Annual Report 2021
Oncoinvent

Content

Annual report for Oncoinvent AS • Published date: 23.03.2022
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Oncoinvent

NOK 550M.
NOK 550 million raised

40 FTE
Highly specialized company of 40 FTEs

0/34
34 patients dosed, no dose limiting toxicity

Oncoinvent was founded with the objective of becoming a global leader in the development of alpha-emitting radiotherapeutics that provide better treatment options to cancer patients. The Company seeks to achieve this through creating innovative new products that maximize medical benefit while minimizing potential safety concerns. Oncoinvent is currently advancing a pipeline of radiopharmaceutical products across a variety of solid cancers. The development leverages robust internal R&D and manufacturing capabilities to enable a clinical supply of radioisotopes. This also includes Radspherin®, a transformative lead product candidate for the treatment of cancer in multiple potential indications.

Radspherin® is a suspension of novel alpha-emitting radioactive microspheres designed for the treatment of metastatic cancers in body cavities. The radium-224–based therapeutic has shown strong and consistent anticancer activity at non-toxic doses in both non-clinical and clinical studies. Radspherin® can potentially treat multiple forms of metastatic cancer, including peritoneal carcinomatosis. During 2021 the Company finalized a phase 1 clinical trial in patients suffering from peritoneal carcinomatosis from colorectal cancer. Preliminary results have demonstrated that the product is safe and that it has a good distribution within the peritoneal cavity. The Company has received approval for amending the study into a phase 2a study to further strengthen the data for a pivotal study. Furthermore, the Company has an ongoing phase 1 clinical trial in patients suffering from peritoneal carcinomatosis from ovarian cancer. The trial is expected to be completed in early 2022 and the Company has received approval for an amendment into a phase 2a trial immediately after completion.

In addition to the lead candidate Radspherin®, the Company is also seeking to develop a targeted radiopharmaceutical candidate for treating solid tumors and currently has several programs in a discovery phase. It is expected that at least one of these programs will enter a preclinical phase during 2022.

The innovations under development by the Company are a result of the two founders, Dr. Roy H. Larsen and Professor of Clinical Oncology Øyvind S. Bruland extensive experience with development of radionuclide-based cancer treatments. Dr. Larsen and Professor Bruland are the inventors of Xofigo®, the first alpha-emitting pharmaceutical product approved by the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) (for the company Bayer AG), and of the beta-emitting radio-immunotherapeutic product candidate Betalutin® (for the company Nordic Nanovector ASA).

Vision and strategy

Vision ↓

Oncoinvent's vision is to become a global leader in the development of alpha-emitting radiopharmaceuticals and thereby provide better treatment options for cancer patients.

Key elements of the Company's strategy are to:

- Continue to clinically develop the versatile and potentially transformative lead product candidate, Radspherin®, across multiple cancer types
- Advance a pipeline of targeted and retained radiopharmaceutical products across a variety of solid cancers that leverages robust internal supply and manufacturing capabilities to enable a clinical supply of radioisotopes
- Leverage the Company's proprietary technology, knowledge, and assets to expand the Company's portfolio of product candidates to target unmet medical needs


camfil
camfil
camfil

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Highlights 2021

STUDY
RAD-18-002
Patient enrollment was completed in the RAD-18-002 study

NOK
250MILL.
250 millions raised for the next phase of clinical trials

Timeline Oncoinvent
January-november

11.01 21

Advancement of Radspherin® to Final Dose Level Cohort in Ongoing RAD–18–002 Phase 1 Trial in Colorectal Cancer Patients. Read more online +

08.03

Progression of Radspherin® to Third Dose Level Cohort in Ongoing RAD-18–001 Phase 1 Trial in Platinum Sensitive Recurrent Ovarian Cancer Patients with Peritoneal Carcinomatosis. Read more online +

09.04

Safety Monitoring Committee Approves 7 MBq as Recommended Clinical Dose for Radspherin® in the Ongoing RAD–18–002 Phase 1 Trial in Colorectal Cancer Patients. Read more online +

23.06

Following a year of outstanding performance, Oncoinvent aims to raise NOK 150–200 million to move into efficacy studies with Radspherin®. Read more online +

29.06

Oncoinvent Secures NOK 250 M in an oversubscribed Pre-IPO Funding Round. Read more online +

28.09

Oncoinvent Announces Advancement of Radspherin® to Fourth Dose Level Cohort in Ongoing RAD–18–001 Phase 1 Trial in Ovarian Cancer Patients. Read more online +

04.10

Oncoinvent Strengthens the Management Team Read more online +

21.10

Oncoinvent to present four posters at the 34th Annual Congress of the European Association of Nuclear Medicine. Read more online +

08.11

Oncoinvent announces completion of enrollment in the RAD–18–002 phase 1 clinical study. Read more online +

Oncoinvent completed several important milestones during the year. Patient enrollment was completed in the RAD-18-002 study treating patients suffering from peritoneal carcinomatosis from colorectal cancer, and the Company concluded that Radspherin® is safe after the trial demonstrated a good distribution of Radspherin without the occurrence of any serious adverse event. The Company is also recruiting patients for the last dose escalation, 7 Mbq, in the RAD-18-001 study treating patients suffering from peritoneal carcinomatosis from ovarian cancer. The completion of these milestones enabled the Company to raise additional funds of NOK 250 million for the next phase of clinical trials (phase 2a) and to focus on developing a pipeline of targeted radiopharmaceuticals.

Operational Review

Currently, the Company has been treating a total of 34 patients with Radspherin® in the two phase 1 studies

Oncoinvent's primary objectives are to obtain market approval for Radspherin® for the treatment of patients suffering from peritoneal carcinomatosis within the seven major markets (7MM) and to continue to develop a robust pipeline of radiopharmaceutical products across a variety of solid cancers.

The Company started the inclusion of patients in the two phase 1 clinical trials in 2020. A total of four centers (two for each trial) have been opened in Norway, Sweden, and Belgium since the beginning of the studies. Despite the challenges experienced from the Covid-19 pandemic at hospitals, the recruitment has progressed on track. Both studies consist of four escalating doses (1, 2, 4, and 7 Mbq) in a dose range finding cohort, followed by a repeated injection cohort and an expansion cohort wherein dosimetry measurements are also performed.

