# **Onco** invent

# **Corporate Presentation**

Developing a New Standard Therapy for Peritoneal Carcinomatosis (PC) with a local, receptor independent, radiopharmaceutical technology

Anders Mansson, CEO

### **Oncoinvent: Investment Opportunity**

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Radiopharma hot-spot

Rapidly growing development area in oncology, substantial interest from investors and Big Pharma.

#### **Experienced Leadership**

Founders and management of Oncoinvent have a proven track record of developing a radiopharmaceutical asset and bringing it to market (Xofigo<sup>®</sup>).

#### **High Unmet Need in Peritoneal Carcinomatosis**

Peritoneal metastases can originate from several cancer types, and there exists a large patient population with a high unmet need.

#### **Pipeline in a Product**

Significant potential for this non-systemic, receptor-independent, alpha-radiation therapy, applicable in many different cancer types.

#### **Potential for Standard of Care**

Radspherin<sup>®</sup> has the possibility to become standard of care for peritoneal metastases from an array of different cancer types.



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# Radiopharmaceuticals is a lucrative and untapped Market Opportunity in Oncology - Investments

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- Radiopharmaceuticals have seen a recent surge of financings and acquisitions, creating a new attractive hot spot in oncology
- The space is projected to experience continued growth and is positioned to surpass conventional cancer therapies

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"Convergent Therapeutics Announces \$90 Million Series A Financing to Advance the Clinical Development of Radiopharmaceuticals for the Treatment of Prostate Cancer and Other Solid Tumors"

Cision 3 May 2023

#### 

"Startup **Mariana** raises \$175M for radiopharmaceutical drug research"

Biopharma Dive 7 Sep 2023

#### 

"RayzeBio stock opens with a big gain, to push valuation up to \$1.4 billion"

Marketwatch 15 Sep 2023

#### 

"Investors pour \$90M onto **ARTBIO**'s palette less than 6 months after launching"

Fierce Biotech 7 Dec 2023

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"Radiopharmaceuticals **Market Size** to Surpass USD 13.67 Bn by 2032"

BioSpace 11 Dec 2023

# Radiopharmaceuticals is a lucrative and untapped Market Opportunity in Oncology - Acquisitions

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"Eli Lilly Jumps Into Radiopharmaceuticals via \$1.4B Point Biopharma Acquisition"

MedCity News 3 Oct 2023

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"Bristol Myers Squibb (NYSE: BMY) and RayzeBio, Inc. (NASDAQ: RYZB) today announced a definitive merger agreement under which **Bristol Myers Squibb will acquire RayzeBio** for \$62.50 per share in cash, for a total equity value of approximately **\$4.1 billion**"

Press release 26 Dec 2023

### **Experienced Developers in Innovative Radiopharmaceuticals**



Radiochemistry and Preclinical Expertise Expert founders and management with decades of experience in developing alpha-emitting therapies for commercialization.



#### Encouraging Clinical Data and Upcoming Milestones

**Clinical studies of Radspherin** demonstrate excellent safety and promising long-term efficacy data. **Initiation of phase 2b trials** in colorectal and ovarian cancer patients is expected in 2024. INDs approved.



#### Innovative Alpha-Particle Product

Versatile and potentially transformative lead product candidate, Radspherin<sup>®</sup>, applicable across numerous cancer types. Receptor independent.

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#### Strong GMP Manufacturing & Supply Chain Capabilities

Internal GMP radiopharmaceutical manufacturing capabilities with multiple sources of radioisotope Thorium-228 to ensure a continuous manufacturing of Radium-224.



#### Leadership Team Experienced in Building Companies and **Bringing Radiopharmaceutical Therapy to Market**



Anders Mansson Chief Executive Officer

Gro Hjellum **Chief Operations Officer** 

Kari Myren Chief Medical Officer



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Tore Kvam **Chief Financial Officer** 

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# **Body Cavity Targeting - Peritoneal Carcinomatosis**

- A multiple cancer type disease area with a significant unmet medical need

- Tumors of the peritoneum are most frequently caused by metastases from other primary cancers: ovarian and colorectal cancers are the commonest causes
- High patient burden and a dramatic impact on quality of life
- Poor prognosis and limited treatment options
- Considerable patient population and a significant unmet medical need



