



**THIRD QUARTER  
INTERIM REPORT**

**2022**

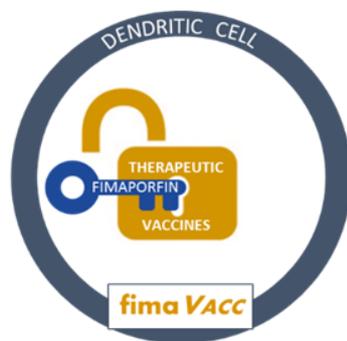
*Enabling  
intracellular  
delivery*



## LEVERAGING THE PCI TECHNOLOGY PLATFORM WITHIN IMMUNOTHERAPY & NUCLEIC ACID THERAPEUTICS

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### TRIGGERED ENDOSOMAL RELEASE



Enhancing cellular  
immune responses



Providing a delivery  
solution for nucleic acid  
therapeutics

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### ABOUT PCI BIOTECH

PCI Biotech is a biopharmaceutical company headquartered in Norway and listed on the Oslo Stock Exchange. The company develops novel therapies through its proprietary photochemical internalisation (PCI) platform technology originating from world-leading research at the Oslo University Hospital – the Norwegian Radium Hospital. The PCI technology works by inducing light-triggered endosomal release, which may unlock the potential of a wide array of modalities.

The **fimaNAc** programme utilises the proven potential of the PCI technology for intracellular delivery of nucleic acids. The technology can be used for most types of nucleic acids, ranging from oligonucleotides through mRNA and plasmids to viral vectors. The development of the **fimaNAc** programme is focused on selected applications within dermatology and bioprocessing, well suited to the specific strengths of the PCI technology. The **fimaVACC** programme aims to enhance immunotherapy in cancer, by triggered endosomal release of antigens or nucleic acids encoding antigens, or immunostimulatory factors. In preclinical experiments **fimaVACC** has proven excellent efficacy with protein- and peptide-based vaccines, with particularly strong cytotoxic (CD8) T-cell immune responses, which are crucial in cancer immunotherapy. The beneficial immune characteristics of **fimaVACC** were successfully verified in humans through a Phase I study with healthy subjects.

## Highlights

### Corporate

- Efforts to finance a Ph II clinical trial in head and neck cancer did not, under the current market conditions, result in a feasible way forward and the company reported in August that it will not conduct a company-sponsored Ph II trial with the **fimaVacc** technology. This entailed a downsizing of the clinical team, which is enacted during the second half of 2022, with full cost reduction effect in Q1 2023. The cash position of NOK 67 million per end of Q3 enables an estimated financial runway into 2024
- The company now focus its efforts and resources on non-clinical research, exploring new fields of use for the PCI technology platform utilising **fimaNac** for dermatology and bioprocessing applications, and **fimaVacc** for intratumoural immunotherapy

### **fimaNac** – dermatology and bioprocessing

- The first step for the dermatology discovery project is to demonstrate **fimaNac**-mediated nucleic acid delivery in a wound model. External feasibility experiments are contracted, with expected readout 1H 2023
- The bioprocessing discovery project exploring applications specifically suited to the strengths of the PCI technology has matured and is now focused on in-house experiments of **fimaNac** for use in viral manufacturing

### **fimaVacc** – intratumoural immunotherapy

- Exploring approaches aiming to identify novel immunotherapy treatment combinations with promising efficacy

### **fimaCHEM**

- All major study closure activities are expected to be completed before the end of the year. The remaining cash effect for the closure process is estimated up to NOK -3 million from 1<sup>st</sup> October 2022

## Collaborations

- In August 2022, a preclinical collaboration was initiated with Mymetics, aiming to explore technological synergies for possible enhancement of cancer therapy
- The collaboration with Mendus has been reviewed for progress and value and was closed in November 2022

## Corporate – other

- Ronny Skuggedal was appointed Interim CEO effective 1<sup>st</sup> June and promoted to CEO effective 1<sup>st</sup> September 2022. Amir Snapir, CMO, left the company in September 2022

## Key figures

(In NOK 1,000)	2022 Q3	2021 Q3	2022 YTD	2021 YTD	2021 FY
Other income	1 188	1 187	3 563	5 085	6 273
Operating expenses	12 132	23 690	52 949	67 842	92 302
Operating results	-10 945	-22 503	-49 387	-62 757	-86 029
Net financial result	250	1 080	988	-586	-2 362
<b>Comprehensive income</b>	<b>-10 695</b>	<b>-21 423</b>	<b>-48 398</b>	<b>-63 343</b>	<b>-88 391</b>
<b>Cash &amp; cash equivalents</b>	<b>67 224</b>	<b>135 513</b>	<b>67 224</b>	<b>135 513</b>	<b>116 118</b>
<b>Cash flow from operating activities</b>	<b>-8 838</b>	<b>-13 141</b>	<b>-48 602</b>	<b>-50 984</b>	<b>-68 307</b>

## Pipeline

Programme	Therapeutics	Preclinical	Phase 1	Phase 2
<b>fimaNAC</b>	Dermatology			
<b>fimaVACC</b>	Intratumoural immunotherapy			
<b>Collaborations</b>	Undisclosed			
Programme	Application	Feasibility	Prototype	Commercial
<b>fimaNAC</b>	Bioprocessing			

## Operational review and programmes overview

### fimaVACC

The **fimaVACC** technology aims to enhance immunotherapy responses and has shown excellent preclinical efficacy with protein- and peptide-based vaccines. The technology has shown particularly strong CD8 T-cell responses, which are important for therapeutic vaccination, as well as enhanced helper (CD4) T-cell and antibody responses. Immune responses and safety have been successfully translated to healthy subjects in a Ph I study<sup>1</sup>. The technology is versatile, as it can potentially be used with several modalities, including nucleic acid based immunotherapy technologies.

