BerGenBio

INTERIM REPORT FOURTH QUARTER 2022

BerGenBio

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Q4 2022 CORPORATE HIGHLIGHTS

"The recent announcement of the topline data from our BCBG008 NSCLC trial corroborates the strategy we enacted and the great strides we took in 2022. The trial showed a survival benefit and disease control provided by bemcentinib in combination with pembrolizumab, substantiating the relevance of AXL inhibition in NSCLC, particularly in patients with AXL-expressing tumors. The results of the trial strongly support our efforts to treat 1L NSCLC patients harboring STK11 mutations, a group in which AXL expression commonly occurs. Bemcentinib's ability to selectively inhibit AXL may serve as a key component in delivering hope to this large, hard-to-treat patient population."

Martin Olin
Chief Executive Officer

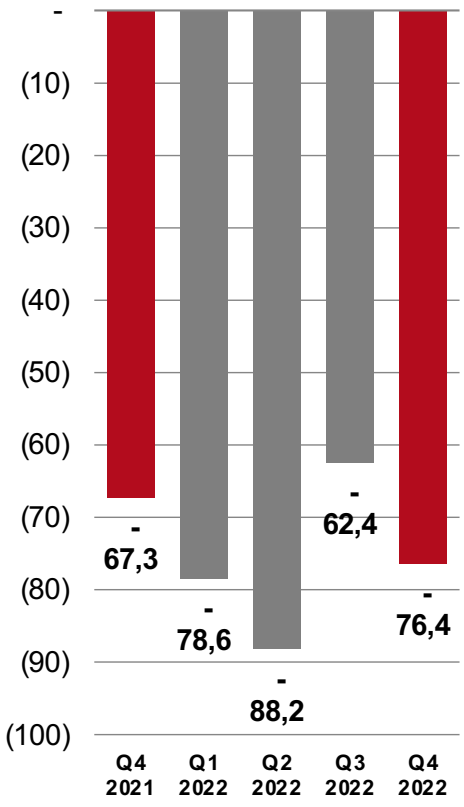
- Phase 2 data in 2nd/3rd line NSCLC patients in combination with pembrolizumab released
- Initiated Phase 1b/2a trial in 1st line NSCLC patients harboring STK11 mutations
- In a difficult financial environment BerGenBio strengthened its financial position by securing up to NOK 100 million loan facility from its largest shareholder. In addition to the cash position of NOK 151 million end of December 2022 the loan facility enables the Company to continue pursuing its focused strategy.

Q4 2022 FINANCIAL HIGHLIGHTS

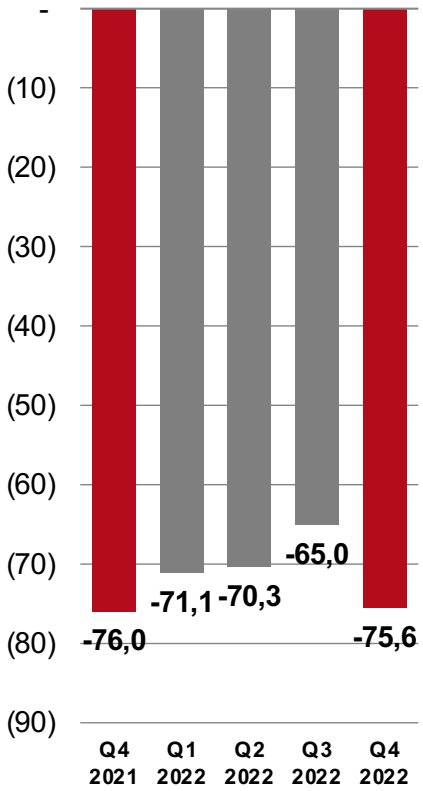
Key financial figures

(NOK million)	Q4 2022	Q4 2021	FY 2022	FY 2021
Operating revenues	0,4	0,8	0,4	0,8
Operating expenses	76,8	68,1	306,0	315,2
Operating profit (-loss)	-76,4	-67,3	-305,6	-314,5
Profit (-loss) after tax	-77,2	-68,8	-302,1	-309,4
Basic and diluted earnings (loss) per share (NOK)	-0.87	-0.78	-3.41	-3.52
Net cash flow in the period	-75,6	-76,0	-282,1	-284,2
Cash position end of period	150,8	436,6	150,8	436,6

