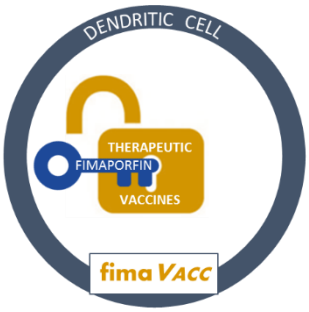
Enabling intracellular delivery

FIRST QUARTER REPORT
2021

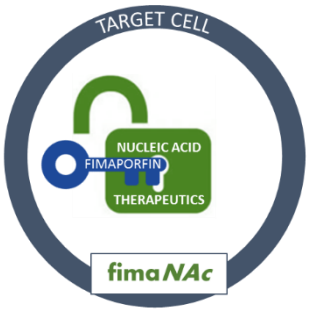
LEVERAGING THE PCI TECHNOLOGY IN THREE DISTINCT AREAS

TRIGGERED ENDOSOMAL RELEASE

Enabling approved drugs to fulfil unmet local treatment need



Enhancing cellular immune responses important for therapeutic vaccines



Providing a delivery solution for 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 small molecules, vaccines and nucleic acids.

PCI Biotech's lead programme is fima*CHEM* with the photosensitiser fimaporfin (Amphinex®), which entered the pivotal RELEASE study in May 2019, following the completion of a Phase I study with encouraging tumour response and survival data. The second programme fima*VACC* is a vaccination technology that enhance the essential cytotoxic effect of therapeutic vaccines. Successful clinical proof of concept was achieved in a Phase I study in healthy volunteers in 2019. The third programme fima*NAC* is a technology for intracellular delivery of nucleic acids, which is currently being evaluated in collaboration with several players in the field.

Highlights

fimaCHEM

- Increased screening and enrolment to RELEASE in Q1 after implementation of the amended protocol and the opening of Asian sites. The full effect of these initiatives is not expected until the Covid-19 situation improves further
- The first US patient was enrolled in the RELEASE study in April
- Continued focus on enrolment of patients into the RELEASE study, with the emphasis going forward being on regular trial management, including performance evaluation and replacement of underperforming sites
- The expected timeline for the planned interim analysis remains in the range from 2H 2022 to 1H 2023

fimaVACC

- Successful Phase I vaccination proof of concept study published in the high impact immunology journal, Frontiers in Immunology, demonstrating that fima*VACC* enhances the immune response to peptide- and protein-based vaccines in healthy volunteers. The focus going forward is utilising the Phase I results in partnering efforts and planning for clinical proof-of-concept in a disease setting

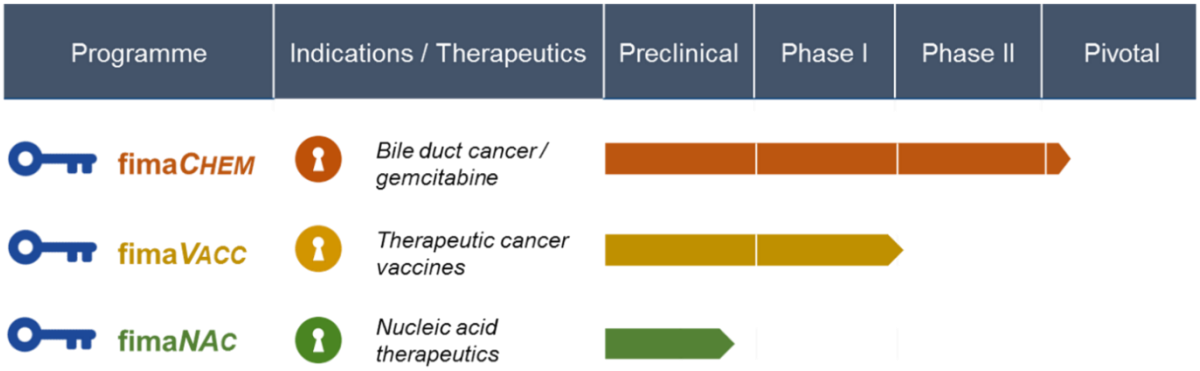
fimaNAc

- Encouraging data on enhanced delivery of mRNA for various medical applications was presented at the UK based 12th Annual RNA Therapeutics Virtual Conference in February 2021
- In May 2021, PCI Biotech entered into an extensive research collaboration with the South Korean company OliX Pharmaceuticals, a leading developer of RNAi therapeutics

Key figures

(In NOK 1,000)	2021 Q1	2020 Q1	2020 FY
Other income	1 588	1 191	7 368
Operating expenses	22 759	17 893	89 488
Operating results	-21 171	-15 974	-82 121
Net financial result	-2 602	20 401	9 881
Comprehensive income	**-23 773**	**4 427**	**-72 239**
Cash & cash equivalents	**164 298**	**258 080**	**187 967**
Cash flow from operating activities	**-20 621**	**- 22 371**	**-77 391**

