



# Annual report 2019





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Annual report for Oncoinvent AS  
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# Annual report for 2019

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Oncoinvent has made important progress in the development of Radspherin® during 2019. The company reformulated Radspherin®, and throughout 2019 the new product formulation has been tested with positive results that indicate the product is effective in treating metastatic disease from ovarian and colorectal cancer in multiple animal models. The new formulation has also proven to be significantly better and more stable than the previous formulations.

The company has decided to increase the number of study sites to be involved in the upcoming clinical phase I studies in 2020 in order to ensure a steady enrollment of patients in the two phase I clinical trials. In the fourth quarter of 2019 the company submitted applications related to the clinical phase I studies in Norway, Sweden, Germany and Belgium. In addition, the company has continued to build a strong organization through the year and is well positioned for the upcoming clinical studies.

## Highlights from 2019

- Oncoinvent receives manufacturing authorization for clinical trial material**  
In the beginning of 2019 Oncoinvent received a manufacturing authorization (GMP certificate) for production of Radspherin® clinical trial material from the Norwegian Medicine Agency.

This important milestone provides Oncoinvent with the necessary capacity and flexibility over the production of clinical trial material of Radspherin® for the upcoming clinical studies.
- Oncoinvent signs distribution agreement with radiopharmaceutical wholesaler**  
Oncoinvent signed an agreement with the Institute of Energy Technology (IFE) in February of 2019 for the distribution of Radspherin (investigational medicinal product) to sites and institutions as part of the company's clinical trial program.  
The agreement enables Oncoinvent to provide sites and patients, participating in the upcoming clinical trial program, access to Radspherin in a timely and predictable manner regardless of geographical location.
- Oncoinvent awarded 4,6 MNOK in Innovation Funding**  
Oslo University Hospital and Oncoinvent were each awarded Innovation Funding to develop Radspherin® as a treatment for colorectal cancer patients suffering from peritoneal carcinomatosis. The two awards make for a combined total of NOK 7,9 million where Oncoinvent will receive 4,6 MNOK and Oslo University Hospital 3,3 MNOK. The Innovation funding will allow Oncoinvent to expand Radspherin®'s potential indications for use and to reach many more patients suffering from peritoneal carcinomatosis more quickly than would have otherwise been possible. The company now plans to initiate two phase I trials in parallel, one in ovarian cancer patients, and a second in colorectal cancer patients.
- Radspherin® patent Issued in Japan**  
The company received notice in July of 2019 that the final procedural processes have been completed and the patent covering lead product candidate Radspherin® has formally been issued in Japan. This patent protection of Radspherin® will remain in effect until July 2036. The company now has patent protection for Radspherin® in the all major pharmaceutical markets including Japan, USA, and Europe.

- **Oncoinvent's 1st Industrial PhD graduate**

Sara Westrøm defended her PhD thesis "Evaluation of Carrier Compounds for Systemic and Intracavitary -Radionuclide Therapy of Cancer" on the 5th of September at the Radium Hospital. Sara's research has resulted in four publications and she is also co-inventor on Oncoinvent's Radspherin® patent. The company congratulates Dr. Westrøm on this major accomplishment and welcomes her to the R&D team.

Based on the success Oncoinvent has experienced with Sara and the two industrial PhD programs

that are still ongoing, the company has decided to engage a new industrial PhD student that will work in Belgium together with the researchers at the University Hospital of Leuven (UZ Leuven) and KU Leuven. The focus of the industrial Ph.D. project will be the preclinical evaluation of the effects of Radspherin® in an immune competent ovarian cancer mouse model. The project is designed to extensively characterize Radspherin® effects and look for optimal combinations with other therapies (such as standard chemotherapy and immunotherapy). Furthermore, the project will include participation in the first evaluation of Radspherin® in ovarian cancer patients.





## Overview of the Business

The company's founders Roy H. Larsen, Øyvind S. Bruland, Tina B. Bønsdorff, and Thóra Johanna Jónasdóttir started Oncoinvent in 2010 with a view to design better cancer treatments by applying known physical and chemical principles of selected novel materials in new ways to maximize their medical benefit while minimizing potential safety concerns. This approach has allowed Oncoinvent to explore and develop multiple technological avenues before selecting the company's first lead product candidate.