The company announced in August 2022 that the previously reported efforts to finance a Ph II clinical trial in head and neck cancer did not, under the current market conditions, result in a feasible way

<sup>1</sup> Otterhaug *et al.* (2021) *Frontiers in Immunology*;11:576756

forward and PCI Biotech will not conduct a company-sponsored Ph II trial with the **fimaVacc** technology. The company will focus its efforts and resources on non-clinical research, and explore new fields of use for the PCI technology utilising **fimaVacc** for intratumoural immunotherapy, with a partnership-driven development strategy.

### **Intratumoural immunotherapy**

Immune checkpoint inhibitors (ICIs) have revolutionised cancer treatment. However, a large proportion of patients do not respond to ICIs, or progress shortly after initial response. As with other systemically administered treatments, safety is a concern, currently preventing increased ICI doses to improve efficacy, as well as combining more than two ICIs together.

Combining ICIs with intratumour immunotherapy is an attractive approach to increase the response rate to ICIs. Intratumour immunotherapy is administered directly into the tumour and constitutes a “local” treatment. As a result, the dose is relatively low, and systemic adverse effects are expected to be limited, which in turn may enable novel combination treatments.

PCI is a technology designed for local enhancement of therapeutic effects and is well suited for delivery of immunotherapy combinations to tumour sites. Thus, PCI can enhance the delivery of proteins, nucleic acids, small molecules, and viral vectors, all of which are relevant for locally administered immunotherapy. In addition, the PCI technology by itself has a local immunostimulatory effect, e.g. by inducing cytokine production.

PCI Biotech is exploring intratumoural immunotherapy approaches, aiming to identify novel immunotherapy treatment combinations with promising efficacy.

### **Ph.D. candidate grant from the Research Council of Norway**

A Ph.D. candidate grant of up to NOK 2.5 million over 3 years is granted by the Research Council of Norway, dedicated to the development of intratumoural immunotherapy and commencing 1<sup>st</sup> January 2023. The grant is subject to final contract negotiations.

## **fimaNAc**

Nucleic acid therapeutics have been established in recent years as an effective treatment approach in many applications. However, efficient and safe delivery to most tissues is still a major barrier to treating new indications.

The **fimaNAc** programme is focusing on development of a targeted intracellular delivery technology for different classes of nucleic acids. It is a preclinical-stage collaborative programme. Results from collaborations and PCI Biotech’s own data indicate that the **fimaNAc** technology provides an attractive intracellular delivery solution in this area. Based on these results and other strategic considerations, PCI Biotech aims to develop the **fimaNAc** technology for selected applications suited to the specific strengths of the PCI technology, with a partnership-driven development strategy for dermatology and bioprocessing.

### **Dermatology**

Pre-clinical experiments have demonstrated that the **fimaNAc** technology can substantially enhance nucleic acid delivery to skin, with spatial specificity. PCI Biotech’s development plans focus on chronic skin ulcers, but the technology may also be applied to other dermatological conditions. Current development is in the discovery phase aiming to demonstrate **fimaNAc**-mediated nucleic acid delivery in an *ex vivo* wound model with topical administration. External feasibility experiments are contracted, with expected readout 1H 2023.

### **Bioprocessing**

Bioprocessing is the manufacturing of biologic drugs (“biologics”), which are complex processes and bottlenecks in the endeavour to offer breakthrough therapies to new and larger patient populations. There is a great need for technologies that enable more effective bioprocessing with higher yield as well

as increased quality at a lower cost. Development of bioprocessing technologies is less complex from a regulatory perspective compared to development of new therapies, allowing shorter timelines and lower costs of development.

PCI Biotech has demonstrated the potential of its technology for use in several areas of bioprocessing. Based upon these results, the company initiated feasibility projects aimed at developing enabling technologies for bioprocessing. The discovery project has matured and is now focused on in-house feasibility experiments of **fimaNAc** for use in viral manufacturing.

## **fima** *CHEM*

The RELEASE trial was terminated in Q1 2022, due to changes in the competitive landscape that rendered the trial challenging to complete and potentially inadequate for approval. PCI Biotech has focused on a swift and cost-efficient closing process of the RELEASE trial. Sites with no ongoing patients (nearly 60%) were closed immediately after the decision to terminate recruitment. The last patient discontinued the study in May and all remaining clinical sites were closed by the end of June 2022. Other major study closure activities are completed during Q3, including publishing the study results in the EU clinical trial database, while publication on [clinicaltrials.gov](https://clinicaltrials.gov) are pending. The trial enrolled a total of 41 patients, of which 34 patients provided efficacy data. Data collected in the study was insufficient to draw conclusions regarding the efficacy of the PCI treatment.

