ADVANCING ORPHAN ONCOLOGY

Ticker symbol: ACE
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www.ascelia.com

Positive Outcome of Orviglance® FDA Meeting in Advance of the NDA Submission

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First Quarter Report 2025

Conference call presentation on 16 May 2025, 10:00 CEST

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FORWARD LOOKING STATEMENTS

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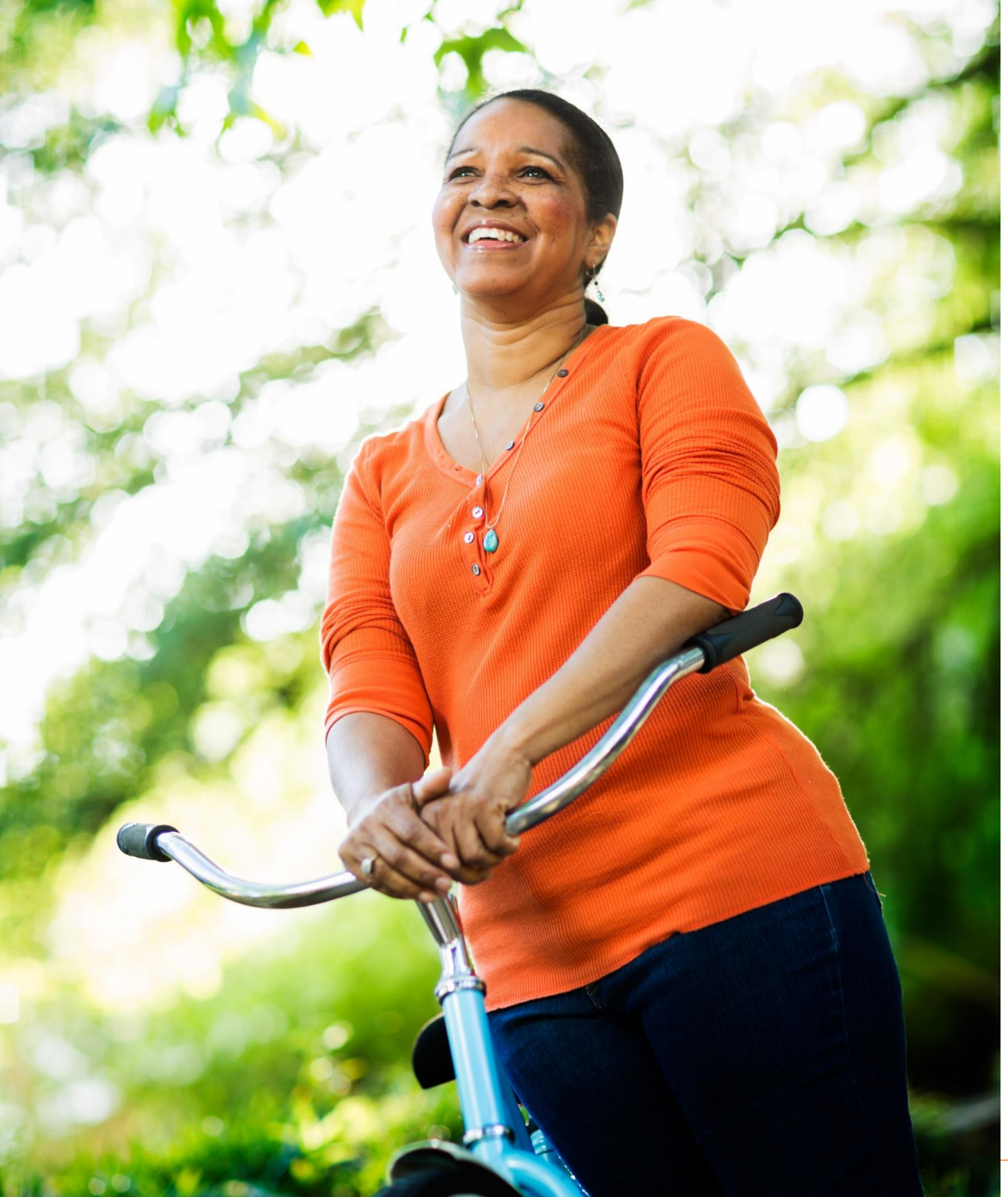

QUARTERLY REPORT Q1 2025 INVESTOR CONFERENCE CALL

Agenda

Recent key events

Portfolio

Financials and priorities ahead

Presenters

CEO - Magnus Corfitzen

Deputy CEO - Julie Waras Brogren

CSO – Andreas Norlin

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ASCELIA PHARMA - HIGHLIGHTS

Pipeline

ORVIGLANCE® – Registration phase

- First-in-class contrast agent for use in liver MRI in patients with severely impaired kidney function
- FDA Orphan Drug Designation
- Global addressable market of USD 800 million
- Phase 3 study successful and clinical development completed

ONCORAL – Phase 2-ready

- Daily, oral irinotecan chemotherapy
- Clinical collaboration with Taiho Oncology
- Opportunity in gastric cancer and other solid tumors

Global outlook and Nordic roots

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

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Q1 2025 PROGRESS

Key events in Q1 2025

- Three scientific abstracts with SPARKLE Phase 3 data accepted for presentation at the ESGAR congress 2025
- Extraordinary General Meeting on 25 February 2025 to adopt an employee stock option proposal
- Nomination Committee appointed for AGM 2025 in Ascelia Pharma AB
- Announcement of positive outcome of FDA Meeting and confirmed plan to submit the NDA for Orviglance mid-2025
- Subscription price for warrants series TO 1 determined to SEK 2.15 and exercise period initiated on 1 April 2025