Operational review and development programmes overview



Implications of the COVID-19 pandemic

COVID-19's impact on the general biotech industry may in broad terms be summarised as hampering the conduct and progress of clinical development, disruption of the supply chain, exchange rate fluctuations, access to resources through the capital market and other health economic aspects. PCI Biotech is closely monitoring potential implications on its short- and long-term operations during the course of the COVID-19 pandemic. PCI Biotech's overriding priority is the safety of its staff and patients participating in the clinical trial and its collaborators. Screening of patients was severely affected in 2020 and the situation was still challenging in Q1 2021. Initial indications of increased screening and enrolment under the amended protocol and after expanding the study into Asia, despite the continued impact of the pandemic is encouraging. The full effect of these initiatives is not expected until the Covid-19 vaccination further reduces the effect of the pandemic on the healthcare systems. The company has not experienced any major shortage in supplies of investigational products and devices for the trial in 2021. For the **fimaVACC** and **fimaNAc** programmes the main implications have been transient downturn in business development activities.

Given the uncertainty surrounding long-term consequences of the COVID-19 pandemic, the anticipated timeline for the planned interim analysis remains in the range from 2H 2022 to 1H 2023. The current cash-position may therefore not be sufficient to reach interim read of the RELEASE trial. The company is closely monitoring progress in relation to timelines and costs.

fimaCHEM

The **fimaCHEM** programme for local enhancement of cancer treatments is the most advanced of PCI Biotech's development programmes. The main focus is now to bring the lead candidate to the market through successful completion of the pivotal RELEASE trial for treatment of inoperable bile duct cancer.

RELEASE is a single randomised pivotal study with registration intent, building on encouraging results from the Phase I study. The first patient of a total of 186 patients was enrolled in May 2019 after final confirmation of the safety of up to two **fimaCHEM** treatments in the Phase I extension study in April the same year.

RELEASE will evaluate PCI Biotech's Amphinex® product -an intravenous formulation of fimaporfin- in combination with the standard of care chemotherapy with gemcitabine and cisplatin.

Bile duct cancer is a rare disease with high unmet medical need and the combination of Amphinex and chemotherapy will be evaluated as a first line treatment, with orphan drug designation granted in both EU and the US.

RELEASE progress and initiatives for increased patient enrolment

The RELEASE study has enthused investigators, which is very important for clinical studies in rare patient groups such as bile duct cancer

Scale-up and optimisation activities for the RELEASE study were carried out during 2020. Most of this work has been implemented and focus will now be on regular trial management. This includes performance evaluation and replacement of underperforming sites, as well as monitoring study specific risks, such as retention of randomised patients and adherence to study procedures and eligibility criteria.

Besides expanding the RELEASE trial into Asia, the most important optimisation is the modification of patient eligibility criteria, made to expand the eligible patient population and thereby increase the enrolment rate with limited increase of the overall study risk. The study accessibility has also been strengthened, both by the establishment of several online tools, interaction with patient organisations and publication of case reports. Ukraine is the last country added to the country mix in Europe. By end-April 2021, 46 sites across 14 countries were open for recruitment.

In Q1 2021 we experienced increased patient screening and enrolment in both Europe and Asia. The situation has been difficult in the US but is slowly easing, with an increased screening activity in Q1 and the first US patient enrolled in April.

The consequences of the pandemic and the effect of the new recruitment initiatives for the RELEASE study timeline cannot yet be fully established and the anticipated timeline for interim read is retained as a range from second half 2022 to first half of 2023. The current cash position may therefore not be sufficient to reach interim read of the RELEASE study and the company will continue to closely monitor progress in relation to timelines and costs.

Expansion of RELEASE to Asia

The expansion of RELEASE to Asia during second half of 2020 was done to enhance patient recruitment and provide access to hospitals and key opinion leaders in this region with higher prevalence of bile duct cancer, and the expansion may also open up the potential upside from a business perspective. The trial is open in South-Korea and Taiwan and other commercially interesting countries are considered to be Japan, Hong Kong and China. The Asian market is known to be fragmented and PCI Biotech do not foresee to commercialise fimaCHEM for bile duct cancer in Asia without a partner.

