



ÅRSREGNSKAPET FOR REGNSKAPSÅRET 2020 - GENERELL INFORMASJON

Enheten

Organisasjonsnummer: 982 611 830
Organisasjonsform: Aksjeselskap
Foretaksnavn: PCI BIOTECH AS
Forretningsadresse: Ullernchausséen 64
0379 OSLO

Regnskapsår

Årsregnskapets periode: 01.01.2020 - 31.12.2020

Konsern

Morselskap i konsern: Nei

Regnskapsregler

Regler for små foretak benyttet: Nei
Benyttet ved utarbeidelsen av årsregnskapet til selskapet: IFRS

Årsregnskapet fastsatt av kompetent organ

Bekreftet av representant for selskapet: Ronny Skuggedal
Dato for fastsettelse av årsregnskapet: 28.06.2021

Grunnlag for avgivelse

År 2020: Årsregnskapet er elektronisk innlevert
År 2019: Tall er hentet fra elektronisk innlevert årsregnskap fra 2020

Det er ikke krav til at årsregnskapet m.v. som sendes til Regnskapsregisteret er undertegnet. Kontrollen på at dette er utført ligger hos revisor/enhetens øverste organ. Sikkerheten ivaretas ved at innsender har rolle/rettighet for innsending av årsregnskapet via Altinn, og ved at det bekreftes at årsregnskapet er fastsatt av kompetent organ.

Brønnøysundregistrene, 21.07.2022



Resultatregnskap

Beløp i: NOK	Note	2020	2019
RESULTATREGNSKAP			
Inntekter			
Other income	5,6	7 368 000	9 392 000
Sum inntekter		7 368 000	9 392 000
Kostnader			
Research and development	7	75 571 000	83 312 000
General and administrative	7,8,9,1 0,13,2 1,22	9 254 000	10 302 000
Sum kostnader	14	84 825 000	93 614 000
Driftsresultat		-77 457 000	-84 222 000
Finansinntekter og finanskostnader			
Financial income	11	2 302 000	2 721 000
Sum finansinntekter		2 302 000	2 721 000
Rentekostnad til foretak i samme konsern	21	2 905 000	6 734 000
Financial expenses	11,22	608 000	690 000
Sum finanskostnader		3 513 000	7 424 000
Netto finans		-1 211 000	-4 703 000
Ordinært resultat før skattekostnad		-78 668 000	-88 925 000
Income tax	12	0	0
Ordinært resultat etter skattekostnad		-78 668 000	-88 925 000
Årsresultat		-78 668 000	-88 925 000
Overføringer og disponeringer			
Allocated retained earnings		-78 668 000	-88 925 000
Sum overføringer og disponeringer		-78 668 000	-88 925 000



Balanse

Beløp i: NOK	Note	2020	2019
BALANSE - EIENDELER			
Anleggsmidler			
Immaterielle eiendeler			
Sum immaterielle eiendeler		0	0
Varige driftsmidler			
Property, plant and equipment	13	7 388 000	5 072 000
Right to use asset	22	605 000	1 211 000
Sum varige driftsmidler		7 993 000	6 283 000
Finansielle anleggsmidler			
Sum finansielle anleggsmidler		0	0
Sum anleggsmidler		7 993 000	6 283 000
Omløpsmidler			
Varer			
Sum varer		0	0
Fordringer			
Other short-term receivables	16	13 076 000	14 578 000
Sum fordringer		13 076 000	14 578 000
Investeringer			
Sum investeringer		0	0
Bankinnskudd, kontanter og lignende			
Cash and cash equivalents	15,17	119 493 000	138 308 000
Sum bankinnskudd, kontanter og lignende		119 493 000	138 308 000
Sum omløpsmidler		132 569 000	152 886 000
SUM EIENDELER		140 562 000	159 169 000

BALANSE - EGENKAPITAL OG GJELD



Balanse

Beløp i: NOK	Note	2020	2019
Egenkapital			
Innskutt egenkapital			
Share capital	18	5 494 000	5 171 000
Overkurs		97 254 000	99 906 000
Sum innskutt egenkapital		102 748 000	105 077 000
Opptjent egenkapital			
Sum opptjent egenkapital		0	0
Sum egenkapital		102 748 000	105 077 000
Gjeld			
Langsiktig gjeld			
Other long-term liabilities	14,15	32 000	2 037 000
Long-term lease liabilities	22	0	539 000
Sum avsetninger for forpliktelser		32 000	2 576 000
Annen langsiktig gjeld			
Sum langsiktig gjeld		32 000	2 576 000
Kortsiktig gjeld			
Leverandørgjeld	21	5 130 000	8 452 000
Public duties payable		1 978 000	4 565 000
Kortsiktig konserngjeld	21	19 021 000	28 011 000
Short-term lease liabilities	22	673 000	657 000
Other current liabilities	20	10 981 000	9 831 000
Sum kortsiktig gjeld	14,15, 19	37 783 000	51 516 000
Sum gjeld		37 815 000	54 092 000
SUM EGENKAPITAL OG GJELD		140 563 000	159 169 000



Unlocking the potential of innovative medicines



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ANNUAL REPORT 2020

PCI Biotech AS

PCI Biotech Holding ASA, Ullernchausséen 64, 0379 Oslo, Norway, Company no: 991036393 VAT
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INTRODUCTION

ABOUT PCI BIOTECH

PCI Biotech AS ("PCI Biotech" or "the Company") is a cancer focused biopharmaceutical company headquartered in Norway. The parent company, PCI Biotech Holding ASA, is listed on the Oslo Stock Exchange. The Company is developing therapeutic products based on its proprietary photochemical internalisation (PCI) technology, which originates from world leading research at the Norwegian Radium Hospital. PCI Biotech's lead product candidate is the photosensitiser fimaPORFIN (Amphinex®) and the Company has an extensive collaboration with Norwegian and international hospitals and companies.

OUR TECHNOLOGY

The PCI technology can enhance the effect of anticancer drugs by targeted, light-directed drug delivery into cancer cells, and can also be used as a platform that may both potentiate the effect of vaccines and enable macromolecules to reach intracellular targets. PCI Biotech applies the technology to three distinct anticancer paradigms: fimaCHEM (enhancement of chemotherapeutics for localised treatment of cancer), fimaVACC (T-cell induction technology for therapeutic vaccination), and fimaNAC (nucleic acid therapeutics delivery).

Chemotherapies and several novel classes of drugs (e.g. certain immunotherapeutics) need access to the inside of their human target cells, such as tumour cells or immune cells, in order to be effective. Unfortunately, many of these substances are by nature encapsulated in so-called endosomes as they enter the target cell. Once inside the cell, most of the active compound may hence be trapped in the endosomes and therefore unable to exert its therapeutic effect. Pharmaceutical companies struggle to find effective methods to release drugs that are entrapped in this way and are actively searching for technologies that provide adequate drug release inside the target cells, in order to achieve the full therapeutic and commercial potential of their products.

The PCI technology platform consists of two elements: a proprietary small molecule photosensitiser (named fimaPORFIN) and a light source. The primary aim of PCI is to introduce drug molecules or macromolecules into the cytosol of the target cells. It is this drug or macromolecule that gives the biological effect in a PCI treatment, and the intended biological effect may range from cell killing (fimaCHEM), through modification of gene expression (fimaNAC) to enhanced antigen presentation (fimaVACC). Needless to say, in the two latter approaches the aim is not to kill the target cells, but PCI is employed to give the cells new properties by modifying the intracellular trafficking of drugs/antigens.

For different applications, fimaPORFIN will be formulated differently and used at different doses e.g. intravenous injection in localised cancer treatment versus minute amounts administered into the skin in the vaccination setting. The light source may also be different for different applications. Red laser light is used in localised cancer treatment to achieve good tissue penetration, while a blue LED light may be used in vaccination, as deep light penetration may not be needed to reach antigen presenting cells (APC's) at the site of vaccination. fimaCHEM and fimaVACC are consequently very different products, although the same basic mechanism of targeted endosomal release is applied.

THREE DISTINCT BUSINESS AREAS

Recent advancements in cancer therapy, not least owing to the development of new classes of drugs, such as immunotherapeutics, imply a potential to significantly improve the prognosis for millions of patients. The potential of fimaPORFIN to improve the efficacy of anti-cancer agents has been convincingly shown in well-established preclinical models as well as in clinical trials, with the first clinical results being published in the renowned medical journal the Lancet Oncology. This was followed by a Phase Ib study in bile duct cancer patients that delivered encouraging early signs of tumour response and survival. Based on these positive findings, PCI Biotech is now developing three parallel programmes.

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INOPERABLE BILE DUCT CANCER AND fimaCHEM

The fimaCHEM programme aims to fulfil unmet medical needs by providing localised targeted enhancement of approved chemotherapies for the benefit of the many patients currently left without effective treatment options. Based on findings from a successful Phase I study in bile duct cancer patients, a single pivotal clinical trial, named the RELEASE study, has been initiated in inoperable extrahepatic bile duct cancer, a rare, but fatal disease with no cure. The RELEASE study design is based on the outcome of meetings with the two leading regulatory authorities, the European Medicine Agency (EMA) and the U.S. Food and Drug Administration (FDA). The RELEASE study will provide the opportunity to generate robust comparative data of importance for market acceptance and has the potential of accelerated/conditional marketing approval as a first line treatment given the rare disease status and high unmet medical need for bile duct cancer patients.

Bile duct cancer (cholangiocarcinoma) affects the cell lining of the bile duct and represents a patient population with a high unmet medical need. It is a rare disease with an incidence rate of 1-2 per 100,000 in the western world, indicating a total patient population of close to 15,000 per year. The incidence rates are increasing worldwide. Overall survival at 5 years is dismal at less than 10%. Resection is today the only potential cure but only possible in 10-35% of the patients. Most patients die of local effects of the tumour and the cancer shows remarkable resistance to chemotherapy. Gemcitabine + cisplatin is the most effective chemotherapy combination and has become a standard treatment for bile duct cancer patients in most regions. Gemcitabine's anti-cancer effect is significantly enhanced by the fimaCHEM technology in preclinical studies.

The potential first line fimaCHEM treatment regimen consists of an intravenous injection of fimaporfin, followed four days later by an intravenous infusion of gemcitabine and a laser light application in the bile duct easily administered through endoscopic methods used routinely in these patients. The patients then follow the standard background treatment with up to 8 chemotherapy cycles of gemcitabine + cisplatin. The fimaCHEM treatment may be repeated during the background chemotherapy treatment cycles. Local tumour response in the bile duct is important to maintain biliary drainage and loco-regional control may therefore be more important for patient long term survival than would be the case for many other cancers. The fimaCHEM treatment boosts the chemotherapy effect locally in the bile duct, thereby directly targeting this area.