Currently, the Company has been treating a total of 34 patients with Radspherin® in the two phase 1 studies. For the RAD-18-002 study, treating patients suffering from peritoneal carcinomatosis from colorectal cancer, the inclusion of patients has been completed. A total of 23 patients have been included in the study. The clinically relevant dose has been identified to be 7 Mbq, and the preliminary results have proven the product to be safe with no serious adverse events and with a good biodistribution. Encouraged by the strong results in the phase 1 study, the Company has received approval for amending the study into a phase 2a study of approximately 30 more patients. The objective is to further strengthen the safety data and the efficacy signals toward an application for a pivotal study.

For the RAD-18-001 study, treating patients suffering from peritoneal carcinomatosis from ovarian cancer, a total of 11 patients have been included. The Company is currently recruiting the last patients for the last dose of the dose escalation cohort (7 Mbq). The preliminary results show a similar safety and biodistribution profile as for the RAD-18-002 study. Once the dose escalation cohort has been completed, the Company intends to amend the study to a phase 2a study. The study will include approximately 30 more patients to further strengthen the data generated. As recruitment has been slower for the RAD-18-001 study, the Company intends to open a further 2 to 3 centers.

The charts on the opposite page shows the number of patients who are currently included in the two studies, the number of patients who are *planned* to take part in phase 2a of these studies, as well as the number of active and *planned* centers.

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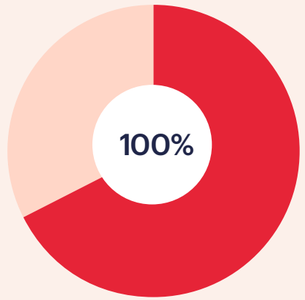
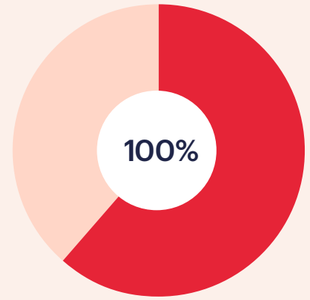
Statistics

Total number of patients



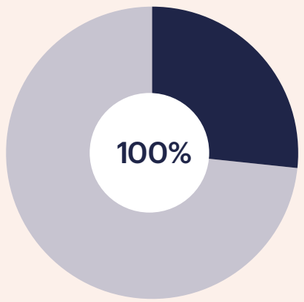
- 23 patients in RAD-18-002
- 11 patients in RAD-18-001

Current and planned centers



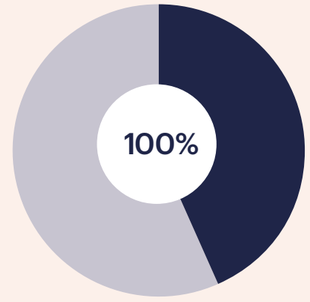
- 4 centers are currently opened
- 2-3 centers are planned to be opened

Patients in RAD-18-001



- 11 patients currently included
- 30 more patients are planned to be included in the phase 2a study

Patients in RAD-18-002



- 23 patients currently included
- 30 more patients are planned to be included in the phase 2a study

Technology

Oncoinvent has established a highly qualified and skilled organization focusing on the development of an alpha-emitting pipeline treating a variety of solid cancers. The Company's primary objectives going forward are to: (i) obtain market approval for Radspherin® for the treatment of patients suffering from peritoneal carcinomatosis within the 7MM, and (ii) continue to develop a robust pipeline of radiopharmaceutical products across a variety of solid cancers.

Radspherin®

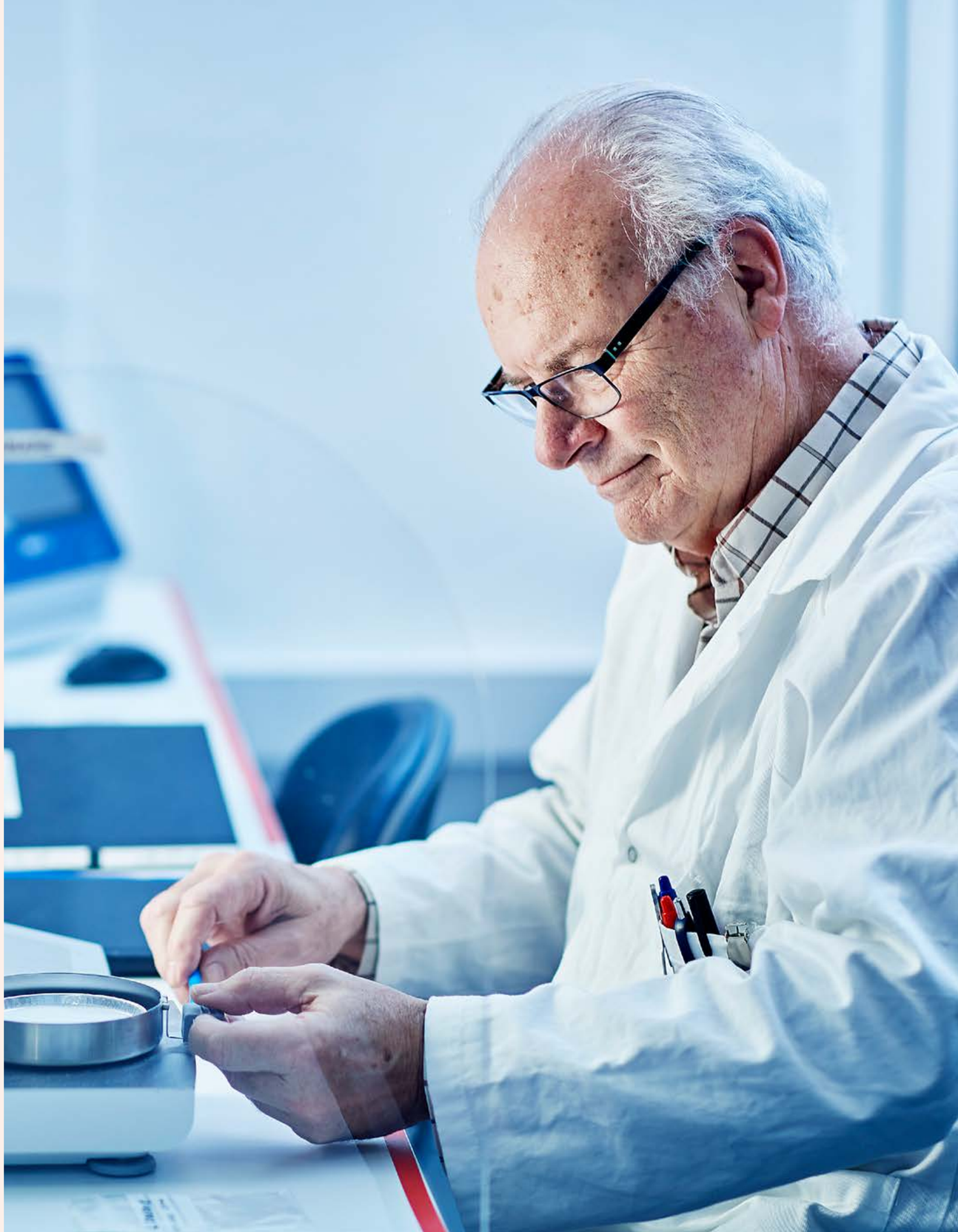
Radspherin® is a novel alpha-emitting radioactive microsphere designed for the treatment of metastatic cancers in body cavities. The product candidate is composed of radioactive spheres for injection and is a suspension of inorganic microspheres labelled with an alpha-emitting radioisotope for regional administration. The therapeutic goal is to treat cancer metastases of intracavitary surfaces and liquid volumes without subjecting deeper regions of organs and tissues to harmful radiation doses.

