PCI BIOTECH
Unlocking the potential of innovative medicines
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The reservation is also made that inaccuracies or mistakes may occur in this information given about current status of the Company or its business. Any reliance on the information is at the risk of the reader, and PCI Biotech disclaims any and all liability in this respect.
Encouraging data from the Phase I study at the dose level selected for the pivotal study
- Initial data suggests that two treatments are well tolerated
- Preparations for pivotal study progressing towards initiation early 2019

Phase I interim data suggests enhancement of several parameters of importance for vaccination
- Focus on analysis and characterisation of the clinical immune response

Extension of the top-10 pharma collaboration
- Established research collaborations with the immunotherapy focused companies IMV in Canada and Bavarian Nordic in Denmark (subsequent event)

Oslo Børs listing, as a transfer from Oslo Axess
- Proposed fully underwritten rights issue of NOK 360 million (subsequent event)
PCI BIOTECH AT A GLANCE

- Unlocking the potential of innovative medicines
- A listed (PCIB:NO) cancer-focused biotech company
- Photochemical internalisation (“PCI”) technology, originating from the Oslo University Hospital – the Radium Hospital

<table>
<thead>
<tr>
<th>Programme</th>
<th>Indications / Therapeutics</th>
<th>Preclinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Pivotal</th>
<th>Status</th>
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<tbody>
<tr>
<td>fimaCHEM</td>
<td>Bile duct cancer / gemcitabine</td>
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<td>fimaVACC</td>
<td>Therapeutic cancer vaccines</td>
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<td>fimaNAC</td>
<td>Nucleic acid therapeutics</td>
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</table>

- Encouraging Phase I results for treatment in the orphan indication bile duct cancer
- Expect to initiate pivotal study early 2019
- Phase I study in healthy volunteers
- Encouraging initial immune results
- One research collaboration
- Six research collaborations

An oncology focused company with three well differentiated assets
PCI TECHNOLOGY

Enabling drugs to reach intracellular therapeutic targets

PCI – the solution to a key challenge for several modalities

- **Enabling approved drugs to fulfil unmet local treatment need**
- **Enhancing cellular immune responses important for therapeutic effect**
- **Providing a delivery solution for nucleic acid therapeutics**
PCI may enhance approximately 20% of relevant approved chemotherapies.

First-in-man study published in Lancet Oncology¹

Encouraging tumour responses and survival in Phase I in inoperable extrahepatic bile duct cancer

Pivotal phase ready, with potential for approval based on interim read

Orphan disease with high price potential

Total sales of cancer vaccines estimated to reach $7.5bn in 2022²

Expected market growth largely driven by therapeutic vaccine combinations with checkpoint inhibitors

Strong preclinical data – ongoing clinical study with encouraging initial results

Aim is to out-license the technology on non-/semi-exclusive basis – opportunity to develop own vaccination products

Main hurdle is delivery into cells

Estimated sales of $18bn in 2030³ (RNAi alone)

Strong preclinical data with several RNAi’s

Collaborative approach

Aim is to out-license the technology on non-/semi-exclusive basis

1) Lancet Oncology (2016) 17(9): p1217–1229
2) GBI Research (2016) Global Cancer Vaccines Market to 2022
3) Research and Markets (2015) RNAi therapeutics market
PCI TECHNOLOGY

► fimaCHEM – mode of action

Cancer cell

Lysosomal breakdown

Chemotherapeutics

E.g.: Cytotoxic antibiotics

DNA intercalation, free radical formation, etc.

Anti-metabolites

DNA/RNA synthesis inhibition; DNA damage

Anti-microtubule agents

Cell cycle arrest

Release into cytosol

Endocytosis
Bile Duct Cancer

► Excellent fit between medical need and fimaCHEM

- Orphan indication, yearly incidence rate of 1-2 per 100,000 in the western world – higher in Asia
- Five-year survival rate of less than 5% and almost 0% when inoperable
- Average survival inoperable: ≈12 months
- Current management
  - Surgery
    - Only potentially curative treatment
    - Less than ⅓ are resectable at presentation
  - Stenting
    - Endoscopic stenting for palliative biliary drainage
  - Chemotherapy
    - No approved chemotherapy
    - Recommended: gemcitabine and cisplatin