The target population for fimaCHEM is inoperable patients, and applying a projection of inoperable patients based on the estimated inoperable portion from the Western world (approx. 75%[1]) and taking

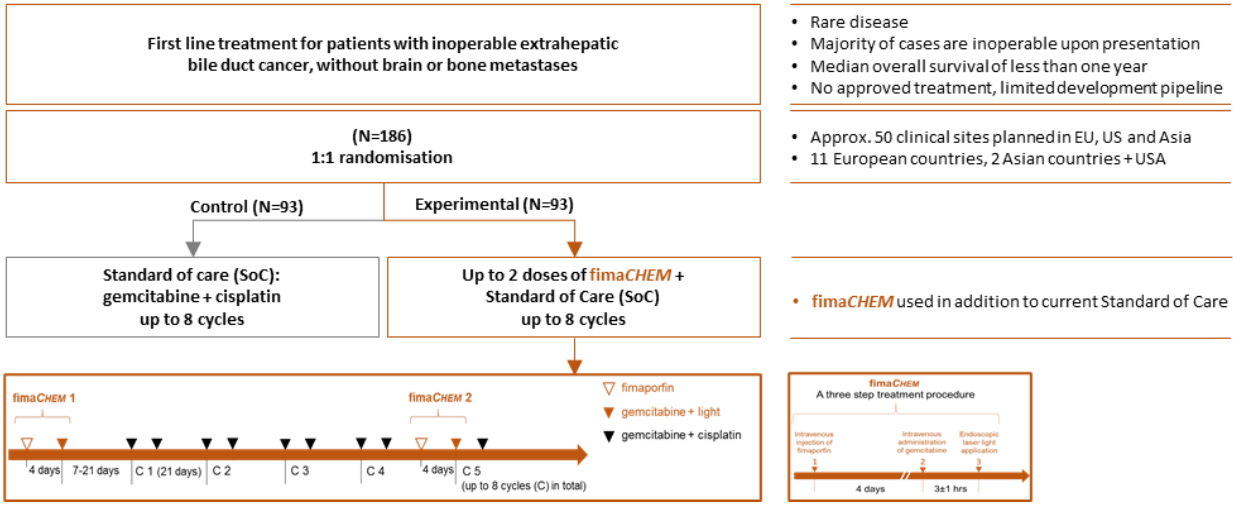
[1] PCIB internal CCA market analysis and KOL advisory meeting

into account that not all parts of the population in China will have access to the treatment, it can be estimated potential access to more than 4,000 patients annually in the commercially interesting part of the Asian market. This preliminary figure is based on publicly available epidemiological information[2].

The design of the pivotal RELEASE study is based on regulatory interactions

The RELEASE study design is based on the outcome of several interactions with the two leading regulatory authorities, the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA).

Study overview:



Milestones and timelines:

First EU patient enrolled in May 2019; first Asian patient enrolled in October 2020; first US patient enrolled April 2021	• Enrolling patients on three continents
Seamless safety review by IDMC* when 8 patients have undergone 2 fimaCHEM treatments	• IDMC safety review expected 2H 2021
Tumour response interim analysis when 120 patients have been through the 3 months scan	• Interim analysis expected 2H 2022 – 1H 2023
Timing and format for study conclusion may be impacted by outcome of Interim analysis	• Final analysis expected approximately 1H 2024

*IDMC = Independent Data Monitoring Committee

Endpoints:

Interim analysis:	Primary Endpoint: Objective Response Rate (ORR) Secondary endpoint: Overall Survival (OS)	• Orphan drug designation in Europe and USA • Potentially accelerated/conditional approval
Final analysis:	Primary endpoint: Progression Free Survival (PFS) Key secondary endpoint: Overall Survival (OS)	• Single randomised trial sufficient based on interaction with US and EU regulatory authorities

Regular communication milestones for the RELEASE study

The planned communication milestones for the pivotal RELEASE study will be quarterly updates on the number of countries and clinical sites open for recruitment, as well as updates on expected timelines for major milestones. Other milestones and updates will be communicated as appropriate, including outcome of the IDMC reviews, as well as further details regarding timing and plan for interim analysis.

[2] Translational Gastrointestinal Cancer, 2012

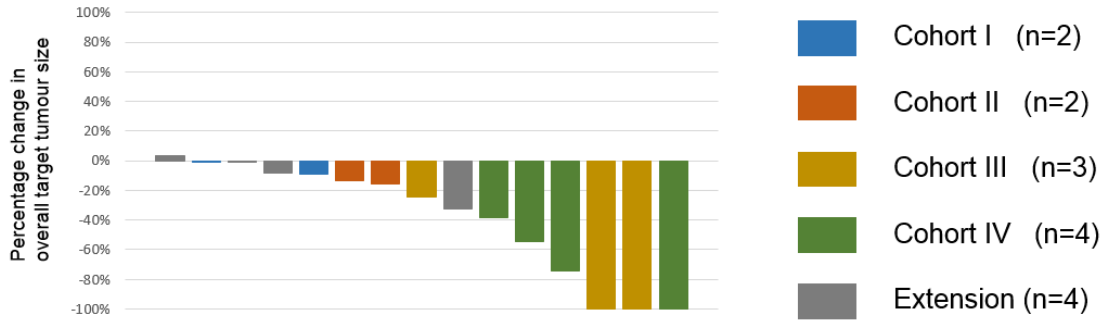
Phase I results paved the way for the pivotal RELEASE trial with registration intent

The RELEASE study builds on the favourable safety results and encouraging early signs of efficacy in the Phase I study, with more than 80% of the patients being progression-free at 6 months.

