PRESENTATION OF Q4-2021 REPORT

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Link webcast:
Ascelia Pharma Q4 Report 2021 (streamfabriken.com)

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COMPANY OVERVIEW

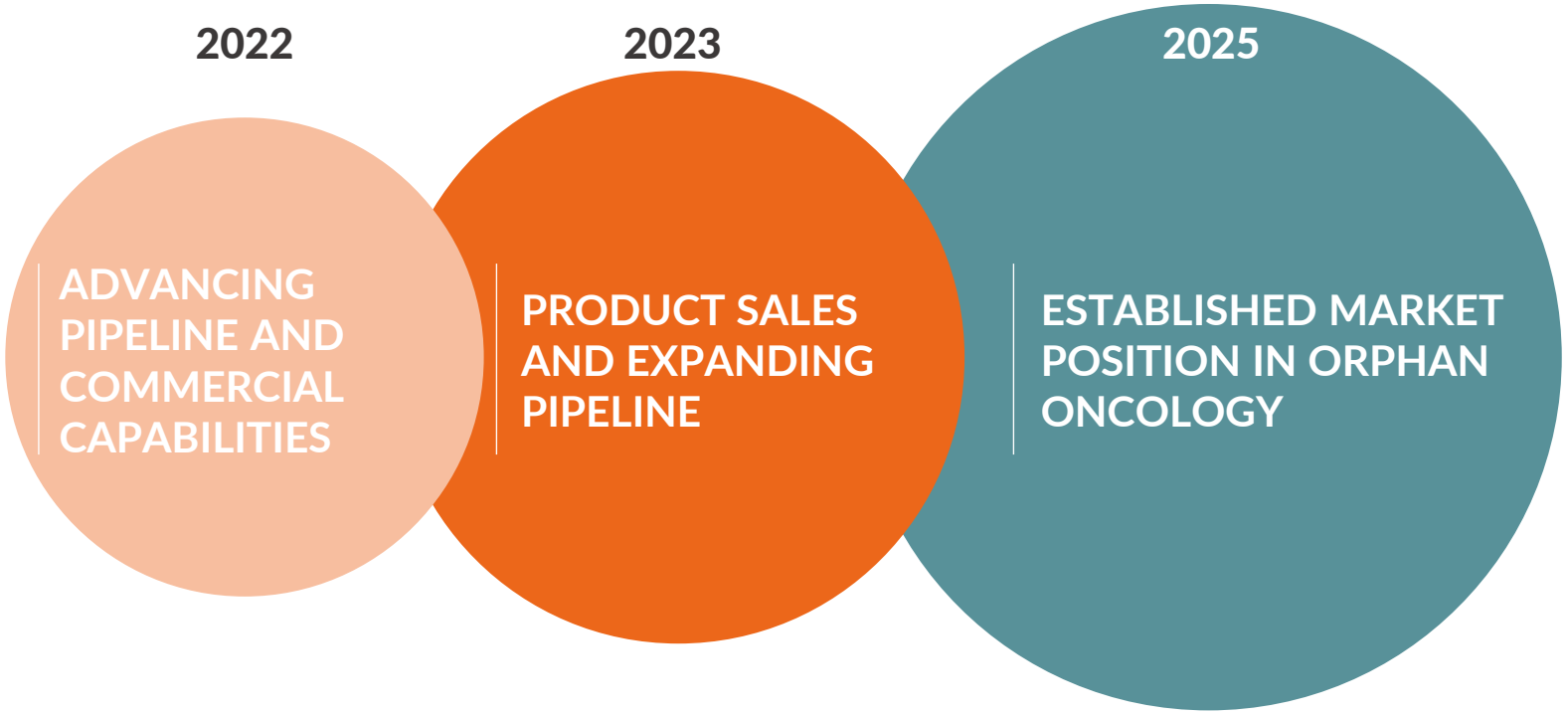
ADVANCING ORPHAN ONCOLOGY

- 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 2022

BUILDING GLOBAL CAPABILITIES

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

BUILDING VALUE



- ORVIGLANCE Phase 3
- ONCORAL Phase 2

- ORVIGLANCE revenue
- ONCORAL Phase 2 ongoing
- Pipeline expansion

- ORVIGLANCE market leader
- ONCORAL Phase 3 ongoing
- Pipeline development
- Pipeline further expansion

RECENT KEY EVENTS

Key events Q4-2021

Oct Food Effect Study with Orviglance successfully completed

Dec Strong results from Orviglance comparison study vs. gadolinium contrast agent presented at the world's largest radiology conference RSNA

Dec FDA approves IND application for Oncoral clinical development

ORVIGLANCE – FOOD EFFECT STUDY SUCCESFULLY 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 include investigating 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 Q1-2022
- A potential removal of the current fasting requirement could further improve the convenience and ease the administration of Orviglance in clinical practice

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ORVIGLANCE – STUDY VS. GADOLINIUM PRESENTED AT RSNA

ORVIGLANCE vs. GADOLINIUM CONTRAST AGENT

- Crossover study (n=20) where Orviglance was compared against a liver specific gadolinium contrast agent (Multihance)
- Compared visualization of lesions and number of detected lesions in the liver

