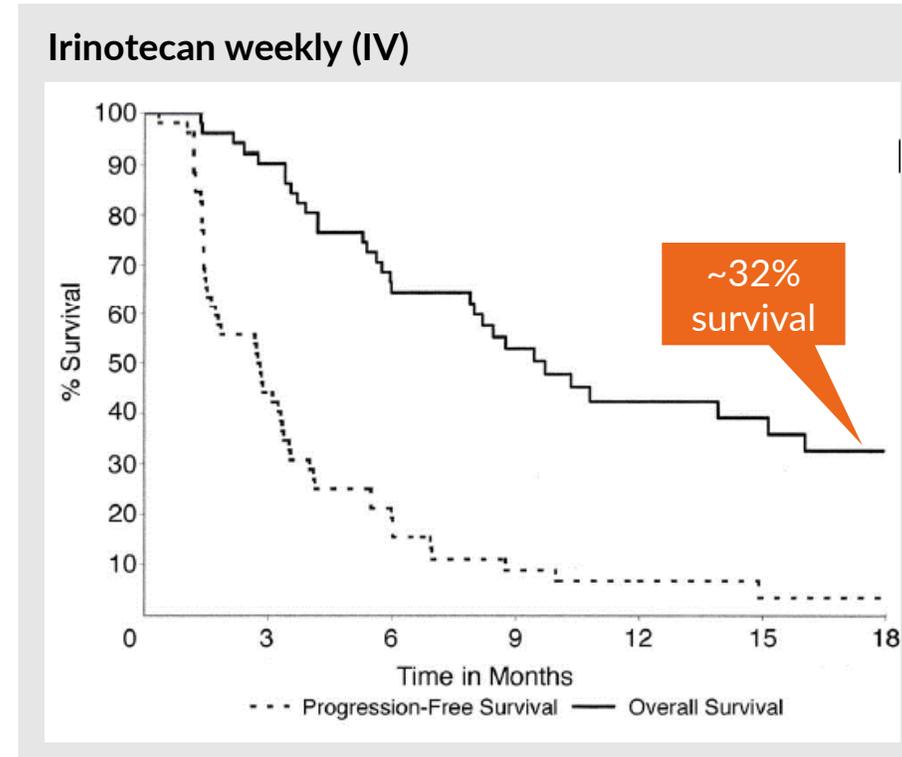
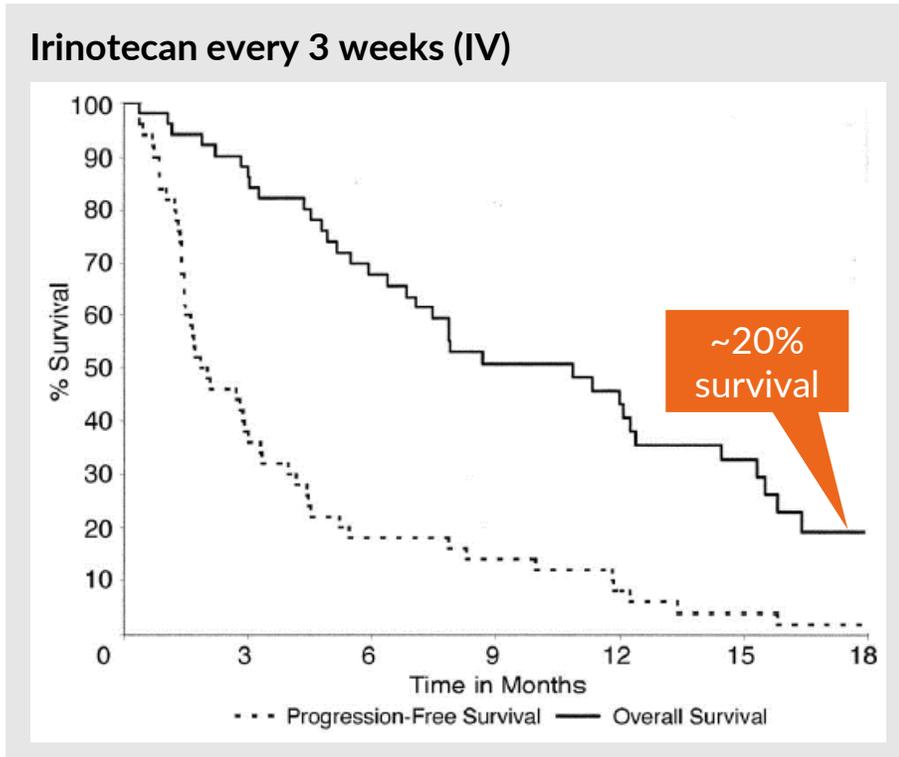
Oncoral Phase 1 results