Oncoinvent has built a Class B GMP production and lab facility for radiopharmaceuticals. The facility received a GMP certificate from the Norwegian Medical Agency in February of 2019. The approval provides the company with the necessary flexibility and capacity for manufacturing clinical trial materials for both planned phase I clinical trials.

## Radspherin®

The company's lead product candidate Radspherin® is a suspension of novel alpha-emitting radioactive microspheres, designed for treatment of metastatic cancers in body cavities. The radium-224 based therapeutic, Radspherin® has shown strong and consistent anticancer activity at doses being essentially non-toxic in preclinical studies. It is anticipated that the product can potentially treat several forms of metastatic cancer including peritoneal carcinomatosis.

### Market

Peritoneal carcinomatosis is one of the most serious complications of gastrointestinal and gynecological malignancies. The classical development of the disease is a fast development, that rarely last for long periods of time, with a deadly outcome.

In 2017 there were just under 100 000 incidences diagnosed with peritoneal carcinomatosis<sup>1</sup> within the 7 major markets (7 MM), and it is expected that there will be an annual growth of ca. 3% (CAGR) until 2028 in the disease.

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).

75% of ovarian cancer patients respond to initial carboplatin chemotherapy, but the majority relapse within 2 years, and then with resistance to subsequent chemotherapy. Hence, the survival rate of these patients is 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 through 2019 performed a reformulation of Radspherin® to secure a better biodistribution and efficacy. Furthermore, Oncoinvent expect to start the clinical development early 2020 through a cooperation with several European clinical research centers.

The global nuclear medicine market is estimated to reach USD 9.4 billion by 2024 growing at a mid-single

<sup>1</sup> Source: Delveinsight, Peritoneal Carcinomatosis, Market insights, Epidemiology and market forecast-2028. November 2019

digit compound annual growth rate (CAGR)<sup>2</sup>. The radiopharmaceuticals segment is expected to be the fastest growing segment at high double digit CAGR from 2017 to 2024 due to technological advancements in 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 market Radspherin® for treatment of metastatic cancers in body cavities based on patients needs, medical practices, managed care organizations, group purchasers, hospitals, medical practices, 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, nuclear medicine and radiation oncology specialists that are community-, hospital- and tertiary center-based.

## Vision and strategy

Oncoinvent is committed to develop new innovative products that provide better treatment options for cancer patients. The company aspires to become a leader in the development of radiotherapeutics for treatment of metastatic cancers.

The company's strategic plan is to:

- Vest most financial and human resources on the rapid development of Radspherin® and focus on accomplishing major milestones
- Pursue an opportunistic approach to research funding
- Leverage the company's proprietary technology, knowledge, and assets to expand the company's portfolio of product candidates to target unmet medical needs

## Operational Review

Oncoinvent's primary objective is to obtain a market approval for Radspherin for the treatment of patient suffering from peritoneal carcinomatosis within the seven major markets.

As a result of the company receiving some unanticipated preclinical results prior to initiating the clinical phase I studies, the company went through a reformulation of Radspherin® in 2019. This resulted in a delay of the planned phase I clinical studies. Consequently, the company has decided to open more clinical sites to participate in the studies to ensure an expedient enrollment of patients in the phase I clinical trials.

By the end of 2019 the company had filed clinical trial applications in Norway, Sweden and Germany as well as to the Federal Agency of Nuclear control in Belgium. It is anticipated that approval will be granted in Q1 of 2020, and that Oncoinvent will be initiating the clinical studies as soon as possible.

As part of the preparation for the coming studies it will be necessary to increase the production capacity of Radspherin®. The increased production capacity is planned through an automation and scale-up of existing facility, but also through establishing a second production facility. It is expected that the company will strengthen the capital in order to implement these plans.

<sup>2</sup> Source: <https://www.businesswire.com/news/home/20180724005773/en/Global-Nuclear-MedicineRadiopharmaceutical-Market-2024---9.36>

## Management



**Jan A. Alfheim**  
*Chief Executive Officer*

Jan A. Alfheim is a business executive with over thirty years' experience bringing product ideas and technology to the chemical and pharmaceutical markets, from product discovery and development phases to final marketing campaign and launch. Alfheim comes to Oncoinvent 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 has 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 a MSc in Chemistry from Concordia University and a MBA from McGill University.



