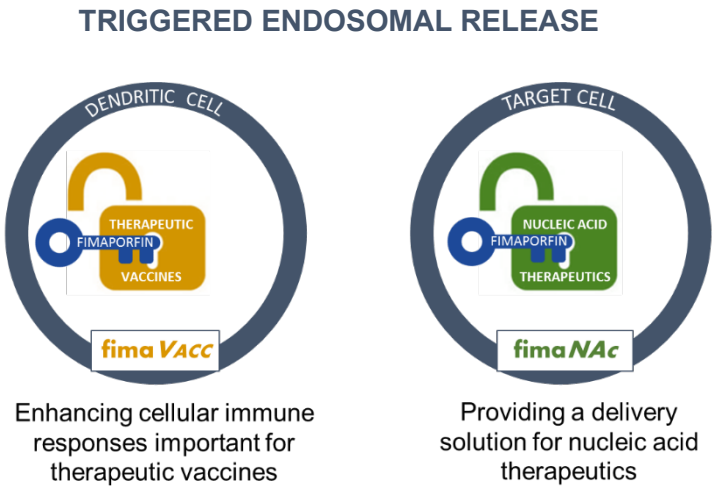
FIRST QUARTER REPORT 2022

Enabling intracellular delivery

PCI Biotech

LEVERAGING THE PCI TECHNOLOGY PLATFORM WITHIN IMMUNOTHERAPY & NUCLEIC ACID THERAPEUTICS



ABOUT PCI BIOTECH

PCI Biotech is an oncology-focused biopharmaceutical company headquartered in Norway and listed on the Oslo Stock Exchange. The company develops novel therapies for the treatment of cancer through its proprietary photochemical internalisation (PCI) technology originating from the 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 true potential of a wide array of therapeutic modalities, such as vaccines and different classes of nucleic acids.

PCI Biotech's lead programme fima*VACC* aims to enhance immunotherapy in cancer, by triggered endosomal release of antigens or nucleic acids encoding antigens, or immunostimulatory factors. In preclinical experiments fima*VACC* 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 fima*VACC* were successfully verified in humans through an extensive Phase I study in healthy subjects and a Phase II study is in planning with the aim to demonstrate enhancement of immunotherapy for treatment of solid tumours. The second programme fima*NAC* utilises the proven potential of the PCI technology for intracellular delivery of therapeutic nucleic acids. The technology can be used for most types of nucleic acids, ranging from oligonucleotides through mRNA and plasmids to some types of viral vehicles. The development of the fima*NAC* programme is focused on selected applications well suited to the specific strengths of the PCI technology and with several research collaborations established.

Highlights

fimaVACC

- The programme is progressing towards initiation of a Phase II clinical proof-of-concept study
- Established group of international clinical experts to provide clinical guidance and support the development and performance of the trial
- Good project readiness – preparation of clinical trial application and sourcing of study treatments ongoing, and selection of clinical sites in EU5 started

fimaNAC

- Progressing the focused development plan, targeting applications suited to the specific strengths of the PCI technology
- Established a preclinical collaboration with the South Korean company MDimune, developing innovative drug delivery technologies for modifying cellular and disease processes

fimaCHEM

- The RELEASE trial was closed to recruitment in January 2022 due to changes in the competitor situation that renders the trial challenging to complete and potentially inadequate for approval
- Available data from the RELEASE trial have been reviewed – there is not sufficient data to show differences between the treatment arms and last patient will leave the study in May
- RELEASE will be closed as quickly as possible, with an expected future cash effect of up to NOK -10 million

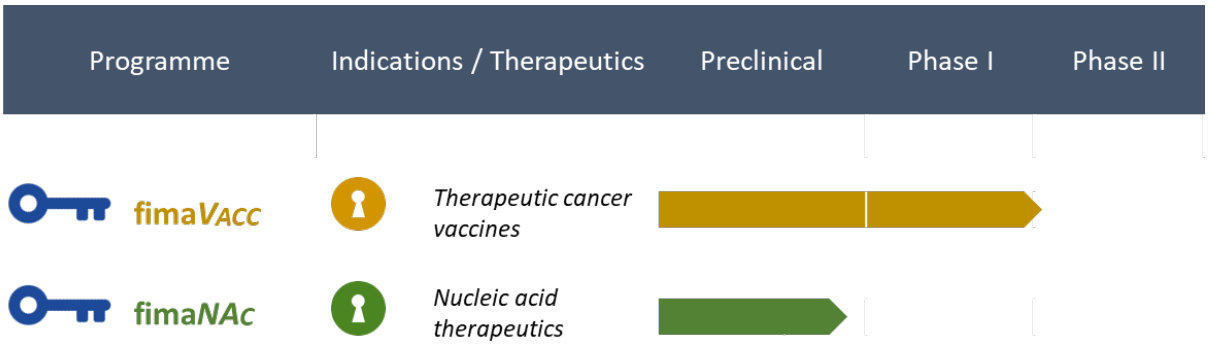
Corporate

- Per Walday will step down as CEO at the end of May 2022 and Ronny Skuggedal, CFO, is appointed as Interim CEO effective 1st June
- The CBO, Ludovic Robin, will leave the company in May 2022
- The organisation has been reduced by 4 FTE (25%), with notice periods ending during Q2. The financial runway, with current commitments, is estimated to be towards the end of 2023
- The Scientific Advisory Committee is further strengthened with Prof. Ernst Wagner at the Ludwig-Maximilians-Universität (LMU) and the Center of Nanoscience in Munich, Germany, contributing with distinguished expertise and experience in the field of targeted delivery of nucleic acids and protein therapeutics