Key events after the period

- Study on Orviglance target patients accepted for presentation at the ISPOR 2025 conference
- Publication of scientific article on Orviglance in Investigative Radiology
- Ascelia Pharma receives gross proceeds of SEK 43 million from exercise of warrants series TO 1
- Bulletin from the Annual General Meeting in Ascelia Pharma AB on 7 May 2025

ATTRACTIVE ORVIGLANCE OPPORTUNITY

- A well-defined unmet need for liver imaging in cancer patients with impaired kidney function
- A global addressable market opportunity of USD 800 million
- Clinical development completed with 9 studies and strong phase 3 results
- Commercial scale manufacturing
- Orviglance advances to regulatory filing and approval phase

SUBSTANTIAL ORVIGLANCE VALUE CREATION OPPORTUNITIES

	Advance to approval	Secure partnering and commercialization readiness
Objectives	**Timely submission and approval** by the US FDA as an orphan drug with an optimal label for the use in the target population	**Focused launch** for well-defined patient population with 800 MUSD annual addressable market **Partner** driven global commercialization
Milestones	✓ Full SPARKLE Clinical Study Report early **Q4 2024** ✓ Conclusions from FDA meeting in **Q1 2025** ▪ NDA submission **mid-2025** with Ascelia Pharma and partner readiness	▪ Advance **launch readiness** ▪ Establish commercialization **partnership(s)**

Mid-2025 refers to the three months from mid-May to mid-August

ORVIGLANCE®

Liver diagnostic imaging drug

ONCORAL

Daily, oral chemotherapy

PORTFOLIO

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ORVIGLANCE – FILLING AN UNMET NEED IN LIVER MRI

Patient Landscape

Liver metastases are 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 severe 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 (NSF)

ORVIGLANCE

Aims to be the imaging option without gadolinium-related safety risks in patients with severe kidney impairment

- 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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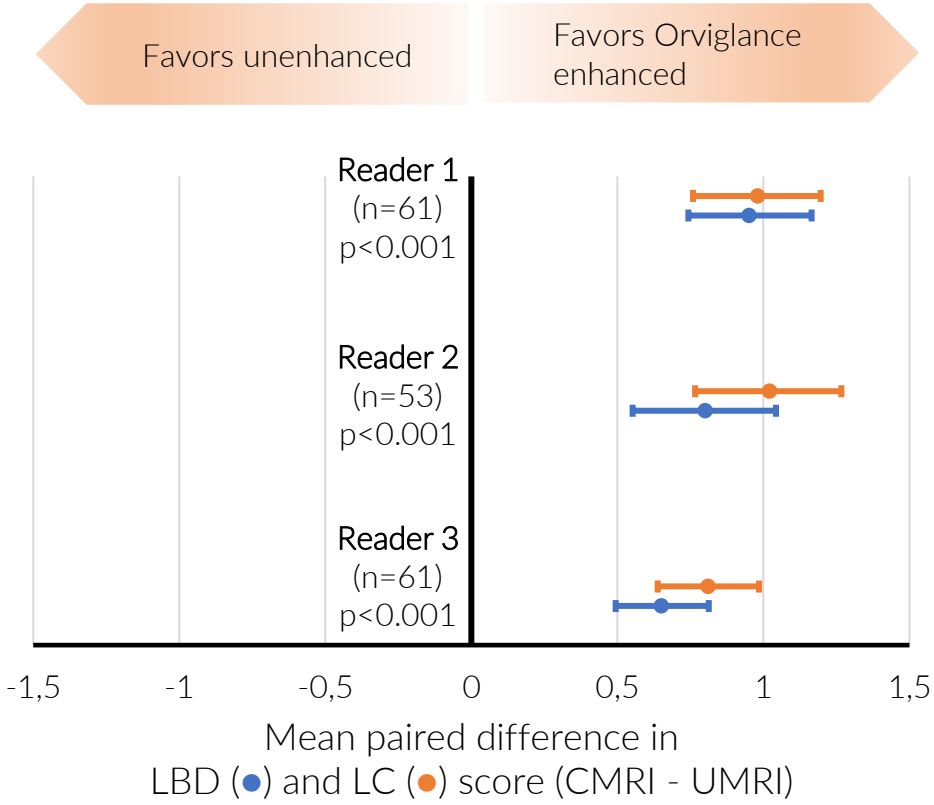
STRONG SUPERIORITY OF ORVIGLANCE IN PHASE 3

Successful Phase 3 Study

- Phase 3 study demonstrated **strong superiority** in visualization of focal liver lesions with Orviglance (CMRI) compared to unenhanced MRI
- Visualization scored **significantly higher** with Orviglance than without for all three readers with statistical significance ($p<0.001$) and high reliability of the data, including
  - *For Orviglance-enhanced images*, the median boarder delineation and lesion contrast scores increased from 2.1 and 3.0 to 3.0 and 4.0 respectively across readers*
- **Secondary efficacy endpoints support** primary analysis and confirm the robustness of the positive results, including
  - *Detection of lesions: across all readers at least one new lesion were detected in 40-52% of patients with Orviglance***
- Common adverse events were consistent with previous studies, such as mild to moderate nausea; **no serious adverse drug reactions** were observed



Data presented as mean paired differences for matched lesions per patient for combined MRI (CMRI) and unenhanced MRI (UMRI) with 95% Confidence Intervals. Statistical evaluation by one-sided paired t-test (α=0.025). Total N=85, n=number of patients with matched lesions.