Bile duct cancer is an orphan indication with a range of development and market incentives. PCI Biotech has obtained orphan drug designation (ODD) for fimaporfin in this disease in both EU and the US, meaning that regulatory authorities may expedite a market approval process, and that a market exclusivity period can be secured under the orphan drug legislations in both regions. ODD is a significant regulatory milestone and it recognises the therapeutic benefits fimaCHEM seek to bring to the bile duct cancer patients in need of better local treatments.

The immediate target for PCI Biotech is inoperable patients with advanced or metastatic extrahepatic disease without bone or brain metastases. Across Europe and USA approximately 3,000 patients annually are assumed to be eligible for fimaCHEM treatment. Asia is a potential upside from a business perspective. Applying a projection of inoperable patients based on the estimated inoperable portion from the Western world and taking into account that not all parts of the population in China will have access to the treatment, it can be estimated potentially more than 4,000 patients annually in the commercial interesting part of the Asian market, considered to be South-Korea, Japan, China, Taiwan and Hong Kong. The price potential is normally attractive for orphan drugs of this rarity.

There is a potential for obtaining a significant majority share of the identified eligible market due to the anticipated benefits, such as no competing marketable treatment alternatives, limited development pipeline, greater efficacy due to local chemotherapy boosts and fimaCHEM being an add-on to the current standard of care with easy light access through established standard procedures.



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IMMUNOTHERAPY AND *fimaVacc*

Immunotherapy utilises the body's own immune system to fight cancer, which is a radically different approach to treating cancer than chemotherapy. The armamentarium of cancer immunotherapies includes many different therapeutic approaches including antibody-based treatments, cell-based therapies, and therapeutic vaccines. The pharmaceutical industry has long recognised the potential of therapeutic cancer vaccination and the objective of a therapeutic vaccine is to treat an established disease using the body's natural defences. Whereas in a traditional anti-infectious vaccine, the main component of the vaccine is the infectious agent antigen, in the case of a cancer vaccine the main component can be a peptide or protein found on the surface of tumour cells. By vaccinating with such tumour-specific antigens, the body's natural defences can be trained to recognise and destroy cancer cells.

Peptide and protein based vaccines are a subgroup of therapeutic cancer vaccines. There is a broad consensus that therapeutic peptide and protein based cancer vaccines have so far not been able to elicit sufficiently strong immune responses. A fundamental challenge for most existing therapeutic vaccine approaches is to produce a strong and relevant cellular immune response (T-cell activation). A potent induction of Cytotoxic T-cells is considered paramount for successful therapeutic vaccination. This is a main need in the market, which could be addressed by using the *fimaVacc* technology. In addition to the use in therapeutic vaccination for cancer, *fimaVacc* also has the potential to be used for both therapeutic and prophylactic vaccination for several infectious diseases.

fimaVacc is an endosomal escape technology that may realise the true benefit of innovative therapeutic vaccines by modifying the intracellular machinery of immune cells in such a way that antigens are more efficiently processed and induce antigen specific cytotoxic T-cells. The innovative and well characterised mode of action of *fimaVacc* can be applied to a wide range of cancer vaccine technologies and provide PCI Biotech with a strategic opportunity to enter the field of cancer immunotherapy at a time where the understanding of cancer biology and the potential of modulating the immune response to fight cancer is growing at a rapid pace.

In terms of type of vaccination, *fimaVacc* is also a versatile technology that can be used in multiple settings including, intradermal, intranodal, and intratumoural administration. Preclinical research has shown that it could also be developed in conjunction with *ex vivo* vaccination. Another promising way forward in the development of therapeutic vaccines is to combine vaccination with other cancer immunotherapy modalities such as checkpoint inhibitors (CPIs). There is a strong scientific rationale for combining CPIs with the *fimaVacc* technology: *fimaVacc* increases the number of T-cells induced by cancer vaccines while the CPIs prevent the tumour from evading the immune response.

In addition to T-cell enhancement, the *fimaVacc* features also include antibody enhancement, suggesting that the technology has a clear potential to contribute to the development of new prophylactic vaccines for infectious diseases lacking effective vaccines. Prominent examples are malaria and tuberculosis, but there are also many other potential target diseases for *fimaVacc* based prophylactic vaccination.

Significant efforts are being invested by the global health community to research and develop potential treatments against COVID-19. Most vaccine companies are currently focused on reaching or progressing clinical development of their own established technologies and may not be open for the inclusion of new technologies in the short term. PCI Biotech is nevertheless closely monitoring and exploring potential *fimaVacc* compatible opportunities, as the immune response characteristics of the PCI technology may fit well with the medical needs.

Vaccine technologies commonly utilise adjuvants to enhance immune responses, but the consensus is that each one of the adjuvants available today has shortcomings, like variation in efficacy and toxicity issues. *fimaVacc* is expected to increase vaccines' efficacy and generate the immune response faster, and to be user-friendly since illumination of the target area is considered to be a minor inconvenience. *fimaVacc* has the potential to increase patient safety if it can reduce the antigen payload and adjuvant volume per treatment and reduce the number of treatments needed. Increased efficacy for a broad range of peptide and protein based vaccines and patient safety are *fimaVacc*'s key competitive differentiators.

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The proprietary fimaVACC technology was successfully translated into humans through a Phase I study in healthy volunteers after having demonstrated strong preclinical efficacy. The immune results in man provide Proof-of-Concept and clinical support of fimaVACC's potential to enhance overall T-cell responses, by demonstrating improvement of the immunogenicity of vaccines in healthy volunteers. It is anticipated that a significant number of the cancer vaccines in development could use fimaVACC to boost their activation of T-cells and increase their efficacy. There are competing peptide vaccine enhancing technology platforms; for example adjuvants, liposomes and nanoparticles. For some of these technologies fimaVACC has shown synergistic effects in the preclinical setting.

NUCLEIC ACID THERAPEUTICS AND THE *fimaNAC* DELIVERY TECHNOLOGY

PCI Biotech's nucleic acid therapeutics program (*fimaNAC*) aims at improving the efficacy of novel nucleic acid based therapies. The *fimaNAC* technology addresses a main hurdle in the development of nucleic acid based therapies: Sufficient release of therapeutics inside the targeted cells. The therapeutic molecules are, due to their size and charge, notoriously difficult to deliver in large payloads inside cells. Nucleic acids are in most cells taken up by endocytosis, but are then trapped in endosomes, constituting a barrier severely limiting the achievable therapeutic effect. Thus, nucleic acids are very good candidates for enhancement by an endosomal release technology like *fimaNAC*, and preclinical experiments have shown that *fimaNAC* can give a substantial improvement in the effect of very important classes of nucleic acids such as oligonucleotides and mRNA. Nucleic acid therapeutics are widely acknowledged to have a large potential as therapeutic agents, and numerous clinical trials with nucleic acid therapeutics are underway. The commercial exploitation of most such drugs has been hampered by the lack of technologies for efficient delivery of the therapeutic molecules to their molecular targets inside cells. PCI Biotech's *fimaNAC* drug delivery technology has the potential to address this issue, as demonstrated in numerous preclinical models.

Nucleic acids have emerged as very promising therapeutic candidates for a wide range of diseases and are now considered the third major drug class, in addition to antibodies and small molecules. Recent progress has been rapid and broad, with more than eight nucleic acid based drugs on the market and more than one hundred in clinical trials.

fimaNAC is well positioned to capture a significant part of the nucleic acid therapeutics delivery market as demonstrated by the partnering activities of PCI Biotech in this field. The main *fimaNAC* strategy is to collaborate with biotech or pharmaceutical companies and develop long-term relationship with companies having early stage innovative nucleic acid based technology.

The *fimaNAC* programme, aiming at improving the efficacy of novel nucleic acid based therapies, is a preclinical stage collaborative programme where partners are exploring synergies between their proprietary nucleic acid technologies and the *fimaNAC* technology, with potential for further deepening of the partnerships. PCI Biotech see great potential for further development of our intracellular delivery technology, not least within the emerging field of mRNA.



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PCI Biotech AS – financial statement

STATEMENT OF COMPREHENSIVE INCOME For the year ended 31 December 2020 (1.1 - 31.12)

(figures in NOK 1.000)

	Note	2020	2019
Other income	5,6	7 368	9 392
Total income		7 368	9 392
Research and development	7,8	75 571	83 312
General and administrative	7,8,9,10,13	9 254	10 302
Total operating expenses	21,22	84 825	93 614
Operating results		-77 457	-84 222
Financial income	11	2 302	2 721
Financial expenses, intragroup		2 905	6 734
Financial expenses	11,22	608	690
Net financial results		-1 211	-4 703
Profit/Loss before income tax		-78 668	-88 925
Income tax	12	-	-
Net profit/loss for the year		-78 668	-88 925
Other comprehensive income, net of tax			
Items that will not be reclassified to income statement		-	-
Items that subsequently may be reclassified to income statement		-	-
Total comprehensive income for the year		-78 668	-88 925



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PCI Biotech AS

BALANCE SHEET for the year ended 31 December 2020

ASSETS <i>(figures in NOK 1.000)</i>	Note	2020	2019
Non-current assets			
Property, plant and equipment	13	7 388	5 072
Right to use assets	22	605	1 211
Total non-current assets		7 994	6 283
Current assets			
Other short-term receivables	16	13 076	14 578
Total receivables	15	13 076	14 578
Cash and cash equivalents	14,15,17	119 493	138 308
Total current assets		132 569	152 886
Total assets		140 562	159 169




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BALANCE SHEET for the year ended 31 December 2020

EQUITY AND LIABILITIES <i>(figures in NOK 1.000)</i>	Note	2020	2019
Equity			
Share capital	18	5 494	5 171
Share premium		97 254	99 906
Retained earnings		-	-
Total equity	8	102 748	105 077
Liabilities			
Non-current liabilities			
Other long-term liabilities	14	32	2 037
Long-term lease liabilities	22	-	539
Total non-current liabilities		32	2 576
Current liabilities			
Trade account payables		5 130	8 452
Current lease liabilities	22	673	657
Public duties payables		1 978	4 565
Other current liabilities, intragroup	19	19 021	28 011
Other current liabilities	20	10 981	9 832
Total current liabilities	14,19	37 783	51 516
Total liabilities	15	37 815	54 092
Total equity and liabilities		140 562	159 169


Oslo, 17 June 2021
Board of Directors and Chief Executive Officer,
PCI Biotech AS



Per Walday
Chairman



Ronny Skuggedal
Director



Anders Høgset
Director



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STATEMENT OF CHANGES IN EQUITY for the year ended 31 December 2020

(figures in NOK 1,000)

