



Q1 2023

INTERIM REPORT

*Enabling
intracellular
delivery*



LEVERAGING THE PCI TECHNOLOGY PLATFORM WITHIN IMMUNOTHERAPY & NUCLEIC ACID THERAPEUTICS

ABOUT PCI BIOTECH

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

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

KEY FIGURES

<i>(In NOK 1,000)</i>	2023 Q1	2022 Q1	2022 FY
Other income	232	1 188	4 750
Operating expenses	6 611	23 988	61 197
Operating results	-6 379	-22 801	-56 447
Net financial result	423	-212	1 352
Comprehensive income	-5 956	-23 012	-55 095
Cash & cash equivalents	51 121	93 680	56 596
Cash flow from operating activities	-5 364	-21 592	-59 041

HIGHLIGHTS

fimaNAc

bioprocessing and dermatology

The bioprocessing program for use of **fimaNAc** in gene therapy manufacturing has generated new results that add to the initial patent application filed in 2H 2022. Upcoming work will focus on generating results that can trigger testing with potential customers to get feedback and develop a competitive technology.

The run-in phase of the dermatology project to demonstrate topical **fimaNAc**-mediated nucleic acid delivery in a preclinical wound model is ongoing. Readout is expected to be reported in the Q2 2023 interim report. Positive results will be utilised for seeking co-development with partners having therapeutic nucleic acid-based candidates.

fimaVACC

intratumoural immunotherapy

PCI Biotech is exploring approaches aimed at identifying novel immunotherapy treatment combinations, and a patent application for an undisclosed treatment approach was filed in Q1 2023.

CORPORATE

The cash position of NOK 51 million enables a financial runway towards the end of 2024 with current plans.

PIPELINE

Programme	Description	Preclinical	Phase 1	Phase 2
fimaNAC	Dermatology			
fimaVACC	Intratumoural immunotherapy			
Collaborations	Various			
Programme	Application	Feasibility	Prototype	Commercial
fimaNAC	Bioprocessing			

OPERATIONAL REVIEW

BIOPROCESSING - MANUFACTURING OF BIOLOGICAL DRUGS



fimaNAC

Bioprocessing is the manufacturing of biological drugs, which involves complex processes that are bottlenecks in the endeavor to offer breakthrough therapies to new and larger patient populations. Development of technologies for use in bioprocessing is less complex from a regulatory perspective compared to clinical development of new therapies, allowing shorter timelines and lower costs.

There is a great need for technologies that enable more effective bioprocessing with higher yield as well as increased quality at a lower cost, and in 2022, PCI Biotech initiated a project aimed at using **fimaNAC** for solving these challenges in gene therapy manufacturing.

During Q1 2023, new internal data have been generated to strengthen the first patent application filed in 2H 2022. We continue to advance the application to generate proof-of-principle data in a small-scale system.

The positive initial external feedback on **fimaNAC**'s value proposition was further confirmed during the BioEurope Spring event in March, warranting further studies working towards alpha testing with potential customers.

DERMATOLOGY



fimaNAc

Nucleic acid therapeutics have the potential to improve treatment of dermatological diseases, but delivery remains an obstacle. This is a challenge **fimaNAc** is uniquely positioned to solve, by achieving site-directed intracellular delivery. PCI Biotech has initiated a project aimed at developing an easy-to-use topical formulation for efficacious delivery of nucleic acids using **fimaNAc**.

The first development phase aims to demonstrate **fimaNAc**-mediated nucleic acid delivery in an *ex vivo* wound model with topical administration. The study is performed by an expert contract research organisation. The run-in part of the study is ongoing, and readout is expected to be reported in the Q2 2023 interim report. Positive results may provide opportunities for early-stage collaborations with partners developing therapeutic nucleic acid candidates.

INTRATUMOURAL IMMUNOTHERAPY



fimaVacc

PCI Biotech is exploring intratumoural immunotherapy approaches within the **fimaVacc** program, aiming at identifying novel treatment combinations to overcome resistance to immune-checkpoint inhibitors and safety-issues associated with such treatments. **fimaVacc** is a technology designed for local enhancement of therapeutic effects and is well suited for delivery of immune stimulants to tumour sites. As such, the technology can enhance the delivery of peptides, proteins, nucleic acids, small molecules, and viral vectors, all of which are relevant for locally administered immunotherapy.