*Improvements compare to scores for unenhanced images on a 4-point scale (from 1 ("poor") to 4 ("excellent") pooled for all three readers, **Compared to unenhanced.
Please refer to the Q3 2024 Report presentation for a more detailed summary of the SPARKLE study results

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CLINICAL DEVELOPMENT COMPLETED

Nine studies with consistent positive efficacy and safety results[1-7]

286 patients and healthy volunteers

Phase 1 studies demonstrated safety, absorption and signal intensity

Total 4 studies with 126 healthy volunteers

Phase 2 studies demonstrated efficacy and safety in patients with known metastases

Total 4 studies with 75 patients

Orviglance efficacy confirmed vs. gadolinium & unenhanced in re-evaluation

Re-read of phase 2 study (20 patients) with liver metastases with same endpoint as in phase 3

Phase 3 study confirmed efficacy and safety in the target population

Pivotal study on visualization of focal liver lesions and safety in patients with severe kidney impairment (85 patients)

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 presented at RSNA and ESGAR conferences between 2022 and 2023

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POSITIVE FDA MEETING CONFIRMS PATH FOR NDA FILING

FDA meeting in advance of the NDA submission

- Ascelia presented the plan for the submission including:
  - How to analyze and present the clinical data
  - Finalization of Statistical Analysis Plan
  - Manufacturing documentation
  - Structure of the NDA
- The FDA provided clear and concrete feedback which will allow Ascelia to finalize the NDA documentation package
- The NDA submission continues to be planned for mid-2025; most likely the first half of August

PRESS RELEASE

18 March 2025 22:05:00 CET

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Ascelia Pharma Announces Positive Outcomes of FDA Meeting and Confirms Plan to Submit the NDA for Orviglance mid-2025

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today announced that the Company has received final minutes from the meeting with the FDA, providing positive guidance for the Orviglance NDA to progress with the submission mid-2025 as planned.

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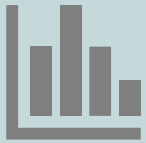
ADVANCING ORVIGLANCE TOWARDS APPROVAL

Clinical

Nonclinical



CMC

US FDA

Timely submission and approval by the US FDA as an orphan drug with an optimal label for use in the target population

- ✓ Full Clinical Study Report early **Q4 2024**
- ✓ Conclusions from FDA meeting by **Q1 2025**
- ▪ NDA submission **mid-2025**

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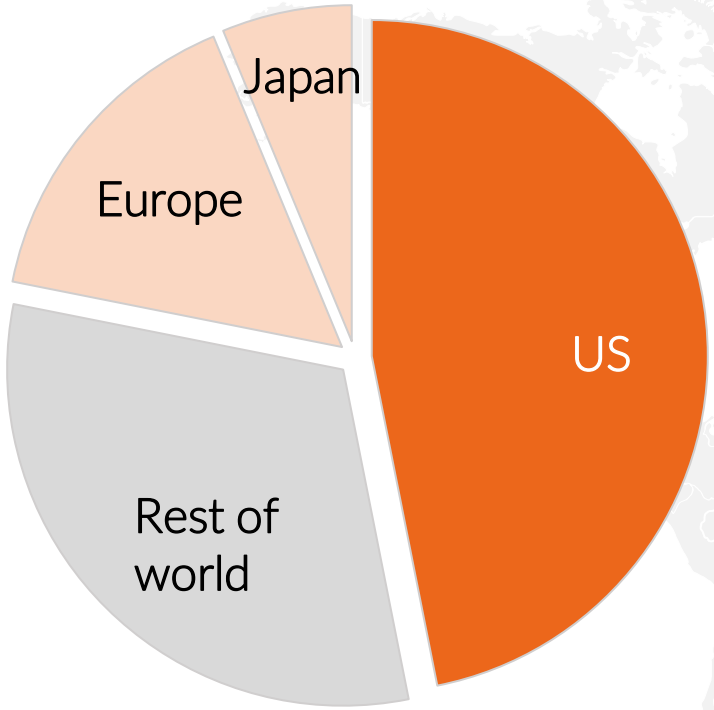
ADDRESSABLE MARKET OF USD 800 MILLION ANNUALLY