The **fima*CHEM*** treatment boosts the chemotherapy effect locally in the bile duct. Local tumour response in the bile duct is important to maintain biliary drainage, and the primary tumour response may therefore be more important for survival outcome than would be the case for many other cancers.

Overview best overall response – patients with measurable disease in all cohorts (n=15)

(Cohort I, II & Extension: data from local read, Cohort III & IV: data from centralised read)



Tumour response translates into encouraging survival data

All patients have been followed-up for survival post-study and the finally confirmed median overall survival (mOS) for the full study ended on 16.1 months at final censoring, with two patients still being alive.

The group in the dose escalation study that received the RELEASE study dose (n=6, cohort IV) had a mOS of 22.8 months and half of these patients exceeded 30 months survival. The mOS in the extension group (n=7), where patients received up to two **fima*CHEM*** treatments of the RELEASE dose was 16.6 months, with one patient still alive at final censoring. Five of the seven extension patients received two **fima*CHEM*** treatments.

Although these are small patient groups with considerable heterogeneity, positive signs of objective tumour response seem to translate into encouraging survival data.

Phase I study results presented and published

The early encouraging results from the Phase I study have over time been presented at several relevant conferences as the data matured. In November 2020 a case report series from the Phase I study was published in Endoscopy International Open[3]. The article provides detailed descriptions of treatment effects in three select patients at the dose chosen for the RELEASE study. The title of the publication is "Photochemical Internalisation and gemcitabine combined with first-line chemotherapy in perihilar cholangiocarcinoma – observations in three patients".

[3] Endosc Int Open 2020; DOI: 10.1055/a-1276-6366

Bile duct cancer and the fima*CHEM* technology

Bile duct cancer originates in the ducts that drain bile from the liver into the small intestine. It is a rare disease with an annual incidence rate of 1-2 cases per 100,000 in the Western world but higher prevalence (1-4 cases per 100,000) in the most relevant Asian countries.

There is currently no approved treatment specifically for extrahepatic bile duct cancer and the development pipeline for new potential treatments is limited. Bile duct cancer is also characterised by a remarkable resistance to common chemotherapy, leaving surgery as the only possibly curative treatment today. However, the majority of new cases are deemed inoperable upon presentation, meaning that there is a high unmet need for new drug classes, improved treatment technologies, or alternative methods in order to increase overall survival and quality of life for these patients.

The current Standard of Care (SoC) for inoperable extrahepatic bile duct cancer patients is stenting to keep the bile duct open, followed by a combination treatment with the chemotherapies gemcitabine and cisplatin. In preclinical studies, the fima*CHEM* technology has significantly enhanced the effect of gemcitabine, which is the most studied and used chemotherapy drug in bile duct cancer treatment.

The bile duct is easily accessible for light application through routinely used endoscopic methods.

Comparator data for inoperable bile duct cancer
The median overall survival (mOS) in the studies that established the combination of gemcitabine and cisplatin as Standard of Care in bile duct cancer was 11.7 and 11.2 months respectively (Valle *et al.* NEJM (2010) 362:1273-81 and Okusaka *et al.* BJC (2010) 103:469-74).

While these results represent the best available published comparator data it should be noted that the results are not directly comparable to the data on inoperable extrahepatic bile duct cancer in the fima*CHEM* Phase I study. The published studies include a wide range of different inoperable bile duct cancer patients, while the fima*CHEM* treatment is focused solely on inoperable extrahepatic bile duct cancer.

fima*VACC*

The fima*VACC* technology aims to enhance immune responses important to the therapeutic effect of vaccines and has proven 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. The technology is versatile, as it can potentially be used with several modalities, including nucleic acid based technologies.

Successful clinical proof-of-concept in healthy volunteers

PCI Biotech has successfully translated fima*VACC* with peptide- and protein-based vaccines into humans through a Phase I study in healthy volunteers. The immune results provide Proof-of-Concept and clinical support of fima*VACC*'s potential to enhance overall T-cell responses, by demonstrating improvement of the immunogenicity of vaccines in healthy volunteers. More than 90 subjects were included, and tolerability of intradermal treatment with fima*VACC* is established across a wide range of doses.

fima*VACC* provides highly desired features for therapeutic vaccination technologies:

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

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 responses were more robust with **fima*VACC*** and exhibited increased functionality compared to control.