Key figures

(In NOK 1,000)	2022 Q1	2021 Q1	2021 FY
Other income	1 188	1 588	6 273
Operating expenses	23 988	22 759	92 302
Operating results	-22 801	-21 171	-86 029
Net financial result	-212	-2 602	-2 362
Comprehensive income	**-23 012**	**-23 773**	**-88 391**
Cash & cash equivalents	**93 680**	**164 298**	**116 118**
Cash flow from operating activities	**-21 592**	**-20 621**	**-68 307**

Pipeline



Operational review and development 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 Phase I study. The technology is versatile, as it can potentially be used with several modalities, including nucleic acid-based immunotherapy technologies.

fimaVACC provides highly desired features for therapeutic vaccination technologies:

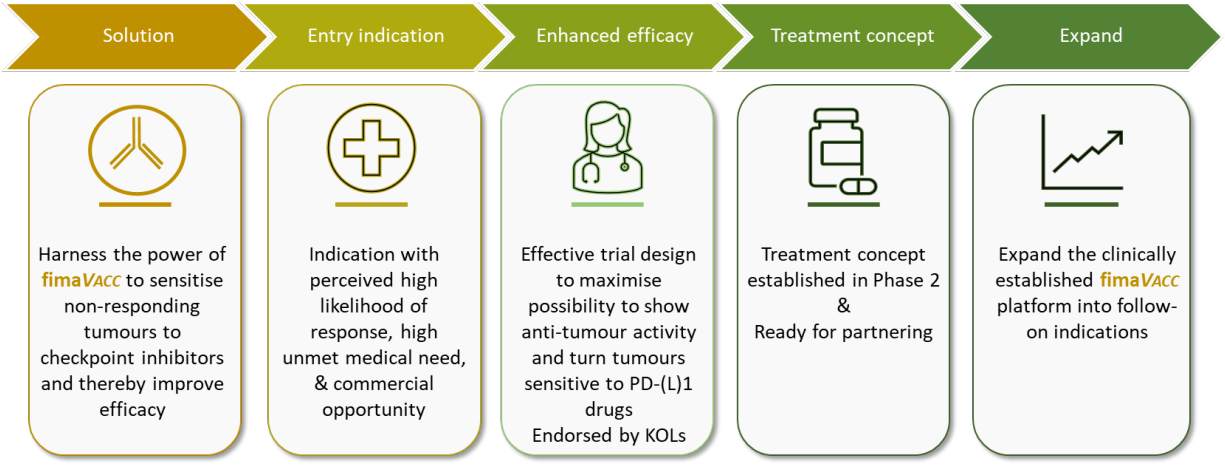
- ✓ **Increased number of responders**
- ✓ **Enhanced T-cell responses**
- ✓ **Improved T-cell functionality**

Targeting a cancer indication with high need for immune sensitisation

Immune checkpoint inhibitors (ICI) has revolutionised cancer treatment, as this class of drugs may induce long-lasting effects in those patients responding to immunotherapy. Unfortunately, most patients do not respond to ICI therapy and different treatment combination strategies are explored with the aim to increase the response rates. Combining ICIs with therapeutic cancer vaccines that induce relevant immune responses, such as induction of T-cells, is regarded as one of the most promising strategies. As next development step for fimaVACC, PCI Biotech is actively preparing for a Phase II clinical proof-of-concept (PoC) study for therapeutic vaccination of patients with recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC) who are resistant to ICI treatment. The planned PoC study is going to be an open-treatment, single arm study with read-out after 18 to 20 patients. Efficacy data will emerge as the study progress, with top line results expected in the first half of 2024.

The company has taken advice from a group of renowned international experts, including Prof. Kevin Harrington, Institute of Cancer Research, UK and Prof. Ezra Cohen, University of California, San Diego, US, to assess the best possible development opportunities in R/M HNSCC. A network of international expert investigators and advisors is established under the leadership of Prof. Harrington to provide clinical guidance and support the development and performance of the trial.

