ADVANCING ORPHAN ONCOLOGY

Ticker symbol: ACE
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RE-EVALUATION OF SPARKLE PHASE 3 STUDY IMAGES PROGRESSES ACCORDING TO PLAN

Q3 2023 REPORT

Conference call presentation on 8 Nov 2023, 10:00 CET

ASCELIA PHARMA

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Q3 2023 CONFERENCE CALL

Agenda

Ascelia Pharma highlights

Recent key events

Portfolio

Financials and priorities

Presenters

CEO - Magnus Corfitzen
Deputy CEO - Julie Waras Brogren
CSO - Andreas Norlin

ASCELIA PHARMA – HIGHLIGHTS

ADVANCING ORPHAN ONCOLOGY

- Identify, develop and commercialize novel drugs that address unmet needs in rare cancers
- Two drugs in advanced clinical development
  - **ORVIGLANCE** – Phase 3 patient enrollment completed; FDA Orphan Drug Designation
  - **ONCORAL** – Ready for Phase 2

BUILDING GLOBAL CAPABILITIES

- Based in Malmö (Sweden), US affiliate in New Jersey (US)
- Listed on NASDAQ Stockholm (Ticker: ACE)

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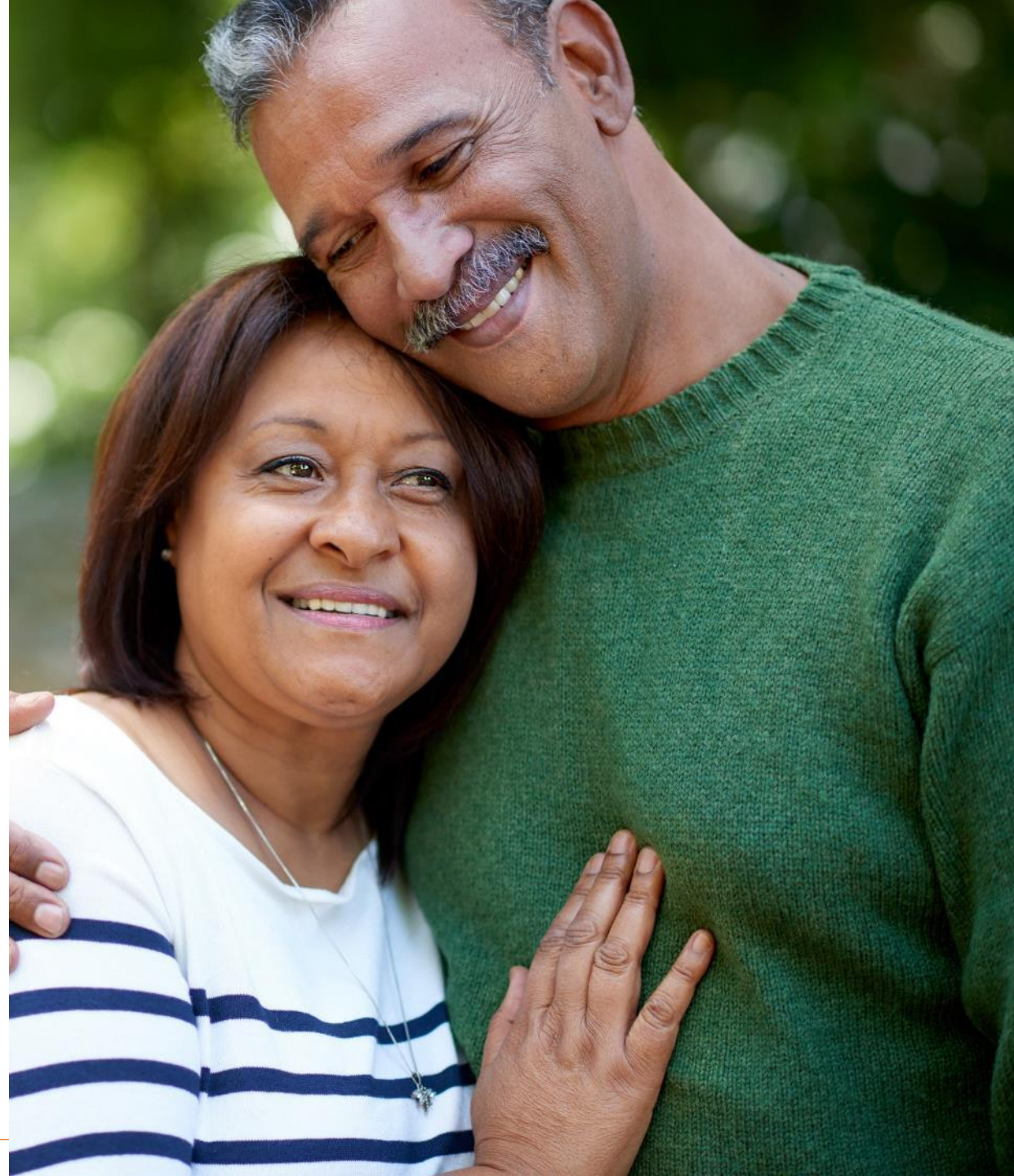
RECENT KEY EVENTS