Radspherin®, a radium-224–based therapeutic, has shown strong and consistent anticancer activity at non-toxic doses in non-clinical studies. In animal models Radspherin® has been shown to cause a reduction in tumor cell growth and a significant increase in survival rates. It is anticipated that the product can potentially treat several forms of metastatic cancer. The first clinical indication for Radspherin® is the treatment of peritoneal carcinomatosis originating from ovarian cancer and from colorectal cancer. Peritoneal carcinomatosis is one of the most serious complications of gastrointestinal and gynecological malignancies. The Company believes that a successful development of Radspherin® will present a novel treatment modality for a group of patients with poor prognosis.

Discovery program

Beyond the lead product candidate, the Company is focusing on the development of a pipeline where the main delivery mechanism will be targeted agents with ligands that can carry radioisotopes to target tumor cells.

OI-3 and OI-1 antibodies are product candidates in an early stage of development. The Company intends to develop both assets as targeted alpha radiotherapeutic products. Potential first tumor targets for OI-3 are gliomas and pleural mesothelioma, while for OI-1 the potential first targets are osteosarcoma and ovarian cancer. OI-3 targets CD146, a cell adhesion molecule that is closely associated with an advanced stage of malignant melanoma, prostate cancer, or ovarian cancer. The Company considers OI-3 a potential candidate for targeted alpha radiotherapeutics for the treatment of gliomas and pleural mesothelioma. The product concept for OI-1 is similar, with potential treatment indications including osteosarcoma and ovarian cancer.



Production facilities

Oncoinvent made a strategic choice to construct a Class B GMP facility for the production of radiopharmaceuticals back in 2017. The Company received a GMP certificate from the Norwegian Medical Agency in January 2019. The pilot production facilities have been a strategic choice of vital importance which has provided the Company with a flexible production process over which it has full control. This includes the production of the radioisotopes. This has enabled the Company to speed up the clinical trials and has given it the ability to develop a core competence in the production of Radspherin®.

As part of the preparation for the next studies, the Company has initiated a process to automate and up-scale its existing production facility for Radspherin® in Oslo, Norway. Going forward, the Company plans to establish commercial production through a tech transfer to a contracted manufacturing facilities in Northern America and Europe.

Health, safety, and environment (HSE)

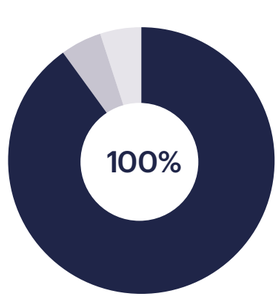
Due to the nature of the business Oncoinvent has implemented an extensive quality, safety, and environmental program. This was important when the company established the research facility in 2017 when a comprehensive ventilation and air purification system to remove emissions that are produced during the Radspherin production process was installed. Despite our efforts, in 2020 and 2021, Oncoinvent unfortunately experienced periods of limited, but measurable thoron emissions of varying, non-hazardous levels. The company notified the Norwegian Radiation and Nuclear Safety Authority (DSA) about the accidental emissions. Significant measures to solve the problem has been put in place. The thoron gas that has been emitted is a radon isotope (Radon-220) which has a half-life of only 56 seconds.

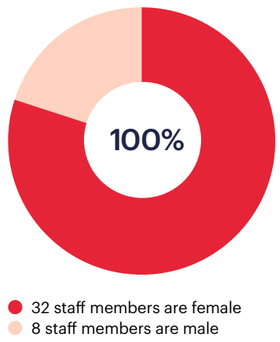
In light of the situation, DSA chose to carry out an on-site inspection of Oncoinvent in November 2021 and concluded that the company had not provided sufficient notification of the emissions and that not all remedial measures had been implemented as planned. To prevent any further unwanted emissions, all Radspherin production has been temporarily suspended. The company has currently completed all necessary actions and we are awaiting the processing of an application for emissions permit from the DSA.

As the health and safety area is of upmost importance, the company chose to strengthen the team focusing on HSE work early in 2021. The Company is working closely with the radiation authorities to ensure the proper handling of nuclides, as the innovation also includes the development of new production methods together with the product candidates.

The Company has a good safe working environment with a low level of reported sick leave.

At year's end there were a total of 36 full-time employees, 2 part-time employees and 2 Industrial Ph.D. candidates. The Company is an equal opportunity employer; 32 members of staff are women and 8 are men. The Company therefore believes it has taken sufficient active, targeted, and systematic efforts to promote equality.





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Market

Oncoinvent has an objective to develop and commercialize Radspherin® for the treatment of metastatic cancers in body cavities (...)