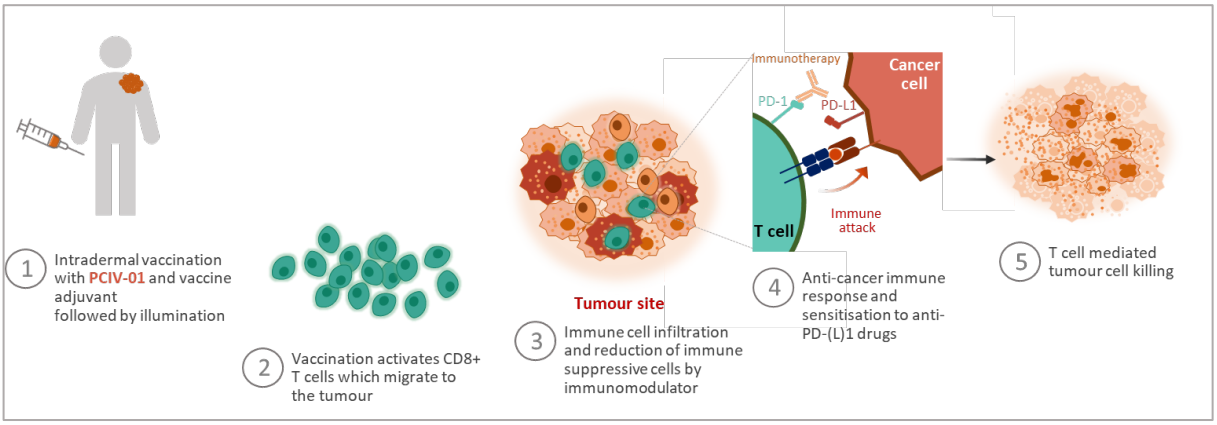
The development strategy is to leverage the expected strengths of the fimaVACC technology, initially focusing on a study in R/M HNSCC before a potential broadening of the deployment of the versatile platform. There is a high unmet medical need in R/M HNSCC, as most of these patients progress within 6 months of starting treatment with a PD-1 immune checkpoint inhibitor.



The study will evaluate efficacy, safety, and immunogenicity of a combination treatment with the vaccine product (PCIV-01), a toll-like receptor agonist adjuvant (Hiltonol), and an ICI. To decrease

immunosuppressive cells that may prohibit a proper immune response, an additional immunomodulator will be added to the combination treatment during the initial vaccination cycles. The combination of study treatments will be given to patients not responding to ICI treatment, with the aim to sensitise the tumour in these patients and by this achieve better efficacy.

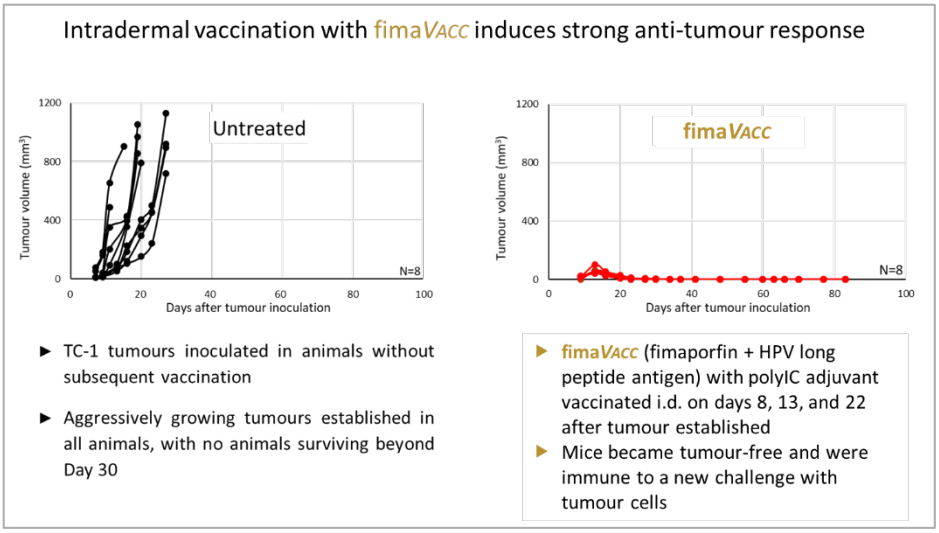
PCIV-01 consists of fimaporfin, HNSCC-associated antigen peptides and a helper T-cell stimulator peptide. The selected antigens are ranked among top cancer vaccine target antigens. The combination of PCIV-01 and Hiltonol is expected to synergistically induce cytotoxic T-cell priming and tumour infiltration, triggering an anti-cancer immune response.



The study preparations continue while financing opportunities are being explored, and the company will revert with more details regarding cost and timelines. Current activities are focused on production of the vaccine components, protocol development and operational activities required for timely initiation of the trial.

Scientifically validated platform with strong immune data and broad patent protection

The mechanism of action and the effect of the **fimaVACC** technology with peptide- and protein-based vaccines have been extensively elucidated in preclinical experiments. Strong synergistic effects have been shown in combination with several types of adjuvants, not least toll-like-receptor (TLR) agonists and PCI Biotech has use patents granted in major markets for such combinations. Preclinical experiments have shown that intradermal injection of this combination with relevant antigens has the power to eradicate aggressively growing inoculated tumours in mice, such as the HPV driven TC-1 tumours (see figure below).