A patent application for an undisclosed treatment approach was filed in Q1 2023. A Ph.D. candidate grant of up to NOK 2.5 million over 3 years, commencing 1st January 2023 and dedicated to the development of intratumoural immunotherapy, has been granted by the Research Council of Norway,

CORPORATE



The cash position of NOK 51.1 million per end of March 2023 enables an estimated financial runway towards the end of 2024 with current plans, providing an opportunity window to demonstrate the commercial potential of the technology platform. The company will continue to explore financing and strategic opportunities as the pre-clinical pipeline matures.

RESEARCH COLLABORATIONS



PCI Biotech has an active collaborative strategy for **fimaNAc** and **fimaVacc**. The collaboration partners include MDimune, OliX Pharmaceuticals, and IMV. In these collaborations, the companies will combine their know-how and technology to explore synergies. The partnerships are governed by research collaboration agreements, under which evaluations of technology compatibility and synergy will be assessed. A collaboration with Mymetics was recently closed.

The collaboration with the Norwegian Institute of Marine Research, aiming to explore the use of photochemical treatments to combat salmon lice in fish farming, has demonstrated killing of free-swimming sea lice. Refinement of the principle is ongoing to evaluate if sea lice attached to fish can be combated, and a patent application was filed in Q1 2023. This is an opportunistic, early-stage project, where domain expertise is ensured by collaboration with experts in the field, and further partnership is particularly important for progress.

PCI Biotech continues to pursue new and value-adding collaborative opportunities for the **fimaNAc** and **fimaVacc** programmes.

FINANCIAL REVIEW

INCOME STATEMENT

PCI Biotech has not recorded any revenues for the financial years 2023 or 2022. Grants received from public sources, such as the Norwegian Research Council, are recorded as other income. PCI Biotech recognised in 2022 a grant by the Research Council of Norway via the tax incentive scheme (SkatteFUNN) and an application for a new SkatteFUNN grant for 2023-2025 is filed. An industry Ph.d. grant is recognised for Q1 2023.

The restructuring of the company during 2022 makes comparison of cost items in the P&L for Q1 2023 versus Q1 2022 irrelevant.

Operating expenses are mainly driven by the R&D activity and R&D costs were NOK 3.4 million for Q1 2023. Total operating expenses were NOK 6.6 million.

Net financial result is based on ordinary interest income on cash deposits placed in NOK, and other minor items.

Net result for Q1 2023 were NOK -6.0 million.

CASH FLOW AND BALANCE SHEET

The Group held cash and cash equivalents of NOK 51.1 million at the end of Q1 2023, compared to NOK 56.6 million per year-end 2022. Cash flow from operations is mainly dependent on R&D activities and the restructuring of the company during 2022 makes comparison of cash flow from operations for Q1 2023 versus Q1 2022 irrelevant.

The cash position by the end of March 2023 enables an estimated financial runway for the company towards the end of 2024, with current plans. The company will continue to explore financing and strategic opportunities as the pipeline matures.

EQUITY

Pursuant to section 3-5 of the Norwegian Public Limited Liability Companies Act, the board has a duty to implement measures if the Company's equity is reduced to less than half of the share capital. As of 31 March 2023, less than 50% of the Company's share capital was retained. The board has therefore assessed its duty to act in accordance with section 3-5 of the Norwegian Public Limited Liability Company's Act and proposed for the upcoming annual general meeting, 25th May 2023, that a write-down of the share capital is carried out by way of a reduction of the nominal value of the Company's shares in order to establish a capital structure that is sound and reasonable for the business the Company currently operates.

OTHER

RISKS AND UNCERTAINTY FACTORS FOR 2023

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 2022, the most important risks the company is exposed to in 2023 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 2022.

POST-CLOSING EVENTS

PCI Biotech is not aware of any post-closing events which could materially influence this interim financial statement, except for the proposed write-down of the share capital.

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, and develop new technologies and innovative products. The PCI technology has the opportunity to play a significant role in the realisation of several new therapeutic modalities, including nucleic acid therapeutics (**fimaNAc**) and immunotherapy (**fimaVacc**).

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

The main current priorities of PCI Biotech are to:

- Focus efforts and resources on pre-clinical research, for technology platform development
- 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, 11 May 2023

Hans Peter Bøhn
 Chairman (sign)

Christina Herder
 Director (sign)

Hilde Furberg
 Director (sign)

Andrew Hughes
 Director (sign)

Lars Viksmoen
 Director (sign)

Ronny Skuggedal
 CEO (sign)