► Combining therapy with gemcitabine and cisplatin is recommended
► Gemcitabine is significantly enhanced by fimaCHEM
► Enhancing systemic therapy locally

Easy illumination through standard endoscopic methods

- Patients are treated with endoscopic methods (ERCP) for diagnosis and stenting
- Optic fibre and illumination easily included in the ERCP procedure

Boosting chemotherapy effect where it is most needed

- Tumours tend to block the bile duct
- Liver function is often affected
- Biliary drainage is key for patient treatment and survival

Inducing immunogenic tumour cell death

- Preclinical and clinical data supports the notion of potential abscopal effects with fimaCHEM
- May be ideal for combination with checkpoint inhibitors
BILE DUCT CANCER – CLINICAL PHASE I/II STUDY

Encouraging early signs of efficacy in Phase I

Interim average overall survival (OS) of all 16 patients in Phase I is 18.5 months per August 2018, with 19% of the patients still being alive. Median OS ended at 14.4 months.

Best Overall Response* (all radiologically evaluable patients)

*Cohort 1 & 2: local read; Cohort 3 & 4: central read
**Bile Duct Cancer — Clinical Phase I Study**

Cohort IV is selected dose for pivotal study – limited but encouraging data (Aug 2018)

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Cohort IV (N=6) (0.25mg/kg)</th>
<th>Phase I – full study (N=16) (0.06-0.25mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Average number gemcitabine/cisplatin cycles</td>
<td>6.0 (range: 0 - 8)</td>
<td>6.4 (range: 0 - 8)</td>
</tr>
<tr>
<td>2) Patients w/ radiologically measurable lesions</td>
<td>5/6 (83%)</td>
<td>11/16 (69%)</td>
</tr>
<tr>
<td>3) Average overall tumour size</td>
<td>5.2 cm (range: 2.1 - 7.8 cm)</td>
<td>4.1 cm (range: 1.5 - 7.8 cm)</td>
</tr>
<tr>
<td>4) Objective Response Rate (ORR)</td>
<td>3/5 patients (60%) (2 PR; 1 CR)</td>
<td>4/12 patients (33%) (2 PR; 2 CR)</td>
</tr>
<tr>
<td>5) Interim average Duration of Response (DoR)</td>
<td>15.4 months (range: 8.0 – 20.2 months)</td>
<td>12.4 months (range: 6.5 – 20.2 months)</td>
</tr>
<tr>
<td>6) Overall Survival (OS)</td>
<td>interim median OS: <strong>21.2 months</strong> interim avg OS: 19.0 months (33% alive)</td>
<td>median OS: <strong>14.4 months</strong> interim avg OS: 18.5 months (19% alive)</td>
</tr>
</tbody>
</table>

The table contains key background and measured endpoints for the Phase I dose-escalation study. The background parameters (1-3) were essentially similar for Cohort IV and the full Phase I study. The data is limited, but the measured endpoints (4-6) show a clear trend towards improved outcome in Cohort IV compared to the full study and is also encouraging when seen in relation to the most appropriate published comparator data (see quarterly report for more details).
Exploring safety of repeating the fimaCHEM treatment in an extension to Phase I, to allow for repeated treatment in the pivotal study

- Seven patients have been included in the study
- Four patients have so far passed the safety window, which includes approx. 3 weeks after the second fimaCHEM
- Data not yet mature enough for efficacy evaluation

The pivotal study will commence with up to two scheduled treatments, with IDMC\textsuperscript{a} performing a safety review when eight pivotal study patients have received two treatments

\textsuperscript{a} IDMC: Independent Data Monitoring Committee
INOPERABLE EXTRAHEPATIC BILE DUCT CANCER

► Status and strategy going forward

► Orphan designation
  ▪ Granted in both the US and EU, recognising the medical need and potential therapeutic benefits

► Phase I dose-escalation completed with good tolerability and promising early signs of efficacy
  ▪ Tumour shrinkage in almost all radiologically evaluable patients
  ▪ Encouraging overall survival data at the selected dose level

► Fastest way to market determined through regulatory interactions with authorities
  ▪ Single randomised pivotal study with potential for accelerated / conditional approval based on interim analysis