The swift wind-down of RELEASE allowed the company to reallocate resources to the other development programmes. The remaining cash effect for the closure process of RELEASE, from 1<sup>st</sup> October 2022, is estimated up to NOK -3 million.

## **Research collaborations**

PCI Biotech has an active collaborative strategy for **fimaNAc** and **fimaVacc**. The collaboration partners include MDimune, OliX Pharmaceuticals, IMV, and Mymetics. In these collaborations, PCI Biotech and the partners are exploring synergies between their proprietary technologies, with potential expansion of the partnerships. Previous collaborations have provided valuable data and know-how for further development of PCI Biotech's programmes. PCI Biotech continues to pursue new and value-adding collaborative opportunities for the **fimaNAc** and **fimaVacc** programmes.

In January 2022, PCI Biotech entered a new **fimaNAc** research collaboration with MDimune, a South Korean biotech company developing a versatile drug delivery system based on nanosized vesicles obtained from cells. In August 2022 a **fimaVacc** research collaboration was initiated with Mymetics, a company based in Switzerland and a pioneer in the research and development of virosome-based vaccines and immunotherapies against infectious and life disabling diseases, aiming to explore technological synergies for the possible enhancement of cancer therapy.

In these collaborations, the companies will combine their know-how and technology platforms to explore synergies. The partnerships are governed by research collaboration agreements, under which evaluations of technology compatibility and synergy will be performed using preclinical studies.

The collaboration with Mendus was recently reviewed for progress and value. Priorities are set by both parties and the collaboration was closed in November 2022.

## Corporate

### Organisational changes

Following the termination of RELEASE in January 2022 the clinical team was reduced during the first half of 2022. The decision in August 2022 not to pursue a PCI Biotech-sponsored **fimaVacc** Ph II study entailed additional reduction of the clinical team, which is enacted during the second half of 2022 with a full cost reduction effect in Q1 2023. Amir Snapir, CMO, left the company in September 2022.

Ronny Skuggedal, CFO, was appointed Interim CEO effective 1st June, and promoted to CEO effective 1st September 2022, holding both positions.

### Conferences

The company participated on-site at the following conferences during Q3: NLS Days (Malmö, Sweden), BIO-Europe (Leipzig, Germany) and European Society for Gene and Cell Therapy (ESGCT/BSGCT) Collaborative Congress (Edinburgh, UK).

## Financial review

### Income Statement

(Figures in brackets = same period 2021 unless stated otherwise)

The Group has not recorded any revenues for the financial years 2022 or 2021. Grants received from public sources, such as the Norwegian Research Council, are recorded as other income. Other income amounted to NOK 1.2 million (NOK 1.2 million) for Q3 and NOK 3.6 million (NOK 5.1 million) for YTD 2022.

Research and development (R&D) expenses for Q3 and YTD 2022 ended at NOK 6.2 million (NOK 18.6 million) and NOK 39.7 million (NOK 50.8 million) respectively, including a write-down of the carrying value of NOK 5.8 million for devices following the decision to terminate the RELEASE trial.

General and administrative (G&A) expenses for Q3 and YTD 2022 ended at NOK 6.0 million (NOK 5.1 million) and NOK 13.3 million (NOK 17.1 million) respectively. The change in G&A for YTD 2022 compared to last year, is mainly driven by accounting effect fluctuations for the share option scheme, without direct cash flow effects and the staff downsizing. In Q3 2022 a total number of 480,000 outstanding share options lapsed, resulting in a reversal of cost from previous periods of NOK 3 million.

Operating expenses for Q3 and YTD 2022 were NOK 12.1 million (NOK 23.7 million) and NOK 52.9 million (NOK 67.8 million) respectively. Operating expenses are mainly driven by the R&D activity level and the fimaCHEM RELEASE trial was the main cost driver in both 2022 and 2021.

Net financial results for Q3 and YTD 2022 were NOK 0.3 million (NOK 1.1 million) and NOK 1.0 million (NOK -0.6 million) respectively. The variations in net financial results are mainly driven by exchange rate fluctuations on bank deposits placed in foreign currency, as a hedge of the foreign currency risk for the clinical RELEASE trial.

Net loss for Q3 and YTD 2022 were NOK 10.7 million (NOK 21.4 million) and NOK 48.4 million (NOK 63.3 million) respectively.

### Cash flow and balance sheet

The decision to terminate the RELEASE trial impacted property, plant and equipment as this balance sheet item included a medical device specifically designed to be used in the trial. The post-decision value of the device was considered negligible and the devices were depreciated in full in Q1 2022 without cash-flow effect.

The Group held cash and cash equivalents of NOK 67.2 million at end of Q3 2022, compared to NOK 116.1 million per year-end 2021. Cash flow from operations is mainly dependent on R&D activities and may vary between periods due to ordinary timing differences. Cash flow from operating activities was NOK -8.8 million for Q3 2022 (NOK -13.1 million), and NOK -48.6 million (NOK -51.0 million) for YTD

2022. All cash and cash equivalents are placed as bank deposits. Exchange rate effects on bank deposits in foreign currency were NOK 0.1 million negative (NOK 1.1 million positive) for Q3 2022. For the first nine months, the effect was 0.2 million positive for 2022, compared to 0.8 million negative for 2021.