In preclinical studies, combining **fima*VACC*** with ICIs can improve the anti-tumour effect in tumour-bearing mice and a patent for this combination is granted in the US, while still pending in Europe and Asia.

PCI Biotech has successfully translated the immune response characteristics of **fima*VACC*** into humans through a Phase I study in healthy subjects, using both peptide- and protein-based antigens. The immune results provide PoC and clinical support of **fima*VACC***'s potential to enhance overall T-cell responses, by demonstrating improvement of the immunogenicity of vaccines in healthy subjects. Safety and tolerability of intradermal treatment with **fima*VACC*** was established across a wide range of doses.

The Phase I results show a substantial increase in number of T-cell responders to HPV peptides already after two vaccinations, and a clear enhancement in the T-cell responses compared to the control group with a state-of-art vaccine adjuvant. The important CD8 T-cell responses were also more robust with **fima*VACC*** and exhibited increased functionality compared to control. The full study results have been published in Frontiers in Immunology[1], a high impact immunology journal.

Publication of preclinical BCG vaccination results

In January 2022, positive results from preclinical studies on BCG vaccination performed in collaboration with The University of Zurich and ETH Zurich were accepted for publication in Frontiers in Immunology, a high impact immunology journal. The article title is "Photochemically-mediated inflammation and cross-presentation of Mycobacterium bovis BCG proteins stimulates strong CD4 and CD8 T-cell responses in mice". Infectious diseases are not within PCI Biotech's core focus areas, but the results support our general understanding of **fima*VACC***'s mode of action and the potential of the technology.

Immunotherapy with the fima*VACC* technology

The pharmaceutical industry has long recognised the potential of therapeutic cancer vaccination, i.e. vaccines that treat cancer by inducing or strengthening the body's own immune response to cancer cells. The potential of combining cancer vaccination with immune checkpoint inhibitors has triggered a renewed interest in therapeutic cancer vaccines over the past years.

However, key issues remain to be solved, and the task of improving the immunogenicity of vaccine candidates is a main priority within the immunotherapy field. PCI Biotech believes the fima*VACC* technology can play a key role in solving this challenge.

Effective induction of cytotoxic T-cells will be critical to realise the potential of therapeutic cancer vaccines, and today's vaccines often fail to generate such responses. One of the main reasons is likely insufficient delivery of vaccine antigens to the appropriate presentation pathway in the immune cells. The fima*VACC* technology has the potential to effectively enhance intracellular delivery and vaccine presentation through these pathways.

fima*NAc*

The **fima*NAc*** programme provides a targeted intracellular delivery technology for many potential therapeutic applications with different classes of nucleic acids. It is currently a preclinical stage collaborative programme, with established research collaborations with companies developing nucleic acid based therapies. The results from these collaborations suggest that the **fima*NAc*** technology provides an appealing intracellular delivery solution for certain applications within this emerging class of therapeutics. Based on these results and other strategic considerations, the Company focus on selected applications suited to the specific strengths of the PCI technology. The focus will be on applications which are easily illuminable and have supporting preclinical results, such as skin applications where preclinical experiments suggest substantial enhancement of delivery and transfection, with excellent spatial specificity.

[1] doi.org/10.3389/fimmu.2020.576756

fima*CHEM*

In January 2022, the company decided to close recruitment to the RELEASE study and focus the drug development efforts on the promising immunotherapy opportunities with both **fima*VACC*** and **fima*NAC*** assets.

The decision to close recruitment to the RELEASE study was based on randomised Phase III clinical trial results presented at the American Society of Clinical Oncology Gastrointestinal Cancer Symposium (ASCO GI, January 20-22, 2022) from the TOPAZ-1 study, demonstrating that a combination of immune checkpoint inhibition with gemcitabine and cisplatin provides a significant survival benefit to patients with advanced biliary tract cancer compared with placebo plus gemcitabine and cisplatin. These results are expected to rapidly change the first-line standard treatment for patients with unresectable perihilar or distal bile duct cancer, which is the intended patient population of the RELEASE trial. Such a change in the standard of care treatment will render the RELEASE trial challenging to complete and the clinical results potentially inadequate for approval and significantly diminish the opportunity for PCI Biotech's treatment approach in this patient population.

The impact of the recent clinical trial results presented at ASCO GI has been discussed with key opinion leaders, confirming an expected rapid change and early adoption of immunotherapy plus chemotherapy as the new standard of care treatment for the RELEASE trial's target population.

The RELEASE trial has been a tremendous effort and the company is obliged to all external contributors, not least the enrolled patients, the clinical sites, and our investors, for their willingness to contribute to the benefit of future patients and their relatives.