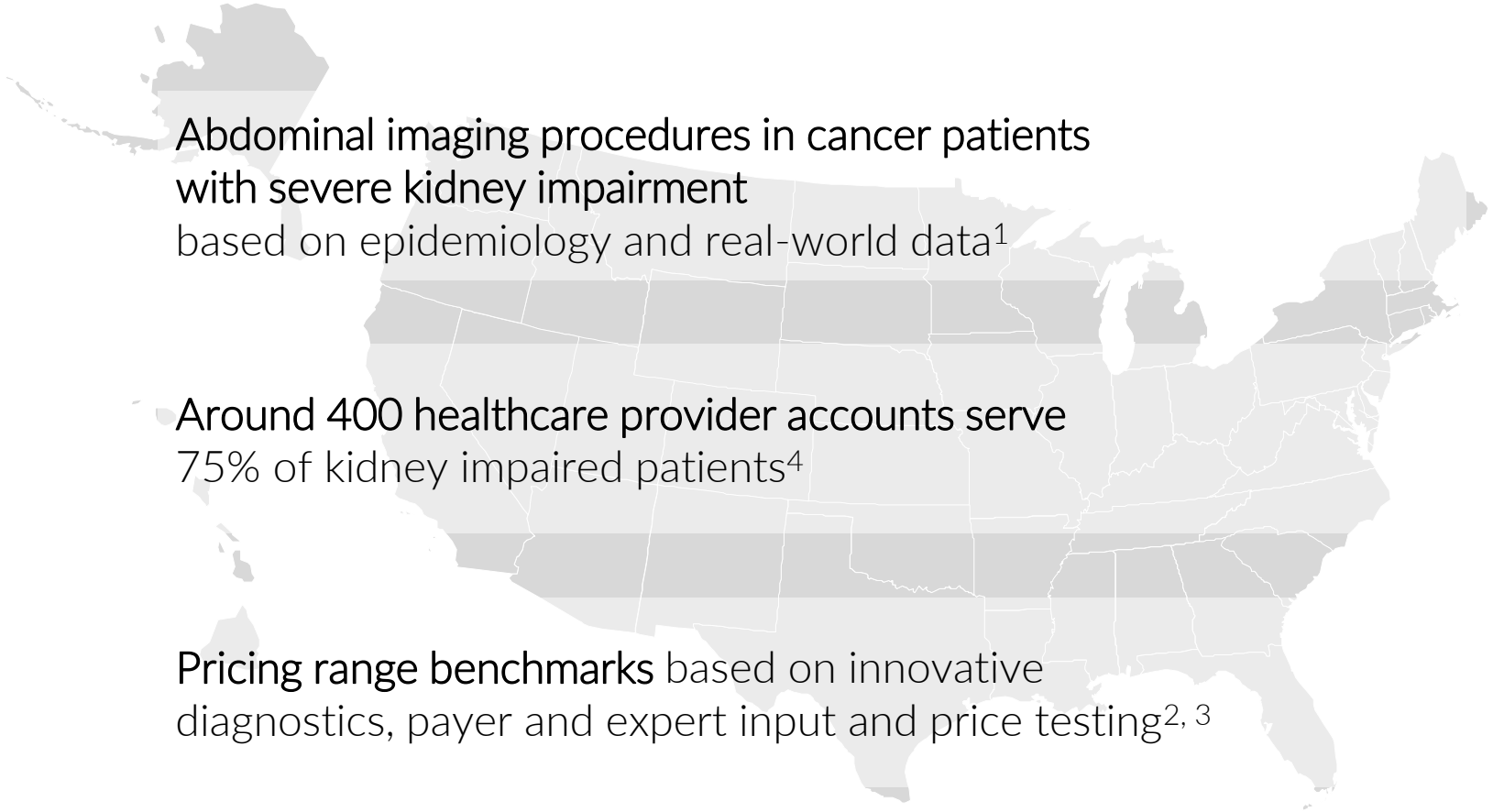
Global addressable market of USD 800 million, half of this in the US

Focused launch for well-defined patient population in liver imaging in cancer patients with severe kidney impairment

Global commercialization through partners

Sources:
Ascelia Pharma market research on real-world volumes 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

ATTRACTIVE US OPPORTUNITY



Abdominal imaging procedures in cancer patients with severe kidney impairment
based on epidemiology and real-world data[1]

Around 400 healthcare provider accounts serve
75% of kidney impaired patients[4]

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

~100,000
procedures annually

~400 accounts

$3,000-4,500

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

UNMET NEED RECOGNIZED IN CLINICAL PRACTICE

"Those of us who have seen NSF are frightened by it… you'll get **buy-in from a lot of nephrologists**…".
- Head of Renal section at US university hospital (from Ascelia Pharma Advisory Board meeting)

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

""The college [American Colleague of Radiology]…have a **growing sense of responsibility and accountability** about using these agents in high-risk patients…. our perception of which agents are "safe" has changed… this is another place where practice needed to evolve"
- SPARKLE Investigator and Head of Radiology at US university hospital

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 excreted in urine is discharged into our environment and drinking water

Future with less/no gadolinium

focus of leading gadolinium manufacturers

Low dose full-body gadolinium contrast agents pursued by GBCA players with one approved by the FDA in priority review

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

Almost all gadolinium is exported from China

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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ON TRACK FOR OPTIMAL COMMERCIALIZATION

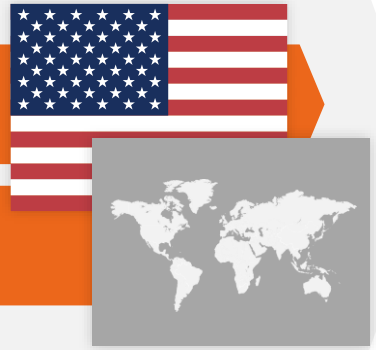
Strategic objectives for commercialization

- Optimal balance between investment required and future revenues
- Leverage established commercialization capabilities
- Maximize value with global launch strategy

Global commercialization through partners

Secure launch readiness

Establish commercial partnerships



Dialogue with potential partners progressing

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RECOGNITION IN THE SCIENTIFIC COMMUNITY

Orviglance data accepted at major conferences so far with
4 oral presentations and 4 abstract presentations