	Note	Share capital	Share premium	Other paid-in capital	Retained earnings	Total equity
Equity at 31 December 2018	8,18	4 848	51 718	0	0	56 566
Capital increase		323	134 677	-	-	135 000
Share-based payments		-	-	2 436	-	2 436
Total comprehensive income		-	-86 489	-2 436	-	-88 925
Equity at 31 December 2019	8,18	5 171	99 906	0	0	105 077
Capital increase		323	67 677	-	-	70 000
Share-based payments		-	-	6 339	-	6 339
Total comprehensive income		-	-72 329	-6 339	-	-78 668
Equity at 31 December 2020	8,18	5 494	97 254	0	0	102 748

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CASH FLOW STATEMENT

for the year ended 31 December 2020

(figures in NOK 1,000)

	Note	2020	2019
Profit/Loss before income tax		-78 668	-88 925
Depreciation and amortisation	7,13	2 208	955
Leasing interest cost	22	75	37
Share-based payments	8	6 339	2 436
Currency gain (-) / loss (+) not related to operations	17	-115	121
Changes in accounts receivables		1 502	-7 118
Changes in account payables		-3 323	7 759
Changes in other net operating assets and liabilities		-3 373	2 101
Cash flow from operating activities		-75 354	-82 634
Disbursement intragroup interest-bearing loan		-4 184	-3 753
Proceeds intragroup interest-bearing loan		65 194	73 925
Acquisition of non-current assets	13	-3 919	-5 405
Net cash flow from investing activities		57 091	64 767
Payment principal portion of lease liability	22	-668	-657
Net cash flow from financing activities		-668	-657
Net changes in cash and cash equivalents		-18 930	-18 524
Exchange rate effect on bank deposits in foreign currency	17	115	-121
Cash and cash equivalents at 1 January		138 308	156 953
Cash and cash equivalents at 31 December	17	119 493	138 308



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PCI BIOTECH AS – ACCOUNTING PRINCIPLES 2020

1. Corporate information

The annual accounts for 2020 for PCI Biotech AS (the Company or PCI Biotech) was approved for publication by the Board of Directors on 17th June 2021.

PCI Biotech AS is a wholly owned subsidiary of PCI Biotech Holding ASA, a public listed company at Oslo Børs and domiciled in Norway. The business of PCI Biotech is associated with research and development of pharmaceutical products and related technical equipment. The office address is Ullernchausséen, N-0379 Oslo.

2. Significant accounting policies

2.1 Basis of preparation

The Company's annual accounts are prepared in accordance with International Financial Reporting Standards (IFRS) as specified by the International Accounting Standards Board and implemented by the EU as per 31 December 2020.

The annual accounts for the Company have been prepared on the basis of historical cost. The financial income statement is presented by function of expense.

NOK (Norwegian kroner) is the functional currency. In the absence of any statement to the contrary, all financial information is reported in whole thousands. As a result of rounding adjustments, the figures in the financial statements may not add up to the totals.

2.2 Summary of significant accounting policies

a) Current versus non-current classification

The Company presents assets and liabilities in statement of financial position based on current/non-current classification. An asset is current when it is:

- Expected to be realised or intended to sold or consumed in normal operating cycle
- Held primarily for the purpose of trading
- Expected to be realised within twelve months after the reporting period

Or

- Cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least twelve months after the reporting period

All other assets are classified as non-current.

A liability is current when:

- It is expected to be settled in normal operating cycle
- It is held primarily for the purpose of trading
- It is due to be settled within twelve months after the reporting period

Or

- There is no unconditional right to defer the settlement of the liability for at least twelve months after the reporting period

The Company classifies all other liabilities as non-current. Deferred tax assets and liabilities are classified as non-current assets and liabilities.

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b) Government grants

Government grants are presented as other income, see Note 5 for further information. Government grants are recognised where there is reasonable assurance that the grant will be received and all attached conditions will be complied with. When the grant relates to an expense item, it is recognised as income on a systematic basis over the periods that the related costs, for which it is intended to compensate, are expensed. When the grant relates to an asset, it is recognised as income in equal amounts over the expected useful life of the related asset.

c) Taxes

Current income tax

Current income tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted, at the reporting date.

Current income tax relating to items recognised directly in equity is recognised in equity and not in the statement of profit or loss. Management periodically evaluates positions taken in the tax returns with respect to situations in which applicable tax regulations are subject to interpretation and establishes provisions where appropriate.

Deferred tax

Deferred tax is provided using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date. Deferred tax liabilities are recognised for all taxable temporary differences.

Deferred tax assets are recognised for all deductible temporary differences, the carry forward of unused tax credits and any unused tax losses. Deferred tax assets are recognised to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carry forward of unused tax credits and unused tax losses can be utilised.

The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilised. Unrecognised deferred tax assets are re-assessed at each reporting date and are recognised to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

Deferred tax relating to items recognised outside profit or loss is recognised outside profit or loss. Deferred tax items are recognised in correlation to the underlying transaction either in OCI or directly in equity. Deferred tax assets and deferred tax liabilities are offset if a legally enforceable right exists to set off current tax assets against current tax liabilities and the deferred taxes relate to the same taxable entity and the same taxation authority.

d) Foreign currencies

The Company's financial statements are presented in NOK, which is the company's functional currency.



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Transactions and balances

Transactions in foreign currencies are initially recorded by the Company at their respective functional currency spot rates at the date the transaction first qualifies for recognition. Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency spot rates of exchange at the reporting date. Differences arising on settlement or translation of monetary items are recognised in profit or loss.

e) Cash dividend distribution to equity holders of the parent

The Company recognises a liability to make cash distributions to equity holders when the distribution is authorised and the distribution is no longer at the discretion of the Company. As per the corporate laws in Norway, a distribution is authorised when it is approved by the shareholders. A corresponding amount is recognised directly in equity.

f) Property, plant and equipment

Tangible fixed assets are recognised at cost less deductions for accumulated depreciation and write-downs. Tangible fixed assets are depreciated over the expected useful life of the assets taking any residual value into consideration. Costs accrued for major replacements and upgrades of tangible fixed assets are added to cost if it is probable that the costs will generate future economic benefits for the Company and if the costs can be reliably measured. Ordinary maintenance is expensed as incurred.

Tangible fixed assets are depreciated on a straight-line basis over the estimated useful life of the asset as follows:

- Production and test equipment 3-5 years
- Furniture and equipment 3–5 years

g) Leases

The Company assesses at contract inception whether a contract is, or contains, a lease. That is, if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. The Company applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Company recognises lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

The Company recognises right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognised, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received.

Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease term and the estimated useful lives of the assets. If ownership of the leased asset transfers to the Company at the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset. The right-of-use assets are also subject to impairment.

At the commencement date of the lease, the Company recognises lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Company and payments of penalties for terminating the lease, if the lease term reflects the Company exercising the option to terminate. Variable lease payments that do not depend on an index or a rate are recognised as expenses (unless they are incurred to produce inventories) in the period in which the event or condition that triggers the payment occurs.

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In calculating the present value of lease payments, the Company uses its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in the lease payments (e.g., changes to future payments resulting from a change in an index or rate used to determine such lease payments) or a change in the assessment of an option to purchase the underlying asset.

The Company applies the short-term lease recognition exemption to its short-term leases of machinery and equipment (i.e., those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the lease of low-value assets recognition exemption to leases of office equipment that are considered to be low value. Lease payments on short-term leases and leases of low-value assets are recognised as expense on a straight-line basis over the lease term.

h) Intangible assets - Research and development costs

Research costs are expensed as incurred. Internal development costs related to development of products are recognised in the income statement in the year incurred unless it meets the asset recognition criteria of IAS 38 "Intangible Assets". Development expenditures on an individual project are recognised as an intangible asset when the Company can demonstrate:

- The technical feasibility of completing the intangible asset so that the asset will be available for use or sale
- Its intention to complete and its ability and intention to use or sell the asset
- How the asset will generate future economic benefits
- The availability of resources to complete the asset
- The ability to measure reliably the expenditure during development

Following initial recognition of the development expenditure as an asset, the asset is carried at cost less any accumulated amortisation and accumulated impairment losses. Amortisation of the asset begins when development is complete and the asset is available for use. It is amortised over the period of expected future benefit. Amortisation is recorded in cost of sales. During the period of development, the asset is tested for impairment annually. The Company has currently no development expenditure that qualifies for recognition as an asset under IAS 38.

i) Impairment of non-financial assets

The Company assesses, at each reporting date, whether there is an indication that an asset may be impaired. If any indication exists, or when annual impairment testing for an asset is required, the Company estimates the asset's recoverable amount. An asset's recoverable amount is the higher of an asset's fair value less costs of disposal and its value in use. When the carrying amount of an asset exceeds its recoverable amount, the asset is considered impaired and is written down to its recoverable amount. Right-of-use assets are also subject to impairment.

j) Financial instruments

Financial assets

Financial assets are classified, at initial recognition, as subsequently measured at amortised cost, fair value through other comprehensive income (OCI), and fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset's contractual cash flow characteristics and the Company's business model for managing them. The Company initially measures a financial asset at its fair value plus, in the case of a financial asset not at fair value



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through profit or loss, transaction costs. In order for a financial asset to be classified and measured at amortised cost or fair value through OCI, it needs to give rise to cash flows that are 'solely payments of principal and interest (SPPI)' on the principal amount outstanding.

Subsequent measurement

For purposes of subsequent measurement, financial assets are classified in four categories:

- Financial assets at amortised cost (debt instruments)
- Financial assets at fair value through OCI with recycling of cumulative gains and losses (debt instruments)
- Financial assets designated at fair value through OCI with no recycling of cumulative gains and losses upon derecognition (equity instruments)
- Financial assets at fair value through profit or loss

Financial assets at amortised cost

This category is the most relevant to the Company. The Company measures financial assets at amortised cost if both of the following conditions are met:

- The financial asset is held within a business model with the objective to hold financial assets in order to collect contractual cash flows and
- The contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding

Financial assets at amortised cost are subsequently measured using the effective interest (EIR) method and are subject to impairment. Gains and losses are recognised in profit or loss when the asset is derecognised, modified or impaired.

The Company does not have financial assets at fair value through profit and loss.

Derecognition

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognised (i.e., removed from the Company's statement of financial position) when:

- The rights to receive cash flows from the asset have expired

or

- The Company has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a 'pass-through' arrangement; and either (a) the Company has transferred substantially all the risks and rewards of the asset, or (b) the Company has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset

Impairment of financial assets

Further disclosures relating to impairment of financial assets are also provided in the following notes:

- Note 14 Financial risk
- Note 16 Receivables by year end
- Note 17 Cash and cash equivalents

The Company recognises an allowance for expected credit losses (ECLs) for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Company expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

For trade receivables and contract assets, the Company applies a simplified approach in calculating ECLs. Therefore, the Company does not track changes in credit risk, but instead recognises a loss allowance based on lifetime ECLs at each reporting date, meaning that a loss allowance is made for losses expected over the remaining life of the exposure.