EFFICACY PARAMETERS AND RESULTS

Efficacy parameter	Results from three independent blinded readers
1. Number of lesions detected	3 (out of 3) detected more lesions with Orviglance
2. Size of the detected lesions	3 (out of 3) saw smaller lesions with Orviglance
3. Lesion border delineation	2 (out of 3) reported higher scores for Orviglance
4. Lesion contrast compared to liver	2 (out of 3) reported higher scores for Orviglance

Note: Please observe that the results are not statistically sufficient to conclude that Orviglance is superior to gadolinium

RSNA® 2021
REDEFINING RADIOLOGY
November 28 to December 2

CONCLUSIONS

- → *Robust evidence of the diagnostic value that Orviglance offers*
- → *Important value message to healthcare payers and providers*
- → *Strengthens the data package to regulatory authorities*

ONCORAL – FDA APPROVAL OF IND APPLICATION

Approved IND application for Oncoral clinical trial

- In December 2021, FDA approved Investigational New Drug (IND) application to start the Phase 2 study with Oncoral
- The initial portion of the planned global Phase 2 study will be conducted at hospitals in Europe, whereas the subsequent randomized part will also include US sites
- The Phase 2 study will include around 100 patients with metastatic gastric cancer
- First patient visit is expected in Q2 2022 / Q3 2022

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PORTFOLIO

ORVIGLANCE (MANGORAL)

Liver diagnostic drug in ongoing Phase 3

ONCORAL

Daily oral chemotherapy starting Phase 2

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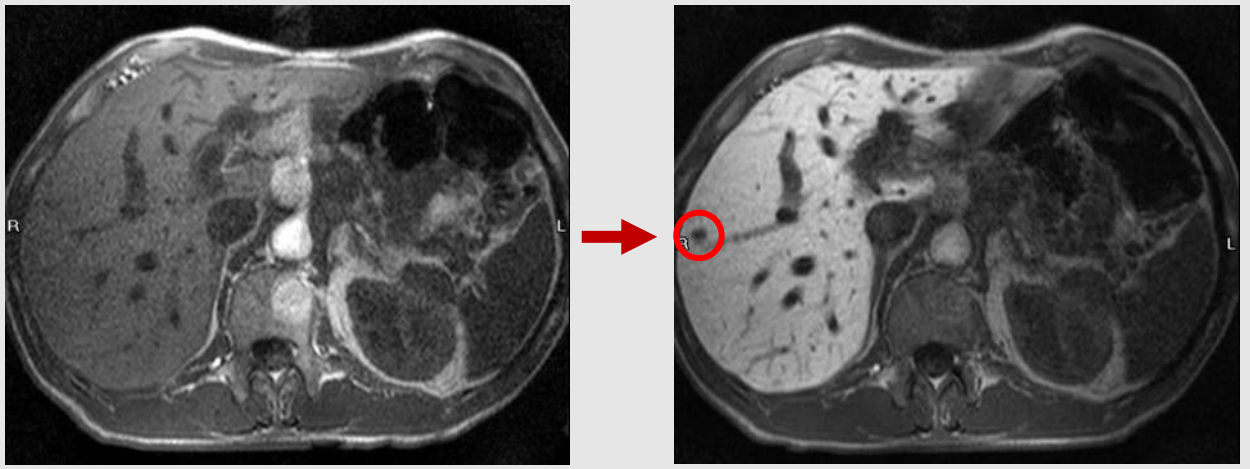
ORVIGLANCE – PHASE 3 LIVER MRI CONTRAST AGENT

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



Liver MRI without contrast agent

No metastases visible

ORVIGLANCE enhanced liver MRI

Liver metastasis appear with Orviglance

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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**

Proceed into Phase 3

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

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

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ORVIGLANCE ONGOING PHASE 3 STUDY – SPARKLE

Patients 	• Global study, 200 patients • Known or suspected focal liver lesions and severe renal impairment • Protocol amended to include patients on hemodialysis and patients with moderate hepatic impairment	Status update: US, Europe, Latin America 40+ sites increasing to over 50 sites
Comparator 	Unenhanced MRI + ORVIGLANCE MRI vs. Unenhanced MRI	No randomization – each patient as own control
Endpoint 	Lesion visualization • Lesion border delineation • Conspicuity	• Same endpoints as in Phase 2 • Same endpoints as for approved gadolinium agents
Follow-up 	Less than a week	Expected pivotal study patient enrollment: H1 2022

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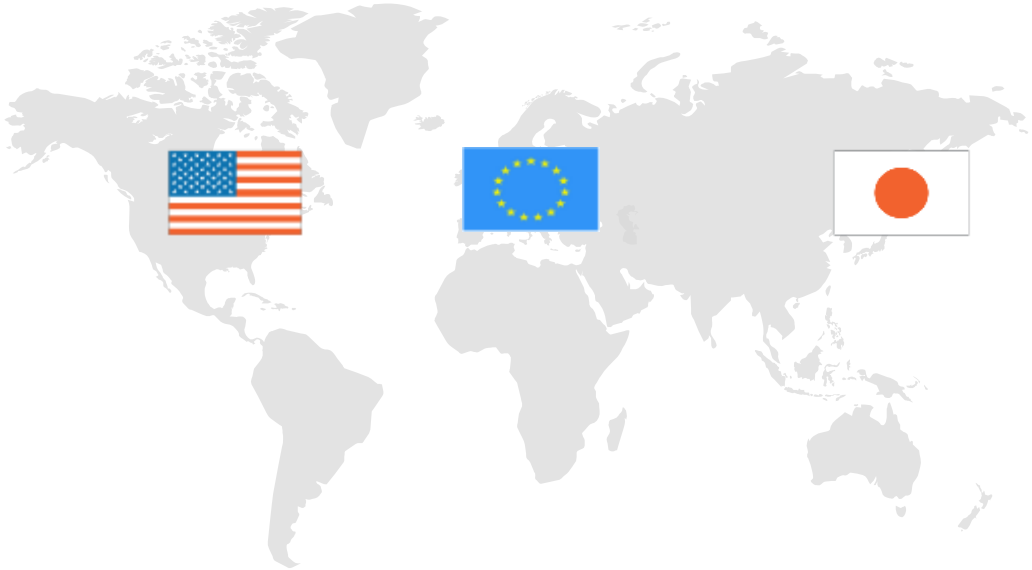
ORVIGLANCE MARKET $500-600 MILLION ANNUALLY