Radiological Society of North America (RSNA), Annual Meeting, December 2024

Science Session (Value Based, Equitable and Sustainable Radiology) | M6-STCE2

Session Type: Learning Center Theater Presentations

Monday, Dec 2 | **1:30 PM - 2:00 PM CST** | LEARNING CENTER THEATER 2

SPARKLE: A MULTICENTER, OPEN-LABEL STUDY TO EVALUATE THE SAFETY AND DIAGNOSTIC EFFICACY OF ACE-MBCA IN PATIENTS WITH KNOWN OR SUSPECTED FOCAL LIVER LESIONS AND SEVERE RENAL IMPAIRMENT | M6-STCE2-3

Alvin C. Silva, MD, Presenter

Ascelia Pharma Announces Acceptance of Study on Burden of Illness Real-World Data of Orviglance Target Patients for Presentation at the ISPOR 2025 Conference

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today announced that the abstract titled 'Burden of Illness in US Patients with Liver Cancer and Kidney Disease – A Real-World Claims Analysis' has been accepted for presentation at the Professional Society for Health Economics and Outcomes Research (ISPOR) Conference, taking place 13-16 May in Montreal, Canada.

Ascelia Pharma Announces Acceptance of Three Scientific Abstracts with SPARKLE Phase 3 Data at the European Society of Gastrointestinal and Abdominal Radiology Annual Meeting

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today announced that two oral presentations and one scientific poster with clinical data from the SPARKLE Phase 3 study with Orviglance have been accepted for presentation at the European Society of Gastrointestinal and Abdominal Radiology (ESGAR) Annual Meeting, taking place 13-16 May in Amsterdam, Netherlands.

Ascelia Pharma Announces Acceptance of SPARKLE Phase 3 Data for Presentation at the Society of Abdominal Radiology Congress 2025

Ascelia Pharma AB (publ) (ticker: ACE), a biotech focused on improving the life of people living with rare cancer conditions, today announced that two scientific abstracts with clinical data from the SPARKLE Phase 3 study with Orviglance have been accepted as an oral presentation and a scientific poster at the Society of Abdominal Radiology Congress, taking place from 16-21 February 2025 in Tucson, AZ, US.

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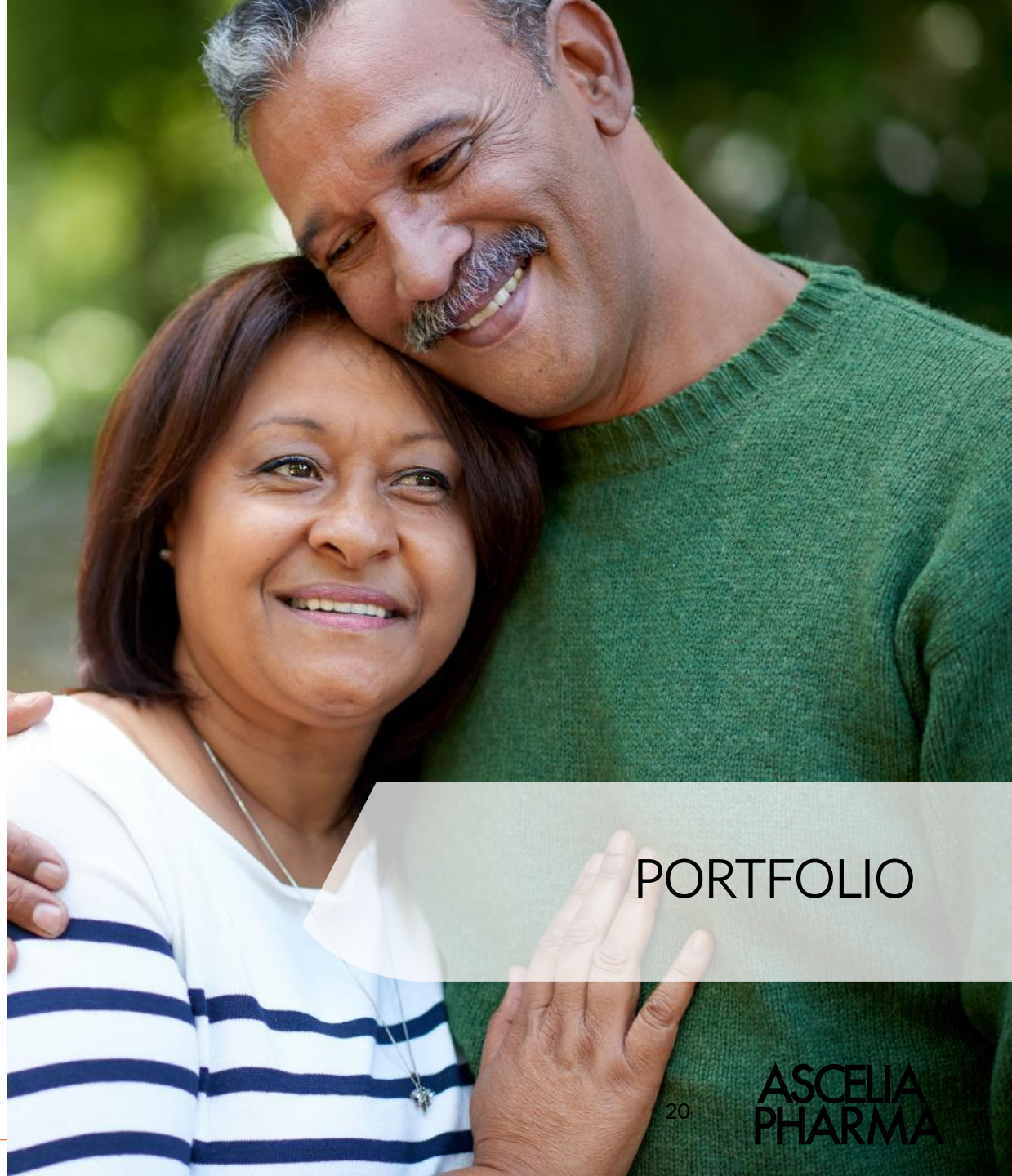
ORVIGLANCE®