PCI Biotech has focused on a swift and cost-efficient closing process of the RELEASE trial. The sites with no ongoing patients, nearly 60%, were closed immediately after the decision to terminate recruitment. Collection of efficacy data continued for ongoing patients until the earliest possible closure of the remaining sites. The trial enrolled a total of 41 patients, of which 34 patients provided efficacy data on PFS and ORR endpoints, which did not allow conclusion on potential differences between the treatment arms. All further follow-up assessments have ceased and the last patient will leave the study in May. The swift wind-down of RELEASE allows the company to reallocate resources to the other drug development programmes. The future cash effect for the closure process of RELEASE is estimated up to NOK -10 million. The study results will be published on clincialtrials.gov and in the EU clinical trial database.

Research collaborations

PCI Biotech has an active collaborative strategy for **fima*NAC*** and **fima*VACC***. The collaboration partners include MDimune, OliX Pharmaceuticals, Immunicum, eTheRNA immunotherapies, IMV and Aposense. In these collaborations, partners are exploring synergies between their proprietary technologies and the PCI technology, with potential for further expansion of the partnerships. Previous collaborative interactions and results with other key players 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 **fima*NAC*** and **fima*VACC*** programmes.

Encouraging collaborative data on the delivery of RNA molecules and on the use of the **fima*NAC*** delivery technology in the exciting field of RNA based therapies suggest that the **fima*NAC*** technology provides an appealing intracellular delivery solution for certain applications within this class of therapeutics. PCI Biotech see great potential for further development of our intracellular delivery technology, not least within the emerging field of immunotherapy. PCI Biotech continues to pursue new and value-adding collaborative opportunities for the **fima*NAC*** programme and in January 2022, PCI Biotech entered into a research collaboration with MDimune, a South Korean biotech company developing a versatile drug delivery system based on nanosized vesicles obtained from cells. The companies will combine their know-how and technology platforms to explore synergies. The partnership is governed by a research collaboration agreement, under which extensive evaluations of technology

compatibility and synergy will be performed using preclinical studies. The companies will evaluate the results achieved from the research collaboration to explore the potential for further development and partnership.

Corporate

Organisational changes during first half of 2022

The CEO, Dr. Per Walday, resigned in March to assume a new position. Dr. Walday has a six months notice period ending 30 September, but it is mutually agreed that he will step down from his position at the end of May. CFO, Ronny Skuggedal, is appointed Interim CEO effective 1 June and will then hold both positions.

Following the termination of RELEASE the CBO, Ludovic Robin, will leave the company in May 2022, and the clinical team will be reduced by two full-time employees by the end of June 2022.

Taking these organisational changes into account the PCI Biotech team will count 14 full-time equivalents (FTE), which constitutes a reduction in FTE of 25% compared to the beginning of the year.

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 for Q1 amounted to NOK 1.2 million (NOK 1.6 million).

Research and development (R&D) expenses for Q1 ended at NOK 21.8 million (NOK 16.7 million), including a write-down of devices that were used in the RELEASE trail. These devices were recognised with a carrying value of NOK 5.8 million at the start of the year, which has been depreciated in full in Q1 without cash-flow effect.

General and administrative (G&A) expense for Q1 ended at NOK 2.2 million (NOK 6.1 million). The change in G&A for Q1 2022 compared to last year, is mainly driven by accounting effect fluctuations for the share option scheme, without direct cash flow effects. In Q1 2022 a total number of 520,000 outstanding share options lapsed, resulting in a reversal of cost from previous periods of NOK 4 million. Operating expenses for Q1 were NOK 24.0 million (NOK 22.8 million). Operating expenses are mainly driven by the R&D activity level and the pivotal fima*CHEM* trial (RELEASE) was the main cost driver for the quarter in both 2022 and 2021. There were two non-recurring items in the quarter, write-down of lasers and reversal of costs related to the share option scheme, with a net accounting effect of NOK 1.8 million in operating expenses.

Net financial results for Q1 were NOK -0.2 million (NOK -2.6 million). 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 pivotal RELEASE study.

Net loss for Q1 was NOK 23.0 million (NOK 23.8 million).

Cash flow and balance sheet

The decision to stop the RELEASE trial impacted property, plant and equipment as this balance sheet item includes a device specifically designed to be used in the trial. The post-decision value of the device is considered to be low or of no value and the devices are depreciated in full in Q1 2022 without cash-flow effect.

The Group held cash and cash equivalents of NOK 93.7 million at end of Q1 2022, compared to NOK 116.0 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 -21.6 million for Q1 2022 (NOK -20.6 million). All cash and cash equivalents are placed as bank deposits. Exchange rate effects on bank deposits in foreign currency were NOK 0.7 million negative for Q1 2022 (NOK 2.7 million negative).

Based on the decision to terminate the RELEASE trial, and the organisational changes during first half of 2022, the current cost base for the company will be reduced. The future cash effect for closure of RELEASE is estimated up to NOK -10 million. The cash position by the end of Q1 2022 enables an estimated financial run-way for the company towards the end of 2023, with current commitments.

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.