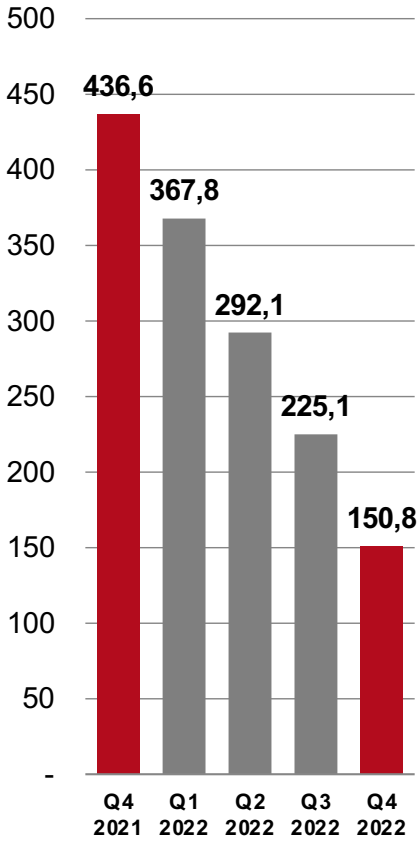
Operating loss



Cash Flow



Cash position



Q4 2022 QUARTERLY OVERVIEW

Clinical Development

Bemcentinib

BerGenBio's lead compound, bemcentinib, is a potentially first-in-class, oral, highly selective inhibitor of the receptor tyrosine kinase AXL, which is expressed and activated in response to oxidative stress, inflammation, hypoxia, and drug treatment, resulting in a number of deleterious effects in cancer and severe respiratory infections. Bemcentinib selectively inhibits AXL activation to prevent the progression of serious diseases through the modulation of resistance mechanisms and the adaptive immune system.

Bemcentinib is currently being developed in STK11 mutated NSCLC and severe respiratory infections including COVID-19. Its novel mechanisms of action and primary accumulation in the lungs uniquely position it to address these severe lung diseases.

Oncology: NSCLC

Second-Line+ NSCLC (BGBC008)

Subsequent to quarter end, the Company announced topline data from the BGBC008 (2L+) NSCLC trial on February 15, 2023. The trial enrolled 90 evaluable patients who received at least one prior line of therapy: chemotherapy, immunotherapy or the combination. Topline results from the total evaluable population:

A clinically meaningful survival benefit and evidence of disease control was demonstrated with bemcentinib in combination with pembrolizumab regardless of prior therapy, providing a median overall survival (mOS) of 13.0 months (95% CI: 10.1, 16.7), median progression free survival (mPFS) of 6.2 months (95% CI: 4.6, 9.8), disease control rate (DCR) of 51.1% (95% CI: 40.3, 61.8) and overall response rate (ORR) of 11.1% (95% CI: 6.2, 18.1).

A significant (p-value < 0.05) and clinically meaningful improvement in mOS based on AXL tumor proportion score (TPS) was observed. Patients with AXL TPS > 5 (46% of evaluable patients) achieved a mOS of 14.8 months (95% CI: 12.4, 29.6) compared to patients with AXL TPS < 5, who achieved a mOS of 9.9 months (95% CI: 6.7, 17.4). In addition, patients with an AXL TPS > 5 had a mPFS of 8.7 months (95% CI: 6.0, 14.8) compared to 4.6 months (95% CI: 2.7, 8.1) for patients with AXL TPS < 5. The ORR for AXL TPS > 5 was 21.9%.

The observed mOS was similar regardless of patient PD-L1 status.

Treatment with bemcentinib in combination with pembrolizumab was well-tolerated.

Second-Line+ NSCLC Trial (BGBIL005)

In addition to the encouraging ORR and DCR data previously presented from the Investigator Led Study phase 1 trial in which bemcentinib was combined with docetaxel, the final mPFS of 3.1 months and mOS of 12.3 months support the clinical benefit of combining bemcentinib with chemotherapy.

1L STK11m NSCLC (BGBC016)

BerGenBio announced in October 2022 the initiation of a global, open label phase 1b/2a trial evaluating bemcentinib in combination with the current standard of care, pembrolizumab and platinum doublet chemotherapy, for the treatment of 1L NSCLC patients harboring STK11 mutations. The trial is designed to determine the safety, tolerability, and efficacy of bemcentinib with standard of care in 1L advanced/metastatic non-squamous NSCLC patients with STK11 mutations and no other actionable co-mutations.