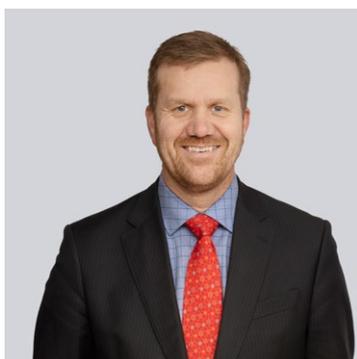
**Tina B. Bønsdorff**  
*Chief Scientific Officer*

Dr. Tina B. Bønsdorff has more than 15 years of research experience in molecular biology. She has a Ph.D. 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 dog 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 start-up and was the CEO of the company from August 2013 to September 2016.



**Øyvind Sverre Bruland**  
*Chief Medical Officer*

Dr. Øyvind S. Bruland is a MD, Ph.D. and professor of Clinical Oncology with the Faculty of Medicine, University of Oslo and senior consultant oncologist at the Dept. of Oncology, Oslo University Hospital and has supervised a large number of Ph.D. students in this capacity. He founded Algeta ASA in 1997 together with Dr. Roy H. Larsen, and he was one of the founders of Nordic Nanovector ASA (2009) and of Oncoinvent AS (2010). Øyvind S. Bruland served as a member of the board of Oncoinvent AS from 2010 to 2016. Professor Bruland's main clinical experience and research has been devoted to primary bone and soft tissue cancers (sarcomas).



**Tore Kvam**  
*Chief Financial Officer*

Tore Kvam has an extensive experience as CFO within technology driven companies and with a 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 a MSc Computer Science degree from the George Washington University, an MBA from the Norwegian Business School BI and is a Certified European Financial Analyst (CEFA).



**Kristine Lofthus**  
*Head of Quality Assurance*

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



**Kari Skinnemoen**  
*Head of Regulatory Affairs*

Kari Skinnemoen has more than 35 years' experience in the pharmaceutical and medical device industries within global regulatory affairs, quality assurance, quality control and research and development. This experience includes management and project management positions within the development of contrast media (Nycomed Imaging now GE Healthcare), photodynamic therapy of skin cancers (Photocure) and in-vitro diagnostic products (Alere Technologies now Abbott). She is licensed as Qualified Person for batch certification and release at Oncoinvent. Kari holds a cand. real. degree (M.Sc.) from University in Oslo in chemistry, mathematics and biology with a thesis in organic chemistry.



**Helén Blanco**  
*Head of Clinical Operations*

Helén Johansen Blanco has 20 years of clinical development experience, ranging from Phase I to III clinical trials leading to the successful launch of several oncology products. She has experience in project management of large global clinical trials conducted in all continents of the world. Mrs. Blanco has previously worked for large international pharma companies such as Astra Zeneca, Mylan Biologics and Celgene, as well as medium sized biotechnology companies and recognized clinical research organizations such as Covance. She holds a MSc in Biophysics and medical technology from NTNU.



**Hans Hild**  
*Head of Production*

Dr. Hans M. Hild has more than 15 years' experience in the GMP compliant production of sterile- and aseptically produced pharmaceuticals and radiopharmaceuticals. He previously has 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 an Dipl. Ing. (FH) degree in Chemical Engineering from FH Frankfurt am Main, an M.Sc. in Biochemical Engineering from the University of Birmingham and a Ph.D. in Biochemical Engineering from Imperial College London.



**Gro Hjellum**  
*Head of Quality Control*

Gro Hjellum has more than 25 years of experience within research & development and operations in the pharmaceutical and biotech industry, ranging from analytical sciences, quality control and bio-analysis from preclinical product development through to regulatory approval of products. Prior to joining Oncoinvent, Gro 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 US and Japan. Ms. Hjellum holds an MSc degree in radiochemistry from the University of Oslo.