Key events in Q3-2023

- Re-evaluation required after intra-reader inconsistency in scoring of images from phase 3 study SPARKLE
- Ascelia Pharma significantly reduces organization to reach SPARKLE headline results
- Ascelia Pharma to reach headline results from SPARKLE re-evaluation by May 2024 with current funding

Key events after Q3-2023

- Ascelia Pharma gets acceptance for publication of Orviglance® review article in Investigative Radiology
- Ascelia Pharma convenes an Extraordinary General Meeting on November 13, 2023 to vote on a proposal to introduce an employee stock option program



ORVIGLANCE®

Liver diagnostic imaging drug

ONCORAL

Daily, oral chemotherapy

PORTFOLIO

ORVIGLANCE – FILLING AN UNMET NEED IN LIVER MRI

Patient Landscape

Liver metastases critical in cancer care

Liver metastases are common in many cancer types and often the cause of mortality [1-3]

- Colorectal cancer, metastatic breast cancer, gastric cancer

Treatments

Contrast enhanced MRI is the gold standard

Contrast enhanced MRI

- Detection and visualization
- Surgery & drug treatment plan
- Post-treatment surveillance

Unmet Need

A role for ORVIGLANCE in patients with kidney impairment

Patients with healthy kidneys

- Receive MRI with gadolinium-based contrast agent (GBCA)

Patients with severe kidney impairment

- Black Box warning for gadolinium contrast agents
- Risk of severe side effects, incl. Nephrogenic Systemic Fibrosis

ORVIGLANCE

Aims to be the imaging option without gadolinium-related safety risks patients with poor kidney function

- Manganese based
- Liver specific

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

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STRONG RESULTS FROM EXTENSIVE CLINICAL PROGRAM

Consistent positive efficacy and safety in completed studies[7]
Total Program of 9 studies in 286 patients and healthy volunteers

Six Studies Completed [1-6]

Evaluating safety and efficacy

Totally 127 subjects (2 placebo) healthy volunteers and patients

Evaluation Before Phase 3

Re-read of efficacy across all studies

Enriched with 68 patients from a compassionate use program

New Evaluation (P004A): Orviglance vs. Gadolinium and Unenhanced

Re-read of 20 patients with liver metastases, by 3 blinded, independent readers

Phase 1 & 2

Food Effect Study

Effect of food intake on absorption and signal intensity (39 subjects)

Hepatic Impairment Study

Effect of liver impairment on the safety, pharmacokinetics (35 subjects)

Phase 3 Pivotal Study - SPARKLE

Evaluates the safety and efficacy in target patient population (85 patients)

Phase 3 Program

1) Thomsen HS *et al*, Acad Radiol 2004: 11: 630-636
2) Thomsen HS et al. Eur Radiol 2007, 17: 273-278
3) Rief M *et al.* Invest Radiol. 2010; 45: 565-71
4) Brismar TB *et al.*. Eur Radiol 2012; 22:633-41
5) Albiin N *et al.* MAGMA. 2012; 25:361-368
6) Study CMC-P005, primary objective to study of Orviglance for imaging of bile ducts (not published)
7) Results from Phase 1 and 2 and Food Effect and Hepatic Impairment Studies

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PHASE 3 SUCCESSFUL IF 2 OF 3 READERS REACH SIGNIFICANCE

SPARKLE CLINICAL STUDY

	Number of patients	Liver lesion types*	Primary endpoint	Image evaluation by readers	Superior to unenhanced	Statistical significance
Orviglance Phase 3 Study SPARKLE	85	Known or Suspected Lesion (Metastases, primary tumors, benign lesions)	Co-primary: Border Delineation; Lesion Contrast	Reader 1	?	P<x
				Reader 2	?	P<x
				Reader 3	?	P<x

* Apart from the difference in population heterogeneity, other differences between P004A Re-read and SPARKLE includes e.g., dose and MR hardware/software technology

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RE-EVALUATION OF IMAGES REQUIRED TO REACH HEADLINE RESULTS FROM SPARKLE

SPARKLE Phase 3 patient recruitment completed

- Unenhanced and Orviglance enhanced images and other study data are collected from 85 patients
- Common adverse events were in line with previous studies