Proof-of-concept in healthy volunteers presented and published

The overall study results from the Phase I study were presented at the ESMO Immuno-Oncology Congress in December 2019 and the full study results were published early January 2021 in Frontiers in Immunology[4], a high impact immunology journal. The study was performed in collaboration with international experts, including staff at the Department of Medical Oncology at Leiden University Medical Centre (LUMC) under the leadership of Professor Sjoerd van der Burg.

Development considerations for the fima*VACC* platform

The Phase I study provided proof-of-concept by demonstrating improvement of vaccine immunogenicity in healthy volunteers applying peptide- and protein-based vaccines. As a next development step, PCI Biotech is actively exploring and preparing for a potential clinical proof-of-concept study for therapeutic vaccination in a relevant cancer disease.

The **fima*VACC*** technology has potential to also enhance other vaccination technologies, such as mRNA.

The company is using international experts to assess the best possible development opportunities across vaccination technologies and diseases. The aim is to leverage the expected strengths of the **fima*VACC*** technology, such as intratumoural and intradermal vaccine delivery, initially focusing on the most apposite cancer indication before a potential broadening of the deployment of this versatile platform. The company was in Q1 2021 granted a patent related to therapeutic vaccines for melanoma, but this patent is not a decision driving factor in the ongoing development considerations.

Research and development supported by a grant

The **fima*VACC*** programme is supported by a government grant from the Research Council of Norway (BIA-programme) of up to NOK 13.8 million distributed over four years, ending first half of 2021.

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. 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 may 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 five research collaborations established.

The collaboration partners include OliX Pharmaceuticals, DCprime, eTheRNA immunotherapies, IMV and Aposense. In all these collaborations, partners are exploring synergies between their proprietary nucleic acid technologies and the **fima*NAc*** technology, with potential for further deepening of the

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

partnerships. Previous collaborative interactions and results with other key players have provided valuable data and knowhow for PCI Biotech to be utilised for the further development of **fima*NAc***.

In February 2021 encouraging 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 were presented at the 12th Annual RNA Therapeutics Virtual Conference, a UK based online event. The conference was set to explore the latest developments in RNA delivery agents and RNA-based therapeutics with the latest case studies on advanced mRNA technologies, oligonucleotide delivery, therapeutic applications and future trends and innovations. The presented results 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.

In May 2021, PCI Biotech entered into an extensive research collaboration with the South Korean company OliX Pharmaceuticals, a leading developer of RNAi therapeutics. OliX Pharmaceuticals and PCI Biotech will combine their know-how and technology platforms to explore synergies and further partnership.

The partnership is governed by a research collaboration agreement, under which the collaborators will perform an extensive evaluation of technology compatibility and synergy based on preclinical studies. The companies will evaluate results achieved from this research collaboration to explore the potential for further development and partnership.

The fima*NAc* technology and nucleic acid therapy

Several forms of nucleic acids are widely acknowledged to have significant therapeutic potential and numerous clinical trials are underway.

The therapeutic potential of compounds such as nucleic acids is however limited by the challenge of delivering sufficient amounts of large molecules into the cells. PCI Biotech believes the fima*NAc* technology may resolve this issue through enhanced delivery of the majority of nucleic acid types.

Corporate

Financial review

Income Statement

(Figures in brackets = same period 2020 unless stated otherwise)
The Group has not recorded revenues for the financial years 2021 or 2020. Grants received from public sources as the Norwegian Research Council “BIA” and “SkatteFUNN” are recorded as other income. Other income for Q1 amounted to NOK 1.6 million (NOK 1.9 million).

Research and development (R&D) expenses for Q1 ended at NOK 16.7 million (NOK 15.6 million). General and administrative (G&A) expense for Q1 ended at NOK 6.1 million (NOK 2.3 million). The change in G&A in Q1 2021 compared to last year, is partly driven by increased number of employees, but mainly due to accounting effect fluctuations for the share option scheme, without direct cash effects. Operating expenses for Q1 were NOK 22.8 million (NOK 17.9 million). Operating expenses are mainly driven by the R&D activity level and the pivotal fima*CHEM* trial (RELEASE) is the main cost driver.

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 financial results for Q1 were NOK -2.6 million (NOK 20.4 million).

Net loss for Q1 were NOK 23.8 million, compared to a net profit of NOK 4.4 million in Q1 2020. Last year's net profit was mainly driven by a net positive financial result, resulting from the above mentioned exchange rate fluctuations.

Cash flow and balance sheet

The Group held cash and cash equivalents of NOK 164.3 million at end of Q1 2021, compared to NOK 188.0 million per year-end 2020. Cash flow from operations is mainly dependent on R&D activities and cash flow from operating activities was NOK -20.6 million for Q1 2021, compared to NOK -22.4 million for Q1 2020. All cash and cash equivalents are placed as bank deposits. Exchange rate effects on bank deposits in foreign currency were NOK 2.7 million negative for Q1 2021, compared to NOK 19.9 million positive for Q1 2020.