► Preparations for pivotal phase progressing towards initiation early 2019
  ▪ Extensive feasibility study ongoing to aid in the selection of high quality sites with large catchment areas
Bile Duct Cancer – Pivotal Study

- Randomised pivotal study in newly diagnosed patients with inoperable extrahepatic bile duct cancer +/- liver metastases
- Study design based on thorough discussions with the EMA\textsuperscript{a} and the US FDA\textsuperscript{b}
- Will involve approx. 40 key hospital sites across Europe and USA
- Approx. 36 months to interim and 50 months to final analysis

- Randomisation (1:1) of 186 patients to treatment with either fima\textit{CHEM} + SoC\textsuperscript{c} or SoC only
- Primary endpoint: Progression Free Survival (PFS), with Overall Survival (OS) as key secondary
- Interim analysis primary endpoints: PFS followed by Objective Response Rate (ORR)
- Regular IDMC\textsuperscript{d} review, but no formal futility stop

\textsuperscript{a} EMA: European Medicines Agency; \textsuperscript{b} FDA: Food and Drug Administration; \textsuperscript{c} SoC: standard of care treatment with gemcitabine + cisplatin; \textsuperscript{d} IDMC: Independent Data Monitoring Committee
PCI TECHNOLOGY

► **fima Vacc** – mode of action

- **Dendritic cell**
  - MHC I
  - MHC II
  - Nucleus
  - Endosome
  - Proteasomes
  - PCI

- **Vaccine**
  - MHC Class I
  - MHC Class II

- Generate more disease specific cytotoxic T-cells
- Attack cancer and virus infected cells more efficiently
- Antibodies and helper T-cells

► **fima Vacc** – strong potential

- Opportunity to play a key role in second generation immunotherapy
- Unique mode of action
  - Indication of CTL-induction by MHC class I antigen presentation in dendritic cells and macrophages
- Broad applicability
  - Peptide and protein antigens
  - Prophylactic & therapeutic vaccination
- Excellent stability
  - Few logistical challenges (stable at room temperature in solution and can be autoclaved)
- Important recent IP generation
PROGRESSING CLINICAL TRANSLATION

Phase I study in healthy volunteers

- Overall objective:
  - Determine the safety, tolerability and immune response of fimaVacc in healthy subjects

- Study consists of three parts:
  1. Tolerability of intradermal fimaporfin, adjuvant and light (without vaccine)
  2. fimaVacc vaccination: dose finding (fimaporfin and light) and cohort expansion
  3. Optimisation of the fimaVacc regimen

- Status:
  - More than 90 subjects have so far been treated
  - Part 1 is completed
  - Part 2 is completed
    - Initial data suggest enhancement of antigen specific T-cell response at tolerable doses, with earlier responses and higher response rates
    - Vast number of study samples available – near-term focus on characterisation of the immune response
  - Part 3 TBD
  - Expected study completion: 2H 2018

Vaccination features:
- Enhanced T-cell responses
- High T-cell response rates
- Early T-cell responses

Patented disposable “band-aid-like” device for user-friendly illumination of the vaccination site
PCI TECHNOLOGY
► fimaNAC – mode of action