Re-evaluation of images are required to reach headline results

- As per FDA guidance, a pre-defined number of patients were evaluated twice
- Two of three readers had high intra-reader variability; i.e. scorings are are unreliable and cannot be used
- A re-evaluation of all images by new radiology readers is required

RE-EVALUATION ON TRACK

- All activities and resources are focused on the re-evaluation of SPARKLE images
- Cost-saving initiatives have been taken, including a significant reduction of the organization
- Headline results are expected by May 2024 and with currently available funding

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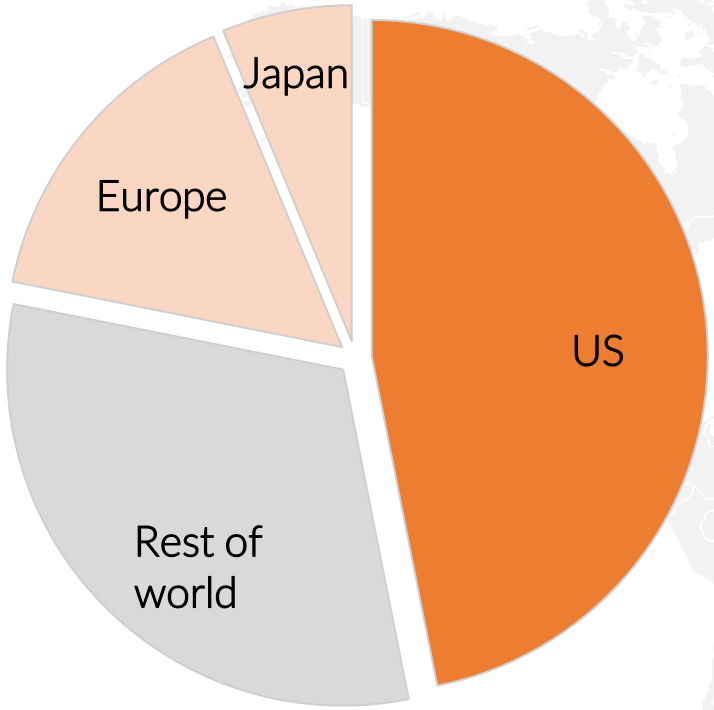
ATTRACTIVE ADDRESSABLE MARKET



Global addressable market of USD 800 million

Well defined unmet need for liver imaging in cancer patients with severe kidney impairment

Attractive pricing and access opportunity based on recognized value proposition[1]

Underlying growth driven by prevalence and cancer survival as well as access and quality of care in rest of world markets[2]

Sources:
Ascelia Pharma market research with Decision Resources Group, 2020.
Ascelia Pharma market access research and analyses with Revenue Reimbursement Solutions and Charles River Associates (2020), Triangle (2022) and Trinity (2022), incl. 75 stakeholder and expoert interactions
1) Final pricing strategy is subject to Phase 3 data, payer evidence, negotiations, discounts and access strategy
2) In rest of world markets addressable market patient population incorporates restricted access to care, with market-based assumptions ranging from 10% upwards

ATTRACTIVE US OPPORTUNITY

Abdominal imaging procedures in cancer patients with severe kidney impairment (CKD 4/5/AKI)
based on epidemiology and real-world data[1]

~100,000 procedures annually

Pricing range benchmarks
based on innovative diagnostics, payer and expert input and price testing[2, 3]

$3,000-4,500

Volume growth driven by demographics as well as prevalence and long-term care in cancers and kidney disease

4-5% vol. annually

Sources:
1) Ascelia Pharma market research with Decision Resources Group, 2020. Literature on prevalence and epidemiology of kidney disease, cancer and liver metastases.
2) Ascelia Pharma market access research and analyses with Revenue Reimbursement Solutions and Charles River Associates (2020), Triangle (2022) and Trinity (2022)
3) Final pricing strategy is subject to Phase 3 data, payer evidence, negotiations, discounts and access strategy

UNMET NEED RECOGNIZED

NSF* risk
with warnings for target population

+90%

of HCPs are concerned by issues relating to GBCAs (including NSF)

+16%

of providers have experienced GBCA-induced NSF

*nephrogenic systemic fibrosis

Source: Independent research by Two Labs Pharma Services for Ascelia Pharma in the USA conducted in Q4 2021/Q1 2022 included 16 in depth interviews and a survey of 254 healthcare professionals (HCPs), including 154 radiologists, 50 nephrologists and 50 oncologists. Participants in the study were asked about their choices of imaging and contrast agents in patients with cancer