Other long-term liabilities relate to potential future social security liabilities in connection with the company's share option program, and the liability fluctuates with the share price and number of outstanding 'in-the-money' share options. Social security liabilities for 'in-the-money' share options that are vested, or may vest during the next 12 months, are disclosed as other short-term liabilities.

Other

Risks and uncertainty factors for 2021

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 2020, the most important risks the company is exposed to in 2021 are associated with 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 2020, which also covers implications of the COVID-19 pandemic.

Post-closing events

The first US patient was enrolled into the RELEASE study in April 2021. In May 2021, PCI Biotech entered into an extensive research collaboration with the South Korean company OliX Pharmaceuticals, a leading developer of RNAi therapeutics. 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***).

Although the company's focus is divided over the three programmes, most resources are currently spent on progressing the lead project of **fima*CHEM***, which is clinical development of fimaporfin with gemcitabine for the treatment of inoperable extrahepatic bile duct cancer; a rare disease with high unmet medical need. Based on the encouraging early signs of efficacy in Phase I, the company worked with regulators in Europe and the U.S. receiving important guidance for the design of a pivotal phase study.

The company is fully committed to advance the **fima*CHEM*** programme with the ambition of helping patients currently left without effective treatment options to achieve a good quality of life. The ongoing COVID-19 pandemic has affected the progress of the pivotal study and the company is currently focusing on effective execution of the study, with the aim to recoup as much as possible of the delays.

In parallel, the two other programmes, **fima*VACC*** and **fima*NAC***, are proceeding in accordance with the established development strategy. The Phase I study in healthy volunteers provided affirmative results on translation of the **fima*VACC*** technology into humans and key data to support the programme's further development. The **fima*NAC*** programme continues to follow a collaborative approach, by pursuing out-licensing opportunities in the most attractive areas for the technology.

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

- Effectively drive the **fima*CHEM*** development programme in inoperable extrahepatic bile duct cancer towards the market
- Implement the strategy for the next phase of development for **fima*VACC***
- Manage alliance and partnering activities across all commercially interesting areas for the PCI platform

The Board of Directors and CEO
PCI Biotech Holding ASA
Oslo, 6 May 2021

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 2021	Q1 2020	FY 2020
Other income	*6*	**1 588**	**1 919**	**7 368**
Research and development	*7,8*	16 653	15 580	75 571
General and administrative		6 106	2 313	13 917
Operating expenses		**22 759**	**17 893**	**89 488**
Operating results		**-21 171**	**-15 974**	**-82 121**
Financial income and expenses				
Financial income		205	20 700	10 796
Financial expenses		2 807	299	915
Net financial result	*7*	**-2 602**	**20 401**	**9 881**
Profit/Loss before income tax		**-23 773**	**4 427**	**-72 239**
Income tax	*9*	0	0	0
Net profit/loss		**-23 773**	**4 427**	**-72 239**
Other comprehensive income		0	0	0
Total comprehensive income	*5*	**-23 773**	**4 427**	**-72 239**

Balance sheet *(in NOK '000)*	Note	31.03 2021	31.03 2020	31.12 2020
Non-current assets				
Property, plant and equipment	*16*	7 083	5 194	7 388
Right to use asset	*15*	454	1 060	605
Total non-current assets		**7 537**	**6 254**	**7 994**
Current assets				
Short term receivables	*7*	14 475	16 594	13 162
Cash & cash equivalents	*7*	164 298	258 080	187 967
Total current assets	*14*	**178 773**	**274 673**	**201 129**
Total assets		**186 310**	**280 927**	**209 123**
Equity and liabilities				
Equity				
Paid in capital	*10,11*	562 443	562 126	562 443
Other reserves		-393 702	-301 674	-373 199
Total equity		**168 741**	**260 452**	**189 244**
Long term liabilities				
Other long term liabilities	*13*	0	738	32
Lease liabilities	*15*	0	380	0
Total long term liabilities		**0**	**1 119**	**32**
Short term liabilities				
Trade debtors		2 871	2 828	5 191
Lease liabilities	*15*	505	668	673
Other short term liabilities	*7,12*	14 193	15 862	13 983
Total short term liabilities		**17 568**	**19 357**	**19 847**
Total liabilities	*14*	**17 568**	**20 476**	**19 879**
Total equity and liabilities		**186 310**	**280 927**	**209 123**

CHANGE IN EQUITY

(in NOK '000)	Q1 2021	Q1 2020	FY 2020
Equity at beginning of period	**189 244**	**254 828**	**254 828**
Capital increase	0	0	316
Share option scheme	3 270	1 195	6 339
Comprehensive income in the period	-23 773	4 427	-72 239
Equity at end of period	**168 741**	**260 452**	**189 244**