Based on the decision to terminate the RELEASE trial in January 2022, and the reported organisational changes in August 2022 the current cost base for the company will continue to be reduced. The remaining cash effect for closure of RELEASE is estimated up to NOK -3 million from 1<sup>st</sup> October 2022. The cash position by the end of Q3 2022 enables an estimated financial runway for the company into 2024, with current plans. The company continues to explore financing and strategic opportunities as the non-clinical pipeline matures.

## Other

### Risks and uncertainty factors for 2022

PCI Biotech is exposed to uncertainties and risk factors, which may influence some or all of the company's activities. As described in the Annual Report 2021, the most important risks the company is exposed to in 2022 are associated with financial risk, progress and performance of R&D programmes, and the associated regulatory affairs and market risk. No circumstances have been identified that significantly change the uncertainties and risk factors described in the Annual Report 2021, which also covers implications of the COVID-19 pandemic and the war in Ukraine.

### Collaboration with Norwegian Institute for Marine Research (NIMR)

NIMR (Havforskningsinstituttet) received in 2021 a NOK 4.5 million grant from the Norwegian Seafood Fund for a 2-year collaboration project with PCI Biotech ending June 2023. The project aims to explore the use of photochemical treatments to combat salmon lice in fish farming. NIMR will perform the research, and PCI Biotech will provide expertise and compounds and retain commercial rights to the results of the project.

### Post-closing events

PCI Biotech is not aware of any post-closing events which could materially influence this interim financial statement.

## Outlook

PCI Biotech's proprietary PCI technology enables intracellular delivery, which provides the possibility to unlock the true potential of certain classes of innovative medicines. The PCI technology has the opportunity to play a significant role in the realisation of several new therapeutic modalities, including immunotherapy (**fimaVacc**) and nucleic acid therapeutics (**fimaNAc**).

The **fimaVacc** programme aims to enhance immunotherapy in cancer, by triggered endosomal release of antigens or nucleic acids encoding antigens, or immunostimulatory factors. The **fimaNAc** programme follows a collaborative approach, by development of applications in the most attractive areas for the technology and pursuing out-licensing opportunities.

The main current priorities of PCI Biotech are to:

- Focus efforts and resources on non-clinical research, for exploration of new fields of use for the PCI technology
- Manage alliance and partnering activities across all commercially interesting areas for the PCI platform
- Finalise the closing of the RELEASE study

The Board of Directors and CEO  
PCI Biotech Holding ASA  
Oslo, 22 November 2022

Hans Peter Bøhn  
Chairman (sign)

Christina Herder  
Director (sign)

Hilde Furberg  
Director (sign)

Andrew Hughes  
Director (sign)

Lars Viksmoen  
Director (sign)

Ronny Skuggedal  
CEO (sign)

## CONDENSED INTERIM CONSOLIDATED FINANCIAL INFORMATION

<b>PROFIT AND LOSS</b> (in NOK '000)	Note	Q3 2022	Q3 2021	YTD 2022	YTD 2021	FY 2021
<b>Other income</b>	6	1 188	1 187	3 563	5 085	6 273
Research and development	7,8	6 167	18 611	39 657	50 790	71 707
General and administrative		5 966	5 080	13 293	17 052	20 595
<b>Operating expenses</b>		<b>12 132</b>	<b>23 690</b>	<b>52 949</b>	<b>67 842</b>	<b>92 302</b>
<b>Operating results</b>		<b>-10 945</b>	<b>-22 503</b>	<b>-49 387</b>	<b>-62 757</b>	<b>-86 029</b>
<b>Financial income and expenses</b>						
Financial income		339	1 289	1 930	2 493	789
Financial expenses		90	209	942	3 079	3 151
<b>Net financial result</b>	7	<b>250</b>	<b>1 080</b>	<b>988</b>	<b>-586</b>	<b>-2 362</b>
<b>Profit/Loss before income tax</b>		<b>-10 695</b>	<b>-21 423</b>	<b>-48 398</b>	<b>-63 343</b>	<b>-88 391</b>
Income tax	9	0	0	0	0	0
<b>Net profit/loss</b>		<b>-10 695</b>	<b>-21 423</b>	<b>-48 398</b>	<b>-63 343</b>	<b>-88 391</b>
Other comprehensive income		0	0	0	0	0
<b>Total comprehensive income</b>	5	<b>-10 695</b>	<b>-21 423</b>	<b>-48 398</b>	<b>-63 343</b>	<b>-88 391</b>