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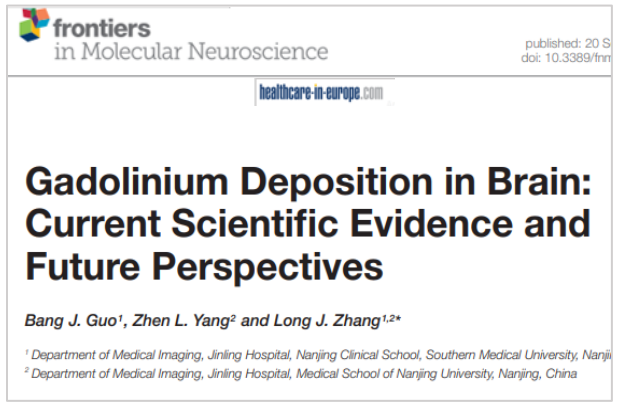
MOMENTUM FOR AN ALTERNATIVE TO GADOLINIUM

Deposition in brain & organs

concerns around safety for all patients

New safety category recommended for Symptoms Associated with Gadolinium exposure (SAGE), by Am. College of Rad. (2022)

Multiple-GBCA effect on body movement and mental skills study requested by the FDA (ODYSSEY, 2020)


frontiers in Molecular Neuroscience

published: 20 S
doi: 10.3389/fnm

healthcare-in-europe.com

Gadolinium Deposition in Brain: Current Scientific Evidence and Future Perspectives

Bang J. Guo[1], Zhen L. Yang[2] and Long J. Zhang[1,2]*

[1] Department of Medical Imaging, Jinling Hospital, Nanjing Clinical School, Southern Medical University, Nanji
[2] Department of Medical Imaging, Jinling Hospital, Medical School of Nanjing University, Nanjing, China

Water contamination

scrutiny of environmental impact

Gadolinium is excreted in urine. Hard to remove in our sewage systems, it is discharged into our environment and drinking water

> "The increasing use of gadolinium-based contrast agents (GBCAs) for MRI is leading to widespread contamination of freshwater and drinking water systems"[1]

Future with less/no gadolinium

focus of leading gadolinium manufactures

Low dose full-body gadolinium contrast agents

- FDA approved in priority review (gadopiclenol, Guerbet/Bracco 2022)
- Initiation of Phase 3 (gadoquatrane, Bayer 2023)

Completion of Phase 1 patient enrollment in full-body IV manganese-based contrast agent (GE HealthCare 2023)

1) Brünjes R. et al. Anthropogenic gadolinium in freshwater and drinking water systems, Water Research, Volume 182, 2020..
Other sources include:
Macke et al. Fast and automated monitoring of gadolinium-based contrast agents in surface waters, Water Research, Volume 207, 2021.
Oluwasola et al, Gadolinium based contrast agents (GBCAs): Uniqueness, aquatic toxicity concerns, and prospective remediation. Journal of Contaminant Hydrology, Volume 250, 2022.
M. Nicholl. Seeking alternatives to gadolinium-based contrast agents. Healthcareineurope.com. July 22022
Bang G. Gadolinium Deposition in Brain: Current Scientific Evidence and Future Perspectives. Mol. Neurosci., 20 September 2018.

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EXPANDED COMMERCIALIZATION OPTIONS FOR ORVIGLANCE

Ascelia led commercialization

- Retain **topline**
- Build **strategic capabilities**
- Optimize selected outsourcing **operations**
- **Milestone** based investment approach

Several go-to-market options available

Partner led commercial operations

- **Low Ascelia investment** for launch
- Leverage **established** capabilities
- Use global internal **strategic competencies**