# onco invent **Peritoneal Carcinomatosis – Room for Further Expansion**

- Addressable market, beyond ph3 target, with significant unmet medical need



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"Historically, the survival rate for gastric carcinoma patients with peritoneal carcinomatosis has been poor, ranging from 2.2 to 8.8 months and no survival at 5 years."<sup>3</sup>

1 source: <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4655111/</u>

2 source: http://www.cancer.org/cancer/ovariancancer/detailedguide/ovarian-cancer-survival-rates

3 source: Cytoreductive Surgery and Hyperthermic Intraperitoneal Chemotherapy for Gastric Cancer - PMC (nih.gov)

### **Clinical Administration of Radspherin®**

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- Delivering highly effective receptor-independent alpha-therapy directly to target area
- A catheter is left after Cytoreductive Surgery (CRS)
- Through that catheter a single dose of Radspherin<sup>®</sup> microparticles, dispersed in a solution, are injected directly into the peritoneum, avoiding the need for systemic administration
- The alpha-radiating microparticles spread throughout the cavity eradicating micro-metastases
- After microparticles have lost their capacity for radiation, the calcium-carbonate based carrier material is naturally dissolved, absorbed, and excreted by the body
- Easy-to-use, non-invasive radiotherapy with non-systemic administration.



#### **Radspherin® for the Treatment of Peritoneal Metastasis**

- Delivering highly effective receptor independent alpha-therapy directly to target area

- Non-systemic, single-dose, intraperitoneal Radspherin<sup>®</sup> aims to eliminate residual micro-metastases after cytoreductive surgery and thus prolong disease-free period and survival
- Treatment effective independently of cancer cell type and cellular resistance mechanisms
- The size and slow degradation of the microparticles combined with the half-life of 3.6 days of radium-224, provides sustained treatment effect over days
- Alpha radiation is highly effective, yet shortrange in tissue. Ideal for large body cavity surfaces



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### **Radspherin® - Clinical Development**

- Clinical dose established, enrollment to phase 2a in completion



• Two Phase 1/2a studies - assessing dose, safety and tolerability, dosimetry and signal of efficacy of intraperitoneal Radspherin

RAD-18-001: Ovarian/fallopian tube cancer	<ul> <li>Oslo/Norway(PI: Yun Wang)</li> <li>Leuven, Belgium (PI: Els van Nieuwenhuysen/Ignace Vergote)</li> <li>Madrid/Pamplona, Spain (PI: Luis Chiva)</li> </ul>
RAD-18-002: Colorectal carcinoma	<ul> <li>Oslo, Norway (PI: Stein Larsen)</li> <li>Uppsala, Sweden (PI: Wilhelm Graf)</li> </ul>

For both studies, dose escalation is completed and the highest dose of 7 MBq selected, recruitment to expansion cohorts ongoing – more than 50 patients treated in total. Continued stream of follow-up data

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# **Radspherin® Robust Safety Profile**

- Well tolerated and minimal organ toxicity

Well tolerated and considered safe to use	<ul> <li>No dose limiting toxicities observed at any dose level</li> <li>Well tolerated with only grade 1-2 events reported as possibly related to Radspherin<sup>®</sup></li> </ul>
Clinically relevant dose determined	<ul> <li>7 MBq dose determined to be safe. Single-dosing!</li> </ul>
Biodistribution measured	<ul> <li>80% of radioactivity dose remains in the peritoneal cavity</li> <li>Absorbed doses to other organs way below those associated with any toxicity</li> </ul>
Good safety profile for hospital staff	<ul> <li>Low amount of activity in blood and urine</li> <li>No precautions related to external exposure required</li> </ul>

#### Frøysnes et al. J Surg Oncol. 2016 Aug;114(2):222-7 Quenet et al. Lancet Oncol. 2021 Feb;22(2):256-266 ASCO 2023 poster presentation, abstract number 3518 PSOGI 2023 poster presentation

### Clinical Phase 1/2a

- No peritoneal recurrences in recommended dose group in first cohort

- Expected median time to progression after CRS-HIPEC is around 12 months
  - Meaning that 50 % of patients are expected to have recurred at 12 months

**15-months** safety and efficacy presented at ASCO 2023, June

 At the 15-month time point of follow-up, only 25% of patients that received the recommended clinical dose of Radspherin<sup>®</sup> had experienced recurrences overall, and no peritoneal recurrences had occurred in the recommended dose group **18-months** safety and efficacy presented at PSOGI 2023, October