CASH FLOW

(in NOK '000)	Q1 2021	Q1 2020	FY 2020
Ordinary profit before taxes	-23 773	4 427	-72 239
Depreciation, amortisation and write off	627	429	2 208
Leasing interest cost	0	19	75
Share options	3 270	1 195	6 339
Currency gain (-)/ loss (+) not related to operations	2 709	-19 917	-8 526
Changes in working capital and other non-cash adjustments	-3 455	-8 525	-5 248
Cash flow from operating activities	**-20 621**	**-22 371**	**-77 391**
Acquisition of non-current assets	-170	-400	-3 919
Net cash flow from investing activities	**-170**	**-400**	**-3 919**
Cash flow from financial activities			
Payment principal portion of lease liabilities	-168	-168	-668
Net proceeds from share issues	0	0	316
Net cash flow from financial activities	**-168**	**-168**	**-352**
Net change in cash during the period	**-20 960**	**-22 940**	**-81 662**
Exchange rate effect on bank deposits in foreign currency	-2 709	19 917	8 526
Cash and cash equivalents at the beginning of the period	187 967	261 103	261 103
Cash and cash equivalents at the end of the period	**164 298**	**258 080**	**187 967**

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 fully 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 both existing drugs and 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 drugs 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 up-front payments, milestone payments and royalties from sales. PCI Biotech works on the development of PCI products for enhanced delivery of existing cancer drugs (fima*CHEM)*, and as a platform that may both potentiate the effect of vaccines (fima*VACC*) and delivery of nucleic acids (fima*NAC*). PCI Biotech has two active clinical development programmes; one project in the fima*CHEM* programme and the other in the fima*VACC* programme. The fima*CHEM* project runs the pivotal clinical RELEASE study with registration intent for the lead candidate fimaporfin (Amphinex) in combination with the chemotherapeutic agent gemcitabine for treatment of inoperable extrahepatic bile duct cancer. The fima*VACC* project has completed a Phase I study in healthy volunteers, which has provided clinical proof-of-concept of fima*VACC'S* ability to enhance and direct the response of vaccines towards a stronger cellular immune response. The fima*NAC* programme is in preclinical stage.

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 2020 (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 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 6 May 2021.

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 2021 is consistent with the consolidated financial statements for the year ended 31 December 2020.

The new standards and interpretations or amendments to published standards that were effective for the annual period beginning on January 1, 2021 or later and that could affect PCI Biotech are discussed in accounting principles, part 4, to the consolidated financial statements for 2020.

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, 2020.

5. Earnings per share

Earnings per share

	Q1 2021	Q1 2020	FY 2020
Result allocated to shareholders (in NOK '000)	(23 773)	4 427	(72 239)
Weighted average of outstanding shares (in NOK '000)	37 326	37 266	37 286
Earnings per share (NOK per share)	-0,64	0,12	-1,94

Diluted earnings per share:

	Q1 2021	Q1 2020	FY 2020
Result allocated to shareholders (in NOK '000)	(23 773)	4 427	(72 239)
Weighted average of outstanding shares (in NOK '000)	37 326	37 971	37 286
Earnings per share (NOK per share)	-0,64	0,12	-1,94

Weighted average of outstanding diluted shares is weighted number of average number of shares adjusted with share options that are in the money. Earnings per share is not affected by the dilution if negative results in the period. The weighted average of outstanding shares for Q1 2021 are 310 thousand share options (Q1 2020: 705 thousand and FY 2020: 645 thousand)

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 grants from the Norwegian Research Council (BIA) and 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 2020 and 2021 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	7 151	810	5 326	1 188	14 475
Total receivables	**7 151**	**810**	**5 326**	**1 188**	**14 475**

Most of the short-term receivables relates to accrued, not received government grants (BIA) and 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 Q1 2021 a negative accounting effect of 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 2021	Q1 2020	FY 2020
Clinical studies	12 906	12 430	57 761
Pre-clinical studies	1 405	1 504	6 607
CMC and equipment	1 327	1 049	6 637
Patents	1 014	597	4 566
Other costs	0	0	0
Total	**16 653**	**15 580**	**75 571**

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 130,3 million in 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 31.12.2020	31.03.2021
2022 - Q3	21.48	325 000	325 000
2024 - Q3	25.78	320 000	320 000
2025 – Q3	50.36	540 000	540 000
Total		**1 185 000**	**1 185 000**

The current authorisation, granted by the Annual General Meeting on 27 May 2020, for the employee share option program allows for a total of 2,790,000 share options, of which 1,245,500 have been granted by the Board of Directors per end of the quarter. 60,500 share options were exercised in Q3 2020.