## Health, safety and environment

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

At year's end there were a total of 20 full-time employees, 3 part-time employees and 3 Industrial Ph.D. students. The company is an equal opportunity employer and fourteen of the staff are of female gender and six of the staff are of male gender. As such the company believes that it has taken sufficient active, targeted, and systematic efforts to promote equality.

Oncoinvent has designed and implemented multiple safeguards into its laboratory and production facilities and standard operating procedures to prevent potential environmental impacts from its operations.



## 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 brackets refer to the corresponding period or balance date in 2018, unless otherwise specified)

### Income statement

#### *Operating revenues*

Oncoinvent recorded operating revenues of NOK 11.412 million in 2019 (NOK 10.459 million). Government support for its research and development activities from the Research Council of Norway was recognized as income.

#### *Operating expenses*

Net operating expenses for the year amounted to NOK 55.284 million (NOK 45.197 million). The cost increase was driven by the expansion program with recruitment of new staff members, operation of the new laboratory facilities and preparations for clinical trials. The operating loss for Oncoinvent amounted to NOK -43.872 million (NOK -34.738 million).

#### *Net financial items*

Net financial income amounted to NOK 1.798 million (NOK 1.686 million). Interest income from ordinary bank deposits came to NOK 1.751 million (NOK 1.656 million).

#### *Net result*

Losses after tax for the year were NOK 42.200 million (NOK 33.052 million). The loss is proposed allocated from the share premium.

Loss per share amounted to NOK 3.20 in 2019 compared to NOK 2.51 in 2018.

### Financial position

#### *Assets*

Property, plant and equipment at year-end amounted to NOK 16.253 million (NOK 19.524 million). During 2019 NOK 1.164 million was activated. Neither of these expenses was associated with the construction of the new laboratory.

Cash and cash equivalents were NOK 118.338 million (NOK 153.553 million). The change reflects increased operational activity level. Total assets by year end 2019 decreased to NOK 147.505 million (NOK 185.189 million).

#### *Equity and liabilities*

Total equity as of 31 December 2019 was NOK 135.561 million (NOK 177.637 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 10.307 million (NOK 7.552 million), the increase driven primarily by higher accounts payable and provisions.

### Research and development

While the research and development strategy are 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 extend 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 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 2019 were NOK 32.695 mill. (NOK 30.399 million), whereas NOK 16.037 mill. (NOK 20.788 million) were classified as other operating expenses and NOK 16.658 mill. (NOK 9.611 million) were classified as payroll.

## Financial risks

### *Interest rate risk*

The Company holds NOK 118.338 million (NOK 153.553 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 1.751 million (NOK 1.656 million) in interest income as of 31 December 2019.

### *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 dollar (USD) and Canadian dollar (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 rate if it deems it necessary.

### *Credit risk*

Credit risk is the risk of counterparty's default in a financial asset, liability or customer contract, giving 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 is 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 2019 and the Company considers its credit risk as 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-end 2019 was NOK 118.338 million (NOK 153.553 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 24 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 is currently in preclinical trials. 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 31 December 2019, there were 13 190 411 shares outstanding. The Company had 292 shareholders at 31 December 2019.

**Subsequent events**

The company has made the necessary preparations for the initiation and execution of the clinical studies in the first part of 2020 together with clinical sites at the participating hospitals. Operations at hospitals throughout Europe have been affected by the Covid-19 epidemic, and this will affect the initiation and the recruitment of patients for the two Radspherin® phase I studies. At the current time it is too early to predict how significant the impact of Covid-19 outbreak will be on the clinical studies, however it is expected that the studies will take significantly more time to complete than previously anticipated.