- 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

1) Camptosar prescribing information 2) Furman et al 1999 3) Perez et al 2004 4) Kumler et al 2018

IMPROVING IRINOTECAN EFFICACY BY FREQUENT LOW DOSING

OVERALL SURVIVAL: IMPROVED FROM 20% (DOSING EVERY THIRD WEEK) TO 32% (WEEKLY DOSING)¹



Study in patients with metastatic refractory breast cancer, N=103

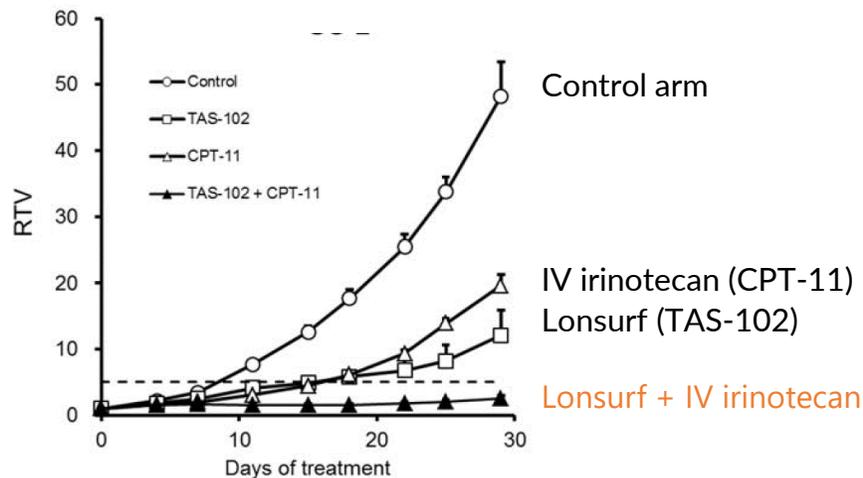
1) Perez et al. J Clin Oncol 2004: Randomized Phase II Study of Two Irinotecan Schedules for Patients With Metastatic Breast Cancer Refractory to an Anthracycline, a Taxane, or Both

ONCORAL PHASE 2 IN GASTRIC CANCER

STRONG RATIONALE FOR GASTRIC CANCER

- High unmet need and clinically demonstrated
- Potential for synergistic effect between Lonsurf and irinotecan

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



LONSURF AND IRINOTECAN COMBINATION

RANDOMIZED CONTROLLED PHASE 2 STUDY

- ~100 patients with metastatic gastric cancer
- Study arms: Oncoral + Lonsurf vs. Lonsurf
- Endpoints: Progression Free Survival (Primary), Response Rate, PK, Safety (Secondary) and Overall Survival (follow-up)
- IND approved in the US
- To focus all resources on Orvigance, patient enrollment is not initiated until it can be done effectively