CONDENSED INTERIM CONSOLIDATED FINANCIAL INFORMATION

PROFIT AND LOSS (in NOK '000)	Note	Q1 2023	Q1 2022	FY 2022
Other income	5	232	1 188	4 750
Research and development	6	3 430	21 809	44 756
General and administrative	8	3 181	2 180	16 441
Operating expenses		6 611	23 988	61 197
Operating results		-6 379	-22 801	-56 447
Financial income and expenses				
Financial income		472	382	1 711
Financial expenses		49	594	359
Net financial result		423	-212	1 352
Profit/Loss before income tax		-5 956	-23 012	-55 095
Income tax	7	0	0	0
Net profit/loss		-5 956	-23 012	-55 095
Other comprehensive income		0	0	0
Total comprehensive income		-5 956	-23 012	-55 095

Balance sheet (in NOK '000)	Note	31.03 2023	31.03 2022	31.12 2022
Non-current assets				
Property, plant and equipment		16	30	18
Right to use asset	14	617	1 700	705
Total non-current assets		632	1 730	723
Current assets				
Short term receivables	13	5 861	14 000	6 162
Cash & cash equivalents		51 121	93 680	56 596
Total current assets	12	56 982	107 679	62 758
Total assets		57 615	109 409	63 482
Equity and liabilities				
Equity				
Share capital	8,9	111 979	111 979	111 979
Other reserves		-59 819	-23 179	-54 577
Total equity		52 161	88 800	57 403
Long-term liabilities				
Other long-term liabilities	10	0	0	0
Lease liabilities	14	288	1 119	327
Total long-term liabilities		288	1 119	327
Short term liabilities				
Trade debtors		245	4 406	495
Lease liabilities	14	383	629	443
Other short-term liabilities	10	4 538	14 455	4 814
Total short-term liabilities		5 166	19 489	5 752
Total liabilities	12	5 454	20 609	6 079
Total equity and liabilities		57 615	109 409	63 482

CHANGE IN EQUITY

<i>(in NOK '000)</i>	Q1 2023	Q1 2022	FY 2022
Equity at beginning of period	57 403	113 792	113 792
Capital increase	0	0	0
Share option scheme	713	-1 980	-1 294
Comprehensive income in the period	-5 956	-23 012	-55 095
Equity at end of period	52 161	88 800	57 403

CASH FLOW

<i>(in NOK '000)</i>	Q1 2023	Q1 2022	FY 2022
Ordinary profit before taxes	-5 956	-23 012	-55 095
Depreciation, amortisation and write off	91	5 930	6 406
Leasing interest cost	12	19	78
Share options	713	-1 980	-1 294
Currency gain (-)/ loss (+) not related to operations	0	671	-198
Changes in working capital and other non-cash adjustments	-224	-3 221	-8 938
Cash flow from operating activities	-5 364	-21 592	-59 042
Acquisition of non-current assets	0	0	0
Net cash flow from investing activities	0	0	0
Cash flow from financial activities			
Payment principal portion of lease liabilities	-111	-175	-678
Net proceeds from share issues	0	0	0
Net cash flow from financial activities	-111	-175	-678
Net change in cash during the period	- 5 475	-21 767	-59 720
Exchange rate effect on bank deposits in foreign currency	0	-671	198
Cash and cash equivalents at the beginning of the period	56 596	116 118	116 118
Cash and cash equivalents at the end of the period	51 121	93 680	56 596

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.

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 2022 (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 11 May 2023.

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 2023 are consistent with the consolidated financial statements for the year ended 31 December 2022.

New standards effective from 1 January 2023 are not expected to have a material impact on the interim financial reporting.

4. IMPORTANT ACCOUNTING VALUATIONS, ESTIMATES AND ASSUMPTIONS

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

In preparing these condensed interim financial statements, the significant judgements made by management in applying the group's accounting policies and the key sources of estimation uncertainty were the same as those applied to the consolidated financial statements for the year ended December 31, 2022.

5. 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. PCI Biotech recognised in 2022 a grant by the Research Council of Norway via the tax incentive scheme (SkatteFUNN). The company has filed an application for a new SkatteFUNN grant for 2023-2025. An industry Ph.d. grant is recognised for Q1 2023.

6. RESEARCH AND DEVELOPMENT

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.

7. DEFERRED TAX AND DEFERRED TAX ASSETS

At the end of the quarter, the group held NOK 157.5 million in estimated non-capitalised deferred tax assets (22% tax rate), which mainly relates to carry-forward losses.

8. 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	
		31.12.2022	31.03.2023
2024 - Q3	25.78	150 000	150 000
2025 - Q3	50.36	130 000	130 000
2026 - Q3	19.41	150 000	150 000
2027 - Q3	1.90	570 000	570 000
Total		1 000 000	1 000 000

The current authorisation, granted by the Annual General Meeting in May 2022, for the employee share option program allows for a total of 2,790,000 share options, of which 1,000,000 have been granted by the Board of Directors per end of the quarter.