A significant subgroup comprising approximately 20% (> 30,000 patients in US and EU5) of non-squamous NSCLC patients harbor STK11 mutations, which are associated with immunosuppression and poor prognosis with standard treatment in 1L NSCLC. Data suggests that STK11m NSCLC patients almost universally have AXL tumor expression and activation, resulting in the development of drug resistance, immune evasion, and metastases.

Topline data from the 2L+ NSCLC (BGBC008) trial show clinically meaningful mOS, mPFS and DCR with the combination of bemcentinib and pembrolizumab, regardless of prior therapy. In patients with an AXL TPS > 5, a clinically significant improvement in mOS was observed providing supporting evidence for the relevance of AXL inhibition in the treatment of NSCLC. Further, data from the 2L+ NSCLC (BGBIL005) trial indicated promising clinical benefits from administering bemcentinib with chemotherapy.

The results of the BCBG008 and BCBIL005 trials provide clinical evidence of the anti-tumor effects of bemcentinib and its ability to modulate the tumor microenvironment to enhance the effects of immunotherapy and chemotherapy and provide strong support for the ongoing 1L NSCLC trial in patients harboring STK11 mutations, that are characterized by a severely immunosuppressed, pro-tumorigenic microenvironment and AXL activation.

Screening of patients for the 1L STK11m NSCLC (BCBG016) trial is ongoing.

Oncology: Relapsed/Refractory AML

As previously announced, the Company expects to report topline results from the phase 2 BGBC003 trial in Relapsed/Refractory AML in H1 2023.

Severe Respiratory Infections

The Company believes that bemcentinib blocks viral entry and replication, stimulates the innate immune system, and promotes lung tissue repair positioning it for the treatment of severe respiratory infections including COVID-19.

Previously the Company has completed two phase 2 trials with bemcentinib in hospitalized COVID-19 patients, showing promising clinical activity and is currently enrolling patients into the EUSolidAct phase 2b platform trial in hospitalized COVID-19 patients.

The trial is sponsored, and majority funded by the EUSolidAct platform, a pan-European research project designed to investigate treatment options for hospitalized patients with COVID-19 and emerging infectious diseases. The sponsor and the Company are currently monitoring the evolution of the pandemic and its impact on the trial execution. Further guidance on the trial is expected in H1 2023.

Additionally, bemcentinib is being evaluated in preclinical studies for SRIs causing Acute Respiratory Distress Syndrome (ARDS) and initial results are expected during 2023.

Corporate Activities

Shareholder Loan Facility

BerGenBio announced in October that it secured a shareholder loan facility of up to NOK 100 million from Meteva AS, a 27.23% shareholder in BerGenBio. The Company can draw on the facility from Q2 2023. In addition to the Company's existing cash position, the facility will enable BerGenBio to continue advancing its lead compound, bemcentinib, in 1L STK11m NSCLC and hospitalized COVID-19 patients.

Oncology Scientific Advisory Board

Subsequent to the quarter end, BerGenBio announced in February the formation of a scientific advisory board to enhance the development of bemcentinib for the treatment of NSCLC patients with STK11m, consisting of four world-renowned non-small cell lung cancer experts from top oncology centers around the globe: Enriqueta Felip, M.D., Ph.D., Head of the Thoracic Cancer Unit at Vall d'Hebron University Hospital, Spain; John Heymach, M.D., Ph.D., Chair of Thoracic/Head and Neck Medical Oncology at the MD Anderson Cancer Center, Texas; Tony Mok, M.D., BMSc., Professor and Chairman of the Department of Clinical Oncology at the Chinese University of Hong Kong; and Solange Peters, M.D., Ph.D., Professor and Head of Medical Oncology and Thoracic Malignancies at the Department of Oncology at Lausanne University, Switzerland.

Risks and Uncertainties

The Group operates in a highly competitive industry sector with many large players and may be subject to rapid and substantial technological change.