Clinical collaboration with

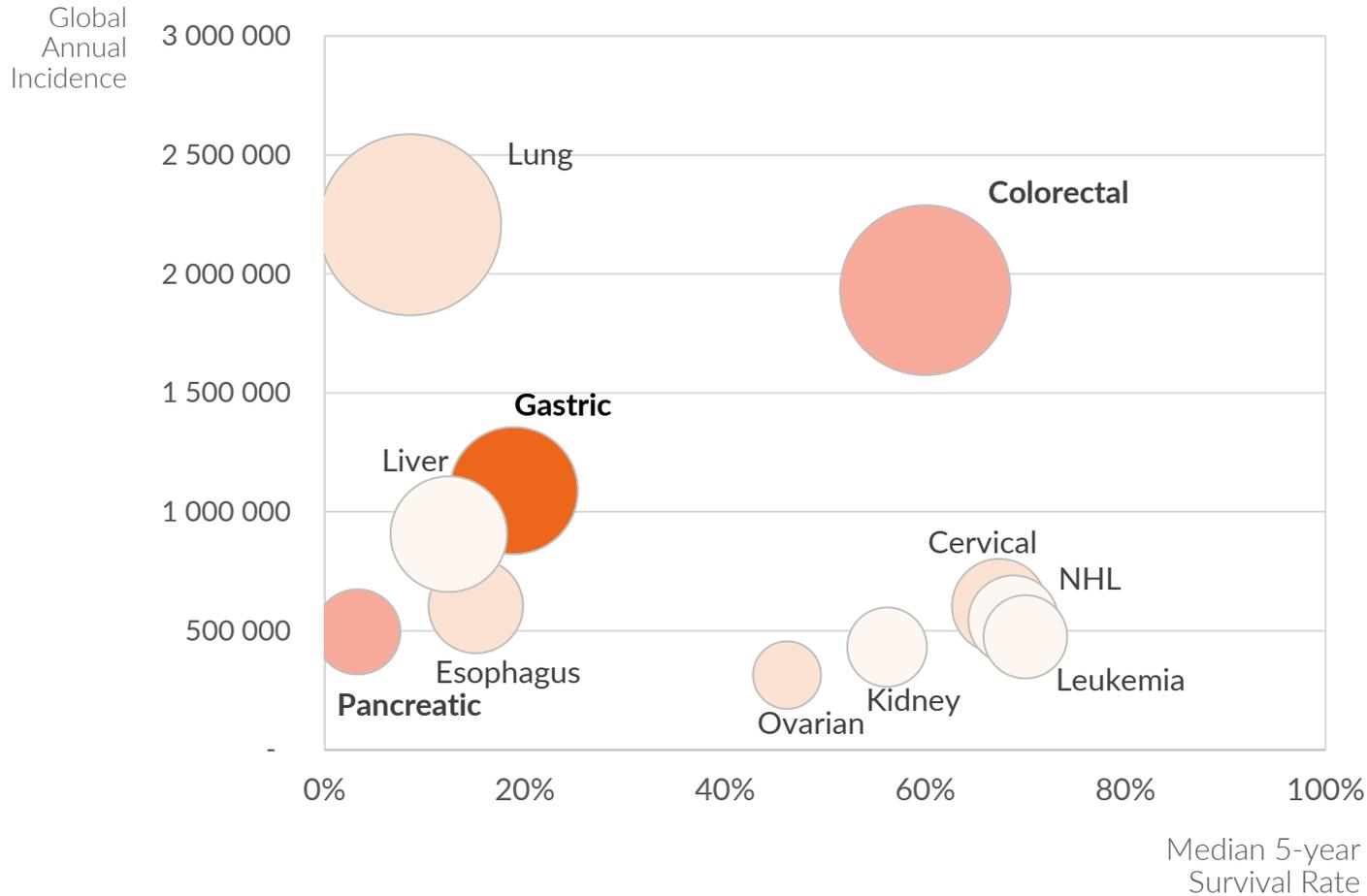


LONSURF is approved for treatment of metastatic gastric cancer and metastatic colorectal cancer

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

HIGH VALUE OPPORTUNITY IN GASTRIC CANCER AND EXPANSION

POTENTIAL FOR ORAL, DAILY DOSING OF IRINOTECAN³



A WELL-ESTABLISHED CHEMOTHERAPY with recognized anti-tumor effect in solid tumors