<b>Balance sheet</b> (in NOK '000)	Note	30.09 2022	30.09 2021	31.12 2021
<b>Non-current assets</b>				
Property, plant and equipment	16	22	6 290	5 806
Right to use asset	15	1 391	1 965	1 854
<b>Total non-current assets</b>		<b>1 413</b>	<b>8 255</b>	<b>7 660</b>
<b>Current assets</b>				
Short term receivables	7	5 300	10 913	12 200
Cash & cash equivalents	7	67 224	135 513	116 118
<b>Total current assets</b>	14	<b>72 524</b>	<b>146 427</b>	<b>128 318</b>
<b>Total assets</b>		<b>73 937</b>	<b>154 682</b>	<b>135 978</b>
<b>Equity and liabilities</b>				
<b>Equity</b>				
Paid in capital	10,11	562 443	562 443	562 443
Other reserves		-498 960	-426 307	-448 651
<b>Total equity</b>		<b>63 483</b>	<b>136 136</b>	<b>113 792</b>
<b>Long-term liabilities</b>				
Other long-term liabilities	13	0	0	0
Lease liabilities	15	805	1 386	1 277
<b>Total long-term liabilities</b>		<b>805</b>	<b>1 386</b>	<b>1 277</b>
<b>Short term liabilities</b>				
Trade debtors		2 334	2 090	3 745
Lease liabilities	15	629	623	629
Other short-term liabilities	7,12	6 687	14 446	16 535
<b>Total short-term liabilities</b>		<b>9 650</b>	<b>17 159</b>	<b>20 909</b>
<b>Total liabilities</b>	14	<b>10 455</b>	<b>18 546</b>	<b>22 186</b>
<b>Total equity and liabilities</b>		<b>73 937</b>	<b>154 682</b>	<b>135 978</b>

## CHANGE IN EQUITY

<i>(in NOK '000)</i>	Q3 2022	Q3 2021	YTD 2022	YTD 2021	FY 2021
<b>Equity at beginning of period</b>	<b>75 932</b>	<b>153 961</b>	<b>113 792</b>	<b>189 244</b>	<b>189 244</b>
Capital increase	0	0	0	0	0
Share option scheme	-1 754	3 599	-1 911	10 235	12 939
Comprehensive income in the period	-10 695	-21 423	-48 398	-63 343	-88 391
<b>Equity at end of period</b>	<b>63 483</b>	<b>136 136</b>	<b>63 483</b>	<b>136 136</b>	<b>113 792</b>

## CASH FLOW

<i>(in NOK '000)</i>	Q3 2022	Q3 2021	YTD 2022	YTD 2021	FY 2021
Ordinary profit before taxes	-10 695	-21 423	-48 398	-63 343	-88 391
Depreciation, amortisation and write off	159	635	6 247	1 892	2 541
Leasing interest cost	20	10	58	29	38
Share options	-1 753	3 599	-1 911	10 235	12 939
Currency gain (-)/ loss (+) not related to operations	-1 902	-1 090	-235	793	2 529
Changes in working capital and other non-cash adjustments	3 342	5 128	-4 363	-590	2 036
<b>Cash flow from operating activities</b>	<b>-8 838</b>	<b>-13 141</b>	<b>-48 602</b>	<b>-50 984</b>	<b>-68 307</b>
Acquisition of non-current assets	0	0	0	-341	-341
<b>Net cash flow from investing activities</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>-341</b>	<b>-341</b>
<b>Cash flow from financial activities</b>					
Payment principal portion of lease liabilities	-176	-168	-526	-336	-673
Net proceeds from share issues	0	0	0	0	0
<b>Net cash flow from financial activities</b>	<b>-176</b>	<b>-168</b>	<b>-526</b>	<b>-336</b>	<b>-673</b>
<b>Net change in cash during the period</b>	<b>-9 013</b>	<b>-13 309</b>	<b>-49 129</b>	<b>-51 661</b>	<b>-69 321</b>
Exchange rate effect on bank deposits in foreign currency	-90	1 090	235	-793	-2 529
Cash and cash equivalents at the beginning of the period	76 328	147 732	116 118	187 967	187 967
<b>Cash and cash equivalents at the end of the period</b>	<b>67 224</b>	<b>135 513</b>	<b>67 224</b>	<b>135 513</b>	<b>116 118</b>

## SELECTED EXPLANATORY NOTES:

### 1. Nature of operation

PCI Biotech Holding ASA (PCI Biotech) was established in 2008, and comprises PCI Biotech Holding ASA and the wholly owned subsidiary PCI Biotech AS. The PCI Biotech shares have been listed on Oslo Børs since 27 April 2018 under the ticker PCIB, as a transfer of listing from Oslo Axess. The company is headquartered in Oslo, Norway.

PCI Biotech has developed a unique and patented photochemical intracellular drug delivery technology for use in cancer therapy and other diseases. Photochemical Internalisation (PCI) is a proprietary technology for light-directed intracellular drug delivery by triggered endosomal release. The technology may also be used to enhance the immunological response of vaccines. The company collaborates closely with The Norwegian Radium Hospital in Oslo, Norway and receives funding on several projects from the Research Council of Norway. The company has an extensive international collaboration network with recognised expert groups in both drug delivery and vaccination.