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For debt instruments at fair value through OCI, the Company applies the low credit risk simplification. At every reporting date, the Company evaluates whether the debt instrument is considered to have low credit risk using all reasonable and supportable information that is available without undue cost or effort. In making that evaluation, the Company reassesses the internal credit rating of the debt instrument. In addition, the Company considers that there has been a significant increase in credit risk when contractual payments are more than 30 days past due.

The Company considers a financial asset in default when contractual payments are 90 days past due. However, in certain cases, the Company may also consider a financial asset to be in default when internal or external information indicates that the Company is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Company. A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

Financial liabilities

Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, loans and borrowings, payables, or as derivatives designated as hedging instruments in an effective hedge, as appropriate. All financial liabilities are recognised initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs. The Company's financial liabilities include trade and other payables. The Company does not have financial liabilities at fair value through profit and loss.

Derecognition

A financial liability is derecognised when the obligation under the liability is discharged or cancelled or expires.

k) Cash and short-term deposits

Cash and short-term deposits in the statement of financial position comprise cash at banks and short-term deposits with a maturity of three months or less, which are subject to an insignificant risk of changes in value.

l) Provisions

Provisions are recognised when the Company has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation.

m) Pensions and other post-employment benefits

PCI Biotech AS has an agreement with a life assurance company concerning contribution-based pensions for employees. Contributions, ranging from 7% to 21% of the employee's ordinary salary up to 12 times the basic amount (G) of the Norwegian National Insurance scheme, are paid into the employee's contribution account with the life assurance company. The Company's payment of contributions is expensed in the period it is accrued. Any prepayments made to the contribution fund are recognised in the balance sheet.

n) Share-based payments

Employees (including senior management) of the Company receive remuneration in the form of share-based payments from the parent company PCI Biotech Holding ASA, whereby employees render services as consideration for equity instruments (equity-settled transactions).



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Equity-settled transactions

The cost of equity-settled transactions is determined by the fair value at the date when the grant is made using the Black-Scholes valuation model. That cost is recognised, together with a corresponding increase in other capital reserves in equity, over the period in which the service conditions are fulfilled in employee benefits expense. The cumulative expense recognised for equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and the Company's best estimate of the number of equity instruments that will ultimately vest. The statement of profit or loss expense or credit for a period represents the movement in cumulative expense recognised as at the beginning and end of that period and is recognised in employee benefits expense. See Note 8 Salary expenses and other remuneration for further information.

No expense is recognised for awards that do not ultimately vest, except for equity-settled transactions for which vesting are conditional upon a market or non-vesting condition. These are treated as vesting irrespective of whether or not the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied. When the terms of an equity-settled award are modified, the minimum expense recognised is the expense had the terms not been modified, if the original terms of the award are met. An additional expense is recognised for any modification that increases the total fair value of the share-based payment transaction, or is otherwise beneficial to the employee as measured at the date of modification.

o) License costs

Agreements with external parties concerning access to technology in the form of license agreements and agreements that allow the use of patented technology are expensed when they occur according to the agreement and are disclosed as "Research and development expenses" in the income statement.

p) Segment reporting

Segments are reported similarly as the internal reporting to the Company's senior decision makers. Senior decision makers are defined as the Company's management group. The Company has only one segment and see Note 6 for further information.

q) Cash-flow statement

The statement of cash flows distinguishes between cash flows from operating, investing and financing activities and the statement has been prepared in accordance with the indirect method. For the purpose of the statement of cash flows, cash and cash equivalents consist of cash at banks and short-term deposits with a maturity of three months or less. Cash and cash equivalents denominated in foreign currencies are translated at the functional currency spot rates of exchange at the reporting date. Differences arising from translation of these monetary items are not considered to be related to operations and are presented as part of net changes in cash and cash equivalents. Interest paid and interest received are included under cash flow from operating activities. Cash flows from share issues are recognised as cash flows from financing activities.

r) Events after the balance sheet date

New information regarding the Company's financial position on the balance sheet date has been taken into account in the annual accounts. Events after the balance sheet date that do not affect the Company's financial position on the balance sheet date, but which will affect the Company's financial position in the future, are reported if they are significant.

s) Contingent liabilities and assets

Contingent liabilities are defined as:

- Possible liabilities as a result of earlier events where their existence depends on future events

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- Liabilities that is not included because it is not probable that they will lead to an outflow of resources from the Company
- Liabilities that cannot be measured with sufficient reliability.

Contingent liabilities are not included in the annual accounts. Notes on significant contingent liabilities are provided, with the exception of contingent liabilities with little probability of occurring. Contingent assets are not included in the annual accounts, but are reported in cases in which there is a certain likelihood of their resulting in a benefit to the Company.

2.3 Changes in accounting policies and disclosures

New and amended standards and interpretations

The Company applied for the first-time certain standards and amendments, which are effective for annual periods beginning on or after 1 January 2020, but they do not have an impact in the financial statement of the Company. The Company has not early adopted any other standard, interpretation or amendment that has been issued but is not yet effective.

The following standards and amendments are applied for the first time in the 2020 accounts,

- * Amendments to IFRS 7, IFRS 9 and IAS 39 Interest Rate Benchmark Reform
- * Amendments to IAS 1 and IAS 8 Definition of Material
- * Conceptual Framework for Financial Reporting issued on 29 March 2018 (revised)

These amendments had no impact on the financial statement of the Company for 2020.

3. Significant accounting judgments, estimates and assumptions

The preparation of the Company's financial statement requires management to make judgments, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and the accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of assets or liabilities affected in future periods.

Other disclosures relating to the Company's exposure to risks and uncertainties includes:

- Financial risk management and policies Note 14 Financial risk.

Judgments

In the process of applying the Company's accounting policies, management has made the following judgments, which have the most significant effect on the amounts recognised in the financial statements:

- The fair value of employee options is calculated according to the Black-Scholes method. This method involves the use of estimates and discretionary judgment, as described in more detail in Note 8. The allocation of options to employees of subsidiary is made directly from the parent company and the financial presentation is correspondingly reported in the subsidiary.
- The Company has not recognised a deferred tax asset related to carry forward losses, as described in more detail in Note 12 Tax.
- Regarding development of pharmaceuticals and medical equipment the Company cannot render probable future earnings large enough to justify recognising development costs in the balance sheet before marketing approval has been obtained, in accordance with IAS 38 Intangible assets. Own development costs are therefore recognised as an expense as incurred until national market approval for the product and indication has been obtained. Any further development of the product after marketing approval has been obtained and market launch completed will be recognised in

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the balance sheet to the extent that this involves significant changes to the product, which is considered likely to generate future financial benefits.

- Regarding IFRS 16 and leasing costs, the Company cannot readily determine the interest rate implicit in the lease, therefore, it uses its incremental borrowing rate (IBR) to measure lease liabilities. The IBR is the rate of interest that the Company would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the right-of-use asset in a similar economic environment. The IBR therefore reflects what the Company 'would have to pay', which requires estimation when no observable rates are available.

4. Standards issued, but not yet effective

The new and amended standards and interpretations that are issued, but not yet effective, up to the date of issuance of the Company's financial statements are disclosed below. The Company intends to adopt these new and amended standards and interpretations, if applicable, when they become effective.

Amendments to IAS 1: Classification of Liabilities as Current or Non-current. The Company is currently assessing the impact the amendments will have on current practice.

The following other standard are currently not applicable to the Company:

*IFRS 17 Insurance contracts.

*Property, Plant and Equipment: Proceeds before Intended Use – Amendments to IAS 16.

*Onerous Contracts – Costs of Fulfilling a Contract – Amendments to IAS 37.

*IFRS 1 First-time Adoption of International Financial Reporting Standards – Subsidiary as a first-time Adopter.

*IFRS 9 Financial Instruments – Fees in the '10 per cent' test for derecognition of financial liabilities.

*IAS 41 Agriculture – Taxation in fair value measurements



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5 OTHER INCOME

OTHER INCOME

(figures in NOK 1,000)

	2020	2019
SkatteFUNN	4 750	5 777
Grants from the Research Council of Norway	2 573	3 615
Other	45	0
Total other income	7 368	9 392

Government grants are recognised at the value of the contributions at the transaction date. Grants are not recognised until it is probable that the conditions attached to the contribution will be achieved. The grant is recognised in the statement of profit and loss in the same period as the related costs, and are disclosed as other income. R&D projects have been approved for SkatteFUNN for the period 2020 through 2022. The Company is awarded a grant from The Research Council of Norway (user-driven research-based innovation programme (BIA)) of up to NOK 13.8 million in total for the period June 2017 through June 2021 and per end of 2020 a total of NOK 12.0 million are recorded. Grant receivables as of year-end are disclosed in Note 16 Receivables.

6 OPERATING SEGMENTS

The Company has only one operating segment, which is research and development, and had no revenues for the reporting periods. Norwegian government grants that are received in the reporting periods are disclosed as other income, see Note 5 Other income.

7 STATEMENT OF COMPREHENSIVE INCOME ACCORDING TO CLASSIFICATION AND R&D EXPENSES BY CATEGORY

Operating costs according to classification.

(figures in NOK 1,000)

	Note	2020	2019
Salary expenses	8	21 967	23 291
R&D exclusive salary and other operating expenses		55 389	64 341
Depreciation and amortisation	13,22	2 208	955
Other operating expenses		5 261	5 025
Total operating expenses		84 825	93 614

Of the total salary expenses NOK 15 379 relates to R&D activities (2019: NOK 16 021).

Specification of other operating expenses

	2020	2019
Travel expenses	132	912
Patent, legal and other fees	2 720	1 818
Other expenses	2 409	2 296
Total other operating expenses	5 261	5 025



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R&D expenses by category:

	2020	2019
Clinical studies	57 761	62 971
Pre-clinical studies	6 607	6 198
CMC and equipment	6 637	10 716
Patents	4 566	3 427
Other expenses	0	0
Total R&D expenses	75 571	83 312

The Company has no development expenditure that qualifies for recognition of an asset under IAS 38 and intangible assets and all research expenditures are charged through the income statement, in line with previous years. A new batch of the product under development (fimaporfin) was produced in 2019 and an estimated cost value of fimaporfin in stock per year end is NOK 3.8 million (2019: NOK 4.3 million).