Target cell

Nucleic acid therapeutic

Nucleus

lysosome

endosome

target

Target cell

Nucleic acid therapeutic

Endocytosis

Release into cytosol

E.g.: siRNA

mRNA

CRISPR

miRNA

DNA

Lysosomal breakdown

Knockdown of gene expression

Therapeutic protein production

Repair of genetic defects
**RESEARCH COLLABORATIONS**

Six active collaborations within nucleic acid therapeutics and vaccination

<table>
<thead>
<tr>
<th>Top-10 large pharma</th>
<th>Top-10 large pharma</th>
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</thead>
<tbody>
<tr>
<td><strong>fimaNAc</strong></td>
<td><strong>fimaVacc</strong></td>
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<td>RXi</td>
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<td>Top-10</td>
<td>Top-10</td>
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<tr>
<td>large pharma</td>
<td>large pharma</td>
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<tr>
<td>- Collaboration initiated 2Q 2015</td>
<td>- Collaboration initiated 2Q 2018</td>
</tr>
<tr>
<td>- Listed on Nasdaq, developing innovative therapeutic siRNA</td>
<td>- A listed Canadian clinical stage immunotherapy biotech</td>
</tr>
<tr>
<td>- Collaboration expanded to immuno-oncology following RXi’s MIRImmune acquisition</td>
<td>- Multiple clinical-stage programmes in cancer and infectious diseases</td>
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<tr>
<td><strong>biontech</strong></td>
<td><strong>etherna</strong></td>
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<td>Top-10</td>
<td>Top-10</td>
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<tr>
<td>large pharma</td>
<td>large pharma</td>
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<tr>
<td>- Collaboration initiated 3Q 2015</td>
<td>- Collaboration initiated 3Q 2016</td>
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<tr>
<td>- A global leader in nucleic acid therapeutics</td>
<td>- German biotech company developing individualised cancer immunotherapies</td>
</tr>
<tr>
<td>- Collaboration expanded to include <em>in vivo</em> studies and duration to end 2018</td>
<td>- Clinical programmes in melanoma, head &amp; neck, breast, ovarian and pancreatic cancer</td>
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<td><strong>etherna</strong></td>
<td><strong>imuv</strong></td>
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<tr>
<td>large pharma</td>
<td>large pharma</td>
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<tr>
<td>- Collaboration initiated 4Q 2016</td>
<td>- Collaboration initiated 2Q 2018</td>
</tr>
<tr>
<td>- Belgian biotech with proprietary TriMix platform programming dendritic cells</td>
<td>- A listed Danish clinical stage immunotherapy biotech</td>
</tr>
<tr>
<td>- Clinical programmes in melanoma, head &amp; neck, breast, ovarian and pancreatic cancer</td>
<td>- Multiple clinical-stage programmes in cancer and infectious diseases</td>
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<td><strong>imuv</strong></td>
<td><strong>bavarian nordic</strong></td>
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<td>- Collaboration initiated 3Q 2018</td>
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<td>- A listed Danish clinical stage immunotherapy biotech</td>
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<td>- Multiple clinical-stage programmes in cancer and infectious diseases</td>
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<td><strong>bavarian nordic</strong></td>
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<tr>
<td>large pharma</td>
<td>large pharma</td>
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<tr>
<td>- Collaboration initiated 1Q 2016</td>
<td>- Collaboration initiated 1Q 2016</td>
</tr>
<tr>
<td>- Norwegian immunotherapy company</td>
<td>- Therapeutic cancer vaccine against human telomerase</td>
</tr>
</tbody>
</table>
FINANCE

► Proposed fully underwritten rights issue of NOK 360 million

► Important milestone for the fimaCHEM development programme
  ▪ fully funded until interim read-out of pivotal study
  ▪ enables the company to reach potential marketing authorisation through accelerated approval

► The underwriting syndicate
  ▪ supported by major shareholders
  ▪ significant interest from external investors
  ▪ international specialist investor
## FINANCE

► Use ofProceeds

<table>
<thead>
<tr>
<th></th>
<th>fimaChem</th>
<th>fimaVacc</th>
<th>fimaNAC</th>
<th>General corporate purposes</th>
<th>Total</th>
</tr>
</thead>
</table>

**fimaChem** – expected to cover financing need to interim read of pivotal study, including marketing application filing (conditional / accelerated approval)
  - additional funding requirement to final analysis is estimated to NOK 80-90 million

**fimaVacc** – commercial optimisation and partnering activities

**fimaNAC** – collaborative strategy, with focus on business development activities and alliance management

* Annual SkatteFUNN grant of NOK 9 million included
** Annual BIA grant of NOK 4 million for year 2019-2020 included
*** Estimated figures are subject to several risk factors (foreign exchange rate, patient inclusion rate, number- and location of sites etc). Transaction costs not included
## Timeline for the Rights Issue