Oslo, March 11th 2020



Roy Hartvig Larsen  
Chairman of the Board



Jonas Einarsson  
Board member



Thora J. Jonasdottir  
Board member



Leiv Askvig  
Board member



Ludvik Sandnes  
Board member



Jan Alan Alfheim  
CEO

# Income Statement

INCOME STATEMENT	NOTE	2019	2018
<b>Operating revenues</b>			
Sales Revenue		246 770	299 904
Other operating revenues	7	11 164 759	10 158 946
<b>Total operating revenues</b>		<b>11 411 529</b>	<b>10 458 850</b>
<b>Operating expenses</b>			
Cost of goods		-	9 300
Payroll and related costs	6	23 883 378	15 617 140
Depreciation	8	4 434 609	3 987 007
Other operating expenses	10	26 964 978	25 583 454
<b>Total operating expenses</b>		<b>55 282 965</b>	<b>45 196 901</b>
<b>OPERATING INCOME</b>		<b>-43 871 436</b>	<b>-34 738 051</b>
<b>Financial items</b>			
Other interest income		1 751 092	1 655 881
Other financial income		47 063	88 902
<b>Total financial income</b>		<b>1 798 155</b>	<b>1 744 783</b>
Other interest expenses		1 556	3 973
Other financial expenses		124 546	54 683
<b>Total financial income</b>		<b>126 102</b>	<b>58 656</b>
<b>Net financial items</b>		<b>1 672 053</b>	<b>1 686 127</b>
Income before tax		-42 199 383	-33 051 924
<b>NET INCOME</b>		<b>-42 199 383</b>	<b>-33 051 924</b>
<b>Distribution of profit and funds</b>			
Uncovered loss		42 199 383	33 051 924
<b>Total distribution of profit and funds</b>		<b>42 199 383</b>	<b>33 051 924</b>

# Balance sheet

ASSETS	NOTE	31.12.2019	31.12.2018
<b>FIXED ASSETS</b>			
Tangible fixed assets			
Land, Buildings and other property		8 404 378	9 605 003
Running equipment, tools etc.		7 848 839	9 918 887
<b>Total tangible fixed assets</b>	<b>8</b>	<b>16 253 217</b>	<b>19 523 890</b>
<b>Total fixed assets</b>		<b>16 253 217</b>	<b>19 523 890</b>
<b>CURRENT ASSETS</b>			
Receivables			
Accounts receivables		126 500	62 500
Other short-term receivables	5	12 787 886	12 048 987
<b>Total receivables</b>		<b>12 914 386</b>	<b>12 111 487</b>
Cash and cash equivalents	6	118 337 860	153 553 317
<b>Total current assets</b>		<b>131 252 246</b>	<b>165 664 804</b>
<b>TOTAL ASSETS</b>		<b>147 505 463</b>	<b>185 188 694</b>
<b>LIABILITIES AND EQUITY</b>			
<b>EQUITY</b>			
Paid-in capital			
Share capital	3,4	1 319 041	1 318 718
Share premium reserve	4	234 893 414	234 768 737
<b>Total paid-in capital</b>		<b>236 212 455</b>	<b>236 087 455</b>
Retained earnings			
Uncovered loss		100 650 321	58 450 938
<b>Total retained earnings</b>		<b>-100 650 321</b>	<b>-58 450 938</b>
<b>Total equity</b>	<b>4</b>	<b>135 562 134</b>	<b>177 636 517</b>
<b>LIABILITY</b>			
Current liabilities			
Accounts payables		6 779 892	4 242 222
VAT, social security costs, etc.		1 330 738	1 214 041
Other current liabilities		3 832 699	2 095 914
<b>Total short-term liability</b>		<b>11 943 329</b>	<b>7 552 177</b>
<b>Total liabilities</b>		<b>11 943 329</b>	<b>7 552 177</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>147 505 463</b>	<b>185 188 694</b>

Oslo, March 11th 2020



Roy Hartvig Larsen  
Chairman of the Board



Jonas Einarsson  
Board member



Thora J. Jonasdottir  
Board member



Leiv Askvig  
Board member



Ludvik Sandnes  
Board member



Jan Alan Alfheim  
CEO



# Notes

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## 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 through 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 – Taxes****2.1 Specification of temporary differences**

	2019	2018	CHANGE
Loss carry forward	120 127 825	73 403 171	46 724 654
<b>Total amount difference</b>	<b>120 127 825</b>	<b>72 291 570</b>	<b>46 724 654</b>
Deferred tax benefits 22%	26 428 121	16 627 061	9 801 060

Deferred tax benefits of tax loss carry forward are not included in the balance sheet as of 31 December 2019.