The PCI technology has potential to improve the efficacy of new classes of drugs, such as therapeutic vaccines, gene therapy and other therapies based on nanotechnology or on biotechnological principles. The company's objective is to prove the clinical usefulness of the technology with various drug classes and subsequently license out the technology to partners for further development and marketing. Revenues will be generated at the time of partnering and onwards from potential up-front payments, milestone payments and royalties from sales. PCI Biotech works on the development of the PCI platform that may both potentiate the effect of vaccines (fimaVACC) and delivery of nucleic acids (fimaNAC). The fimaVACC programme has completed a Phase I study in healthy subjects, which has provided scientific proof-of-concept of fimaVACC's ability to enhance and direct the response of vaccines towards a stronger cellular immune response. The fimaNAC programme is in preclinical stage with focused development of selected applications for nucleic acid therapeutics well suited to the specific strengths of the PCI technology. A third development programme (fimaCHEM) had until recently a pivotal clinical trial, RELEASE, in inoperable extrahepatic bile duct cancer. The RELEASE trial is terminated, and a closing process is ongoing focusing on a swift and cost-effective closure.

### 2. Basis of presentation

These condensed unaudited interim financial statements have been prepared in accordance with IAS 34 Interim Financial Reporting. These condensed interim financial statements should be read in conjunction with the consolidated financial statements for the year ended 31 December 2021 (hereafter 'the Annual Financial Statements'), as they provide an update of previously reported information. The accounting policies used are consistent with those used in the Annual Financial Statements. The presentation of the condensed interim financial statements is consistent with the Annual Financial Statements. This interim financial report has not been subject to an audit. The going concern assumption has been applied when preparing this interim financial report. The board of directors approved the condensed interim financial information on 22 November 2022.

PCI Biotech has Norwegian kroner (NOK) as its functional currency and presentation 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 condensed interim financial statements may not add up to the totals.

### 3. Summary of significant accounting policies

The accounting policies applied and the presentation of the interim condensed consolidated financial information for 2022 is consistent with the consolidated financial statements for the year ended 31 December 2021.

The new standards and interpretations or amendments to published standards that were effective for the annual period beginning on January 1, 2022 or later and that could affect PCI Biotech are discussed in accounting principles, part 4, to the annual financial statements for 2021.

#### 4. Important accounting valuations, estimates and assumptions

Estimates and judgments are evaluated on an on-going basis and are based on historical experience and other factors, including expectations of future events that are considered to be relevant.

In preparing these condensed interim financial statements, the significant judgements made by management in applying the group's accounting policies and the key sources of estimation uncertainty were the same as those applied to the consolidated financial statements for the year ended December 31<sup>st</sup>, 2021.

#### 5. Earnings per share

	Q3 2022	Q3 2021	YTD 2022	YTD 2021	FY 2021
Result allocated to shareholders (in NOK '000)	-10 695	-21 204	-48 398	-63 343	-88 391
Weighted average of outstanding shares (in NOK '000)	37 326	37 326	37 326	37 326	37 326
Earnings per share (NOK per share)	-0.29	-0.57	-1.30	-1.12	-2.37

Earnings per share is not affected by dilution from outstanding share options if negative results in the period. Per end of Q3 2022 there are no outstanding share options that are in the money.

#### 6. Segment information and Other income

PCI Biotech reports only one segment and had no revenues for the reporting period. Government grants are not recognised until it is probable that the conditions attached to the contribution will be achieved. The grants are recognised in the statement of profit and loss in the same period as the related expenses and are disclosed as other income. The Company has recognised a grant by the Research Council of Norway via the tax incentive scheme (SkatteFUNN) in the period.

#### 7. Credit risk, foreign currency risk and interest risk

##### Credit risk

PCI Biotech has no sales for 2021 and 2022 and faces therefore no credit risk on trade receivables.

Maturity profile on other receivables at the end of the quarter (all figures in '000 NOK):

	Not due (prepaid expenses)	Less than 3 months	3 to 12 months	More than 12 months	Total
Other receivables	822	279	636	3 563	5 300
<b>Total receivables</b>	<b>822</b>	<b>279</b>	<b>636</b>	<b>3 563</b>	<b>5 300</b>

Most of the short-term receivables relates to accrued, not received government grants from the tax incentive scheme (SkatteFUNN). A major part of prepaid expenses relates to the RELEASE study.

### Foreign currency risk

PCI Biotech has transactional currency exposure arising from purchases in currencies other than the functional currency (NOK). PCI Biotech has placed parts of the cash positions in Euro deposits as a hedge of the foreign currency risk for the pivotal RELEASE study. PCI Biotech has not implemented any other hedging strategy to reduce foreign currency risk.

Per end of September a positive accounting effect of NOK 1.0 million has been reported as financial income for 2022, resulting from converting Euro cash deposits into NOK as functional currency for the interim report. The effect for the same period in 2021 was NOK 0.8 million negative.

### Interest risk

PCI Biotech has no interest-bearing debt. PCI Biotech faces interest risk on cash deposits.