PCI Biotech has per date of this report not a complete picture of the long-term consequences of the COVID-19 pandemic regarding timelines and costs for clinical studies (the RELEASE trial). In 2020 the pandemic resulted in lower than expected patient recruitment into the RELEASE trial.

8 SALARY EXPENSES AND OTHER REMUNERATION

(figures in NOK 1,000)

	2020	2019
Wages and Board of Directors remuneration	16 000	12 598
Social security contributions	2 629	2 077
Share-based payments, incl social security	1 291	7 199
Pension costs	1 627	1 224
Other expenses	419	194
Total salary expenses	21 967	23 291
No. of full-time equivalent positions	14.2	8.7

Share option programme for employees

Employees (including senior management) of the Company receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity instruments (equity-settled transactions). The employees are employed in the group subsidiary, PCI Biotech AS, and the share-based payment is thus accounted for as a P&L effect in the PCI Biotech AS accounts and an investment in subsidiary in the parent company, PCI Biotech Holding ASA, accounts. The general vesting term in the employee share option scheme is three years, with one third vested each year. The share options expire five years from grant date. All share options will lapse immediately upon the event that the employee's employment with the company are terminated. Each share option gives the right to subscribe for or acquire one share upon PCI Biotech Holding ASA's choice. The strike price is set at market terms and no premium for the share options are paid. The Black-Scholes method is used for fair value assessment of the share options at grant date. Further details about the share option program can be found in PCI Biotech Holding ASA's remuneration policy.



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Valuation method for fair value assessment of share options granted

The Black-Scholes method is used for fair value assessment of the share options at grant date. Volatility is calculated based on PCI Biotech Holding ASA's stock market price. The exercise price is set at market terms, equal to the average volume weighted share price last five days of trade prior to grant date (5 days VWAP), and no premium for the share options are paid. The risk free interest rate is based on Norwegian 3-5 years government bond yield. Each option program is calculated separately with actual exercise price and lifetime for the program. The table below shows the input values used in the fair value assessment model at grant date.

Fair value for share options granted in 2020 were NOK 20.7 million (2019: NOK 6.8 million). The fair value estimated at grant date is amortised over the vesting period of three years.

Share options granted in 2020 and 2019	October 2020	June 2019
Number of share options	540 000	320 000
Dividend	0	0
Historical volatility (%)	107 %	110 %
Risk free interest rate (%)	0.37 %	1.21 %
Expected lifetime (years)	5	5

Authorisation from the annual general meeting

The general meeting held 27 May 2020 authorised the Board of Directors of PCI Biotech Holding ASA to grant the employees with a total of 2,790,000 share options and the authorisation applies for one year. 1,245,500 share options of the current authorisation have been granted by the Board of Directors at year-end 2020, including the 60,500 share options exercised in September 2020. See note 21 Related party transactions for further information.

Share option transactions during the year

Participants in the Company's share option program exercised on 2 September 2020 a total number of 60,500 share options in PCI Biotech Holding ASA, out of these 26,000 share options were exercised at a strike price of NOK 7.84 and 34,500 share options were exercised at a strike price of NOK 3.26. All of the exercised share options were about to expire unless exercised.

Out of the total number of exercised share options, 54,500 share options are exercised in PCI Biotech Holding ASA by the following primary insiders:

Primary insider Per Walday (CEO) has on 2 September 2020 exercised a total number of 9,000 share options at a strike price of NOK 3.26. The share options were granted to Walday in November 2015 and now about to expire unless exercised. Subsequent to the exercise he has sold 4,600 shares in the market at an average price of NOK 45.6 per share in order to finance the cash and tax impact of the transaction.

Primary insider Ronny Skuggedal (CFO) has on 2 September 2020 exercised a total number of 20,000 share options at a strike price of NOK 7.84 and a total number of 6,000 share options at a strike price of NOK 3.26. The share options were granted to Skuggedal in April 2015 and November 2015 and now about to expire unless exercised. Subsequent to the exercise he has sold 14,000 shares in the market at an average price of NOK 45.6 per share in order to finance the cash and tax impact of the transaction.

Primary insider Kristin Eivindvik (PD) has on 2 September 2020 exercised a total number of 6,000 share options at a strike price of NOK 7.84 and a total number of 7,500 share options at a strike price of NOK 3.26. The share options were granted to Eivindvik in April 2015 and November 2015 and now about to expire unless exercised. Subsequent to the exercise she has sold 7,100 shares in the market at an average price of NOK 45.6 per share in order to finance the cash and tax impact of the transaction.



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Primary insider Anders Høgset (CSO) has on 2 September 2020, as a participant in the Company's share option program, exercised a total number of 6,000 share options at a strike price of NOK 3.26. The share options were granted to Høgset in November 2015 and now about to expire unless exercised. Subsequent to the exercise he has sold 4,500 shares in the market at an average price of NOK 45.6 per share.

In accordance with the authorisation granted by the Annual General Meeting 27 May 2020, the Board of Directors of PCI Biotech Holding ASA awarded a total of 540,000 share options to key employees on 6th October 2020. Each share option gives the right to subscribe for or acquire one share per option (after PCI Biotech Holding ASA's choice), at a strike price of NOK 50.36, equal to the volume weighted average share price (VWAP) for the last 5 days of trade prior to the grant date.

The share options vest over approximately three years and can be exercised with 1/3 of the options after approximately one year, further 1/3 after approximately two years and the last third after approximately three years. To ensure long term ownership by executive management, shares shall be held for at least three years after exercise, except shares to be sold immediately to cover transaction costs and tax under a so called cash less exercise.

The Black-Scholes method is used for fair value assessment of the share options at grant date and the fair value is assessed to NOK 20.7 million which will be charged to the profit and loss statement over the vesting period for the share options. The share options are subject to other customary terms and conditions for employee incentive programs and the share options are lapsing in Q3 2025.

Of the 540,000 share options, 400,000 share options were allotted to the following primary insiders: 90,000 share options were allotted to Amir Snapir, CMO. 90,000 share options were allotted to Ludovic Robin, CBO. 70,000 share options were allotted to Per Walday, CEO. 50,000 share options were allotted to Anders Høgset, CSO. 50,000 share options were allotted to Ronny Skuggedal, CFO. 50,000 share options were allotted to Lucy Wabakken, CDO (acting).

Share option transactions during 2019

Participants in the Company's share option program exercised on 20 February 2019 a total number of 61,000 share options in PCI Biotech Holding asa. Out of these share options 30,000 were exercised at a strike price of NOK 19.24, 15,000 share options were exercised at a strike price of NOK 7.84, 11,000 share options were exercised at a strike price of NOK 3.26 and 5,000 share options were exercised at a strike price of NOK 21.48.

Out of the total number of exercised share options, 5,000 share options at a strike price of NOK 21.48 and 6,000 share options at a strike price of NOK 3.26 were exercised by the primary insider Gaël L'Hévéder (CBDO at that time), who sold 5,300 shares in the market at an average price of NOK 25.75 per share in order to finance the cash and tax impact of the share option exercise.

Out of the total number of exercised share options, 30,000 share options at a strike price of NOK 19.24 were exercised by the primary insider Hans Olivecrona (CMO at that time), who has sold 30,000 shares in the market at an average price of NOK 25.75 per share.

The Board of Directors of PCI Biotech Holding ASA awarded in June 2019 a total of 320,000 share options under the employee share option program. Each share option gives the right to subscribe for or acquire one share per option (after PCI Biotech Holding ASA's choice), at a strike price of NOK 25.78, equal to the volume weighted average share price (VWAP) for the last 5 days of trade prior to the grant date. The share options can be exercised with 1/3 of the options after one year, further 1/3 after two years and the last third after three years. To ensure long term ownership by executive management, shares shall be held for at least three years after exercise, except shares to be sold immediately to cover transaction costs and tax under a so called cash less exercise. The share options are subject to other customary terms and conditions for employee incentive programs and the share options are lapsing in Q3 2024.

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The Black-Scholes method is used for fair value assessment of the share options at grant date and the fair value is assessed to NOK 6.8 million which will be charged to the profit and loss statement over the vesting period for the share options. During 2019 a total number of 70,000 non-vested share options were terminated due to cease of employment. Expenses for these share options charged through profit and loss in previous periods have been reversed in 2019, with a net positive effect of NOK 1.0 million.

In September 2019 participants of the company's share option program for employees exercised a total number of 40,000 share options in PCI Biotech Holding ASA. All share options were exercised by the primary insider Ronny Skuggedal (CFO), at a strike price of NOK 8.63. Mr Skuggedal sold at the same time 25,300 shares in the market at an average price of NOK 27.08 per share in order to finance the cash and tax impact of the share option exercise.

P&L and balance sheet effects of the share option programme

The net P&L accounting effect for share-based payments and corresponding social security liability following future share option exercises were a net cost of NOK 1.3 million (2019: NOK 7.2 million). The potential social security liability for future exercises are calculated based upon share options that are in-the-money per reporting date and recognised as a short- or long-term liability in the balance sheet depending on vesting date of the underlying share options.

Share options outstanding at the end of the period have the following expiry date and exercise prices:

Expiry date	Exercise price in NOK per share	Number of share options	
		2020	2019
2020 - Q3	7.84	-	26 000
2020 - Q3	3.26	-	34 500
2022 - Q3	21.48	325 000	325 000
2024 - Q3	25.78	320 000	320 000
2025 - Q3	50.36	540 000	-
Sum		1 185 000	705 500



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Options granted to employees, average exercise price and transactions during the year is listed below:

	2020		2019	
	Number	Average exercise price in NOK per share	Number	Average exercise price in NOK per share
Outstanding at the beginning of the year	705 500	17.70	556 500	17.70
Granted during the year	540 000	50.36	320 000	25.78
Lapsed during the year	0	-	0	7.12
Exercised during the year	60 500	5.23	101 000	11.72
Expired during the year	0	-	70 000	25.14
Outstanding at year end	1 185 000	35.80	705 500	22.04
Exercisable options at year end	431 667	22.54	277 167	17.93

Exercise price and average remaining lifetime for outstanding options per year-end:

Number of options 2020 / 2019	Exercise price in NOK per share	Average remaining lifetime (years)	
		2020	2019
0 / 26 000	7.84	-	0.7
0 / 34 500	3.26	-	0.7
325 000 / 325 000	21.48	1.7	2.7
320 000 / 320 000	25.78	3.7	4.7
540 000 / 0	50.36	4.7	-

9 PENSION EXPENSES

(figures in NOK 1,000)

	2020	2019
Total pension cost from contribution schemes	1 627	1 224

The contribution pension scheme is in compliance with Norwegian public requirements and a total of fourteen employees are included in the scheme at year-end 2020 (2019: twelve employees), in addition to one employee in a Finnish pension scheme.