Market and opportunity driven

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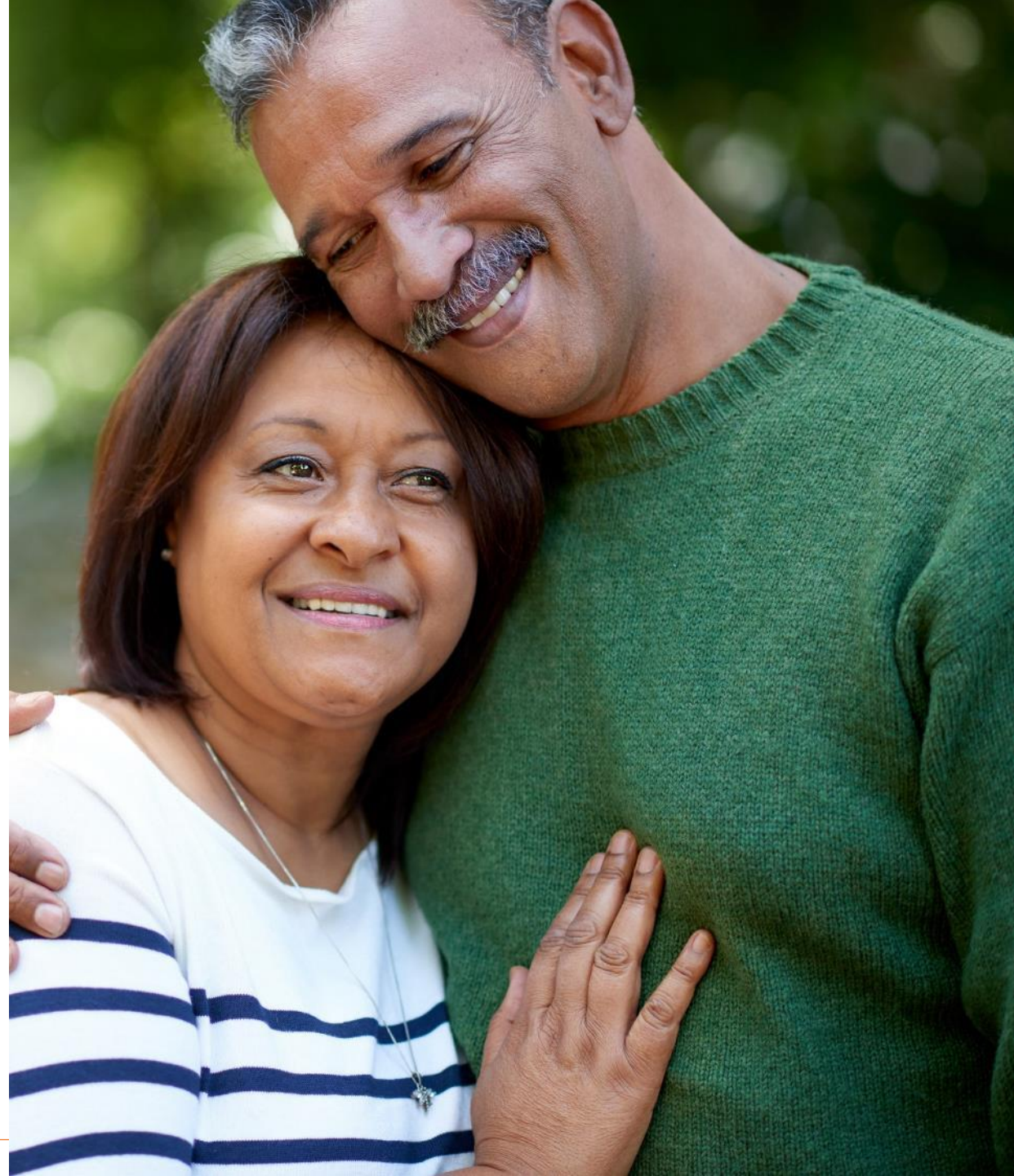
UNCHANGED CONFIDENCE IN ORVIGLANCE

- A well-defined unmet need for liver imaging in cancer patients with poor kidney function
- A global addressable market opportunity of USD 800 million
- Consistent positive efficacy and safety in eight completed Phase 1 and 2 studies
- Patient recruitment and MR image collection for SPARKLE Phase 3 study completed
  - Common adverse events were in line with previous studies
  - Efficacy conclusions from re-evaluation expected by May 2024