$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) 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

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CAPTURING US MARKET VALUE WITH ASCELIA'S TEAM

perform regular liver MRIs in kidney impaired patients[1]

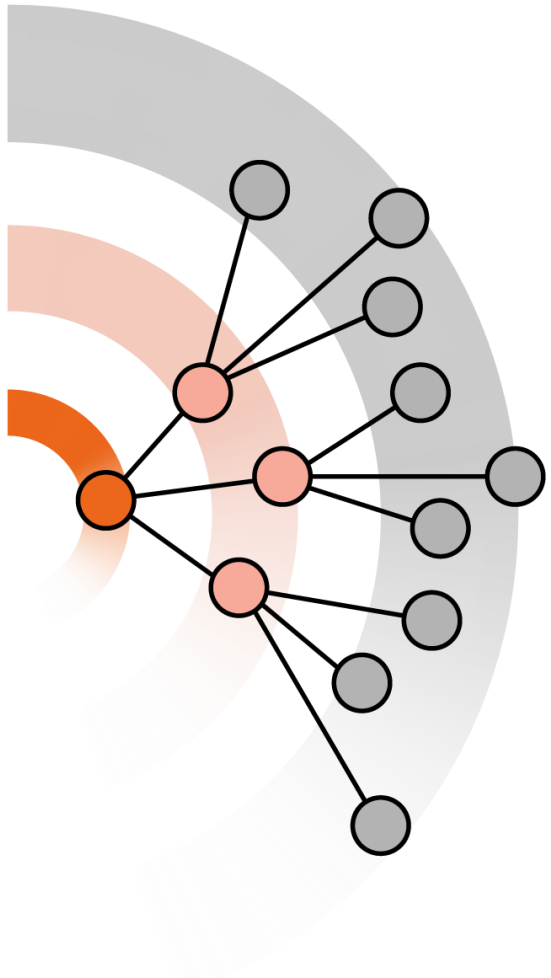
serve ~75% of kidney impaired patients[1]

reach priority decision makers

~2,000 RADIOLOGISTS

~400 CLINICS/ HOSPITALS

FOCUSED FIELD 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 13+ US Sites including Stanford, Mass. General, Duke University, UCLA Medical Center

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

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ORVIGLANCE (MANGORAL)