10 AUDITORS FEE

AUDITOR FEES

(figures in NOK 1,000)

	2020	2019
Statutory audit	63	64
Other assurance services	44	27
Total	107	91



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11 FINANCIAL INCOME AND EXPENSES

(figures in NOK 1,000)

	2020	2019
Interest income	1 765	2 382
Other financial income	537	339
Total financial income	2 302	2 721
Interest expense	15	8
Interest expense leasing	75	37
Other financial expense	518	645
Total financial expense	608	690

12 TAX

(figures in NOK 1,000)

	2020	2019
Comprehensive income before tax	-72 239	-88 925
Expected nominal rate of tax (2020: 22% / 2019: 22%)	-15 893	-19 524
Permanent differences charged through P&L	343	-737
Deferred tax asset not recognised in the balance sheet	15 549	20 261
Total tax expense for the year	0	0

Specification of basis for deferred tax asset / liability

Tax effect of temporary differences:

	2020	2019
Fixed assets	184	423
Other	-101	0
Carry forward loss	-115 469	-98 843
Total tax asset (22% for 2019 / 22% for 2018)	-115 386	-98 420
Deferred tax asset not recognised	115 386	98 420
Deferred tax asset recognised in the balance sheet	0	0

The Company has no history of taxable profit and due to uncertainty of future utilisation, deferred tax asset has not been recognised in the balance sheet. The carry forward loss has no time limit according to current tax legislations.



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13 FIXED AND INTANGIBLE ASSETS

(figures in NOK 1,000)

	Device (laser)	Office equipment	Total
Acquisition cost per 31 December 2018	0	337	337
Additions in 2019	5 349	55	5 405
Disposals and scrapping during 2019	0	0	0
Acquisition cost per 31 December 2019	5 349	392	5 742
Additions in 2020	3 919	0	3 919
Disposals and scrapping during 2020	0	0	0
Acquisition cost per 31 December 2020	9 268	392	9 661
Accumulated depreciation per 31 December 2018	0	320	320
Ordinary depreciation 2019	339	10	349
Disposals in 2019	0	0	0
Accumulated depreciation per 31 December 2019	339	330	669
Ordinary depreciation 2020	1 589	13	1 603
Disposals in 2020	0	0	0
Accumulated depreciation per 31 December 2020	1 928	343	2 272
Book value per 31 December 2019	5 010	62	5 072
Book value per 31 December 2020	7 340	48	7 388

The laser device is for the fimaCHEM programme. The COVID-19 pandemic has not impacted the valuation of fixed assets per year-end 2020.

14 FINANCIAL RISK

This note describes the Company's various financial risks and the management of these. In addition, numerical tables for risk associated with financial risks are also presented.

(I) Organisation of financial risk management

PCI Biotech has an international business operation and is exposed to currency risk, interest risk, liquidity risk and credit risk. The Company has not utilised any derivatives or other financial instruments to reduce these risks during the accounting period. The responsibility for managing financial risk is at group level. The risk associated with centralised activities such as financing, interest rate and currency management is managed at group level. In addition, the group manages the risks associated with the business processes. The financial risk management is monitored by the Board of Directors of PCI Biotech Holding ASA.

Centralised risk management

PCI Biotech has a centralised risk management policy. The most important tasks within risk management are to ensure the group's financial freedom to act both in a short- and long term perspective, and to monitor and manage financial risk in cooperation with the individual units in the group. A hedging-oriented view forms the basis for risk management of the finance department's positions so that all transactions with financial instruments have a counter item in an underlying commercial hedging requirement. Any permits required for borrowing and entering into derivative framework agreements are given on an annual basis by the Board of Directors of PCI Biotech Holding ASA.



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Financial risk

This section describes the most important risk factors within each business area and the management of these. In this context, financial risk is understood as risk associated with financial instruments. These can either be hedging instruments for underlying risk or be considered themselves as a source of risk. Market risk is not hedged with financial instruments.

Research and development activities

PCI Biotech carries out research and development for new innovative medical products based on the company's patented technology. The currency risk in research and development is limited to the purchase of services, primarily related to clinical and pre-clinical studies. Foreign currency risk associated with purchase of goods and services are foremost related to transactions in EUR and GBP. Foreign currency exposure associated with research and development is not normally hedged, but at year-end 2020 the group has placed cash deposits in EURO to hedge the foreign currency risk for the RELEASE study.

(II) Classes of financial risk

Interest rate risk

PCI Biotech does not have any interest-bearing debt, and the group's interest rate risk is primarily associated with the group's cash positions and cash equivalents. This risk is managed at group level. The main strategy is to diversify the risk and invest in cash deposits with fixed or spot interest rates or money market funds with low risk, high liquidity and short duration. All funds are placed as cash deposits per year-end 2020.

Liquidity risk

One of the most important objectives of PCI Biotech's finance policy is to ensure that the group has financial freedom to act in the short and long-term in order to attain strategic and operational goals. PCI Biotech shall have sufficient funds to cover expected capital requirements during the forthcoming 12 month period in addition to a strategic reserve. Cash flow in research and development depends mainly on the activity level of the clinical programmes and the activity levels are adjustable without substantial long term commitments. The finance department monitors the cash flows in a short- and long term perspective. PCI Biotech's most important source of finance are future royalty and milestone payments associated with licence agreements, government grants and the capital market. The capital market is used as a source of liquidity when this is appropriate and the conditions in these markets are competitive. The finance department continually evaluate other sources of financing. PCI Biotech does not have any debt agreements with key business ratio requirements (covenants).

PCI Biotech has per date of this report not a complete picture of consequences of the COVID-19 pandemic regarding timelines and costs for the RELEASE study. Given the uncertainty surrounding long-term consequences of the unprecedented situation with the COVID-19 pandemic, the anticipated timeline for the planned interim analysis is in a range up to 1H 2023, and the current cash-position may therefore not be sufficient to reach interim read of the RELEASE trial. PCI Biotech will continue to closely monitor progress in relation to timelines and costs in the coming months.

Credit risk

PCI Biotech has no sales or receivable balances based on sales for 2020 and 2019 and faces therefore no credit risk. PCI Biotech has no need for monitoring of receivable balances based on sales and no bad debt provision has been recognised during 2020 or 2019. The majority of the Company's financial assets are cash and cash equivalents and these funds are placed in cash deposits in different banks with satisfactory credit ratings. The credit risk for these funds is assessed to be low and no impairment test are performed for 2020 or 2019.



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The following table shows an overview of the maturity structure of the Company's financial obligations, based on non-discounted contractual payments.

(figures in NOK 1,000)

	Remaining period				Total
	Less than 1 month	1-3 months	3-12 months	1-5 years	
31.12.2020					
Other long-term liabilities	0	0	0	32	32
Trade accounts payables	5 130	0	0	0	5 130
Current lease liabilities	168	168	336	0	673
Public duties payables	950	165	863	0	1 978
Other current liabilities, intragroup	0	0	19 021	0	19 021
Other current liabilities	175	4 516	6 290	0	10 981
31.12.2019					
Other long-term liabilities	0	0	0	2 037	2 037
Long term lease liabilities	0	0	0	539	539
Trade accounts payables	8 452	0	0	0	8 452
Current lease liabilities	164	164	329	0	657
Public duties payables	795	0	3 770	0	4 565
Other current liabilities, intragroup	0	0	28 011	0	28 011
Other current liabilities	60	3 986	5 787	0	9 832

Other long-term liabilities relates to estimated social securities for potential future share option exercises in the group's remuneration incentive program.

Foreign currency risk

As NOK is the Company's functional currency, PCI Biotech is exposed to foreign currency risk associated with the Company's foreign net exchange rate exposure. The Company's expenses accrue in various currencies, primarily EUR, GBP, USD, SEK and NOK. The Company evaluates whether measures should be taken to reduce the foreign currency risk through hedging for significant transactions and projects.

The following table details the Company's sensitivity to potential changes in the foreign currency exchange rate, with all other factors constant. The calculation assumes an equal change in exchange rates against all relevant foreign currencies. The estimated effect on operating result is due to changes in value of monetary items in the balance sheet per year end.

	Changes in exchange rates	Effect on operating result
2020	+/- 10 %	+/- 298
2019	+/- 10 %	+/- 1 372



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15 CLASSIFICATION OF FINANCIAL ASSETS AND LIABILITIES

(Figures in NOK 1,000)

31.12.2020

	Financial instruments at amortised cost	Financial instruments at fair value through OCI	Total
Assets			
Other current receivables	13 076	0	13 076
Cash and cash equivalents	0	119 493	119 493
TOTAL FINANCIAL ASSETS	13 076	119 493	132 569
Liabilities - other financial liabilities			
Other long-term liabilities	32	0	32
Trade accounts payables	5 130	0	5 130
Current lease liabilities	673	0	673
Public duties payables	1 978	0	1 978
Other current liabilities, intragroup	19 021	0	19 021
Other current liabilities	10 981	0	10 981
TOTAL FINANCIAL LIABILITIES	37 815	0	37 815

(Figures in NOK 1,000)

31.12.2019

	Financial instruments at amortised cost	Financial instruments at fair value through OCI	Total
Assets			
Other current receivables	14 578	0	14 578
Cash and cash equivalents	0	138 308	138 308
TOTAL FINANCIAL ASSETS	14 578	138 308	152 886
Liabilities - other financial liabilities			
Other long-term liabilities	2 037	0	2 037
Long term lease liabilities	539	0	539
Trade accounts payables	8 452	0	8 452
Current lease liabilities	657	0	657
Public duties payables	4 565	0	4 565
Other current liabilities, intragroup	28 011	0	28 011
Other current liabilities	9 832	0	9 832
TOTAL FINANCIAL LIABILITIES	54 092	0	54 092

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16 RECEIVABLES

Receivables are measured by the amortised cost method, but due to the assets being short term receivables the non-discounted contractual payments are disclosed. No credit losses allowance are recognised at year end 2020 or 2019.

Other current receivables - specification

(Figures in NOK 1,000)

	31.12.2020	31.12.2019
Recognised not received government grants	5 373	6 725
Prepaid payables	7 122	7 365
VAT receivables	581	255
Recognised not received financial income	0	232
Total other receivables	13 076	14 578

17 CASH AND CASH EQUIVALENTS

(Figures in NOK 1,000)

	31.12.2020	31.12.2019
Cash and cash equivalents, restricted ⁽¹⁾	799	1 127
Cash and cash equivalents, non-restricted	118 694	137 181
Sum	119 493	138 308

(1) Restricted cash and cash equivalents are security for the employees' withholding tax and a bank deposit of NOK 111 thousand.