BerGenBio is currently in a development phase involving activities that entail exposure to various risks. BerGenBio's lead product candidate bemcentinib is currently in Phase I and II clinical trials. This is regarded as an early stage of development and the clinical studies may not prove to be successful. Timelines for completion of clinical studies are dependent on external factors outside the control of the Group, including resource capacity at clinical trial sites, competition for patients, etc.

The financial success of BerGenBio and / or its commercial partners requires obtaining marketing authorisation and securing an acceptable reimbursement price for its drugs. There can be no guarantee that the drugs will obtain the selling prices or reimbursement rates foreseen.

BerGenBio and / or its commercial partners will need approvals from the US Food & Drug Administration (FDA) to market its products in the US, and from the European Medicines Agency (EMA) to market its products in Europe, as well as equivalent regulatory authorities in other worldwide jurisdictions to commercialise in those regions. The future earnings are likely to be largely dependent on the timely marketing authorisation of bemcentinib for various indications.

Financial Risks

Interest rate risk

The Group holds cash and cash equivalents and does not have any borrowings but only a loan facility carrying a fixed facility charge. The Group's interest rate risk is therefore primarily in the rate of return of its cash on hand. Bank deposits are exposed to market fluctuations in interest rates, which affect the financial income and the return on cash.

Exchange rate risk

The value of non-Norwegian currency denominated costs will be affected by changes in currency exchange rates or exchange control regulations. The Group undertakes various transactions in foreign currencies and is consequently exposed to fluctuations in exchange rates. The exposure arises largely from clinical trials and research expenses. The Group is mainly exposed to fluctuations in euro (EUR), pounds sterling (GBP) and US dollar (USD). The Group are holding part of the bank deposit in EUR, GBP and USD depending on the need for such foreign exchange.

The foreign currency exposure is also mostly linked to trade payables with short payment terms. The Group might consider changing its current risk management of foreign exchange rate if it deems it appropriate.

Credit risk

Credit risk is the risk of counterparty's default in a financial asset, liability or customer contract, giving a financial loss. The Group's receivables are generally limited to receivables from public authorities by way of government grants. The credit risk generated from financial assets in the Group is limited since it is cash deposits. The Group places its cash in bank deposits in recognised financial institutions to limit its credit risk exposure.

The Group has not suffered any loss on receivables during 2022 and the Group considers its credit risk as low.

Funding and liquidity risk

Liquidity is monitored on a continuing basis by Group management.

The Group works continuously to ensure financial flexibility in the short and long term to achieve its strategic and operational objectives.

Funding of ongoing operations is and will be for some time depending on external sources, mainly equity contributions. Significant changes to financial market conditions may affect the climate for investor investments and consequently the Company's ability to secure adequate funding to pursue its strategy.

In October 2022 the Company secured a shareholder loan facility of up to NOK 100 million.

The current cash position combined with the shareholder loan facility, fund the planned activities through 2023 on a going concern basis. Additional financing options will need to be sought in 2023.

Non-financial risks

Technology risk

The Group's lead product candidate, bemcentinib, is currently in Phase II clinical trials and the Group's clinical studies may not prove to be successful.

Competitive technology

The Group operates in a highly competitive industry sector with many large players and is subject to rapid and substantial technological change.

Patent and IP risks

The success of the company will highly depend on the company's ability to obtain and maintain patent protection for its products, methods, processes and other technologies, to prevent third parties from infringing proprietary rights of the company and to operate without infringing the proprietary rights of third parties. To date, the company holds certain exclusive patent rights in major markets. The patent rights are limited in time. The company cannot predict the range of protection any patents will afford against competitors and competing technologies, including whether third parties will find ways to invalidate the patents, obtain patents claiming aspects similar to those covered by the company's patents and patents applications, and whether the company may be subject to litigation proceedings.

Regulatory & Commercial risks

The financial success of the Group requires obtaining marketing authorisation and achieving an acceptable reimbursement price for its drugs. There can be no guarantee that the Group's drugs will obtain the selling prices or reimbursement rates foreseen by the Group. The Group will need approvals from the US Food and Drug Administration (FDA) to market its products in the US, and from the European Medicines Agency (EMA) to market its products in Europe, as well as equivalent regulatory authorities in other worldwide jurisdictions to commercialise in those regions. The Group's future earnings are likely to be largely dependent on the timely marketing authorisation of bemcentinib for various indications.