Liver contrast agent in ongoing Phase 3

ONCORAL

Daily oral chemotherapy starting Phase 2

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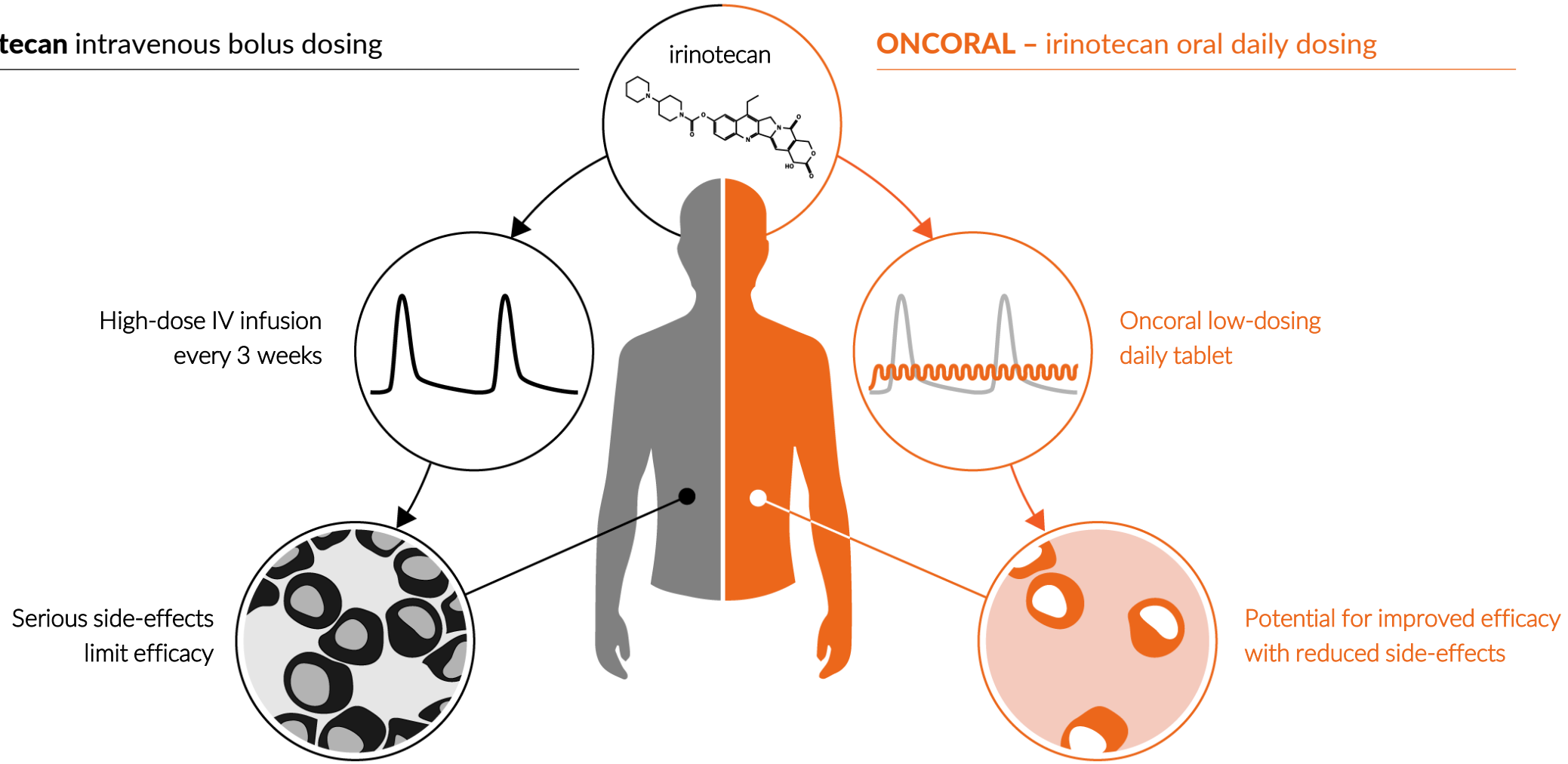
IMPROVING IRINOTECAN **EFFICACY** and **TOLERABILITY**

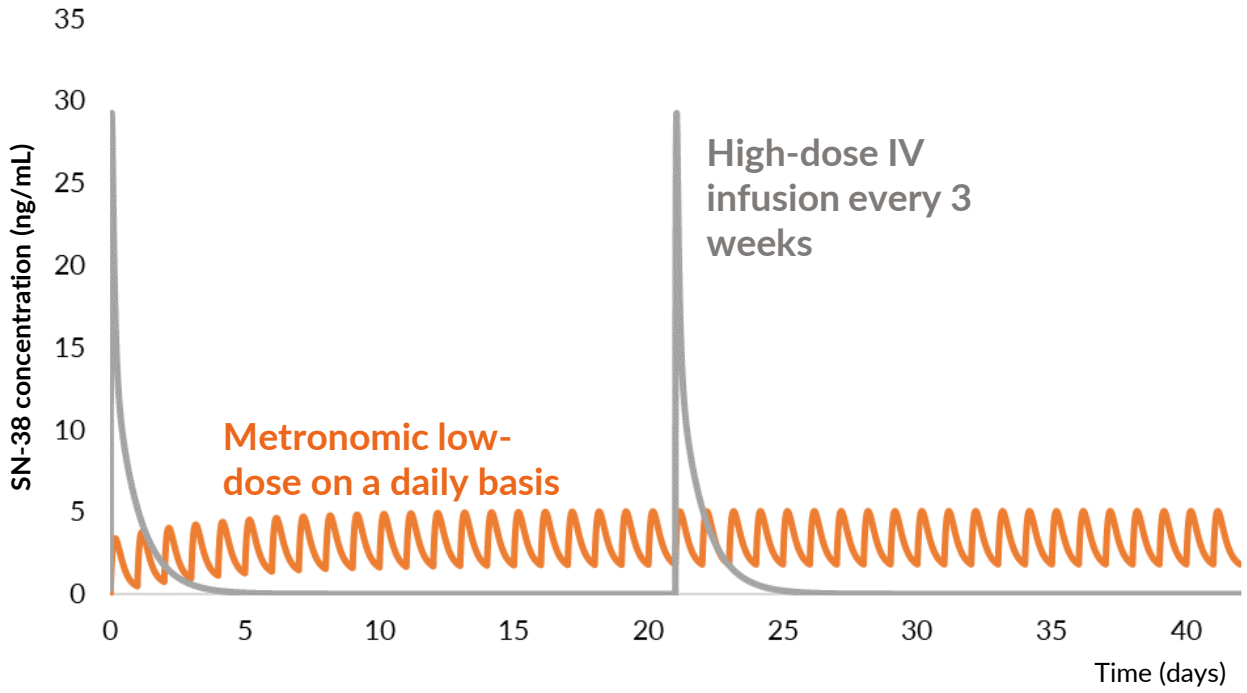
Irinotecan intravenous bolus dosing

ONCORAL – irinotecan oral daily dosing



ONCORAL PHASE 1: ENCOURAGING SAFETY PROFILE

PLASMA LEVELS OF IRINOTECAN



Source: Simulation of Oncoral vs. IV Camptosar 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