- Current focus: Gastric cancer
 - Clinically demonstrated
 - Guidelines recognized
 - 3rd highest cancer deaths¹
 - Orphan disease (US and EU)
 - \$3-4bn market²
- Approved indications for IV irinotecan
- Indications where IV irinotecan are clinically demonstrated & guidelines recognized
- Indications where IV irinotecan 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

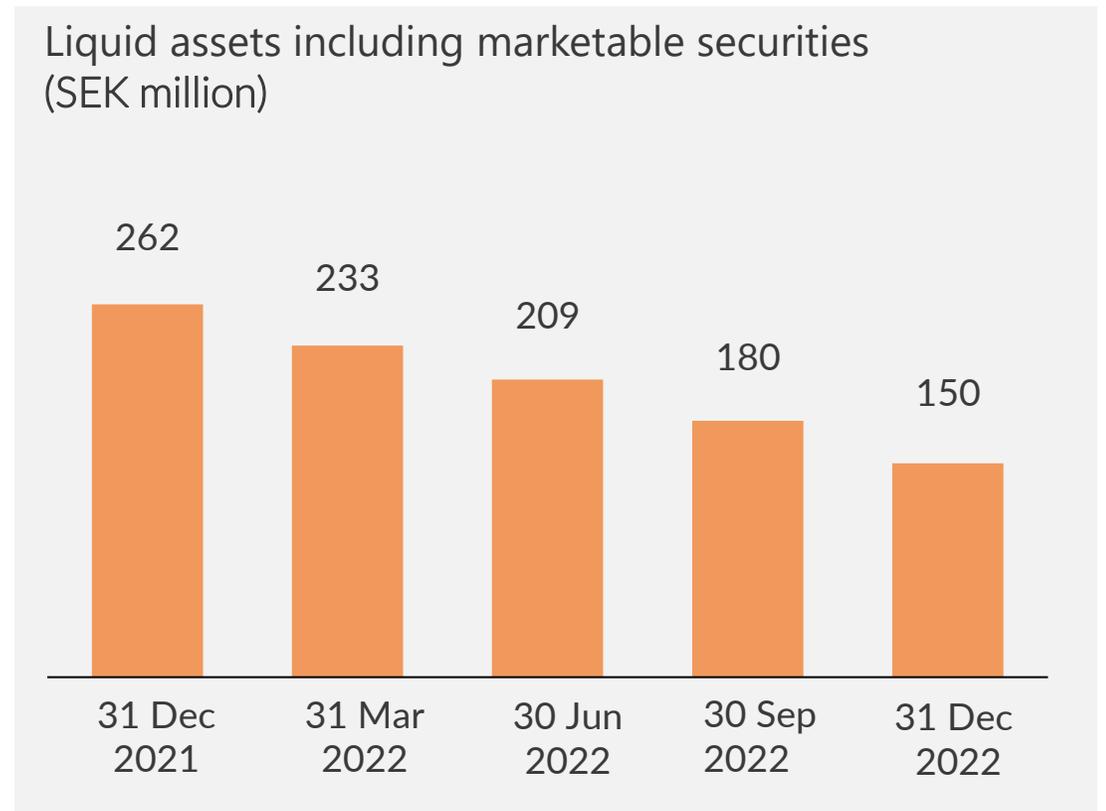


FINANCIALS AND PRIORITIES

FINANCIAL HIGHLIGHTS Q4 2022 – LIQUIDITY POSITION

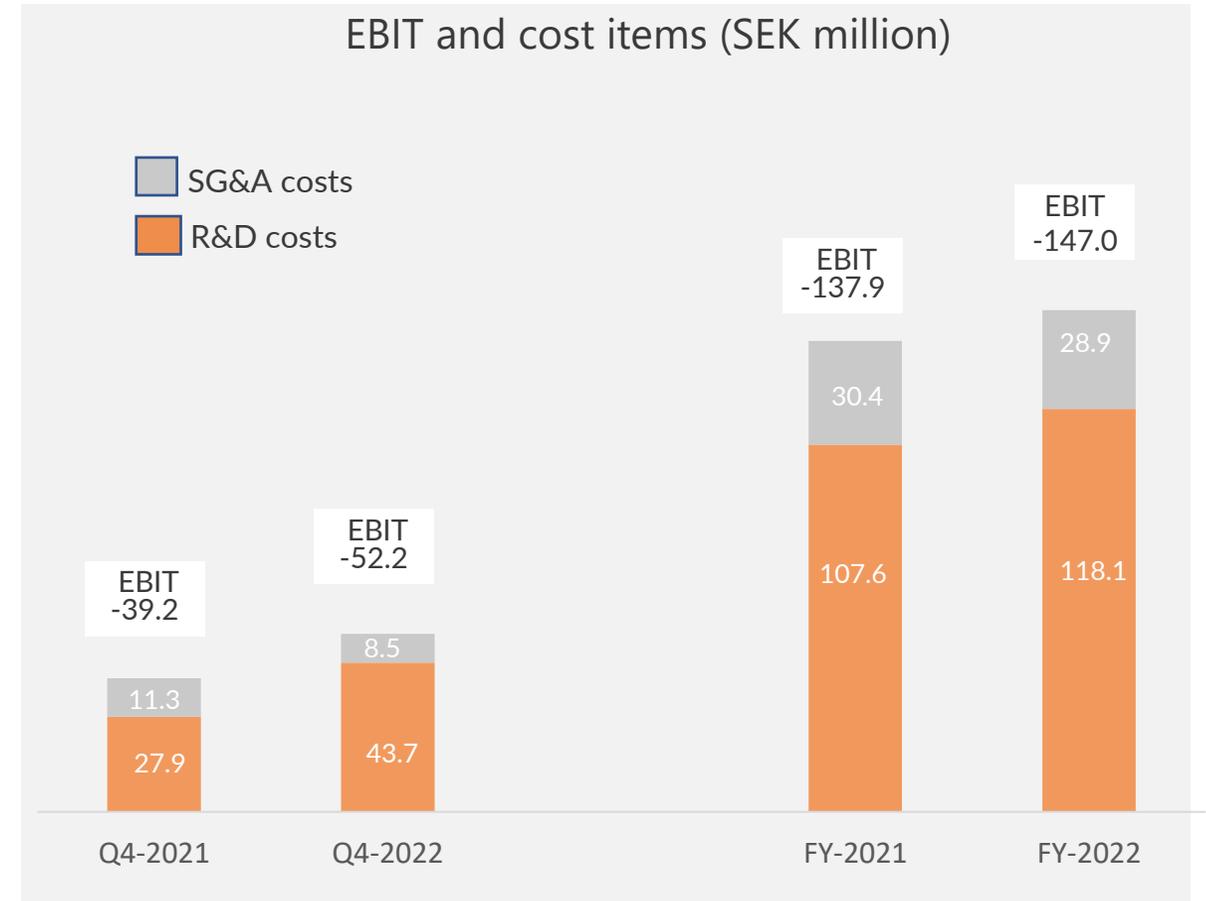
Liquidity position:

- Liquid assets of 150 MSEK (\$14.3 million) by 31 Dec 2022
- Current cash position provides financing into Q4 2023
- Quarterly burn rate in FY 2022 of 36-37 MSEK (\$3.5 million)



FINANCIAL HIGHLIGHTS Q4 2022 – OPERATING RESULTS

- Increased operating loss in Q4 2022 compared to loss in Q4 2021 demonstrate 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 Orvigance Phase 3 clinical study.
- Increased operating loss y/y mainly driven by higher R&D activity for Orvigance Phase 3 study.



Notes:

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



PRIORITIES 2023

● Complete Orvigance Phase 3 patient enrollment

● Generate SPARKLE headline results

● Prepare Orvigance launch

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