COVID-19

The long-term impact of the COVID-19 crisis remains unclear although no greater for BerGenBio than any other business in the sector. Our ability to conduct clinical trials at the expected pace is a risk factor in the evolving pandemic.

FINANCIAL REVIEW

Financial Results

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

Revenue for the fourth quarter 2022 amounted to NOK 0.4 million (NOK 0.8 million) and for the twelve months ended 31 December 2022 NOK 0.4 million (NOK 0.8 million).

Total operating expenses for the fourth quarter 2022 amounted to NOK 76.8 million (NOK 68.1 million) and for the twelve months ended 31 December 2022 NOK 306.0 million (NOK 315.2 million).

Employee expenses in the fourth quarter were NOK 17.6 million (NOK 14.9 million) and for the twelve months ended 31 December 2022 NOK 68.7 million (NOK 74 million). Employee expense increased in fourth quarter mainly affected by short term incentives. Payroll expenses decreased for the full year compared to 2022. This was mainly due to reduction in headcount in 2022 as part of organizational restructuring and focused strategy announced in May 2022 and cost related to CEO change in 2021 including severance payment to departing CEO.

Other operating expenses amounted to NOK 59.1 million (NOK 52.9 million) for the fourth quarter and NOK 236.5 million (NOK 239.9 million) for the twelve months ended 31 December 2022. The decreased costs year on year reflects a combination of increased drug manufacturing activities in preparation for execution of new clinical trials and decreasing levels of clinical trials and translational activities. Other operating expenses are impacted by the fact that company had a significant number of patients recruited on clinical trials in 2021 where some of these studies have completed recruitment and in 2022 have been in a data read-out phase.

The operating loss for the quarter came to NOK 76.4 million (NOK 67.3 million) and for the twelve months ended 31 December 2022 NOK 305.6 million (NOK 314.5 million). The increase in Q4 reflects drug manufacturing activities and employee short term incentive costs. The decrease of costs year on year is mainly due to reduced headcount, CEO change in 2021 and decreased clinical trial activities.

Net financial items amounted to a loss of NOK 0.8 million (loss of NOK 1.4 million) for the fourth quarter. For the twelve months ended 31 December 2022 the net financial items amounted to a gain of NOK 3.5 million (gain of NOK 5.1 million) which represent a results from interest income on bank deposits and money market fund.

Losses after tax for the fourth quarter were NOK 77.2 million (NOK 68.8 million) and for the twelve months ended 31 December 2022 NOK 302.1 million (NOK 309.4 million).

Financial Position

Total assets as of 31 December 2022 decreased to NOK 166.7 million (NOK 235.5 million as of 30 September 2022) mainly due to the operational loss in the period.

Total liabilities were NOK 78.2 million as of 31 December 2022 (NOK 70.6 million 30 September 2022).

Total equity as of 31 December 2022 was NOK 88.5 million (NOK 164.9 million 30 September 2022), corresponding to an equity ratio of 53.1 % (70.0 % 30 September 2022).

Cash Flow

Net cash flow from operating activities was negative by NOK 77.5 million in the fourth quarter (negative by 79.5 million) and negative by NOK 288.2 million for the twelve months ended 31 December 2022 (negative by 303.3 million), mainly driven by the level of activity in the clinical trials.

Net cash flow from investing during the fourth quarter was NOK 1.9 million (NOK 2.6 million) and for the twelve months ended 31 December 2022 NOK 3.2 million (NOK 3.1 million).

Net cash flow from financing activities in fourth quarter 2022 was NOK 0.0 million (NOK 1.0 million) and for the twelve months ended 31 December 2022 NOK 2.9 million (NOK 16.0 million) representing proceeds from issue of share capital.

Cash and cash equivalents decreased to NOK 150.8 million as of 31 December 2022 (NOK 225.1 million 30 September 2022).

Outlook

The Company continues its work towards several upcoming milestones, to be achieved across the Company's clinical pipeline focused on the development of bemcentinib within NSCLC STK11m and respiratory diseases (initially COVID-19).

The recently announced data from its trial in 2L NSCLC evidence in the opinion of the Company promising clinical benefit of bemcentinib and particularly for NSCLC patients that show high levels of AXL activation supporting the on-going trial in 1L STK11m NSCLC patients.