The technological development of advanced radiopharmaceuticals in the global market have provided major impetus for growth. Since the first therapeutic radiopharmaceutical, Xofigo®, was approved by the FDA in 2013, continued and persistent R&D efforts have led to innovations in new application areas that are contributing to the market growth for radiopharmaceuticals. Oncoinvent is initially focusing on peritoneal carcinomatosis, one of the most serious complications of gastrointestinal and gynecological malignancies. The disease typically develops quickly and has a deadly outcome. In 2017, there were just under 100,000 patients diagnosed with peritoneal carcinomatosis within the seven major markets, and it is expected that there will be an annual growth of approximately 3% (CAGR) until 2028.

The standard of care treatment of peritoneal carcinomatosis originating from ovarian cancer and colorectal cancer is cytoreductive surgery of macroscopic/visible tumors. This debulking procedure is combined with treatment with pre- and/or post-adjuvant systemic cytostatic drugs (e.g., paclitaxel, carboplatin, cisplatin, and mitomycin-C).

Approximately 75% of ovarian cancer patients respond to initial carboplatin chemotherapy, but the majority relapse within 2 years with resistance to subsequent chemotherapy. The survival rate of these patients is thus poor. Women diagnosed with stage III ovarian cancer have a five-year survival rate of approximately 35%, and for diagnosis at stage IV the five-year survival rate is approximately 15%.

Radspherin® is anticipated to be able to treat several forms of metastatic cancers, and the Company has performed a reformulation of Radspherin® to secure a better biodistribution and efficacy.

The global nuclear medicine market is estimated to reach USD 9.4 billion by 2024, growing at a mid-single digit compound annual growth rate (CAGR). The radiopharmaceuticals segment is expected to be the fastest growing segment at a high double digit CAGR from 2017 to 2024 due to technological advancements in the targeted treatment of cancers. Potential new radioisotopes in pipeline and advancements in neurological treatments are the key factors driving the growth of the therapeutics market.

Oncoinvent has an objective to develop and commercialize Radspherin® for the treatment of metastatic cancers in body cavities based on patient needs, medical practices, managed care organizations, group purchasers, hospitals, and special patient interest groups, both in terms of product design as well as information dissemination.

The Company will focus future marketing efforts towards prescribing oncologists and nuclear medicine and radiation oncology specialists that are community-, hospital-, and tertiary center-based.

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Management

Jan A. Alfheim
Chief Executive Officer

Jan A. Alfheim is a business executive with 35 years of experience bringing product ideas and technology to the chemical and pharmaceutical markets.

With experience in research, project management, business development & partnering, company start-ups, and product launches, Alfheim comes from Nordic Nanovector ASA where he was Chief Executive Officer from 2011 until 2014 and Chief Operating Officer from 2014 to 2016. Prior to working at Nordic Nanovector he held various senior roles, including Chief Business Officer at Clavis Pharma, President of StemPath Inc., Director of Business Development at Neurochem Inc., and Project Director at Nycomed Imaging. Mr. Alfheim holds an MSc in Chemistry from Concordia University and an MBA from McGill University.

Tina B. Bønsdorff
Chief Scientific Officer

Dr. Tina B. Bønsdorff has more than 15 years of research experience in molecular biology. She has a PhD and postdoctoral experience from the Norwegian School of Veterinary Science, where she worked in the field of gene identification, expression, and mutation analysis. Her postdoctoral research was focused on gene expression analysis of early neoplastic lesions in dogs with inherited cancer syndromes. Dr. Bønsdorff is one of the founders of Oncoinvent AS. Dr. Bønsdorff has been the Chief Scientific Officer of Oncoinvent AS from the beginning and was the CEO of the company from August 2013 to September 2016.

Tore Kvam
Chief Financial Officer

Tore Kvam has an extensive experience as CFO within technology-driven companies and lifelong experience within financial management and operations, as well as working with investors and owners developing companies. In the later years he has also gained significant experience and knowledge within the life science industry working with clinical phase companies in their efforts to advance their product candidates and attract life science investors. Mr. Kvam holds an MS in Computer Science from the George Washington University, an MBA from the Norwegian Business School BI, and is a Certified European Financial Analyst (CEFA).

Kari Myren
Chief Medical Officer

Dr. Kari Myren is a medical professional with a strong clinical background with specialty training in surgery. She has ten years of experience from leading positions in both the pharmaceutical and MedTech industries relating to oncology and early phase immuno-oncology, as well as clinical experience from oncologic surgery. Dr. Myren has previously held the positions of Medical Advisor and Senior Medical Advisor at Novartis and Roche Diagnostics respectively. Dr. Myren comes to Oncoinvent from Photocure ASA where she held the position of Vice President Global Medical Affairs and Clinical Development.

Kristine Lofthus
Chief Quality Officer

Kristine Lofthus has more than 15 years of experience with the manufacturing of pharmaceuticals. Her main field of expertise is the manufacturing of aseptic and terminally sterilized injectables, particularly radiopharmaceuticals. This experience includes production and production management, quality assurance, and the certification and release of batches as a Qualified Person. Mrs. Lofthus holds a cand.pharm. degree (MSc) from the University of Oslo, a Certificate of Advanced Studies (CAS) in Radiopharmaceutical Chemistry/Radiopharmacy from ETH Zurich, and is a licensed Qualified Person at Oncoinvent AS.

Anne-Kirsti Aksnes
VP of Clinical Operations

Dr. Anne-Kirsti Aksnes is a multi-disciplinary clinical research professional with more than 20 years of experience within clinical research and development in the pharmaceutical and biotech industry. Dr. Aksnes has a strong knowledge of all aspects of clinical development and operations and a broad and reputable experiences with clinical studies in all phases (I-IV). She is a physiologist by training with a Medical Doctorate Degree (PhD) from Karolinska Institute in Sweden. Dr. Aksnes has held multiple senior positions including VP Clinical Development at Targovax ASA and Director of Clinical Research at GE Healthcare. Dr. Aksnes also held the position of VP Clinical Development at Algeta ASA and was responsible for the clinical development of Xofigo®, a product that has gone on to become the world's most successful and best-selling radiopharmaceutical.