Overview share options, Senior executives	Total holdings 31.12.2020	Allocated	Lapsed	Exercised	Expired	Total holdings 31.03.2021
Per Walday, CEO	225 000	0	0	0	0	225 000
Ronny Skuggedal, CFO	140 000	0	0	0	0	140 000
Anders Høgset, CSO	150 000	0	0	0	0	150 000
Kristin Eivindvik, CDO	60 000	0	0	0	0	60 000
Lucy Wabakken, CDO (acting)	120 000	0	0	0	0	120 000
Ludovic Robin, CBO	90 000	0	0	0	0	90 000
Amir Snapir, CMO	90 000	0	0	0	0	90 000
Total	**875 000**	**0**	**0**	**0**	**0**	**875 000**

11. Share capital

	No. of shares	Nominal value per share in NOK	Share capital in NOK
31.12.2020	**37 326 390**	**3.00**	**111 979 170**
Transactions	-	-	-
31.03.2021	**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 2020 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 12,016,700 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 6,500 shareholders at end of the quarter.

10 largest shareholders per 31 March 2021:

Name	No. of shares	Ownership
FONDSAVANSE AS	3 760 443	10,07 %
Myrlid AS	2 500 000	6,70 %
MP PENSJON PK	1 686 729	4,52 %
RADFORSK INVESTERINGSSTIFTELSE	1 281 415	3,43 %
NORDNET LIVSFORSIKRING AS	909 813	2,44 %
GRESSLIEN, ODD R.	746 000	2,00 %
Nordnet Bank AB	720 524	1,93 %
BERG-LARSEN, ALEXANDER	483 675	1,30 %
Jandersen Kapital AS	450 000	1,21 %
FORENEDE FORVALTNING AS	334 166	0,90 %
Total 10 largest shareholders	**12 872 765**	***34,49 %***
Others	*24 453 625*	*65,51 %*
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**	**31.12.2020**	**31.03.2021**
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. 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 per end of the quarter in PCI Biotech's employee share option scheme.

14. Financial assets and liabilities

Cash and cash equivalents are measured as financial instruments at fair value through other comprehensive income (OCI). The carrying amount of cash and cash equivalents is applied and disclosed since this approximately equals to fair value since these instruments have a short term to maturity. All other financial assets and liabilities are measured as financial instruments at amortised cost and due to short term to maturity and/or low values, non-discounted values are applied and disclosed.

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. The lease runs to 31 December 2021 with an option for additional three more years. The lease agreement is subject to annual adjustment according to changes in the consumer price index. Amounts of minimum lease payment for non-cancellable operating leases is NOK 0.7 million (non-discounted contractual payments) for the year 2021. Payments of principal portion of the lease liabilities are not charged to profit and loss and will only have cash flow effects. Lease liabilities due in more than 12 months are disclosed as long-term lease liabilities. The Group applies the short-term lease recognition exemption for leases related to office equipment, parking facilities at the office and a flat in Oslo available for disposition for foreign employees. Lease payments for this category of leases are consequently charged directly through profit and loss.

All figures in NOK '000

Right to use asset - office lease	
Initial recognition 01.01.2019	1 815
Acquisitions FY 2020	0
Acquisitions Q1 2021	0
Acquisition costs 31.03.2021	**1 815**
Depreciation FY 2019	604
Depreciation FY 2020	605
Depreciation Q1 2021	152
Accumulated depreciation and impairment as of 31.03.2021	**1 361**
Total right to use assets - office lease as of 31.03.2021	**454**
Lower of remaining lease term or economic life	1.0 years
Depreciation method	Linear

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
Payments principal portion of the lease liability Q1 2021	-167
Interest expenses on the lease liability FY 2019	38
Interest expenses on the lease liability FY 2020	144
Interest expenses on the lease liability Q1 2021	0
Total lease liabilities for office as of 31.03.2021	**505**
Whereof:	
Short term lease liabilities < 1 year	505
Long term lease liabilities > 1 year	0

Income statement effects – office lease	Q1 2021	Q1 2020	FY 2020
Depreciation of right to use asset	-152	-151	-605
Operating expenses for short-term leases	0	0	-170
Effect on Operating results net of tax	**-152**	**-151**	**-775**
Interest expenses on the lease liabilities	0	-18	-144
Effect on Net financial result net of tax	**-152**	**-169**	**-920**
Comprehensive income effect net of tax	**-152**	**-169**	**-920**

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.

Equipment	31.03 2021	31.03 2020	31.12 2020
Carrying value at the beginning of the period	**7 388**	**5 072**	**5 072**
Acquisitions	170	400	3 919
Depreciation	476	278	1 603
Carrying value at the end of the period	**7 083**	**5 194**	**7 388**

17. Subsequent events

The first US patient was enrolled into the RELEASE study in April 2021. In May 2021, PCI Biotech entered into an extensive research collaboration with the South Korean company OliX Pharmaceuticals, a leading developer of RNAi therapeutics. 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

FINANCIAL CALENDAR

First half year report 2021	25 August	2021
Q3 Report 2021	17 November	2021

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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