## 8. Research and Development

All figures in '000 NOK

	Q3 2022	Q3 2021	YTD 2022	YTD 2021	FY 2021
Clinical studies	4 819	14 887	30 987	39 614	57 204
Pre-clinical studies	765	1 720	4 923	5 172	6 966
CMC and equipment	246	580	1 581	2 654	3 332
Patents	337	1 425	2 165	3 350	4 205
Other costs	0	0	0	0	0
<b>Total</b>	<b>6 167</b>	<b>18 611</b>	<b>39 657</b>	<b>50 790</b>	<b>71 707</b>

PCI Biotech has no development expenditure that qualifies for recognition of an asset under IAS 38 Intangible assets. Expenditure on research activities is recognised as an expense in the period in which it was incurred and all research expenses are recorded in the profit and loss statement, in line with previous years.

## 9. Deferred tax and deferred tax assets

At the end of the quarter, the group held NOK 154.8 million in estimated non-capitalised deferred tax assets (22% tax rate), which mainly relates to carry forward losses.

## 10. Share options

Share options outstanding from the company's share option program for employees have the following expiry date and exercise prices:

Expiry date	Exercise price in NOK per share option	Number of share options	
		31.12.2021	30.09.2022
2022 - Q3	21.48	310 000	-
2024 - Q3	25.78	300 000	150 000
2025 - Q3	50.36	520 000	130 000
2026 - Q3	19.41	485 000	150 000
<b>Total</b>		<b>1 615 000</b>	<b>430 000</b>

The current authorisation, granted by the Annual General Meeting on 28 May 2022, for the employee share option program allows for a total of 2,790,000 share options, of which 430,000 have been granted by the Board of Directors per end of the quarter.

Year to date a total of 1,025,000 previously granted share options have lapsed, due to employees entering notice periods. The accounting effect of lapsed share options is a cost-reversal of NOK 7.2 million in the P&L for previously charged costs related to an estimated value for the expected number of share options that will be vested. In addition, a total of 160,000 share options expired in Q3 2022.

Overview share options, Senior executives	Total holdings				Total holdings	
	31.12.2021	Allocated	Lapsed	Exercised	Expired	30.09.2022
Ronny Skuggedal, CEO / CFO	190 000	0	0	0	50 000	140 000
Anders Høgset, CSO	190 000	0	0	0	60 000	130 000
Kristin Eivindvik, CDO	110 000	0	0	0	20 000	90 000
Amir Snapir, former CMO*	150 000	0	150 000	0	0	0
Ludovic Robin, former CBO**	130 000	0	130 000	0	0	0
Per Walday, former CEO***	295 000	0	295 000	0	0	0
<b>Total</b>	<b>1 065 000</b>	<b>0</b>	<b>575 000</b>	<b>0</b>	<b>130 000</b>	<b>360 000</b>

\*Former CMO, Amir Snapir left the company in September

\*\*Former CBO, Ludovic Robin left the company in May

\*\*\*Former CEO, Per Walday left the company in May

## 11. Share capital

	No. of shares	Nominal value per share in NOK	Share capital in NOK
<b>31.12.2021</b>	<b>37 326 390</b>	<b>3.00</b>	<b>111 979 170</b>
Transactions	-	-	-
<b>30.09.2022</b>	<b>37 326 390</b>	<b>3.00</b>	<b>111 979 170</b>

The Company's share capital is NOK 111,979,170 divided by 37,326,390 shares, each with a nominal value of NOK 3.00 and each giving one vote at the Company's general meeting.

The annual general meeting in May 2022 authorised the board of directors to execute share capital increases by issuing up to 2,790,000 shares with a nominal value of NOK 3.00 in connection with the company's employee share option program. The authorisation is valid for one year. In addition, the board of directors were authorised to execute share capital increases with up to NOK 12,034,000 in connection with private placements. The authorisation shall not be used to increase share capital by an amount in excess of 10% of the share capital, based on the share capital per date of the authorisation and potential share capital increases in relation to the employee share option program. The authorisation may be used for general corporate purposes and is valid for one year.

PCI Biotech has around 6,000 shareholders at end of the quarter.

### 10 largest shareholders per 30 September 2022:

Name	No. of shares	Ownership
FONDSAVANSE AS	3 910 443	10,48 %
Myrlid AS	2 100 000	5,63 %
MP PENSJON PK	2 075 801	5,56 %
RADFORSK INVESTERINGSSTIFTELSE	1 082 415	2,90 %
GRESSLIEN	941 800	2,52 %
Nordnet Bank AB	753 181	2,02 %
CLEARSTREAM BANKING S.A.	501 881	1,34 %
RAVI INVESTERING AS	500 000	1,34 %
Jandersen Kapital AS	470 000	1,26 %
BNP Paribas Securities Services	428 283	1,15 %
<b>Total 10 largest shareholders</b>	<b>12 763 804</b>	<b>34,20 %</b>
<i>Others</i>	<i>24 562 586</i>	<i>65,80 %</i>
<i>Total</i>	<i>37 326 390</i>	<i>100,00 %</i>

Shares owned, directly or indirectly, by members of the board, senior executives and their personally related parties:

Name	Position	No. of shares	
		31.12.2021	30.09.2022
Hans Peter Bøhn	Chairman	123 662	123 662
Lars Viksmoen	Board member	12 966	12 966
Christina Herder	Board member	10 000	10 000
Hilde Furberg (Borkenholm AS)*	Board member	4 000	8 000
Andrew Hughes	Board member	0	0
Per Walday**	Former CEO	72 700	NA
Anders Høgset	CSO	64 800	64 800
Ronny Skuggedal	CEO	55 000	55 000
Kristin Eivindvik	CDO	25 200	25 200
Ludovic Robin***	Former CBO	0	NA
Amir Snapir****	CMO	0	NA
<b>Total</b>		<b>378 336</b>	<b>299 628</b>

\*Hilde Furberg's shares are owned via Borkenholm AS, which is a related party to Hilde Furberg.