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

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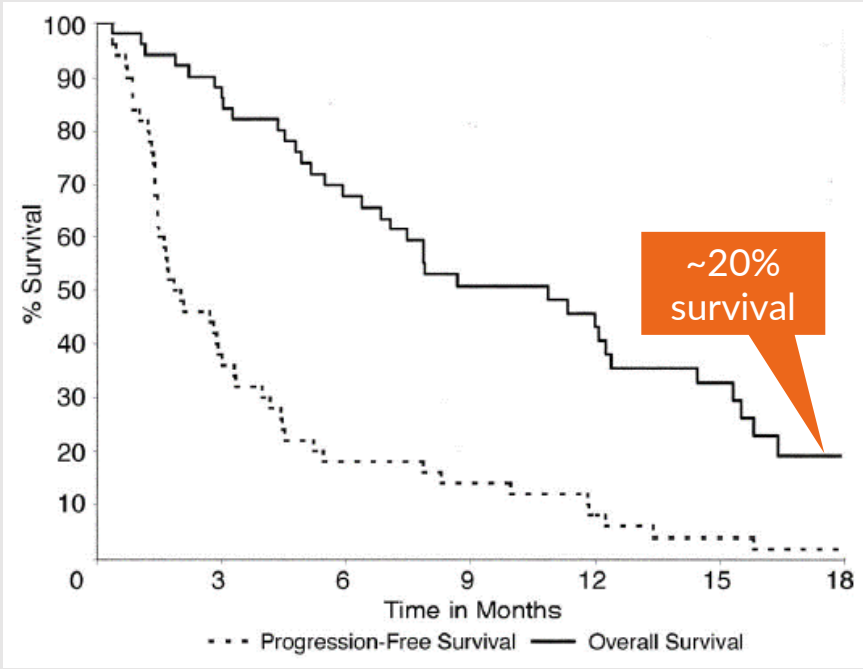
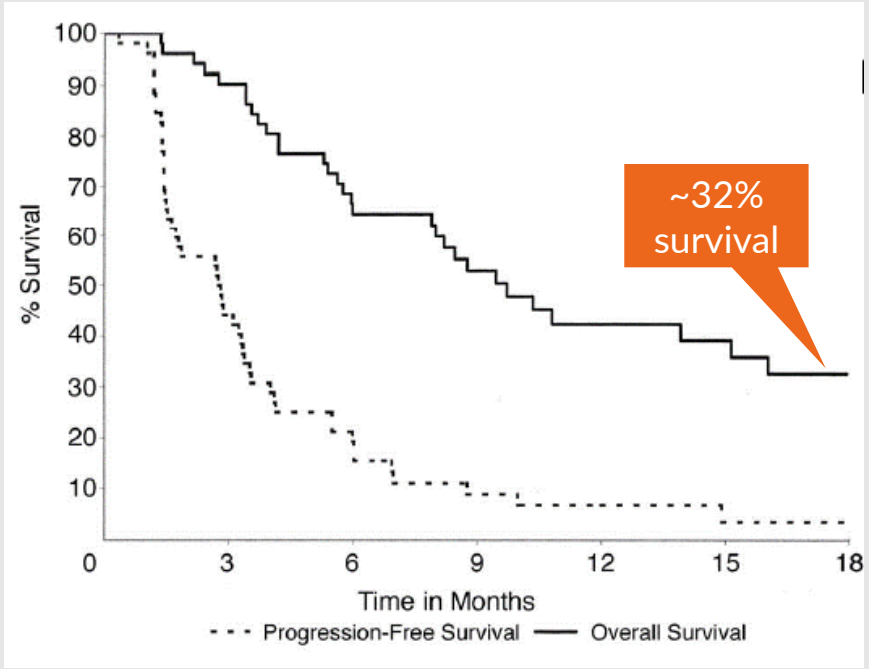
IMPROVING IRINOTECAN **EFFICACY** BY FREQUENT LOW DOSING

Overall survival: Improved from 20% (dosing every third week) to 32% (weekly dosing)[1]

Irinotecan every 3 weeks (IV)



Irinotecan weekly (IV)