Management

Hans Hild

Head of Production

Dr. Hans M. Hild has more than 15 years of experience in GMP-compliant production of sterile and aseptically produced pharmaceuticals and radiopharmaceuticals. He has previously worked for the Institute for Energy Technology, GE Healthcare, Avecia Biotechnology (formerly Zeneca LSM Ltd.) and Degussa AG, and has a strong background in pharmaceutical process development, scale-up, and technology transfer. He has extensive experience in the production of biopharmaceuticals and contrast media for early clinical studies, as well as experience in the commercial production of radiopharmaceuticals. Dr. Hild holds a Dipl.-Ing. (FH) degree in Chemical Engineering from FH Frankfurt am Main, an MSc in Biochemical Engineering from the University of Birmingham, and a PhD in Biochemical Engineering from Imperial College London.

Gro Hjellum

Head of Quality Control

Gro Hjellum has more than 25 years of experience within R&D and operations in the pharmaceutical and biotech industry, ranging from analytical sciences, quality control, and bio-analysis through preclinical product development to regulatory approval of products. Prior to joining Oncoinvent Ms. Hjellum worked for Nycomed/GE Healthcare and Algeta/Bayer. She has a strong background in radiopharmaceutical product development and technology transfer to contract manufacturers in Norway as well as to the US and Japan. Ms. Hjellum holds an MSc in Radiochemistry from the University of Oslo.

Stian Brekke

Head of Regulatory Affairs

Mr. Stian Brekke has worked in regulatory affairs since 2005, as a regulatory affairs manager, regulatory project leader, and QPPV during 11 years in Pharmaq AS, and since April 2019 as a regulatory affairs director at SMERUD, based in Oslo, Norway. Mr. Brekke has led multiple regulatory submissions to various competent authorities, including marketing authorization applications, orphan drug designation applications, variation applications, clinical trial applications, etc. He has ensured regulatory compliance in close collaboration with clinical R&D units, specialized laboratories, consultants, and regulatory authorities as the regulatory representative in drug development projects.

Financial Review

Accounting policies
The financial statements of Oncoinvent AS have been prepared in accordance with the provisions of the Norwegian Accounting Act and generally accepted accounting principles for small businesses. (Figures in parentheses refer to the corresponding period or balance date in 2020, unless otherwise specified).

Income statement
Operating revenues
Oncoinvent recorded operating revenues of NOK 11.258 million in 2021 (NOK 10.377 million). Government support for its research and development activities from the Research Council of Norway as well as Innovation Norway was recognized as income.

Operating expenses
Net operating expenses for the year amounted to NOK 91.359 million (NOK 70.628 million). The cost increase was driven by the expansion program with recruitment of new staff members, ongoing clinical trials, and production of Radspherin® for the trials. The operating loss for Oncoinvent amounted to NOK −80.101 million (NOK −60.251 million).

Net financial items
Net financial income amounted to NOK 0.553 million (NOK 1.199 million). Interest income from ordinary bank deposits came to NOK 0.753 million (NOK 0.877 million).

Net result
Losses after tax for the year were NOK −79.548 million (NOK −59.219 million). The loss is proposed allocated from the share premium.

Loss per share amounted to NOK −4.10 in 2021 (NOK −4.14).

Financial position
Assets
Property, plant, and equipment at year's end amounted to NOK 10.335 million (NOK 13.032 million). During 2021 NOK 2.090 million was activated.

Cash and cash equivalents were NOK 292.031 million (NOK 113.297 million). The change reflects increased operational activity level. Total assets by year's end 2021 increased to NOK 311.078 million (NOK 138.993 million).

Equity and liabilities
Total equity as of December 31, 2021, was NOK 379.469 million (NOK 126.041 million). Deferred tax assets were not recognized in the statement of financial position as Oncoinvent is in a development phase and is currently generating losses.

Total liabilities were NOK 11.156 million (NOK 12.952 million), the increase driven primarily by higher accounts payable and provisions.

Research and development
While the research and development strategy is designed in-house in Oncoinvent, the Company leverages its network of external consultants and contract research organizations (CROs) to execute its development strategy. Oncoinvent also collaborates with academic institutions to expand the research in areas of interest of the Company.

The Company has employed experienced personnel that can direct work that is performed by the consultants and CROs. This approach to product development allows the Company to quickly change research directions and efforts when needed and to quickly bring in new technologies and expertise when necessary.

Uncertainties related to the regulatory approval process and results from future clinical trials generally indicate that the criteria for capitalization of R&D cost are not met until market authorization is obtained

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Statistics

Operating loss
-19.580 mill.

2021: NOK −80.101 million
2020: NOK −60.251 million

Total assets
+172.085 mill.

2021: NOK 311.078 million
2020: NOK 138.993 million

Total equity
+253.428 mill.

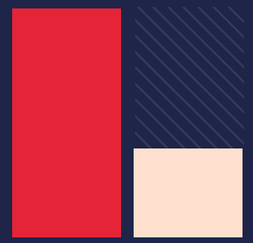
2021: NOK 379.469 million
2020: NOK 126.041 million

Total liabilities
-1.746 mill.

2021: NOK 11.156 million
2020: NOK 12.952 million

Cash and cash equivalents

+ 178.734 mill.

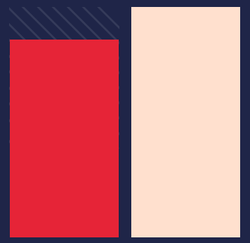


2021: NOK 292.031 million
2020: NOK 113.297 million

Interest income

As of December 31, 2021

- 0,124 mill.



2021: NOK 0,753 million
2020: NOK 0,877 million

from relevant regulatory authorities. The Company has currently no development expenditure that qualifies for recognition as an asset.

Expenses for research and development for the financial year 2021 were NOK 40.361 million (NOK 42.254 million), whereas NOK 25.288 million (NOK 23.237 million) were classified as other operating expenses and NOK 15.073 million (NOK 16.658 million) were classified as payroll.

Financial risks

Interest rate risk

The Company holds NOK 292.031 million (NOK 113.297 million) in cash and cash equivalents and does not have any borrowings. The Company's interest rate risk is therefore in the rate of return of its cash on hand. Bank deposits are exposed to market fluctuations in interest rates, which affect the financial income and the return on cash. The Company had NOK 0.753 million (NOK 0.877 million) in interest income as of December 31, 2021.