The carrying amount of cash and cash equivalents is approximately equal to fair value since these instruments have a short term to maturity. The cash and cash equivalents are placed in cash deposits in NOK and EUR in different banks with satisfactory credit ratings. The credit risk for these funds is assessed to be low and no impairment test are performed for 2020 or 2019.

18 SHARE CAPITAL

	No. of shares	Nominal value per share in NOK	Share capital in NOK
Share capital as per 31.12.2018	3 232 600	1,50	4 848 900
Share issues in 2019	-	0,10	323 260
Share capital as per 31.12.2019	3 232 600	1,60	5 172 160
Share issues in 2020	-	0,10	323 260
Share capital as per 31.12.2020	3 232 600	1,70	5 495 420

All shares have equal voting rights and otherwise have equal rights in the company and one share represents one voting right. Ordinary shares are classified as equity and only one class of shares exists. Expenses that are directly attributable to the issue of ordinary shares are disclosed as reduction of equity.

In November 2020 a capital increase of NOK 70 million was resolved, by contribution in kind of an intragroup loan from the parent company, PCI Biotech Holding ASA. After the transaction the share capital is NOK 5,495,420 divided by 3,232,600 shares, each with a nominal value of NOK 1.70. The company is a wholly owned subsidiary by PCI Biotech Holding ASA.



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Shares owned in the parent company PCI Biotech Holding ASA, directly or indirectly, by members of the board and management team and their personally related parties per 31.12.2020 and per 31.12.2019:

Name	Position	31.12.2020	31.12.2019
Per Walday	CEO	72 700	68 300
Anders Høgset	CSO	64 800	63 300
Ronny Skuggedal	CFO	55 000	43 000
Kristin Eivindvik	CDO	25 200	18 800
Lucy Wabakken, and related parties	CDO (acting)	10 008	NA
Ludovic Robin*	CBO	-	NA
Amir Snapir*	CMO	-	NA
Total		227 708	193 400

* Ludovic Robin and Amir Snapir joined the Company in May 2020, and holdings from that date are reported.

19 FINANCING STRUCTURE

The Company had no external interest-bearing debt as of 31.12.2020 or 31.12.2019. At current stage the Company is in a research and development phase and is financially dependent on support from the parent company, PCI Biotech Holding ASA. See Note 23 Going concern for further details

20 OTHER CURRENT LIABILITIES BY YEAR END

(Figures in NOK 1,000)

	31.12.2020	31.12.2019
Accruals for incurred external R&D expenses	6 440	7 213
Accruals for employee bonus, holiday payments, board remuneration etc.	4 541	2 618
Total other current liabilities	10 981	9 832

Other current liabilities are measured by the amortised cost method, but due to the liabilities being short term liabilities the non-discounted contractual payments are disclosed.

21 RELATED PARTIES TRANSACTIONS

Figures for remuneration are expensed amounts in the financial year.

(Figures in NOK 1,000)	Board		Other Pension		Total	
	remuneration	Salary	Bonus	benefits		
Senior executives 2020						
Per Walday, CEO*	0	2 031	317	400	154	2 902
Ronny Skuggedal, CFO*	0	1 434	258	1 027	153	2 873
Anders Høgset, CSO*	0	1 124	106	273	131	1 633
Kristin Eivindvik, PD*	0	1 017	54	558	130	1 759
Lucy Wabakken, CDO (acting)	0	1 094	92	19	127	1 331
Ludovic Robin, CBO**	0	1 110	0	65	0	1 175
Amir Snapir, CMO**	0	1 271	0	44	183	1 497
Total senior executives remuneration	0	9 080	827	2 386	878	13 171

* "Other benefits" include salary benefits in relation to exercise of share options in PCI Biotech Holding ASA during 2020.

** Ludovic Robin and Amir Snapir joined the Company in May 2020.

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(Figures in NOK 1,000)

	Board remuneration	Salary	Bonus	Other benefits	Pension benefits	Total
Senior executives 2019						
Per Walday, CEO	0	1 812	346	18	132	2 307
Ronny Skuggedal, CFO*	0	1 290	182	751	132	2 355
Anders Høgset, CSO	0	1 092	143	18	111	1 364
Gaël L'Hévéder, CBDO**	0	553	0	198	28	779
Kristin Eivindvik, PD	0	1 090	82	13	113	1 298
Hans Olivecrona, CMO***	0	681	100	273	65	1 119
Total senior executives remuneration	0	6 518	853	1 271	580	9 222

* "Other benefits" include salary benefits in relation to exercise of share options during 2019.

** "Other benefits" include salary benefits in relation to exercise of share options during 2019 and Gaël L'Hévéder resigned from his position by end of March 2019.

*** "Other benefits" include salary benefits in relation to exercise of share options during 2019 and Hans Olivecrona transitioned from an employee to an external consultant from 1 July 2019. Mr. Olivecrona received SEK 233 thousand in consultancy fee's for 2019.

PCI Biotech's policy as regards the determination of salary and other remuneration to senior executives is to have market based remuneration and provide other benefits that are competitive in employment for senior executives. It is important to attract the required expertise and experience to create value and contribute to the mutual interests between owners and senior executives. The performance-based remuneration shall be linked to value creation for shareholders or long-term performance of the group.

The main principles for remuneration of the group's senior executives are as follows:

- Salaries are reviewed annually
- Bonuses are calculated on the basis of goals for the group established by the Board of Directors and achievement of personal goals. The group's Chief Executive Officer (CEO) has a bonus agreement for up to 30% of annual salary, other senior executives have bonus agreements of up to 10 - 25% of annual salary.
- Senior executives, and other key employees, participate in the group's share option incentive scheme
- Senior executives participate in the group's general pension scheme

Bonuses for senior executives are determined on the basis of the group's financial results and development, and achievement of personal goals.

The senior executives participate in the group's pension plan that is a defined contribution plan which entails payment of 7% to 21% of the employee's annual salary up to 12 times the basic National Insurance amount (G). The pension scheme also covers in the event of disability.

The CEO is entitled to six months' notice and has an agreement of additional 6 months' salary on certain terms. There are no agreements beyond the statutory requirements for other senior executives.

Senior executives have not received any remuneration or financial benefits from other companies in the group other than those disclosed above. It is not given additional remuneration for special services outside the normal functions of a senior executive.

There are no loans or pledges to senior executives, board of directors, employees or other persons in elected corporate bodies.

Senior executive's shareholdings in PCI Biotech Holding ASA are disclosed in note 18 Share capital. Allocation, exercise and holdings of share options in the parent company, PCI Biotech Holding ASA, for senior executives are presented in the table below:



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Overview share options, Senior executives	Total holdings 31.12.2019	Allocated	Lapsed	Exercised	Expired	Total holdings 31.12.2020	Average exercise price in NOK
Per Walday, CEO	164 000	70 000	0	9 000	0	225 000	31.61
Ronny Skuggedal, CFO	116 000	50 000	0	26 000	0	140 000	33.02
Anders Høgset, CSO	106 000	50 000	0	6 000	0	150 000	32.25
Kristin Eivindvik, PD	73 500	10 000	0	13 500	0	70 000	28.06
Lucy Wabakken, CDO (acting)	70 000	50 000	0	0	0	120 000	34.59
Ludovic Robin, CBO*	NA	90 000	0	0	0	90 000	50.36
Amir Snapir, CMO*	NA	90 000	0	0	0	90 000	50.36
Sum	529 500	410 000	0	54 500	0	885 000	

* Ludovic Robin and Amir Snapir joined the Company in May 2020 and holdings from that date are disclosed

Related parties:

PCI Biotech Holding ASA:

The parent company, PCI Biotech Holding ASA, has no employees. The group operations are managed through the wholly owned subsidiary PCI Biotech AS that has a management service agreement with the parent company, including services like management, offices, finance and investor relation functions for the group. All transactions are performed at market terms.

The parent company has been charged for operations according to the service agreement of NOK 1.9 million in 2020 (2019: NOK 2.0 million). The parent company has charged PCI Biotech AS interest expenses for intercompany loans of NOK 2.9 million during 2020 (2019: NOK 6.7 million). Net current intragroup liabilities to PCI Biotech Holding ASA at year-end 2020 were NOK 19.0 million (2019: NOK 28.0 million). In 2020 an intercompany loan of NOK 70 million was utilised as contribution in kind from PCI Biotech Holding ASA for a capital increase in PCI Biotech AS.

22 RIGHT TO USE ASSETS AND LEASE LIABILITIES

PCI Biotech has entered into a lease agreement with Oslo Cancer Cluster Incubator, Ullernchausséen 64 Oslo, Norway. The lease originally runs to 31 December 2018, but PCI Biotech exercised an option for three more years and the lease now runs to 31 December 2021 with an option for additional three more years. The lease agreement is subject to annual adjustment according to changes in the consumer price index. Amounts of minimum lease payment for non-cancellable operating leases is NOK 0.7 million (non-discounted contractual payments) per year end 2020 for the year 2021.

In 2019 PCI Biotech recognised NOK 1.8 million in right of use assets and a corresponding lease liability which were disclosed in the balance sheet as long- and short-term liabilities depending on maturity of the corresponding lease payments. The initial recognised amount is based upon contractual minimum lease payments for 2019-2021 and discounted by the incremental borrowing rate at the date of initial application. The relevant non-cancellable operating lease commitment per 1 January 2019 was NOK 2.0 million for 2019-2021, not including an extension option due to not reasonable certainty about option exercise. The discounted value of the operating lease commitment applying an incremental borrowing rate of 6% was NOK 1.8 million. Payments for the principal portion of the lease liabilities are not charged to profit and loss and will only have cash flow effects.



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<u>Right to use asset - office lease</u>	
Initial recognition 01.01.2019	1 815
Acquisition costs 31.12.2019	1 815
<hr/>	
Acquisitions FY 2020	0
Acquisition costs 31.12.2020	1 815
<hr/>	
Depreciation FY 2019	604
Accumulated depreciation and impairment as of 31.12.2019	604
Depreciation FY 2020	606
Accumulated depreciation and impairment as of 31.12.2020	1 210
<hr/>	
Total right to use assets – office lease as of 31.12.2019	1 211
Total right to use assets – office lease as of 31.12.2020	605
<hr/>	
Lower of remaining lease term or economic life - 2019	2.0 years
Lower of remaining lease term or economic life - 2020	1.0 years
Depreciation method	Linear
<u>Lease liabilities - office</u>	
Initial recognition 01.01.2019	1 815
Payments principal portion of the lease liability FY 2019	-657
Payments principal portion of the lease liability FY 2020	-668
Interest expenses on the lease liability FY 2019	38
Interest expenses on the lease liability FY 2020	144
Total lease liabilities for office as of 31.12.2019	1 196
Total lease liabilities for office as of 31.12.2020	673
<hr/>	
Whereof:	
Short term lease liabilities < 1 year 2019 / 2020	657 / 673
Long term lease liabilities > 1 year 2019 / 2020	539 / 0
The Company applies the short-term lease recognition exemption for leases related to office equipment, parking facilities at the office and a flat in Oslo available for disposition for foreign employees. Lease payments for this category of leases are consequently charged directly through profit and loss.	
<u>Income statement effects leasing</u>	
Depreciation of right to use asset	2020 2019
Operating expenses for short-term leases	-606 -604
	-170 -66
Effect on Operating results net of tax	-777 -670
Interest expenses on the lease liabilities	-144 -38
Effect on Net financial result net of tax	-921 -708
Comprehensive income effect net of tax	-921 -708



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The Company had total cash outflows related to leases of NOK 0.8 million in 2020 (2019: NOK 0.7 million). Minimum payments for non-cancellable payments for all leases are NOK 0.9 million per year-end 2020 (2019: NOK 1.4 million).