Changes to the Scientific Advisory Committee (SAC)

To tailor the collective competence of the SAC members to PCI Biotech's strategy we are delighted to announce that Prof. Ernst Wagner has been appointed as a new SAC member. Prof. Wagner is a professor of Pharmaceutical Biotechnology at the Ludwig-Maximilians-Universität (LMU) and the Center of Nanoscience in Munich, Germany. Previously (1991-2001), he was the Director Cancer Vaccines & Gene Therapy at Boehringer Ingelheim in Vienna, Austria, where he supervised the first-in-world polymer-based human gene therapy trial in 1994. Prof. Wagner is an Academician of European Academy of Sciences, a member of the Controlled Release Society (CRS) College of Fellows, and a board member of German Society for Gene Therapy. Prof. Wagner has authored more than 485 publications with more than 45 000 citations. His current academic research projects focus on the targeted delivery of nucleic acids (including mRNA) and protein therapeutics.

Prof. Taskén at Oslo University Hospital has served as a SAC member for PCI Biotech since 2018, and prior to that 10 years as a director, and he will now step out of the SAC. PCI Biotech would like to thank Prof. Taskén for his excellent contributions to PCI Biotech over the years.

Collaboration with Norwegian Institute for Marine Research (NIMR)

NIMR (Havforskningsinstituttet) received in 2021 NOK 4.5 million from the Norwegian Seafood Fund for a collaboration project with PCI Biotech exploring 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

Except for the organisational changes during first half of 2022 described above, PCI Biotech is not aware of any other 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. Supported also by external collaboration partners' opinion, the PCI technology has the opportunity to play a significant role in the realisation of several new therapeutic modalities, including immunotherapy (**fima*VACC***) and nucleic acid therapeutics (**fima*NAc***).

A Phase I study in healthy subjects provided affirmative results on translation of the **fima*VACC*** technology into humans and key data to support the programme's further development. A Phase II study is in planning for development of a defined **fima*VACC*** product, aiming to demonstrate enhanced response to immunotherapy in patients with recurrent/metastatic head and neck cancer.

The **fima*NAc*** programme continues to follow a collaborative approach, by development of treatment applications in the most attractive areas for the technology and pursuing out-licensing opportunities.

In short, the main priorities of PCI Biotech at this time are to:

- Implement the strategy for the next phase of development for **fima*VACC***, towards clinical proof-of-concept in recurrent/metastatic head and neck cancer patients
- Manage alliance and partnering activities across all commercially interesting areas for the PCI platform
- A swift and cost-efficient closing process for the RELEASE study

The Board of Directors and CEO
PCI Biotech Holding ASA
Oslo, 10 May 2022

Hans Peter Bøhn Chairman (sign)	Christina Herder Director (sign)	Hilde Furberg Director (sign)
Andrew Hughes Director (sign)	Lars Viksmoen Director (sign)	Per Walday CEO (sign)

CONDENSED INTERIM CONSOLIDATED FINANCIAL INFORMATION

PROFIT AND LOSS *(in NOK '000)*	Note	Q1 2022	Q1 2021	FY 2021
Other income	*6*	**1 188**	**1 588**	**6 273**
Research and development	*8,16*	21 809	16 653	71 707
General and administrative	*15*	2 180	6 106	20 595
Operating expenses		**23 988**	**22 759**	**92 302**
Operating results		**-22 801**	**-21 171**	**-86 029**
Financial income and expenses				
Financial income		382	205	789
Financial expenses		594	2 807	3 151
Net financial result	*7*	**-212**	**-2 602**	**-2 362**
Profit/Loss before income tax		**-23 012**	**-23 773**	**-88 391**
Income tax	*9*	**0**	0	**0**
Net profit/loss		**-23 012**	**-23 773**	**-88 391**
Other comprehensive income		**0**	0	**0**
Total comprehensive income	*5*	**-23 012**	**-23 773**	**-88 391**

Balance sheet *(in NOK '000)*	Note	31.03 2022	31.03 2021	31.12 2021
Non-current assets				
Property, plant and equipment	*16*	30	7 083	5 806
Right to use asset	*15*	1 700	454	1 854
Total non-current assets		**1 730**	**7 537**	**7 660**
Current assets				
Short term receivables	*7*	14 000	14 475	12 200
Cash & cash equivalents	*7*	93 680	164 298	116 118
Total current assets	*14*	**107 679**	**178 773**	**128 318**
Total assets		**109 409**	**186 310**	**135 978**
Equity and liabilities				
Equity				
Paid in capital	*10,11*	562 443	562 443	562 443
Other reserves		-473 643	-393 702	-448 651
Total equity		**88 800**	**168 741**	**113 792**
Long-term liabilities				
Other long-term liabilities		0	0	0
Lease liabilities	*15*	1 119	0	1 277
Total long-term liabilities	*13*	**1 119**	**0**	**1 277**
Short term liabilities				
Trade debtors		4 406	2 871	3 745
Lease liabilities	*15*	629	505	629
Other short-term liabilities	*7,12*	14 455	14 193	16 535
Total short-term liabilities		**19 489**	**17 568**	**20 909**
Total liabilities	*14*	**20 609**	**17 568**	**22 186**
Total equity and liabilities		**109 409**	**186 310**	**135 978**