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*

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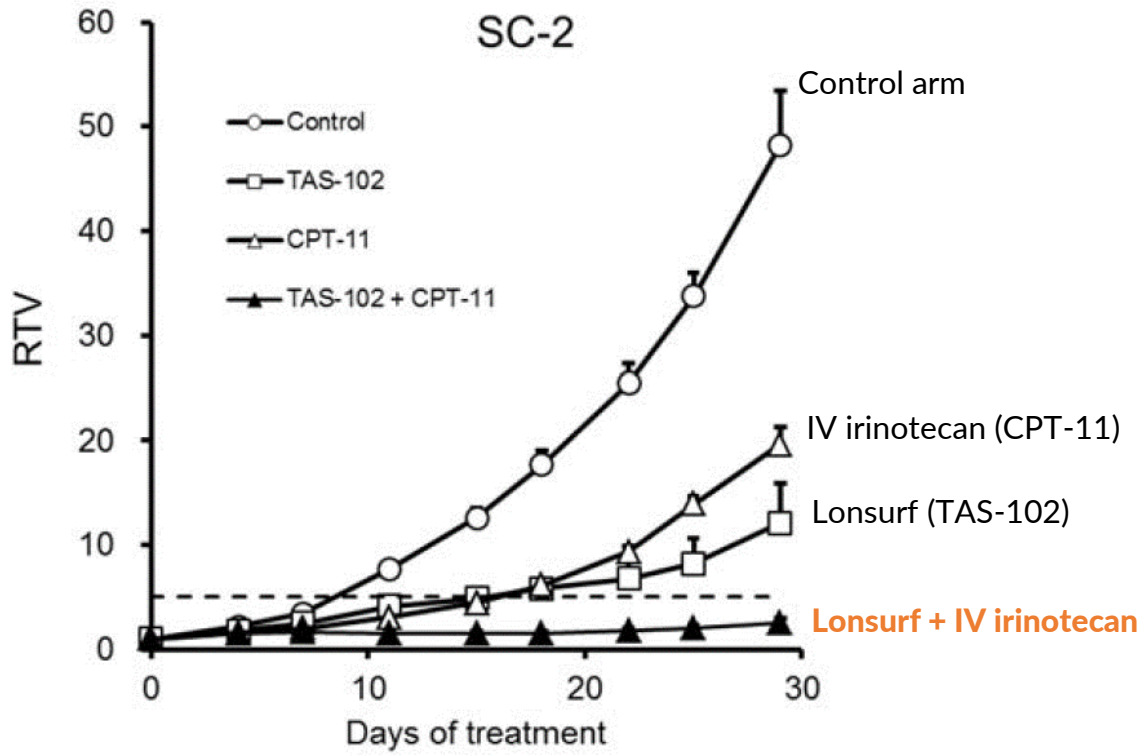
ONCORAL PHASE 2 IN GASTRIC CANCER

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 cancer[1]
(Relative Tumor Volume, RTV)



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

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STUDY DESIGN AND CLINICAL COLLABORATION

STUDY DESIGN (ALL-ORAL COMBINATION STUDY)

Patients	• Around 100 patients • Metastatic gastric cancer • Randomized controlled, multicenter/multinational
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	2022* – 2024

*Study start approval obtained in Dec 2021 (IND approval)

CLINICAL COLLABORATION WITH TAIHO ONCOLOGY

- Clinical collaboration with Taiho Oncology Inc. (part of Otsuka Group)
- Taiho Oncology Inc. 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

TAIHO ONCOLOGY

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

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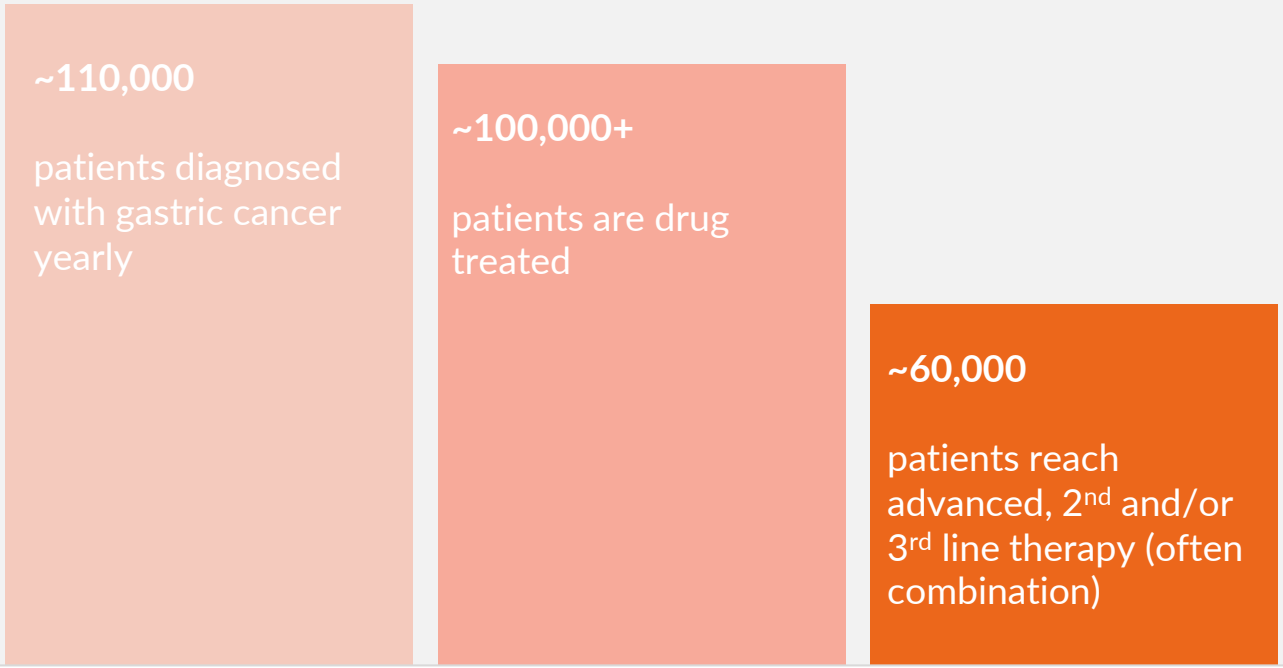
GASTRIC CANCER – A $3BN+ MARKET OPPORTUNITY

US and EU target patent population (orphan disease)



Other key market

Japan and South Korea has high prevalence and high diagnosis rates (~150,000 diagnosed patients/year)

China is the country in the world with the highest number of gastric cancer patients (~400,000 diagnosed patients/year)

…other markets (~400,000 diagnosed patients/year)