Exchange rate risk

The value of non-Norwegian currency denominated revenues and costs will be affected by changes in currency exchange rates or exchange control regulations. The Company undertakes various transactions in foreign currencies and is consequently exposed to fluctuations in exchange rates. The exposure arises largely from the R&D expenses and IP expenses. The Company is mainly exposed to fluctuations in Danish kroner (DKK), Euro (EUR), American dollars (USD), British Pounds (GBP), and Canadian dollars (CAD).

The Company has chosen not to hedge its operational performance as the Company's cash flow is denominated in several currencies and the foreign currency exposure is mostly linked to trade payables with short payment terms. The Company might consider changing its current risk management of foreign exchange rates if it deems it necessary.

Credit risk

Credit risk is the risk of counterparty default in a financial asset, liability, or customer contract, resulting in a financial loss. The Company's receivables are generally limited to receivables from public authorities by way of government grants. The credit risk generated from financial assets in the Company is limited since it consists of cash deposits. The Company only places its cash in bank deposits in recognized financial institutions to limit its credit risk exposure.

The Company has not suffered any loss on receivables during 2021 and the Company considers its credit risk as being low.

Liquidity risk

Liquidity is monitored on a continual basis by Company management. The Company works continuously to ensure financial flexibility in the short and long term to achieve its strategic and operational objectives. Management considers the Company's liquidity situation to be satisfactory. The cash position of the Company at year's end 2021 was NOK 292.031 million (NOK 113.297 million).

Capital markets are used as a source of equity financing when this is appropriate and when conditions in these markets are acceptable. The Board is considering conducting a capital increase within the next 12 months, if market conditions are acceptable. The Board of Directors has reasonable expectation that the Company will maintain adequate funding to maintain operational activity for the foreseeable future.

Non-financial risks

The Company's lead product candidate Radspherin® has currently completed recruitment for one phase 1 trial, while another is still ongoing. This is regarded as an early stage of development and the Company's planned clinical studies may not prove to be successful.

Competitive technology

The Company operates in a highly competitive industry sector with many large players and is subject to rapid and substantial technological change.

Market risks

The financial success of the Company requires obtaining marketing authorization and achieving an acceptable reimbursement price for its products. There can be no guarantee that the Company's products will obtain the selling prices or reimbursement rates foreseen by the Company.

The Company will need approvals from the US Food and Drug Administration (FDA) to market its products in the US, and from the relevant authorities to market its products in Europe, as well as equivalent regulatory authorities in other worldwide jurisdictions to commercialize in those regions. The Company's future earnings are likely to be largely dependent on the timely marketing authorization of Radspherin® for various indications.

Going concern

The Board stated that the annual accounts represent a true and fair view on the Company's financial position at the turn of the year. According to the Norwegian Accounting Act §3-3 (a), the Board of Directors confirmed that the financial statements have been prepared under the assumption of going concern.

Share information

As of December 31, 2021, there were 19 387 895 shares outstanding. The Company had 430 shareholders.

Financial Statement

Income statement

	Note	2021	2020
Operating revenues			
Sales Revenue		360 684	195 500
Other operating revenues	7	10 722 334	10 181 666
Total operating revenues		**11 083 018**	**10 377 166**
Operating expenses			
Payroll and related costs	6	38 310 319	31 401 987
Depreciation	8	4 786 145	4 830 452
Other operating expenses	10	48 812 281	34 395 890
Total operating expenses		**91 925 006**	**70 628 329**
OPERATING INCOME		**–80 841 989**	**–60 251 163**
Financial items			
Other interest income		752 792	876 902
Other financial income		115 575	321 973
Total financial income		**868 366**	**1 198 875**
Other interest expenses		5 441	844
Other financial expenses		309 491	166 635
Total financial expences		**314 932**	**167 479**
Net financial items		**553 434**	**1 031 396**
Income before tax		–80 288 555	–59 219 767
NET INCOME		**–80 288 555**	**–59 219 767**
Distribution of profit and funds			
Uncovered loss		–80 288 555	59 219 767
Total distribution of profit and funds		**–80 288 555**	**59 219 767**

Balance sheet

	Note	31.12.2021	31.12.2020
ASSETS			
FIXED ASSETS			
Tangible fixed assets			
Land, Buildings and other property		6 003 132	7 203 755
Running equipment, tools etc.		4 332 218	5 827 894
Total tangible fixed assets	8	**10 335 350**	**13 031 649**
Total fixed assets		**10 335 350**	**13 031 649**
CURRENT ASSETS			
Receivables			
Other short-term receivables	5	15 129 164	12 644 279
Total receivables		**15 129 164**	**12 664 279**
Cash and cash equivalents	6	292 030 892	113 297 444
Total current assets		**307 160 056**	**125 961 723**
TOTAL ASSETS		**317 495 406**	**138 993 372**
LIABILITIES AND EQUITY			
EQUITY			
Paid-in capital			
Share capital	3,4	1 938 790	1 431 464
Share premium reserve	4	537 400 680	284 479 661
Total paid-in capital		**539 339 470**	**285 911 125**
Retained earnings			
Uncovered loss		240 158 647	159 870 088
Total retained earnings		**- 240 158 647**	**- 159 870 088**
TOTAL EQUITY	4	**299 180 823**	**126 041 037**
LIABILITY			

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	Note	31.12.2021	31.12.2020
Current liabilities			
Accounts payables		7 036 771	4 873 823
VAT, social security costs, etc.		3 054 864	1 698 401
Other current liabilities		8 222 947	6 380 111
Total short-term liability		**18 314 582**	**12 952 355**
Total liabilities		**18 314 582**	**12 952 335**
TOTAL EQUITY AND LIABILITIES		**317 495 406**	**138 993 372**

Oslo, March 21st, 2022

Roy Hartvig Larsen
Chairman of the Board

Thora J. Jonasdottir
Board member

Ludvik Sandnes
Board member

Adrian Senderowicz
Board member

Leiv Askvig
Board member

Ingrid Teigland Akay
Board member

Jan Alan Alfheim
CEO

Notes

Note 1 – Accounting principles

The financial statements have been prepared in accordance with the Norwegian Accounting Act of 1998, and are based on Norwegian accounting principles. The financial statements have been prepared on the basis of applicable rules for preparation of financial statements for small enterprises.

Operations
The company's business is to develop pharmaceutical drugs. So far, the company has not had any income from commercial sales, and its business is therefore primarily financed though equity capital and public grants. In addition to wages and administration costs, the company's expenses are mainly derived from research and development costs, including expenses for the implementation of clinical studies and ongoing securing of patent protection. Said costs are expensed on an ongoing basis.