Overview share options, Senior executives	Total holdings 31.12.2022					Total holdings 31.03.2023
	Allocated	Lapsed	Exercised	Expired		
Ronny Skuggedal, CEO / CFO	360 000	0	0	0	0	360 000
Anders Høgset, CSO	250 000	0	0	0	0	250 000
Kristin Eivindvik, CDO	110 000	0	0	0	0	110 000
Total	720 000	0	0	0	0	720 000

9. SHARE CAPITAL

	No. of shares	Nominal value per share in NOK	Share capital in NOK
31.12.2022	37 326 390	3.00	111 979 170
Transactions	-	-	-
31.03.2023	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 2022 authorised the board of directors to execute share capital increases by issuing up to 2,790,000 shares with a nominal value of NOK 3.00 in connection with the company's employee share option program. The authorisation is valid for one year. In addition, the board of directors were authorised to execute share capital increases with up to NOK 12,034,000 in connection with private placements. The authorisation shall not be used to increase share capital by an amount in excess of 10% of the share capital, based on the share capital per date of the authorisation and potential share capital increases in relation to the employee share option program. The authorisation may be used for general corporate purposes and is valid for one year.

PCI Biotech has around 6 100 shareholders at end of the quarter.

10 largest shareholders per 31 March 2023:

Name	No. of shares	Ownership
FONDSAVANSE AS	3 910 443	10,48 %
MP PENSJON PK	1 805 801	4,84 %
Myrlid AS	1 333 002	3,57 %
Nordnet Bank AB	907 942	2,43 %
ENGLUND, Christer	871 062	2,33 %
GRESSLIEN, ODD R.	858 800	2,30 %
CLEARSTREAM BANKING S.A.	609 471	1,63 %
RAVI INVESTERING AS	500 000	1,34 %
NORDNET LIVSFORSIKRING AS	491 650	1,32 %
BNP Paribas	428 283	1,15 %
Total 10 largest shareholders	11 716 454	31,39 %
<i>Others</i>	<i>25 609 936</i>	<i>68,61 %</i>
<i>Total</i>	<i>37 326 390</i>	<i>100 %</i>

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

Name	Position	No. of shares	
		31.12.2022	31.03.2023
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	8 000	8 000
Andrew Hughes	Board member	0	0
Anders Høgset	CSO	64 800	64 800
Ronny Skuggedal	CEO,CFO	55 000	55 000
Kristin Eivindvik	CDO	25 200	25 200
Total		299 628	299 628

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

10. OTHER SHORT-TERM LIABILITIES

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

11. OTHER LONG-TERM LIABILITIES

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

12. 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.

13. SHORT TERM RECEIVABLES

Short term receivables mainly consist of NOK 4.8 million regarding SkatteFUNN for 2022, and other elements related to various prepayments, VAT refunds, and accrued interest on cash deposits.

14. RIGHT OF USE ASSETS AND LEASE LIABILITIES

PCI Biotech has entered into a lease agreement with Oslo Cancer Cluster Incubator, Ullernchausséen 64 Oslo, Norway. The lease runs to 31 December 2024 and the lease agreement is subject to annual adjustment according to changes in the consumer price index. In December 2022 the lease office space was reduced, and the right to use asset and future lease obligations were reduced accordingly.

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

15. SUBSEQUENT EVENTS

PCI Biotech is not aware of any post-closing events which could materially influence this interim financial statement, except for the proposed write-down of the share capital.

DEFINITIONS AND GLOSSARY

Fimaporfin: Generic name of the photosensitiser active ingredient TPCS2a

fimaNAC: Biotech's development program for delivery of nucleic acids

fimaVacc: Biotech's development program for intratumoural immunotherapy

PCI: Photochemical internalisation

PCIB: PCI Biotech's ticker at Oslo Børs

R&D: Research and Development

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

Q1 Report 2023	12 May 2023
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Q2 Report 2023	31 August 2023
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Q3 Report 2023	22 November 2023
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Please note that the financial calendar may be subject to changes.

INVESTOR CONTACT

Contact person: Ronny Skuggedal, CEO, email: rs@pcibiotech.no, mob: +47 9400 5757

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.

PCI BIOTECH HOLDING ASA
Ullernchausséen 64
N-0379 Oslo
Norway

+47 67 11 54 00
post@pcibiotech.com
www.pcibiotech.com

PCI BIOTECH AS, subsidiary
Ullernchausséen 64
N-0379 Oslo
Norway