With the shareholder loan facility of up to NOK 100 million announced in October 2022 the Company has secured liquidity to progress its activities and with a strong team in place to continue the advancement of its pipeline and working towards delivering new treatment options for patients in need and value for shareholders.

The current cash position combined with the shareholder loan facility, fund the planned activities through 2023 on a going concern basis. Additional financing options will need to be sought in 2023.

The Board today considered and approved the condensed, consolidated financial statement of the twelve months ending 31 December 2022 for BerGenBio.

Bergen 15 February 2023

Board of Directors and CEO of BerGenBio ASA

Anders Tullgren, Chairman

Sally Bennett

Sveinung Hole

François Thomas

Debra Barker

Martin Olin, CEO

Condensed consolidated statement of profit and loss and other comprehensive income

(NOK 1000) Unaudited	Note	Q4 2022	Q4 2021	FY 2022	FY 2021
Revenue		**389**	**774**	**389**	**774**
Expenses					
Payroll and other related employee cost	3, 10	16,296	12,632	66,143	69,929
Employee share option cost	3	1,274	2,265	2,546	4,116
Depreciation	2	113	307	883	1,312
Other operating expenses	6	59,109	52,890	236,451	239,880
Total operating expenses		**76,793**	**68,094**	**306,024**	**315,237**
Operating profit (-loss)		**-76,403**	**-67,320**	**-305,635**	**-314,464**
Finance income		2,234	4,027	15,027	15,993
Finance expense		3,019	5,473	11,514	10,894
Financial items, net		**-785**	**-1,446**	**3,513**	**5,100**
Profit (-loss) before tax		**-77,189**	**-68,766**	**-302,122**	**-309,364**
Income tax expense		0	0	0	0
Profit (-loss) after tax		**-77,189**	**-68,766**	**-302,122**	**-309,364**
Other comprehensive income					
Items that may be reclassified to profit and loss in subsequent periods					
Translation effects		-715	-112	-484	-112
Total comprehensive income (-loss) for the period		**-77,903**	**-68,878**	**-302,606**	**-309,476**
Earnings per share:					
- Basic and diluted per share	7	**-0.87**	**-0.78**	**-3.41**	**-3.52**

Condensed consolidated statement of financial position

(NOK 1000) Unaudited	Note	31 DEC 2022	31 DEC 2021
ASSETS			
Non-current assets			
Property, plant and equipment		43	1,191
Total non-current assets		**43**	**1,191**
Other current assets	5, 8	15,860	12,398
Cash and cash equivalents		150,803	436,646
Total current assets		**166,663**	**449,045**
TOTAL ASSETS		**166,706**	**450,236**
EQUITY AND LIABILITIES			
Equity			
Paid in capital			
Share capital	9	8,866	8,846
Share premium	9	35,780	335,195
Other paid in capital	4, 9	43,852	40,386
Total paid in capital		**88,498**	**384,426**
Total equity		**88,498**	**384,426**
Non-current liabilities			
Long term debt		275	942
Total non-current liabilities		**275**	**942**
Current liabilities			
Accounts payable		29,634	26,726
Other current liabilities		48,299	37,172
Provisions		0	969
Total current liabilities		**77,933**	**64,868**
Total liabilities		**78,208**	**65,810**
TOTAL EQUITY AND LIABILITIES		**166,706**	**450,236**

Condensed consolidated statement of changes in equity

(NOK 1000) Unaudited	Note	Share capital	Share premium	Other paid in capital	Total equity
Balance as of 1 January 2022		**8,846**	**335,195**	**40,386**	**384,426**
Loss for the period			-302,122		-302,122
Other comprehensive income (loss) for the period, net of income tax			-484		-484
Total comprehensive income for the period		**0**	**-302,606**	**0**	**-302,606**
Recognition of share-based payments	3, 4			3,466	3,466
Issue of ordinary shares	9	21	3,198		3,218
Share issue costs	9		-7		-7
Transactions with owners		21	3,191	3,466	6,678
Balance as of 31 December 2022		**8,866**	**35,780**	**43,852**	**88,498**