**Key information relating to the proposed preferential rights issue**

### September 2018

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### October 2018

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### Key dates

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
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<tbody>
<tr>
<td>14-Sep</td>
<td>Extraordinary General Meeting to resolve on the rights issue</td>
</tr>
<tr>
<td>14-Sep</td>
<td>Last day of trading including subscription rights</td>
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<tr>
<td>17-Sep</td>
<td>Ex-rights date – First day of trading excluding subscription rights</td>
</tr>
<tr>
<td>18-Sep</td>
<td>Record date</td>
</tr>
<tr>
<td>On or about 19-Sep</td>
<td>Publication of prospectus</td>
</tr>
<tr>
<td>On or about 19-Sep</td>
<td>First day subscription period</td>
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<tr>
<td>On or about 19-Sep</td>
<td>First day of trading in subscription rights on the Oslo Stock Exchange</td>
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<tr>
<td>On or about 1-Oct</td>
<td>Last day of trading in subscription rights on the Oslo Stock Exchange</td>
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<tr>
<td>On or about 3-Oct</td>
<td>End of subscription period</td>
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<td>On or about 4-Oct</td>
<td>Allocation</td>
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<td>On or about 8-Oct</td>
<td>Payment date</td>
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<td>On or about 9-Oct</td>
<td>Registration of share capital increase</td>
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**Important note to all shareholders:** Subscription rights that are not used to subscribe for new shares before the expiry of the subscription period, or that are not sold before the trading of the subscription rights lapses, will have no value and will lapse without compensation to the holder. Be aware that the subscription period is expected to end on 3-Oct, while the trading of the subscription rights is expected to end on 1-Oct at 16.30 CEST (two days prior to the end of the subscription period)
## Finance

- Key financial figures

- Oslo Børs listing – transfer from Oslo Axess in April 2018

- Public grants (Other income) in line with last year

- Operating result impacted by increased clinical activity for fimaCHEM and fimaVACC

<table>
<thead>
<tr>
<th>(in NOK 1,000)</th>
<th>Q2 2018</th>
<th>Q2 2017</th>
<th>1H 2018</th>
<th>1H 2017</th>
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<tbody>
<tr>
<td>Other income</td>
<td>2,137</td>
<td>2,405</td>
<td>4,375</td>
<td>4,833</td>
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<tr>
<td>Operating results</td>
<td>-7,193</td>
<td>-7,205</td>
<td>-21,855</td>
<td>-17,059</td>
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</table>

<table>
<thead>
<tr>
<th>(in NOK 1,000)</th>
<th>Q2 2018</th>
<th>Q2 2017</th>
<th>1H 2018</th>
<th>1H 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash flow operating activities</td>
<td>-10,142</td>
<td>-9,410</td>
<td>-22,633</td>
<td>-18,737</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(in NOK 1,000)</th>
<th>30.06 2018</th>
<th>31.12 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash</td>
<td>28,405</td>
<td>50,789</td>
</tr>
</tbody>
</table>
KEY NEAR-TERM MILESTONES ANTICIPATED

1H 2018  ✓ Corporate  Transfer of listing from Oslo Axess to Oslo Børs
2H 2018  ✓ Corporate  Financing for pivotal fimaCHEM study
2H 2018  ✓ fimaCHEM  Design of pivotal study finalised
2H 2018  fimaCHEM  Safety of repeated treatment
2H 2018  fimaVACC  Phase I in healthy volunteers completed
1H 2019  fimaCHEM  Initiation of pivotal bile duct cancer study
**INVESTMENT HIGHLIGHTS**

<table>
<thead>
<tr>
<th>Market</th>
<th>Platform technology with three programmes targeting an attractive and growing oncology market, with a clear path to a high unmet need orphan oncology market for the lead product candidate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead product</td>
<td>Amphinex® is a pivotal phase ready orphan designated (EU &amp; US) first-in-class photochemical internalisation product for treatment of bile duct cancer – a disease without approved drugs</td>
</tr>
<tr>
<td>Clinical results</td>
<td>Promising early signs of tumour response in a first-in-man study published in Lancet Oncology, and in a Phase I study specifically targeting bile duct cancer – encouraging survival data</td>
</tr>
</tbody>
</table>
| Pipeline | fima Vacc – a clinical stage vaccination technology with promising cellular immune responses  
  fima NAC – a preclinical gene therapy delivery solution with established key player collaborations |
| Strategy | Development strategy for lead candidate established based on thorough regulatory discussions with FDA and EMA – a single randomised pivotal study with accelerated approval potential |
| Leadership | Management team, Board of Directors and advisors with extensive pharmaceutical industry experience across a range of medical development and commercial areas |
PCI BIOTECH HOLDING ASA

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