CHANGE IN EQUITY

(in NOK '000)	Q1 2022	Q1 2021	FY 2021
Equity at beginning of the period	**113 792**	**189 244**	**189 244**
Capital increase	0	0	0
Share option scheme	-1 980	3 270	12 939
Comprehensive income in the period	-23 012	-23 773	-88 391
Equity at end of the period	**88 800**	**168 741**	**113 792**

CASH FLOW

(in NOK '000)	Q1 2022	Q1 2021	FY 2021
Ordinary profit before taxes	-23 012	-23 773	-88 391
Depreciation, amortisation and write off	5 930	627	2 541
Leasing interest cost	19	0	38
Share options	-1 980	3 270	12 939
Currency gain (-) / loss (+) not related to operations	671	2 709	2 529
Changes in working capital and other non-cash adjustments	-3 221	-3 455	2 036
Cash flow from operating activities	**-21 592**	**-20 621**	**-68 307**
Acquisition of non-current assets	0	-170	-341
Net cash flow from investing activities	**0**	**-170**	**-341**
Cash flow from financial activities			
Payment principal portion of lease liabilities	-175	-168	-673
Net proceeds from share issues	0	0	0
Net cash flow from financial activities	**-175**	**-168**	**-673**
Net change in cash during the period	**-21 767**	**-20 960**	**-69 321**
Exchange rate effect on bank deposits in foreign currency	-671	-2 709	-2 529
Cash and cash equivalents at the beginning of the period	116 118	187 967	187 967
Cash and cash equivalents at the end of the period	**93 680**	**164 298**	**116 118**

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. 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. Photochemical Internalisation (PCI) is a proprietary technology for light-directed intracellular drug delivery by triggered endosomal release.

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 (fima*VACC*) and delivery of nucleic acids (fima*NAC*). The fima*VACC* programme has completed a Phase I study in healthy subjects, which has provided scientific proof-of-concept of fima*VACC'S* ability to enhance and direct the response of vaccines towards a stronger cellular immune response. A Phase II study is in planning with the aim to demonstrate enhancement of immunotherapy for treatment of solid tumours. The fima*NAC* 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 (fima*CHEM*) 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 10 May 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 31st, 2021.

5. Earnings per share

	Q1 2022	Q1 2021	FY 2021
Result allocated to shareholders (in NOK '000)	(23 012)	(23 773)	(88 391)
Weighted average of outstanding shares (in NOK '000)	37 326	37 326	37 326
Earnings per share (NOK per share)	-0.62	-0.64	-2.37

Earnings per share is not affected by dilution from outstanding share options if negative results in the period. Per year-end of Q1 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	7 475	359	4 978	1 188	14 000
Total receivables	**7 475**	**359**	**4 978**	**1 188**	**14 000**

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.

For Q1 2022 a negative accounting effect of NOK 0.7 million (Q1 2021: NOK 2.7 million) has been charged as financial expenses, resulting from converting Euro cash deposits into NOK as functional currency for the interim report.

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

	Q1 2022	Q1 2021	FY 2021
Clinical studies	17 646	12 906	57 204
Pre-clinical studies	2 294	1 405	6 966
CMC and equipment	982	1 327	3 332
Patents	887	1 014	4 204
Other costs	0	0	0
Total	**21 809**	**16 653**	**71 707**

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 148.7 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:

		Number of share options	
Expiry date	Exercise price in NOK per share option	31.12.2021	31.03.2022
2022 - Q3	21.48	310 000	200 000
2024 - Q3	25.78	300 000	220 000
2025 - Q3	50.36	520 000	340 000
2026 - Q3	19.41	485 000	335 000
Total		**1 615 000**	**1 095 000**

The current authorisation, granted by the Annual General Meeting on 28 May 2021, for the employee share option program allows for a total of 2,790,000 share options, of which 1,095,000 have been granted by the Board of Directors per end of the quarter.

During Q1 2022 a total of 520,000 previously granted share options lapsed, due to employees entering notice periods. The accounting effect of lapsed share options is a cost-reversal of NOK 4 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.

Overview share options, Senior executives	Total holdings 31.12.2021	Allocated	Lapsed	Exercised	Expired	Total holdings 31.03.2022
Per Walday, CEO	295 000	0	295 000	0	0	0
Ronny Skuggedal, CFO	190 000	0	0	0	0	190 000
Anders Høgset, CSO	190 000	0	0	0	0	190 000
Kristin Eivindvik, CDO	110 000	0	0	0	0	110 000
Lucy Wabakken, CDO (acting)	160 000	0	0	0	0	160 000
Ludovic Robin, CBO	130 000	0	130 000	0	0	0
Amir Snapir, CMO	150 000	0	0	0	0	150 000
Total	**1 225 000**	**0**	**425 000**	**0**	**0**	**800 000**

11. Share capital

	No. of shares	Nominal value per share in NOK	Share capital in NOK
31.12.2021	**37 326 390**	**3.00**	**111 979 170**
Transactions	-	-	-
31.03.2022	**37 326 390**	**3.00**	**111 979 170**

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 2021 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 more than 6,200 shareholders at end of the quarter.