**2.2 Specification of the basis for tax payable**

	2019	2018
Result for the period	-42 199 383	-33 051 924
Permanent differences	-5 633 090	-5 279 119
Changes in temporary differences	1 170 319	481 027
<b>Basis of calculation for tax payables</b>	<b>-46 662 154</b>	<b>-37 850 016</b>
Tax payable	0	0
Deduction for R&D expenses	5 629 030	5 283 260

**Note 3 – Share capital and shareholder information**

SHAREHOLDERS PR. 31. DEC. 2019	NO. OF SHARES	%
Sciencons AS	3 185 000	24.15%
Geveran Trading Co LTd	1 098 000	8.32%
Roy Hartvig Larsen	678 000	5.14%
Radiumhospitales forskningsstiftelse	670 880	5.09%
Blaahaugen AS	632 500	4.80%
Must Invest	517 000	3.92%
Cancia AS	493 300	3.74%
Bentax AS	450 000	3.41%
Syntax AS	440 000	3.34%
Trond Larsen	310 000	2.35%
Tina Bjørklind Bønsdorff	277 600	2.11%
CGS Holding AS	260 000	1.97%
Helene Sundt AS	260 000	1.97%
Thora Johanna Jonasdottir	255 000	1.93%
Lucellum AS	192 351	1.46%
Inven2 AS	158 500	1.20%
Alpine Capital AS	139 440	1.06%
Artal AS	138 670	1.05%
Other shareholders < 1%	3 034 170	23.00%
<b>Total number of shares</b>	<b>13 190 411</b>	<b>100%</b>

Nominal value per share: NOK 0.10

Total number of shareholders: 292

A capital increase was carried out in 2019, with the issuance of 3.230 shares (RSU)

**Note 4 – Equity**

	SHARE CAPITAL	SHARE PREMIUM	UNCOVERED LOSS	TOTAL EQUITY
Share capital as of 01.01.2019	1 318 718	234 768 737	-58 450 938	177 636 517
Share issuance	323	124 677		125 000
Results of the period			-42 199 383	-42 199 383
<b>Share capital as of 31.12.2019</b>	<b>1 319 041</b>	<b>234 893 414</b>	<b>-100 650 321</b>	<b>135 562 134</b>

**Note 5 – Other receivables**

VAT refund	3 840 563
Prepaid expenses	1 107 960
The Research Council of Norway	2 210 334
Skattefunn <sup>1</sup>	5 629 029
<b>Total receivables</b>	<b>12 787 886</b>

<sup>1</sup> 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**

	2019	2018
Salaries (incl. vacation pay)	19 654 667	12 586 354
Payroll tax	2 899 444	1 946 358
Pension costs (occupational pension scheme)	1 206 362	921 198
Other pension costs	122 905	163 230
<b>Total personnel expenses</b>	<b>23 883 378</b>	<b>15 617 140</b>
<b>Total full-time equivalent</b>	<b>22.8</b>	<b>15.5</b>

**6.2 Specification of remuneration to the management and the board of directors**

		2019	2018
CEO	Salary	1 639 895	1 581 862
	Bonus	145 164	212 312
	Other remuneration	64 681	73 094
<b>Total amount CEO</b>		<b>1 849 740</b>	<b>1 867 268</b>

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 2018 a total of 414 000 stock options has been allocated including 180 000 stock options for the CEO. The stock options have a strike price between NOK 10-38.70 per share depending on the time of allocation.

### 6.3 Specification of remuneration to the board of directors

Paid board remuneration 2018	242 500
Incurred board remuneration 2019	227 500
Incurred board remuneration – RSU registration	260 000
<b>Total amount, board remuneration</b>	<b>730 000</b>

### 6.4 Specification of remuneration to the auditor

	2019	2018
Expensed remuneration to the auditor	51 750	45 000
Other certification services	0	16 800
<b>Total remuneration paid to the auditor</b>	<b>51 750</b>	<b>61 800</b>

### 6.5 Restricted funds

	2019	2018
Restricted funds – Tax deduction	903 083	808 078
Tax payable, 6th term	869 546	805 454