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

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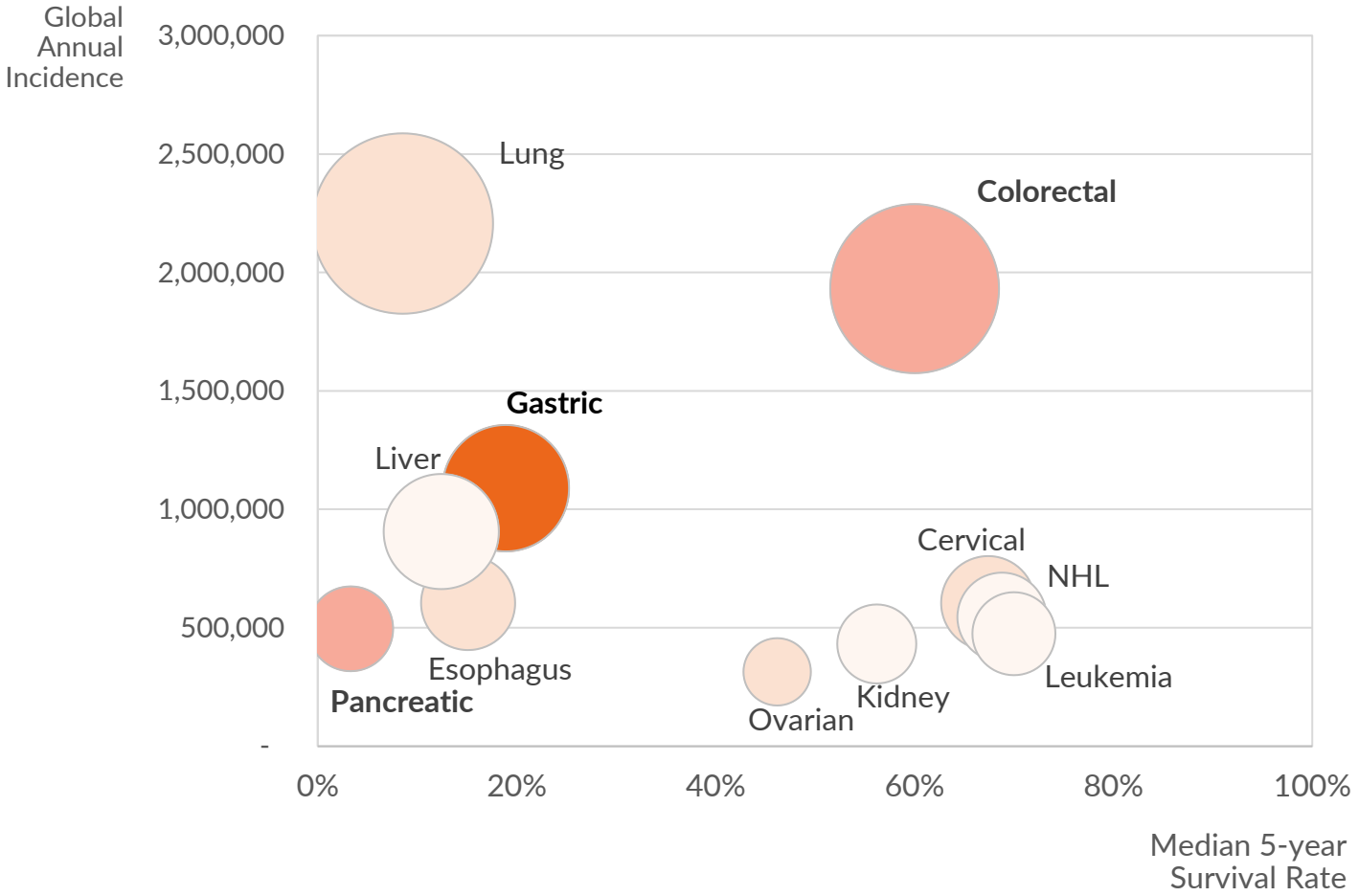
HIGH VALUE OPPORTUNITY IN GASTRIC CANCER AND EXPANSION

POTENTIAL FOR ORAL, DAILY DOSING OF IRINOTECAN[3]



- **Current focus:** Gastric cancer
  - 3rd highest cancer deaths[1]
  - Orphan opportunity (U.S. and EU)
  - $3-4bn market[2]
- 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