ORVIGLANCE®

Liver diagnostic imaging drug

ONCORAL

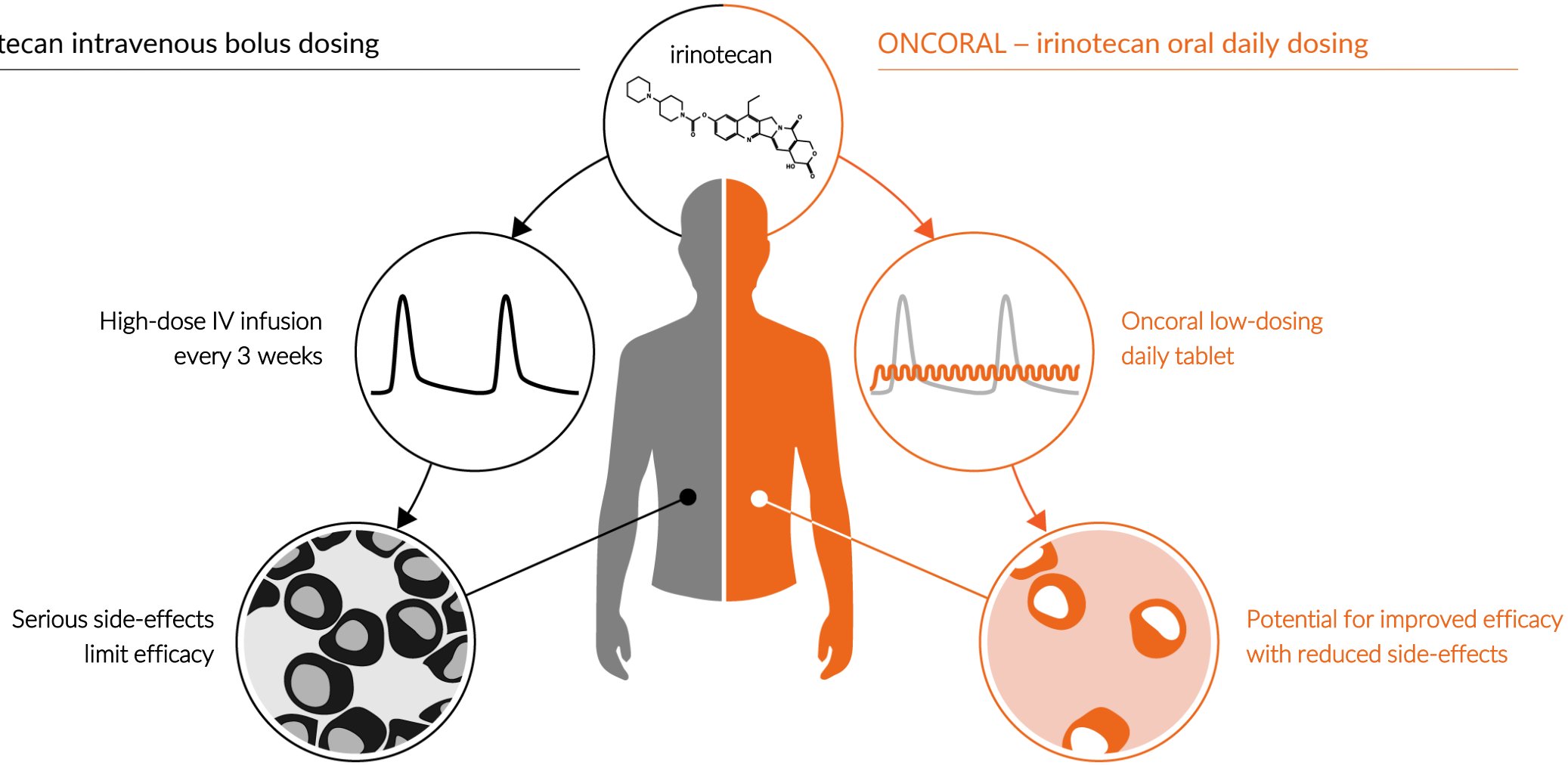
Daily, oral chemotherapy

PORTFOLIO

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

Irinotecan intravenous bolus dosing

ONCORAL – irinotecan oral daily dosing

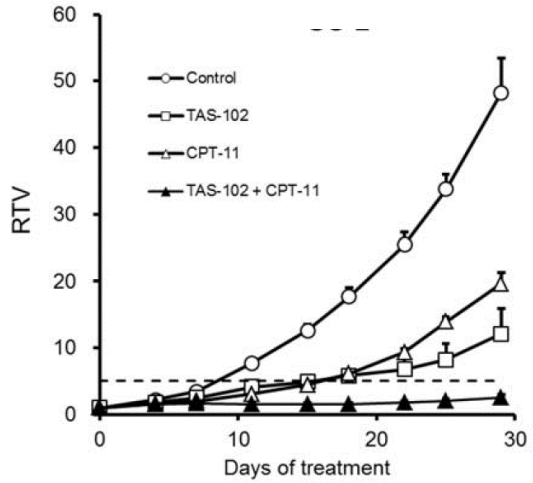


ONCORAL PHASE 2 IN GASTRIC CANCER

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 cancer[1]
(Relative Tumor Volume, RTV)



Control arm

IV irinotecan (CPT-11)
Lonsurf (TAS-102)

Lonsurf + IV irinotecan

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 Orviglance, patient enrollment is not initiated until it can be done effectively

Clinical collaboration with

TAIHO ONCOLOGY

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)