### 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.

	2019	2018
Skattefunn	5 629 029	5 283 260
The Research Council of Norway	5 535 730	4 875 686
<b>Total amount</b>	<b>11 164 759</b>	<b>10 158 946</b>

#### Receivables:

Skattefunn	5 629 030	5 283 260
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**Note 8 – Fixed assets**

	INVENTORY	LAB EQUIPMENT	FIXED BUILDING INVENTORY	OFFICE MACHINERY	TOTAL AMOUNT
Balance 01.01.2019	999 185	11 243 170	12 006 253	1 261 741	25 510 349
Acquisitions	362 610	687 165		114 160	1 163 935
Disposals					
<b>Acquisition cost</b>	<b>1 361 795</b>	<b>11 930 335</b>	<b>12 006 253</b>	<b>1 375 901</b>	<b>26 674 284</b>
Acc. Depreciation	-559 259	-5 146 042	-3 601 874	-1 113 892	-10 421 067
<b>Total</b>	<b>802 536</b>	<b>6 784 293</b>	<b>8 404 379</b>	<b>262 009</b>	<b>16 253 217</b>
Depreciation for the year	258 067	2 655 102	1 200 625	320 815	4 434 609
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**

Lease payment (office)	2 743 727
Rental costs (office machinery and equipment)	32 668
Lab costs, studies, patents, equipment	12 777 589
Repair of equipment	197 096
Foreign services – remuneration	8 379 899
Office expenses	832 623
Travel reimbursement costs	971 366
Advertisement costs	283 395
Representation	28 466
Memberships fees, insurance and other costs	718 149
<b>Total Other operating expenses</b>	<b>26 964 978</b>

# Glossary

<b>GMP</b>	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.
<b>Intraperitoneal</b>	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.
<b>Metastases</b>	Metastasis is the medical term for cancer that spreads to a different part of the body from where it started.
<b>Microparticles</b>	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.
<b>Peritoneal carcinomatosis</b>	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.
<b>Peritoneal cavity</b>	The space within the abdomen that contains the intestines, the stomach, and the liver. It is bound by thin membranes.
<b>Radspherin®</b>	Oncoinvent' s lead product candidate currently being developed to treat peritoneal carcinomatosis.
<b>Radioisotope</b>	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.
<b>Radiotherapeutics</b>	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.

# Auditor's Report

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To the General Meeting of Oncoinvent AS

## Independent Auditor's Report

### Report on the Audit of the Financial Statements

#### *Opinion*

We have audited the financial statements of Oncoinvent AS showing a loss of NOK 42 199 383. The financial statements comprise the balance sheet as at 31 December 2019, 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 accompanying financial statements are prepared in accordance with law and regulations and give a true and fair view of the financial position of the Company as at 31 December 2019, 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 laws, regulations, and auditing standards and practices generally accepted in Norway, including 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 as required by laws and regulations, 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 information*

Management is responsible for the other information. The other information comprises information in the annual report, except the financial statements and our auditor's report thereon.

Our opinion on the financial statements does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

#### *Responsibilities of the Board of Directors and the Managing Director for the Financial Statements*

The Board of Directors and the Managing Director (management) are responsible for the preparation in accordance with law and regulations, including 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. The financial statements use the going concern basis of accounting insofar as it is not likely that the enterprise will cease operations.

#### *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 laws, regulations, and auditing standards and practices generally accepted in Norway, including 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 aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

For further description of Auditor's Responsibilities for the Audit of the Financial Statements, reference is made to <https://revisorforeningen.no/revisjonsberetninger>

#### **Report on Other Legal and Regulatory Requirements**

##### *Opinion on Registration and Documentation*

Based on our audit of the financial statements as described above, and control procedures we have considered necessary in accordance with the International Standard on Assurance Engagements (ISAE) 3000, *Assurance Engagements Other than Audits or Reviews of Historical Financial Information*, it is our opinion that management has fulfilled its duty to produce a proper and clearly set out registration and documentation of the Company's accounting information in accordance with the law and bookkeeping standards and practices generally accepted in Norway.

Drammen, 11 March 2020

**Thorsby AS**



Øyvind Thorsby

*State Authorised Public Accountant*

Note: This translation from Norwegian has been prepared for information purposes only.





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