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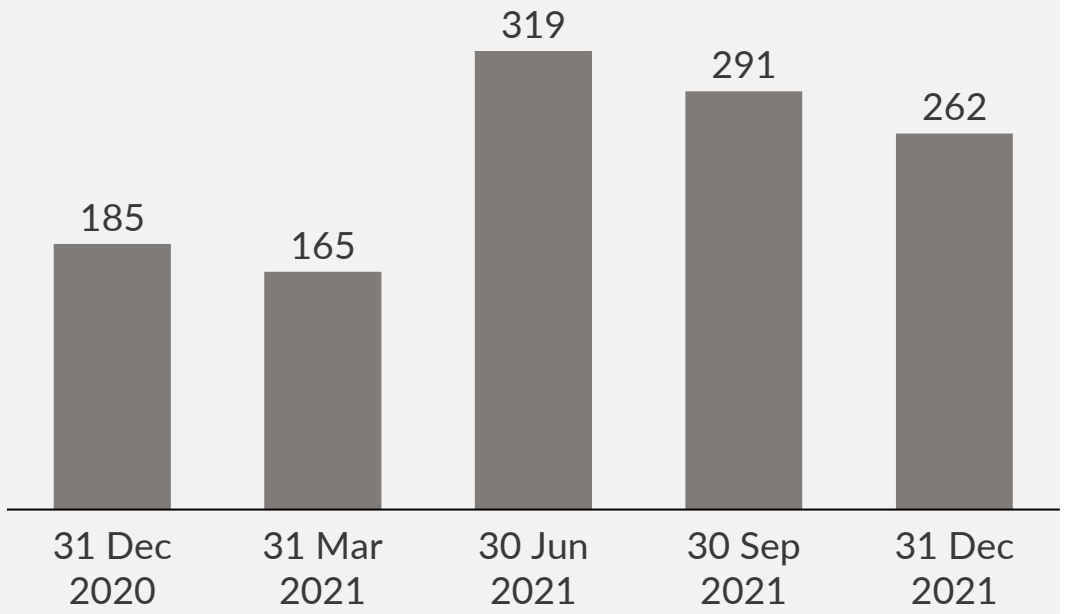
FINANCIALS AND PRIORITIES

FINANCIAL HIGHLIGHTS Q4 2021 – LIQUIDITY POSITION

Solid liquidity position:

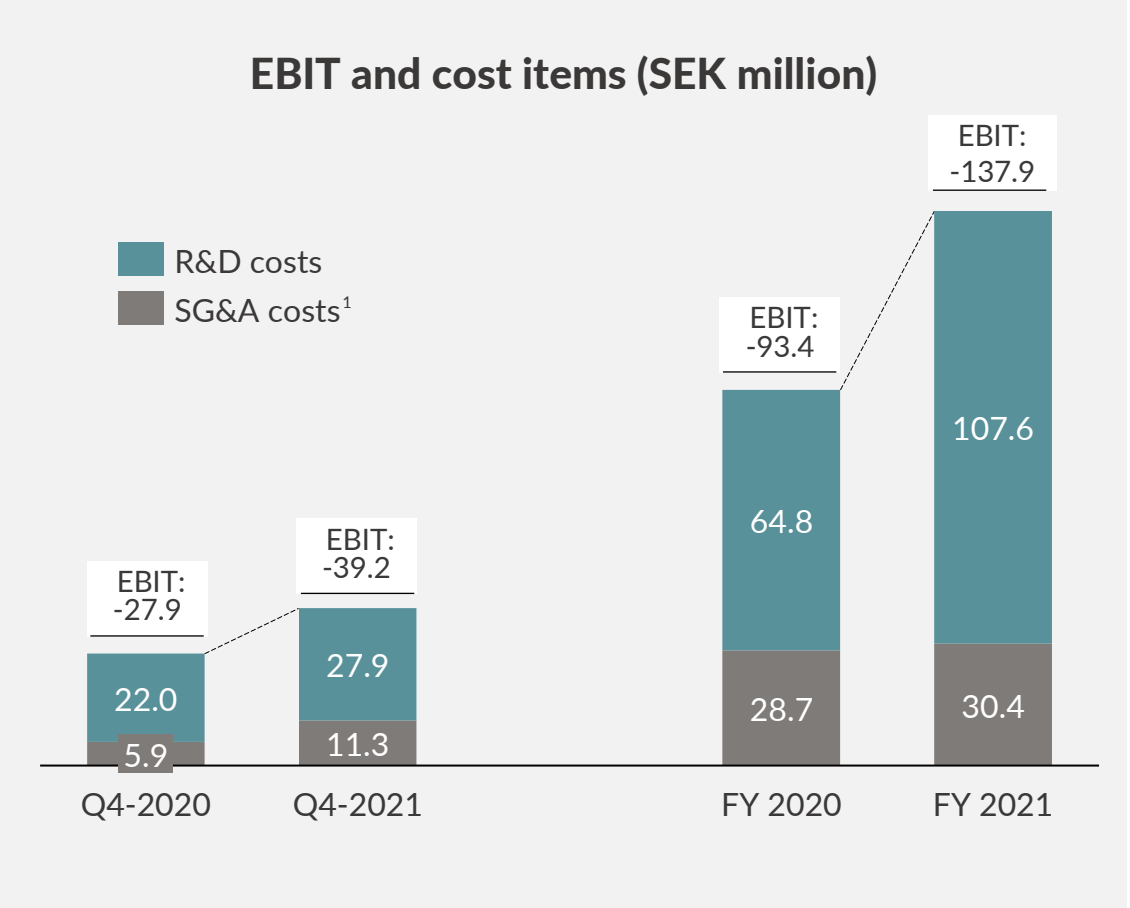
- Liquid assets of 262 MSEK ($29 million) by 31 Dec 2021
- Quarterly burn rate in FY 2021 of 30-35 MSEK ($3.5 million)
- Current cash position provides financing into 2023

Liquid assets including marketable securities
(SEK million)



FINANCIAL HIGHLIGHTS Q4 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

- Complete Orviglance Phase 3 patient enrollment (expected H1-2022)[1]
- Prepare Orviglance launch (planned for H2-2023)[1]
- Oncoral Phase 2 study (first patient visit expected Q2/Q3 2022)[1]

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

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