Liver diagnostic imaging drug

ONCORAL

Daily, oral chemotherapy



PORTFOLIO

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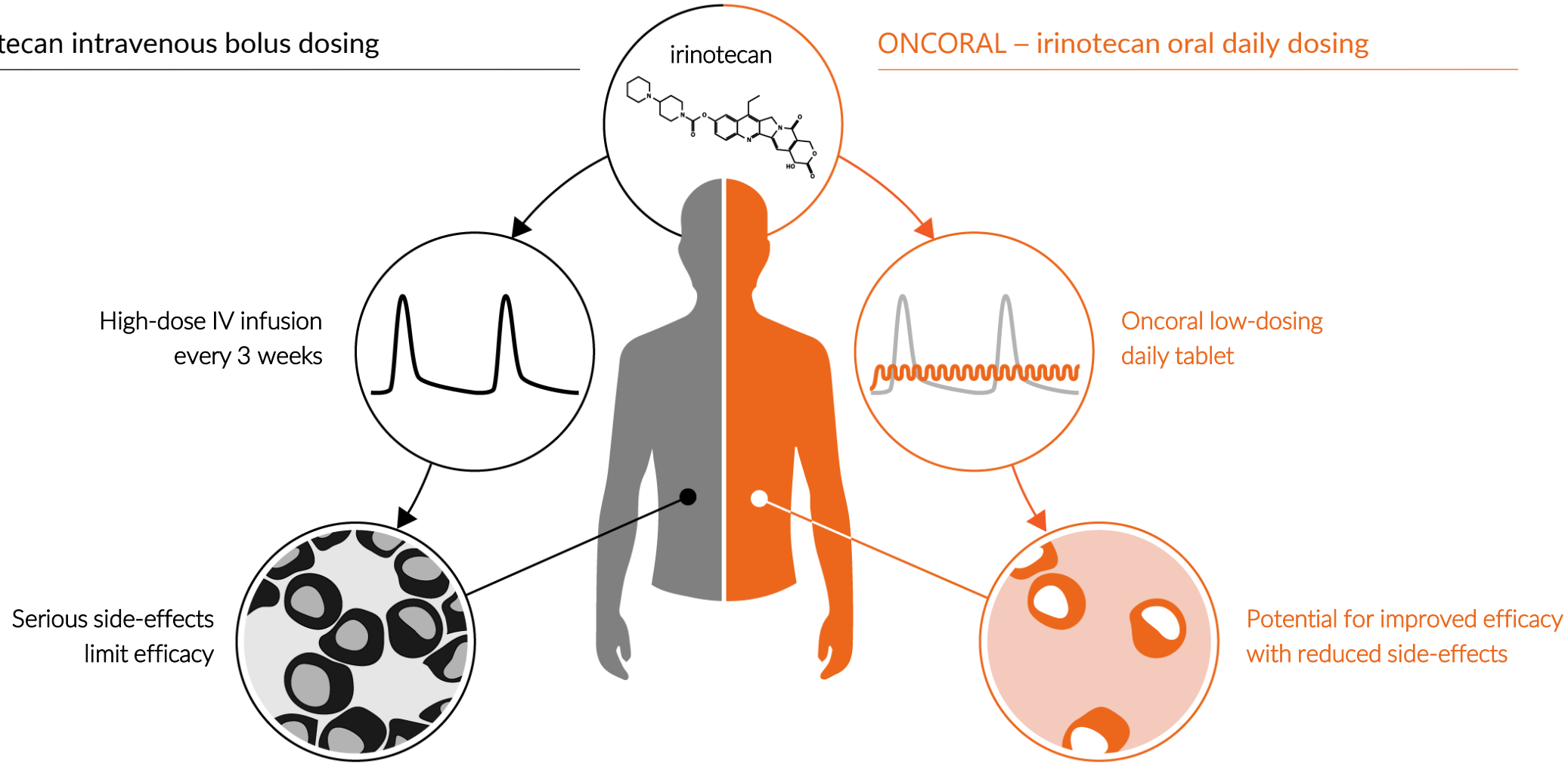
IMPROVING IRINOTECAN **EFFICACY** and **TOLERABILITY**

Irinotecan intravenous bolus dosing

ONCORAL – irinotecan oral daily dosing



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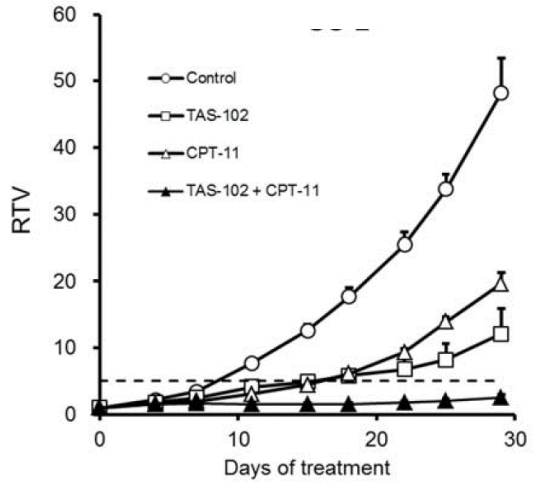
ONCORAL PHASE 2 IN GASTRIC CANCER