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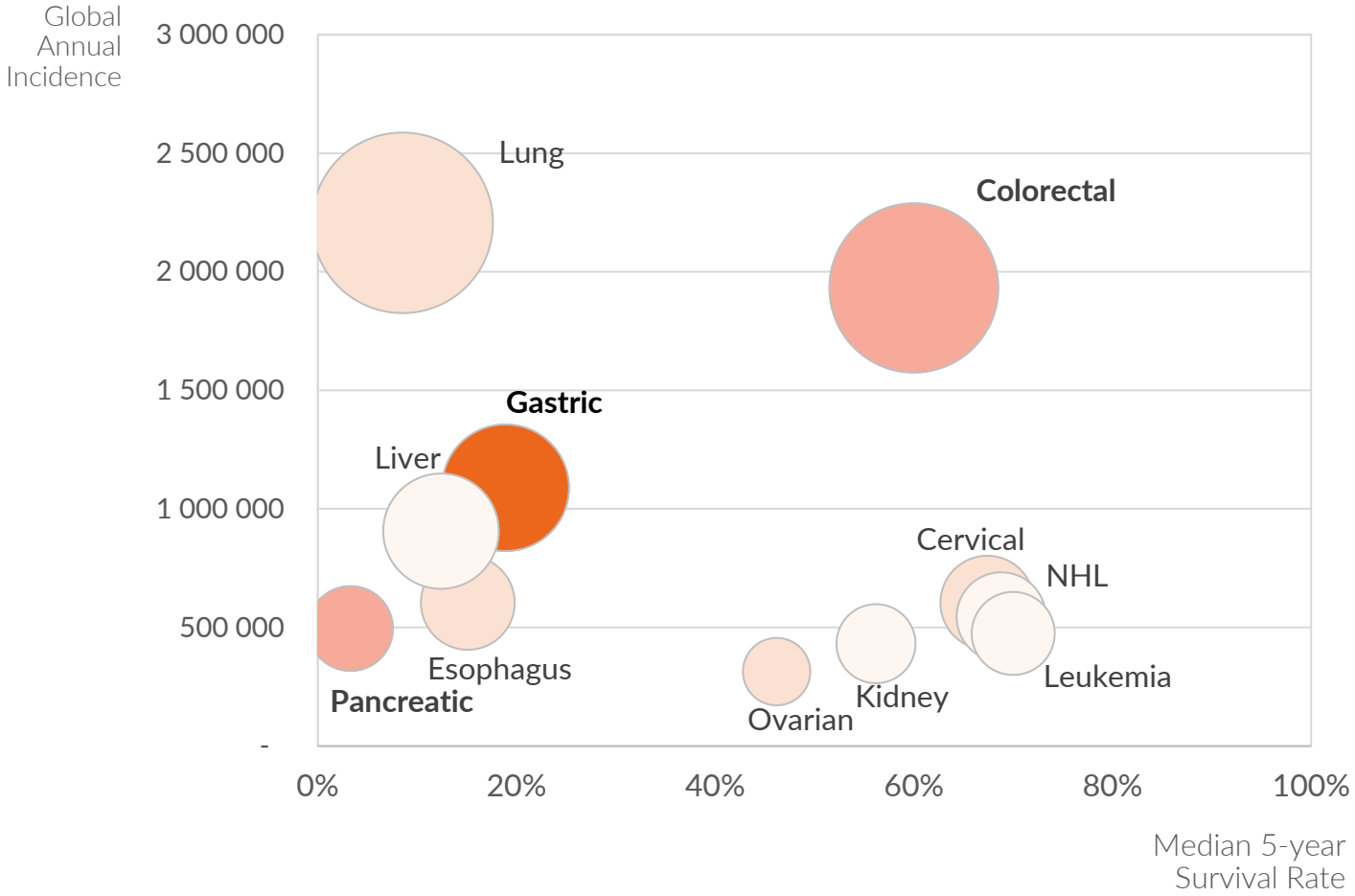
HIGH VALUE OPPORTUNITY IN GASTRIC CANCER AND EXPANSION

POTENTIAL FOR ORAL, DAILY DOSING OF IRINOTECAN[3]



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

- Current focus: **Gastric cancer**
  - Clinically demonstrated
  - Guidelines recognized
  - 3rd highest cancer deaths[1]
  - Orphan disease (US and EU)
  - $3-4bn market[2]
- **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