10 largest shareholders per 31 March 2022:

Name	No. of shares	Ownership
FONDSAVANSE AS	3 910 443	10,48 %
MP PENSJON PK	2 186 729	5,86 %
Myrlid AS	2 100 000	5,63 %
RADFORSK INVESTERINGSSTIFTELSE	1 082 415	2,90 %
GRESSLIEN	900 700	2,41 %
Nordnet Bank AB	751 729	2,01 %
RAVI INVESTERING AS	500 000	1,34 %
NORDNET LIVSFORSIKRING AS	478 959	1,28 %
Jandersen Kapital AS	470 000	1,26 %
FORENEDE FORVALTNING AS	385 188	1,03 %
Total 10 largest shareholders	**12 766 163**	***34,20 %***
Others	*24 560 227*	*65,80 %*
Total	*37 326 390*	*100,00 %*

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

		No. of shares	
Name	**Position**	**31.12.2021**	**31.03.2022**
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	4 000
Andrew Hughes	Board member	0	0
Per Walday	CEO	72 700	72 700
Anders Høgset	CSO	64 800	64 800
Ronny Skuggedal	CFO	55 000	55 000
Kristin Eivindvik	CDO	25 200	25 200
Lucy Wabakken, and related parties	CDO (acting)	10 008	10 008
Ludovic Robin	CBO	0	0
Amir Snapir	CMO	0	0
Total		**378 336**	**378 336**

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

12. Other short-term liabilities

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

13. Long-term liabilities

Total 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

Right to use asset - office lease	
Initial recognition 01.01.2019	1 815
Acquisitions FY 2020	0
Acquisitions FY 2021	1 867
Acquisitions Q1 2022	0
Acquisition costs 31.03.2022	**3 682**
Depreciation FY 2019	604
Depreciation FY 2020	605
Depreciation FY 2021	618
Depreciation Q1 2022	155
Accumulated depreciation and impairment as of 31.03.2022	**1 982**
Total right to use assets - office lease as of 31.03.2022	**1 700**
Lower of remaining lease term or economic life	2.75 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	-175
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
Total lease liabilities for office as of 31.03.2022	**1 748**
Whereof:	
Short term lease liabilities < 1 year	629
Long term lease liabilities > 1 year	1 119

(in NOK 1,000)

Income statement effects – office lease	**Q1 2022**	**Q1 2021**	**FY 2021**
Depreciation of right to use asset	-155	-152	-620
Operating expenses for short-term leases	0	0	0
Effect on Operating results net of tax	**-155**	**-152**	**-620**
Interest expenses on the lease liabilities	-19	-10	-40
Effect on Net financial result net of tax	**-174**	**-162**	**-660**
Comprehensive income effect net of tax	**-174**	**-162**	**-660**

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 have been acquired during 2020 and 2021. A linear depreciation method over the expected lifetime of five years for the equipment is 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.

Equipment	31.12 2021	31.03 2022
Carrying value at the beginning of the period	**7 388**	**5 806**
Acquisitions	341	-
Depreciation	1 922	4
Write-down		5 772
Carrying value at the end of the period	**5 806**	**30**

17. Subsequent events

Except for the organisational changes during first half of 2022 described in more detail under the section 'Organisational changes during first half of 2022' in this report, PCI Biotech is not aware of any other post-closing events, which could materially influence this interim financial statement.

DEFINITIONS AND GLOSSARY

Amphinex:	Trade name of the clinical intravenous formulation of fimaporfin
BIA:	User-driven research-based innovation program by the Research Council of Norway
CCA:	Cholangiocarcinoma – Bile duct cancer
FDA:	US Food and Drug Administration
Fimaporfin:	Generic name of the photosensitiser active ingredient TPCS2a
fima*CHEM*:	PCI Biotech's development program for enhancement of generic chemotherapies
fima*NAC*:	PCI Biotech's development program for delivery of nucleic acids
fima*VACC*:	PCI Biotech's development program for a vaccination technology
HPV:	Human papillomavirus
IDMC:	Independent Data Monitoring Committee
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
SoC:	Standard of Care
NOK:	Norwegian kroner
FY:	Financial year (1st January – 31st December)
1H:	First half year (1st January – 30th June)
2H:	Second half year (1st July – 31st December)
Q1:	First quarter (1st January – 31st March)
Q2:	Second quarter (1st April – 30th June)
Q3:	Third quarter (1st July – 30th September)
Q4:	Fourth quarter (1st October – 31st December)
YTD:	Year to date

Enabling intracellular delivery

FINANCIAL CALENDAR

Annual General Meeting	25 May 2022
Q2 Report 2022	31 August 2022
Q3 Report 2022	23 November 2022

INVESTOR CONTACT

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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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