23 GOING CONCERN

PCI Biotech AS is dependent on financial support from the parent company, PCI Biotech Holding ASA, which finalised a capital increase with gross proceeds of NOK 360 million in October 2018. Major parts of the proceeds have been transferred to PCI Biotech AS during 2018, 2019 and 2020, by capital increases and intragroup debt. The parent company, PCI Biotech Holding ASA, will continue to financial support PCI Biotech AS as this entity is the operational unit within the PCI Biotech group and the company has not reached commercial stage per date of this financial statement.

In accordance with § 3-3a of the Norwegian Accounting Act (NAA) it is confirmed that the conditions for assuming that the Company will continue as a going concern are present and that the financial statements have been prepared on the basis of this assumption.

24 SUBSEQUENT EVENTS

PCI Biotech is not aware of any other subsequent events since year-end 2020 which is of material significance to the financial statements as of 31 December 2020.



Statsautoriserte revisorer
Ernst & Young AS

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Medlemmer av Den norske revisorforening

INDEPENDENT AUDITOR'S REPORT

To the Annual Shareholders' Meeting of PCI Biotech AS

Report on the audit of the financial statements

Opinion

We have audited the financial statements of PCI Biotech AS, which comprise the balance sheet as at 31 December 2020, the statements of comprehensive income, cash flows and changes in equity for the year then ended and notes to the financial statements, including a summary of significant accounting policies.

In our opinion, the financial statements have been prepared in accordance with laws and regulations and present fairly, in all material respects, the financial position of the Company as at 31 December 2020 and its financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards as adopted by the EU.

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 in accordance with the ethical requirements that are relevant to our audit of the financial statements in Norway, and we have fulfilled our ethical responsibilities as required by law and regulations. We have also complied with our other ethical obligations 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

Other information consists of the information included in the Company's annual report other than the financial statements and our auditor's report thereon. The Board of Directors and Chief Executive Officer (management) are responsible for the other information. 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.



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Responsibilities of management for the financial statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with International Financial Reporting Standards as adopted by the EU, 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 law, regulations and generally accepted auditing principles in Norway, including 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 those charged with governance 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.

Independent auditor's report - PCI Biotech AS

A member firm of Ernst & Young Global Limited

Permeo Dokumentnrøkke: BG33M-0L75U-ME486-401K3-6TEME-VKWZL



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 ensure that the Company's accounting information is properly recorded and documented as required by law and bookkeeping standards and practices accepted in Norway.

Oslo, 23 June 2021
ERNST & YOUNG AS

The auditor's report is signed electronically

Tommy Romskaug
State Authorised Public Accountant (Norway)

Penneo Dokumentnøkkel: BG33M-0L75U-ME486-401K3-6TEME-VKWZL



Unlocking the potential of innovative medicines

OTHER INFORMATION

DEFINITIONS AND GLOSSARY

Amphinex:	Trade name of the clinical intravenous formulation of fimaporfin
APC:	Antigen Presenting Cell
BIA:	User-driven research-based innovation program by the Research Council of Norway
CCA:	Cholangiocarcinoma – Bile duct cancer
CPI:	Checkpoint Inhibitor
CRC:	Cohort Review Committee
CSR:	Corporate Social Responsibility
FDA:	US Food and Drug Administration
Fimaporfin:	Generic name of the photosensitiser active ingredient TPCS2a
fimaCHEM:	PCI Biotech's development program for enhancement of generic chemotherapies
fimaNAC:	PCI Biotech's development program for delivery of nucleic acids
fimaVACC:	PCI Biotech's development program for a vaccination technology
HPV:	Human papillomavirus
IDMC:	Independent Data Monitoring Committee
IFRS:	International Financial Report Standards
IND	Investigational New Drug
<i>In vitro</i> :	Studies performed with cells or biological molecules studied outside their normal biological context; for example proteins are examined in solution, or cells in artificial culture medium.
<i>In vivo</i> :	Studies in which the effects of various biological entities are tested on whole, living organisms usually animals.
KLH	Keyhole limpet hemocyanin
NAA:	Norwegian Accounting Act
ODD:	Orphan Drug Designation
ORR:	Overall Response Rate
OS:	Overall Survival
PCI:	Photochemical internalisation
PCIB:	PCI Biotech's ticker at Oslo Børs
PFS:	Progression Free Survival
RELEASE:	Name of PCI Biotech's pivotal study for inoperable extrahepatic bile duct cancer
R&D:	Research and Development
SAC:	Scientific Advisory Committee
SoC:	Standard of Care



Unlocking the potential of innovative medicines

FORWARD LOOKING STATEMENTS

This Report contains certain forward-looking statements relating to the business, financial performance and results of the Company and/or the industry in which it operates. Forward-looking statements concern future circumstances and results and other statements that are not historical facts, and are sometimes identified by the words “believes”, “expects”, “predicts”, “intends”, “projects”, “plans”, “estimates”, “aims”, “foresees”, “anticipates”, “targets”, and similar expressions. The forward-looking statements contained in this Report, including assumptions, opinions and views of the Company or cited from third party sources, are solely opinions and forecasts which are subject to risks, uncertainties and other factors that may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements that are expressed or implied by statements and information in the Report, including, among others, risks or uncertainties associated with the Company’s business, segments, development, growth management, financing, market acceptance and relations with customers, and, more generally, general economic and business conditions, changes in domestic and foreign laws and regulations, taxes, changes in competition and pricing environments, and fluctuations in currency exchange rates and interest rates. None of the Company or any of its subsidiaries or any such person’s directors, employees or advisors provide any assurance that the assumptions underlying forward-looking statements expressed in this Report are free from errors nor does any of them accept any responsibility for the future accuracy of such forward-looking statements.



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Skattedirektoratet

Saksbehandler Torstein Kinden Helleland	Deres dato 22.08.2014	Vår dato 09.09.2014
Telefon 22078139	Deres referanse Per Walday	Vår referanse 2014/586078

PCI BIOTECH HOLDING ASA
Strandveien 55
1366 LYSAKER

Permission to prepare the annual accounts and directors' report in English language

With reference to your letter of 22 August 2014, you apply for permission to keep annual accounts and directors' report in English language. The application in question concerns the following companies;

PCI Biotech Holding ASA org. nr. 991 036 393
PCI Biotech AS org. nr. 982 611 830

Conclusion

Based on a total evaluation, the view of The Directorate of Taxes is that PCI Biotech Holding ASA and PCI Biotech AS may make the directors' report and annual accounts in English language according to the Norwegian Accounting Act § 3-4 third paragraph. The exemption requires that the information that the decision is based on, does not change significantly.

A copy of this letter must be sent to the Register of Company Accounts in Brønnøysund together with the financial statements. It is incumbent on the company to document by this letter that the permit is granted.

Background

PCI Biotech Holding ASA is listed at Oslo Axess. PCI Biotech Holding ASA is granted exemption from the Norwegian language requirement at Oslo Axess. PCI Biotech Holding ASA has one wholly owned subsidiary, PCI Biotech AS, where all employees within the group are located and all operations take place. PCI Biotech's largest shareholder is Photocure ASA, which is a professional player in the international life science industry. The second largest shareholder is The Norwegian Radium Hospital Research Foundation, which is a professional investor within the industry. The majority of the remaining shares are held by professional large investment funds. The above shareholders sum up to 70 % of the shareholder base. PCI Biotech is a Norwegian biopharmaceutical company developing a novel light directed treatment system based on its patented photochemical internalization (PCI) technology. PCI Biotech is currently an R&D focused company doing both pre-clinical and clinical studies. All clinical and most pre-clinical studies are done abroad through international service providers, and the business language is consistently English. Furthermore, the life science industry is an international industry and all potential

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counterparts for commercial related agreements are international. The annual report and financial statements are required to be prepared each year in the Norwegian language only in order to satisfy the requirements of the Norwegian Accounting Act.

Permission to make the annual accounts and the directors' report in Norway in English language

According to the Norwegian Accounting Act § 3-4, third paragraph shall *"the directors' report and annual accounts ... be in Norwegian. The Ministry can in an individual decision decide that the directors' report and/or annual accounts may be in another language"*.

Ot. prp. nr. 42 (1997-1998) About Act about annual accounts etc., says the following about the purpose of the Accounting Act, refer section 1.1:

"The aim of the Government with respect to the Accounting Act is that it shall contribute towards providing informative accounts for different users of accounts. The users of accounts include investors and creditors which provide capital for the companies. Other groups include those who have an interest in knowing how the companies are operated, for example employees and the local community. The information to the capital market is an important basis for the correct pricing of financial instruments. The correct pricing of stocks is an important factor in securing the best possible allocation of resources in the economy. High quality accounts will also make it more difficult for market participants to obtain speculative gains as a result of non-publicly available information."

Hence, one of the main aims of the Accounting Act is to contribute to "informative accounts for different users of accounts". The users of the accounts will include investors, creditors, employees and the local community.

Hence, it is the view of the Ministry that it is crucial that the question of dispensation from the general rule that the annual accounts and/or directors' report should be prepared in Norwegian, not in any significant way deviate from the consideration of users of the accounts.

As mentioned above it is particularly the consideration of the users of the account information which has to be taken into consideration when considering the application for permission. In this assessment, the Directorate of Taxes has emphasized the majority of the shareholder are professional investors. The company is granted exemption from the Norwegian language requirement at Oslo Axess. English is the preferred language for internal and external communication. Further, the working language is English.



We kindly request you to mention "our reference" in written communication with The Norwegian Tax Authorities.

Med hilsen

Rune Tystad
Senior Adviser
Rettsavdelingen, foretaksskatt
Skattedirektoratet

Torstein Kinden Helleland

Dokumentet er elektronisk godkjent og har derfor ikke håndskrevne signaturer