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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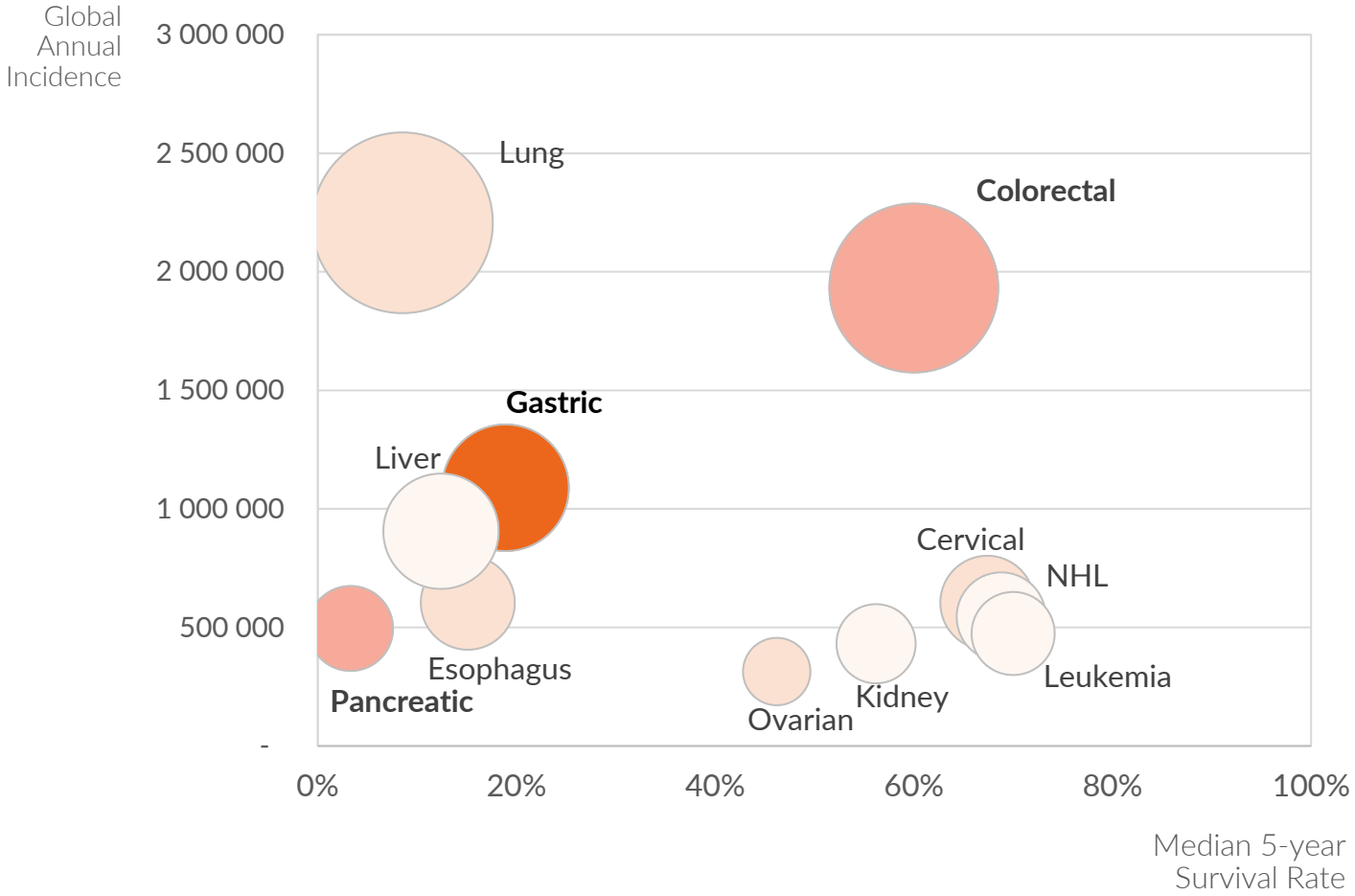
HIGH VALUE OPPORTUNITY IN GASTRIC CANCER AND EXPANSION

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 & OUTLOOK

SUCCESSFUL WARRANTS EXERCISE BRING 43 SEK MILLION

Successful TO 1 warrants exercise

- SEK 43 million additional financing before costs
- Subscription rate of approximately 96 percent

Cash runway to at least end 2025, well beyond the NDA submission

- Includes repayment of the SEK 20 million loan to Fenja and reserved cash for a potential repayment of the SEK 7.5 million convertibles end of 2025.
- Excludes financing from partnering