Operating revenues
Operating revenues are recognized as income as they are earned. The same applies to public grants, which are recognized as other operating revenues.

Research and development costs
Research and development costs are in their entirety expensed. Said costs are not recognized in the balance sheets.

Current assets/current liabilities
Current assets and current liabilities normally include items due for payment within one year after the balance sheet date, as well as items related to goods in production and inventory. Current assets are valued at the lower of acquisition cost and estimated fair value. Current liabilities are recognized at the nominal amount as at the date of establishment.

Fixed assets
Fixed assets are valued at their acquisition cost, but are depreciated to their fair value when the impairment is expected to not be temporary. Fixed assets with a limited economic lifespan are depreciated according to a reasonable depreciation plan.

Receivables
Trade accounts receivables and other receivables are listed at par value less expected loss. Allocation of loss is made on the basis of an individual assessment of each receivable.

Taxes
Taxes are expensed as they accrue, which means that tax expenses are connected to profit before tax.

Tax expenses comprise tax payables (tax on taxable income of that year) and changes in net deferred tax liability. The company has decided not to recognize deferred tax benefits.

Pensions
The company uses a defined contribution-based plan for its employees in accordance with the law's requirements for pension schemes. The annual pension cost corresponds to the annual premium.

Currency
Items in foreign currencies are valued at the prevailing exchange rate at the end of the financial year.

Note 2 – Tax

2.1 Specification of temporary differences	2021	2020	Change
Loss carry forward	276 636 973	183 132 278	93 504 695
Total amount difference	**276 636 973**	**183 132 278**	**93 504 695**
Deferred tax benefits 22%	60 860 134	40 289 101	**20 571 033**

Deferred tax benefits of tax loss carry forward are not included in the balance sheet as of 31 December 2021.

2.2 Specification of the basis for tax payable	2021	2020
Result for the period	–80 288 555	–59 219 767
Permanent differences	–14 800 010	–5 436 095
Changes in temporary differences	1 583 870	1 651 409
Basis of calculation for tax payables	**–93 504 695**	**–63 004 453**
Tax payable	0	0
Deduction for R&D expenses	4 750 000	4 750 000

Note 3 – Share capital and shareholder information

Shareholders per 31. Dec. 2021	No. of shares	%
SCIENCONS AS	3 217 223	16,6 %
GEVERAN TRADING CO LTD	1 771 076	9,1 %
HADEAN CAPITAL I AS	919 772	4,7 %
MUST INVEST AS	786 230	4,1 %
CANICA AS	762 530	3,9 %
RADFORSK INVESTERINGSSTIFTELSE	690 110	3,6 %
ROY HARTVIG LARSEN	678 000	3,5 %
BLAAHAUGEN AS	632 500	3,3 %
HELENE SUNDT AS	546 145	2,8 %
BENTAX AS	450 000	2,3 %
HVENTURES CAPITAL I AB	417 151	2,2 %
SYNTAX AS	400 000	2,1 %
TROND LARSEN	310 000	1,6 %
TINA BJØRNLUND BØNSDORFF	277 600	1,4 %
CGS HOLDING AS	276 915	1,4 %
THORA JOHANNA JONASDOTTIR	261 250	1,3 %
ALPINE CAPITAL AS	233 400	1,2 %
LUCELLUM AS	215 000	1,1 %
INVEN2 AS	210 261	1,1 %
WATRIUM AS	206 923	1,1 %
MP PENSJON PK	186 706	1,0 %
OTHER SHAREHOLDERS < 1%	5 939 103	30,6 %
TOTAL	19 387 895	100,0 %

Nominal value per share: NOK 0.10. Total number of shareholders: 430.
A capital increase was carried out in 2021 increasing the number of shares with 5 073 256 shares.

Note 4 – Equity

	Share capital	Share premium	Uncovered loss	Total equity
Share capital as of 01.01.2021	**1 431 464**	**284 479 661**	**–159 870 088**	**126 041 037**
Share issuance	507 326	252 921 019		253 428 345
Results of the period			–80 288 555	–80 288 555
Share capital as of 31.12.2021	**1 938 790**	**537 400 680**	**–240 158 643**	**299 180 827**

Note 5 – Other receivables

VAT refund	6 635 842
Prepaid expenses	1 933 210
The Research Council of Norway	1 810 112
Skattefunn[1]	4 750 000
Total	**15 129 164**

[1] The SkatteFUNN R&D tax incentive scheme is a governmental program designed to stimulate research and development (R&D) in Norwegian trade and industry. Approved projects may receive a tax deduction of up to 20 per cent of the eligible costs related to R&D activity.

Note 6 – Employees, remuneration, loans to employees, etc.

6.1 Specification of labor costs	2021	2020
Salaries (incl. vacation pay)	31 532 963	26 622 303
Social scurity tax	4 711 300	3 455 027
Pension costs (occupational pension scheme)	2 066 056	1 049 008
Other pension costs	0	275 649
Total personnel expenses	**38 310 319**	**31 401 987**
Total full-time equivalent	40.3	26.8

6.2 Specification of remuneration of the management and the board of directors	2021	2020
CEO		
Salary	1 965 771	1 693 775
Bonus	254 182	166 132
Other remuneration	96 045	65 800
Total amount CEO	**2 315 998**	**1 925 707**

Oncoinvent established an option scheme in 2017 as an important part of the employee's possibility to participate in the value creation of the company. At the end of 2021 a total of 620 100 stock options has been allocated including 191 000 stock options for the CEO. The stock options are vested with ¼ of the stock options after 12 months from grant date, and the next ¾ over the following 36 months. The stock options are booked in the financial statement at date of exercise. The stock options have a strike price between NOK 10-52 per share depending on the time of allocation.

6.3 Specification of remuneration to the board of directors	
Paid board remuneration	350 000
Incurred board remuneration – RSU registration	614 950
Total amount, board remuneration	**964 950**

The Company has established a program pursuant to which board members may resolve to receive the whole or parts of its remuneration in the form of restricted stock units (RSUs). Each RSU gives a right and obligation to acquire one share at nominal value (NOK 0.10) from the Company. The number of RSUs received by each board member is equal to the amount such member resolves to receive in the form of RSUs, divided by the market price of the shares at the time of the general meeting resolving the remuneration. The expense for RSU's is booked according to the vesting period. Any changes in values of the RSU's from time of completion of vesting to the exercise of the RSU's are booked at time of exercise.