 At the 18-month time point of follow-up, only 33% of patients that received the recommended clinical dose of Radspherin<sup>®</sup> had experienced recurrences overall, and still no peritoneal recurrences had occurred in the recommended dose group



# **Radspherin® - Local & Overall DFS Plotting in CRC**



- 18 months *interim* efficacy analysis phase 1/2a (n=22)

• Disease-free survival at 18 months after the addition of 7 MBq Radspherin® to CRS-HIPEC was 67 % (n=12)



Kaplan-Meyer curve of **local disease-free survival** 7 MBq + 2 × 3.5 MBq group



Kaplan-Meyer curve of **overall disease-free survival** 7 MBq +  $2 \times 3.5$  MBq group, with dotted line corresponding to an **expected median of 30 months (vs. 12 months).** 

# **Radiopharmaceuticals Manufacturing Excellence**

- Reliable supply of the starting-material, radioisotope, Thorium-228. Inhouse production of Radium-224.
- Internal expertise in development, manufacturing and quality control of radiopharmaceuticals.
- In-house, state-of-the-art GMP production of Radspherin<sup>®</sup>.
- Manufacturing and release process lasts only 2-3 days.
- Ready-to-use product, shipping to USA and EU no cold chain needed.
- Plans for outsourcing and scale-up of production to CMOs in EU and the USA for phase 3 & commercialization.
- Phase 1/2a completed, on-time delivery of Radspherin<sup>®</sup> to 60+ patients across Europe!

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#### **Radspherin® Clinical Development Plan**





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### **Identified Partner Candidates**



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# Thank You

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# Appendix

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### Phase 2b Target Populations in Peritoneal Carcinomatosis

Peritoneal Carcinomatosis

Ovarian cancer	Colorectal cancer	
~4 000 pat/year	~20 000 pat/year	Populations in Ph 2b
HRD-negative subgroup with pre-operative chemotherapy Median PFS ~12 months	Adjuvant to CRS/HIPEC Median PFS ~12 months	



# **Total Target Populations**

#### Peritoneal Carcinomatosis

Ovarian cancer	Colorectal cancer	Gastric cancer	Other peritoneal and other body cavity lesions (Bladder, Pleura)	
~4 000 pat/year	~20 000 pat/year			Populations in Ph 2b
~ 4 000 - 8 000 pat/year	~20 000 pat/year			Populations in Ph 3 / MA
Same as Ph2b or possibly extended	Same as Ph2b as it is extended to Ph2b/3			
~28 000 pat/year	~90 000 pat/year	~25 000 pat/year	Significant potential	Potential Future Expansion
HRD independent Primary & Secondary	Prophylactic after surgery for high-risk primary tumors			

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### Radspherin<sup>®</sup> Radiopharmaceutical Pricing Benchmarks

Product	PFS Benefit	OS Benefit	Price
Xofigo	N/A	3.6 m	USD 69.000
Lutathera	8.5 m	N/A	USD 190.000
Pluvicto	N/A	4.0 m	USD 255.000

PFS = Progression Free Survival, OS = Overall Survival

 Radspherin<sup>®</sup> has a targeted PFS improvement of 12 months and a minimum acceptable profile of 6 months.

#### **Key Tenets of an Oncoinvent Business Case**

- Targeted Patient Population: 24.000 eligible patients per year (US & Europe)
  - CRC: 20.000 eligible patients (based on Phase 2b target only)
  - Ovarian Cancer: 4.000 eligible Patients (based on conservative, no extension, Phase 2b target only)
- Peak Penetration Estimate (assuming Standard of Care): 70% and rapid uptake
- Average Pricing Estimate given PFS Target: 50.000 USD per treatment

20% of US & Europe sales estimate added for RoW

Peak Sales Estimate (*Phase 3 target only*): 24.000 patients x 70% x 50.000 USD/pat x 120% ~ <u>1 Bill. USD</u>

**Implied future Enterprise Value:** 3-5 x Peak Sales Estimate ~ <u>3-5 Billion USD</u>

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Note that this calculation only takes into consideration volumes as per the specific inclusion criteria from the currently planned phase 2b trials. When put into clinical practice, we are convinced that commercial targets groups within PC will expand significantly.