\*\*Per Walday, former CEO left the company in May 2022

\*\*\*Ludovic Robin, former CBO left the company in May 2022

\*\*\*\*Amir Snapir, former CMO left the company in September 2022

## 12. Other short-term liabilities

Other short-term liabilities mainly consist of accrued R&D and salary related costs and public duties.

## 13. Other long-term liabilities

Other long-term liabilities include public duties payables due in 1-5 years for potential future exercises of "in-the-money" share options in PCI Biotech's employee share option scheme and lease liabilities for right-to-use assets due in more than 12 months.

#### 14. Financial assets and liabilities

All financial assets and liabilities are classified as financial instruments at amortised costs. Financial assets and liabilities at amortised costs are measured at their nominal amount, as the nominal amount is assessed to be fair value due to the immaterial discounting effect for short-term maturities.

#### 15. Right of use assets and lease liabilities (IFRS 16)

PCI Biotech has entered into a lease agreement with Oslo Cancer Cluster Incubator, Ullernchausséen 64 Oslo, Norway, and the lease runs to 31 December 2024. The lease agreement is subject to annual adjustment according to changes in the consumer price index.

Payments for the principal portion of the lease liabilities are not charged to profit and loss and will only have cash flow effects.

All figures in NOK '000

<b>Right to use asset – office lease</b>	
Initial recognition 01.01.2019	1 815
Acquisitions FY 2020	0
Acquisitions FY 2021	1 867
Acquisitions Q1 2022	0
Acquisitions Q2 2022	0
Acquisitions Q3 2022	0
<b>Acquisition costs 30.09.2022</b>	<b>3 682</b>
Depreciation FY 2019	604
Depreciation FY 2020	605
Depreciation FY 2021	618
Depreciation Q1 2022	155
Depreciation Q2 2022	155
Depreciation Q3 2022	155
<b>Accumulated depreciation and impairment as of 30.09.2022</b>	<b>2 291</b>
<b>Total right to use assets - office lease as of 30.09.2022</b>	<b>1 391</b>
Lower of remaining lease term or economic life	2.25 years
Depreciation method	Linear

(in NOK 1,000)

**Lease liabilities – office**

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
Recognition at exercise of lease option for 3 more years FY 2021	1 867
Payments principal portion of the lease liability FY 2021	-673
Payments principal portion of the lease liability Q1 2022	-177
Payments principal portion of the lease liability Q2 2022	-177
Payments principal portion of the lease liability Q3 2022	-177
Interest expenses on the lease liability FY 2019	38
Interest expenses on the lease liability FY 2020	144
Interest expenses on the lease liability FY 2021	40
Interest expenses on the lease liability Q1 2022	19
Interest expenses on the lease liability Q2 2022	19
Interest expenses on the lease liability Q3 2022	19
<b>Total lease liabilities for office as of 30.09.2022</b>	<b>1 434</b>
Whereof:	
Short term lease liabilities < 1 year	629
Long term lease liabilities > 1 year	805

<b>Income statement effects – office lease</b>	<b>Q3 2022</b>	<b>Q3 2021</b>	<b>YTD 2022</b>	<b>YTD 2021</b>	<b>FY 2021</b>
Depreciation of right to use asset	-155	-151	-464	-453	-618
Operating expenses for short-term leases	0	0	0	0	0
<b>Effect on Operating results net of tax</b>	<b>-155</b>	<b>-151</b>	<b>-464</b>	<b>-453</b>	<b>-618</b>
Interest expenses on the lease liabilities	-19	-10	-57	-29	-40
<b>Effect on Net financial result net of tax</b>	<b>-174</b>	<b>-161</b>	<b>-521</b>	<b>-482</b>	<b>-658</b>
<b>Comprehensive income effect net of tax</b>	<b>-174</b>	<b>-161</b>	<b>-521</b>	<b>-482</b>	<b>-658</b>

**16. Property, plant and equipment**

PCI Biotech acquired the first lots of lasers to be used in the RELEASE study during 2019 and further lasers were acquired during 2020 and 2021. A linear depreciation method over the expected lifetime of five years for the equipment was applied. The decision made in Q1 2022 to stop the RELEASE trial made the lasers of no or low value and the carrying amount is depreciated in full in 2022.

<b>Equipment</b>	<b>30.09 2022</b>	<b>30.09 2021</b>	<b>31.12 2021</b>
<b>Carrying value at the beginning of the period</b>	<b>5 806</b>	<b>7 388</b>	<b>7 388</b>
Acquisitions	0	341	341
Depreciation	12	1 439	1 922
Write-down	5 772	-	-
<b>Carrying value at the end of the period</b>	<b>22</b>	<b>6 290</b>	<b>5 806</b>



## **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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