PRESS RELEASE

16 April 2025 17:55:00 CEST

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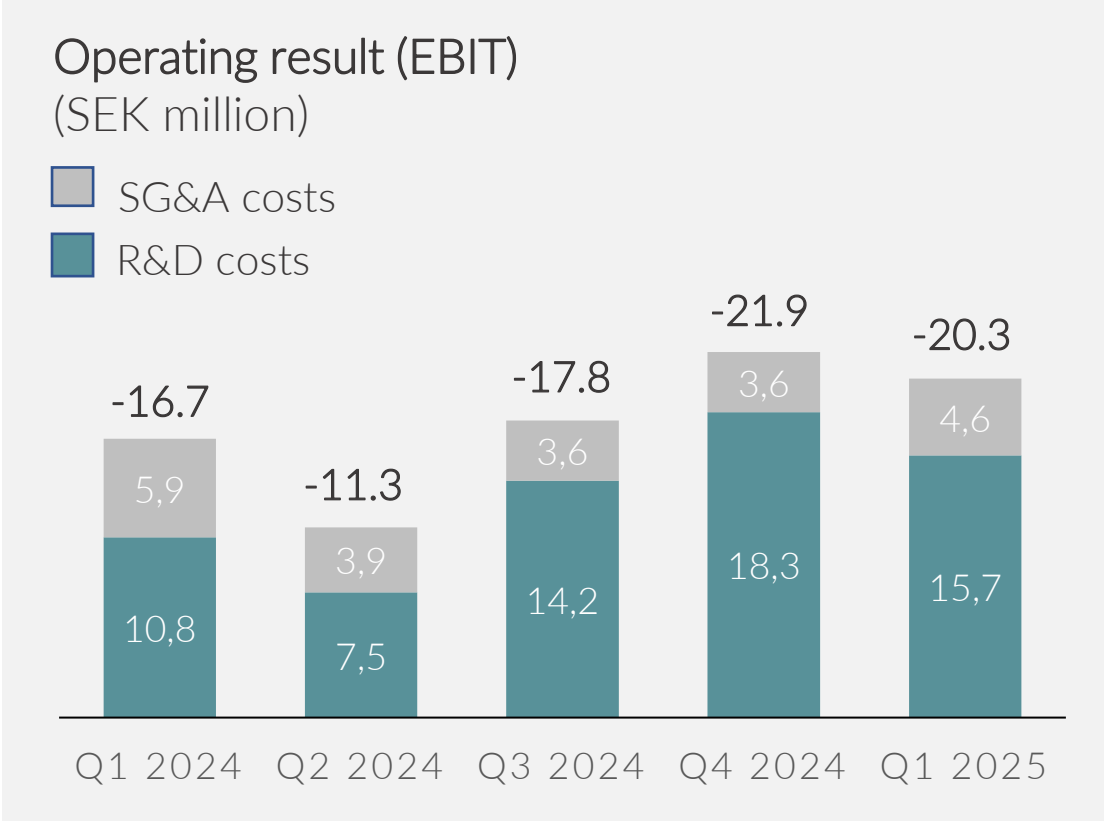
Ascelia Pharma Receives Gross Proceeds of SEK 43 Million from Exercise of Warrants Series TO 1

The exercise period for warrants series TO 1 ("TO 1") in Ascelia Pharma AB ("Ascelia Pharma" or the "Company") ended on 15 April 2025. The outcome shows that a total of 19,919,494 TO 1 were exercised for subscription of 19,919,494 new ordinary shares, corresponding to a subscription rate of approximately 96 percent. Ascelia Pharma thus receives proceeds of approximately SEK 43 million before issue costs.

OPERATING RESULT– MAINTAINED LOW OPERATING EXPENSES

Operating loss of SEK 20.3 million in Q1 2025

Costs are at a similar level compared to Q4 2024 with a continuous focus on NDA submission preparations.



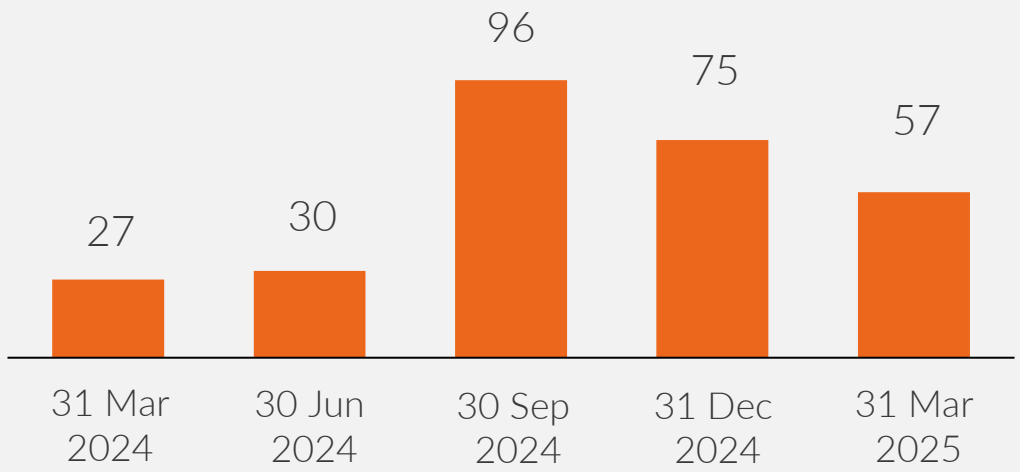
Notes:
1) Other operating income and other operating costs added to SG&A

LIQUIDITY - CASH RUNWAY TO AT LEAST END 2025

Liquid assets of SEK 57 million (31 Mar 2025); excluding SEK 43 million gross proceeds from TO 1 warrants in April 2025.

Cash runway now reaches at least end 2025; with reserve for potential repayment of the SEK 7.5 million Fenja convertible end of 2025 and excluding financing from partnering.

Liquid assets including marketable securities
(SEK million)



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	Advance to approval	Secure partnering and commercialization readiness
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Mid-2025 refers to the three months from mid-May to mid-August

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