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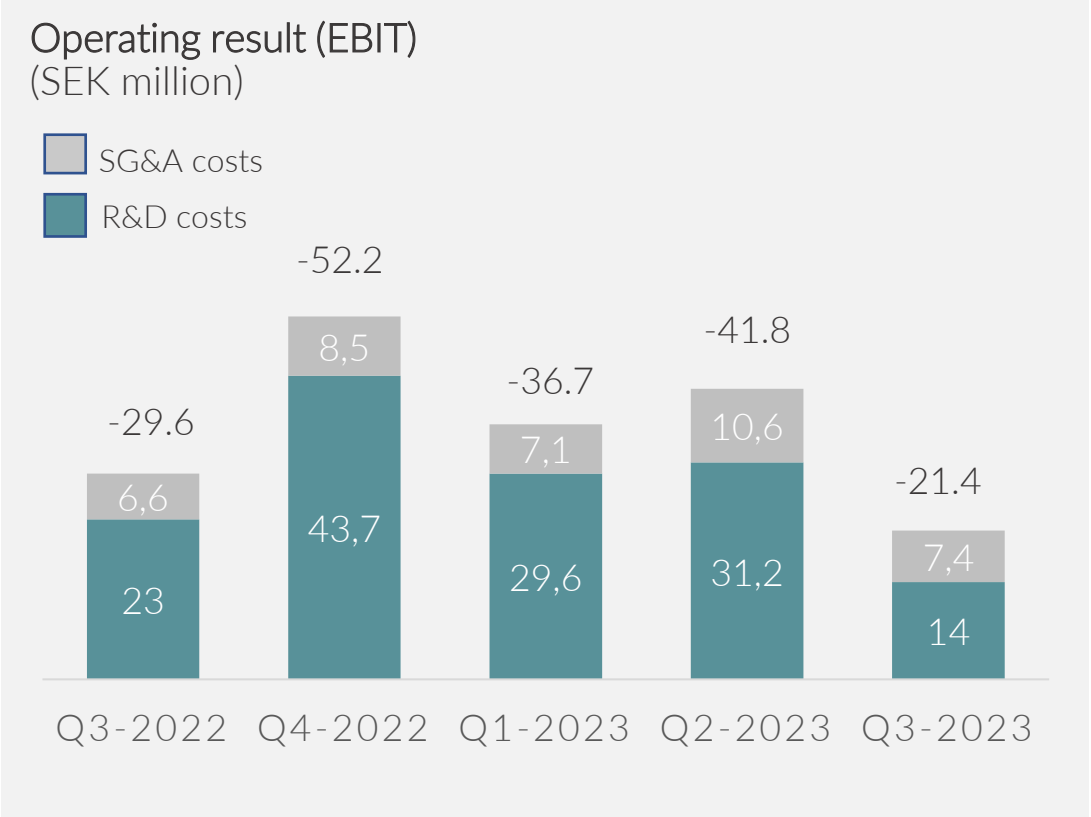
FINANCIALS & PRIORITIES

FINANCIAL HIGHLIGHTS Q3 2023 – OPERATING RESULT

- **Decreased operating loss in Q3 2023** compared to the loss in Q2 2023 driven by
  - lower activity level for SPARKLE following completion of patient recruitment activities
  - costs for organizational reduction included
- **Significantly lower cost level expected** going forward driven by:
  - all resources focused on re-evaluation
  - all other activities on hold
  - lower organizational costs

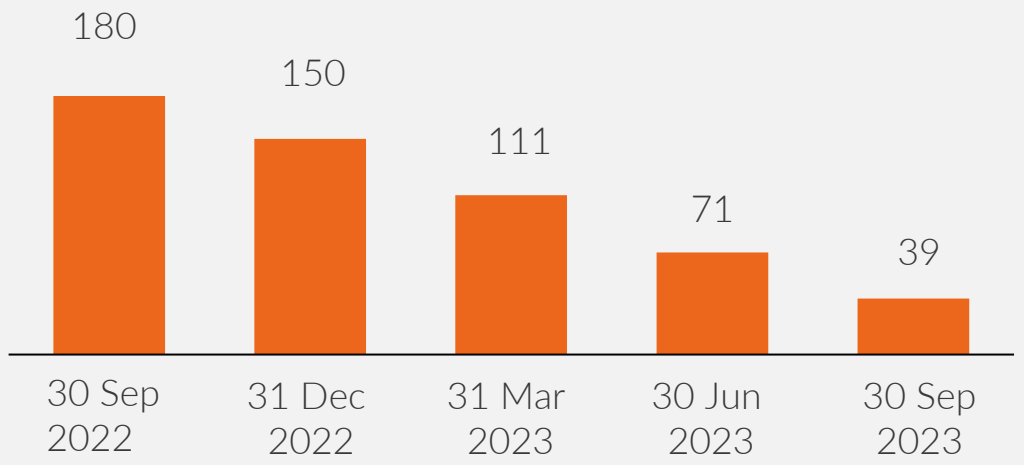


Notes:
1) Other operating income and other operating costs added to SG&A

FINANCIAL HIGHLIGHTS Q3 2023 – LIQUIDITY POSITION

- **Liquid assets** of 39 MSEK ($3.6 million) by 30 Sept 2023
- **Plan to complete SPARKLE image re-evaluation** by May 2024 with currently available funding
  - Activities not related to the re-evaluation are postponed
  - Cost saving initiatives have been implemented, including a significant reduction of the organization
- **Additional funding is needed to grow** Ascelia beyond headline results. Suitable funding options will be explored in due time

Liquid assets including marketable securities
(SEK million)



UNCHANGED CONFIDENCE IN ORVIGLANCE

ORVIGLANCE – a first-in-class orphan diagnostic drug targeting $800m market

✓ 3 Mar 2023	SPARKLE Phase 3 LPLV
✓ 13 Sept 2023	Focused Plan for Re-Evaluation
● May 2024	SPARKLE Headline Results

Oncoral – Phase 2 ready with attractive potential in gastric cancer and other solid tumors

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