6.4 Specification of remuneration to the auditor	2021	2020
Expensed remuneration to the auditor	61 477	47 100
Other certification services	52 789	24 400
Total remuneration paid to the auditor	**114 266**	**71 500**

6.5 Restricted funds	2021	2020
Restricted funds – Tax deduction	1 665 027	1 179 619
Tax payable, 6th term	1 665 027	1 102 703

Note 7 – Other operating revenues – public grants

Other operating revenues consist of public grants received. In relation to the company's activity, the size of the received grants is considered to be of significant importance that revenue recognition provides better information than a cost reduction against the R&D.

	2021	2020
Skattefunn	4 750 000	4 750 000
The Research Council of Norway	2 752 334	4 051 666
Innovation Norway	3 220 000	1 380 000
Total amount	**10 722 334**	**10 181 666**
Receivables:		
Skattefunn	4 750 000	4 750 000

Note 8 – Fixed assets

	Inventory	LAB Equipment	Fixed building inventory	Office machinery	Total amount
Balance 01.01.2021	1 361 796	13 273 279	12 006 253	1 641 841	28 283 169
Acquisitions		1 855 282		234 563	2 089 845
Disposals					
Acquisition cost	**1 361 795**	**15 128 562**	**12 006 253**	**1 876 404**	**30 373 014**
Acc. Depreciation	–1 204 201	–11 296 834	–6 003 121	–1 533 508	-20 037 664
Sum	**157 595**	**3 831 728**	**6 003 132**	**342 896**	**10 335 350**
Depreciation for the year	311 309	3 066 297	1 200 624	207 915	4 786 145
Useful life	5 years	5 years	10 years	3 years	
Depreciation rate	20%	20%	10%	30%	

Note 9 – Currency exchange gains and losses

The company's recognized gains and losses on currency exchange rate relate mainly to the purchase of R&D services from abroad.

Note 10 – Other operating expenses

	2021	2020
Lease payment (office)	3 844 616	3 385 946
Rental costs (office machinery and equipment)	28 436	12 798
Lab costs, studies, patents, equipment	25 184 425	16 742 226
Repair of equipment	895 962	464 363
Foreign services – remuneration	13 910 691	11 520 998
Office expenses	2 937 325	914 778
Travel reimbursement costs	231 672	306 517
Advertisement costs	92 020	108 814
Representation	-	8 827
Memberships fees, insurance and other costs	1 687 134	930 623
Total Other operating expenses	**48 812 281**	**34 395 890**

Auditor´s report

Statsautoriserte revisorer
Ernst & Young AS

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Medlemmer av Den norske Revisorforening

INDEPENDENT AUDITOR'S REPORT

To the Annual Shareholders' Meeting of Oncoinvent AS

Opinion

We have audited the financial statements of Oncoinvent AS (the Company), which comprise the balance sheet as at 31 December 2021, the income statement for the year then ended, and notes to the financial statements, including a summary of significant accounting policies.

In our opinion the financial statements comply with applicable legal requirements and give a true and fair view of the financial position of the Company as at 31 December 2021 and its financial performance for the year then ended in accordance with the Norwegian Accounting Act and accounting standards and practices generally accepted in Norway.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (ISAs). Our responsibilities under those standards are further described in the *Auditor's responsibilities for the audit of the financial statements* section of our report. We are independent of the Company in accordance with the requirements of the relevant laws and regulations in Norway and the International Ethics Standards Board for Accountants' *International Code of Ethics for Professional Accountants (including International Independence Standards)* (IESBA Code), and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Other matters

The financial statements for the year ended 31 December 2020, were audited by another auditor who expressed an unmodified opinion on those statements on 7. april 2021.

Responsibilities of management for the financial statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with the Norwegian Accounting Act and accounting standards and practices generally accepted in Norway, and for such internal control as management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless management either intends to liquidate the Company or to cease operations, or has no realistic alternative but to do so.

Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs will always detect a material misstatement when it exists.

Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Company to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

We communicate with the board of directors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

Oslo, 8. april 2022
ERNST & YOUNG AS

Tommy Romskaug
State Authorised Public Accountant (Norway)

(This translation from Norwegian has been prepared for information purposes only.)

Glossary

GMP
Good manufacturing practices (GMP) are the practices required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture.

Intraperitoneal
Intraperitoneal injection or IP injection is the injection of a substance into the peritoneum (body cavity). The method is widely used to administer chemotherapy drugs to treat some cancers, particularly ovarian cancer.

Metastasis
Metastasis is the medical term for cancer that spreads to a different part of the body from where it started.

Microparticle
Microparticles are particles between 0.1 and 100 micrometers in size. Commercially available microparticles are manufactured in a wide variety of materials, including ceramics, glass, polymers, and metals. Microparticles have been found to have widespread applications in medicine, biochemistry, colloid chemistry, and aerosol research.

Peritoneal carcinomatosis
Peritoneal carcinomatosis is a type of cancer that occurs in the peritoneum, the thin layer of tissue that covers abdominal organs and surrounds the abdominal cavity. The disease develops when cancers of the appendix, colon, ovaries, or other organs spread to the peritoneum and cause tumors to grow.

Peritoneal cavity
The space within the abdomen that contains the intestines, the stomach, and the liver. It is bound by thin membranes.

Radspherin®
Oncoinvent's lead product candidate currently being developed to treat peritoneal carcinomatosis.

Radioisotope
A radioisotope (radioactive nuclide, radionuclide, or radioactive isotope) is an atom that has excess nuclear energy, making it unstable. This excess energy can be either emitted from the nucleus as gamma radiation or create and emit from the nucleus a new particle (alpha particle or beta particle), or transfer this excess energy to one of its electrons, causing that electron to be ejected as a conversion electron. During those processes, the radionuclide is said to undergo radioactive decay.

Radiopharmaceutical
The treatment of disease, especially cancer, by means of alpha or beta particles emitted from an implanted or ingested radioisotope, or by means of a beam of high-energy radiation.