(NOK 1000) Unaudited	Note	Share capital	Share premium	Other paid in capital	Total equity
Balance as of 1 January 2021		**8,726**	**628,231**	**33,272**	**670,229**
Loss for the period			-309,364		-309,364
Other comprehensive income (loss) for the period, net of income tax			-112		-112
Total comprehensive income for the period		**0**	**-309,476**	**0**	**-309,476**
Recognition of share-based payments	3, 4			7,113	7,113
Issue of ordinary shares	9	120	16,510		16,629
Share issue costs	9		-70		-70
Transactions with owners		120	16,440	7,113	23,673
Balance as of 31 December 2021		**8,846**	**335,195**	**40,386**	**384,426**

Condensed consolidated statement of cash flow

(NOK 1000) Unaudited	Note	Q4 2022	Q4 2021	FY 2022	FY 2021
Cash flow from operating activities					
Loss before tax		-77,189	-68,766	-302,122	-309,364
Adjustments for:					
Depreciation of property, plant and equipment		113	307	883	1,312
Share-based payment expense	3, 4	1,503	2,166	3,466	7,113
Movement in provisions and pensions		0	-33	-969	-5,039
Currency -gains/+loss not related to operating activities		-2,017	-3,331	3,280	667
Net interest received		-1,939	-2,572	-2,949	-3,130
Working capital adjustments:					
Decrease in trade and other receivables and prepayments		-5,570	-8,312	-3,462	1,830
Increase in trade and other payables		7,590	1,036	13,641	3,270
Net cash flow from operating activities		**-77,510**	**-79,505**	**-288,231**	**-303,340**
Cash flows from investing activities					
Net interest received		1,939	2,572	2,949	3,130
Sale of property, plant and equipment		0	0	299	0
Net cash flow from investing activities		**1,939**	**2,572**	**3,248**	**3,130**
Cash flows from financing activities					
Proceeds from issue of share capital	9	0	1,050	3,218	16,629
Share issue costs	9	0	-32	-7	-70
Repayment of lease liabilities		0	-66	-307	-565
Net cash flow from financing activities		**0**	**953**	**2,904**	**15,995**
Effects of exchange rate changes on cash and cash equivalents		1,302	3,219	-3,764	-779
Net increase/(decrease) in cash and cash equivalents		-75,570	-75,981	-282,080	-284,216
Cash and cash equivalents at beginning of period		225,072	509,408	436,646	721,641
Cash and cash equivalents at end of period		**150,803**	**436,646**	**150,803**	**436,647**

SELECTED NOTES TO THE INTERIM CONSOLIDATED FINANCIAL STATEMENTS

Note 1

Corporate information

BerGenBio ASA ("the Company") and its subsidiary (together "the Group") is a clinical stage biopharmaceutical company focused on developing novel medicines for aggressive diseases, including advanced cancers and patients hospitalized with COVID-19.

BerGenBio ASA is a public limited liability company incorporated and domiciled in Norway. The address of the registered office is Møllendalsbakken 9, 5009 Bergen, Norway.

The condensed interim financial information is unaudited. These interim financial statements cover the three-months period ended 31 December 2022 and were approved for issue by the Board of Directors on 15 February 2023.

Note 2

Basis for preparation and significant accounting policies

Basis for preparation and significant accounting policies

The accounting policies adopted in the preparation of the interim condensed consolidated financial statements are consistent with those followed in the preparation of the Group's annual financial statements for the year ended 31 December 2021.

The new and amended standards and interpretations from IFRS that were adopted by the EU with effect from 2021 did not have any significant impact on the reporting for Q4 2022.

The Group has not early adopted any standard, interpretation or amendment that has been issued but is not yet effective.

Amounts are in Norwegian kroner (NOK) unless stated otherwise. The functional currency of the group is NOK. BerGenBio Limited has changed functional currency to GBP from 1 November 2021.

Basis for consolidation

The consolidated financial statements comprise the financial statements of the Company and its subsidiary as of 31 December 2022. The subsidiary is BerGenBio Limited, located in Oxford in the United Kingdom and is 100% owned and controlled by the parent company BerGenBio ASA.

Estimates and assumptions

Preparation of the accounts in accordance with IFRS requires the use of judgment, estimates and assumptions that have consequences for recognition in the balance sheet of assets and liabilities and recorded revenues and expenses. The use of estimates and assumptions are based on the best discretionary judgment of the Group's management. The Group works continuously to ensure financial flexibility in the short and long term to achieve its strategic and operational objectives.

Capital markets are used as a source of liquidity when this is appropriate and when conditions in these markets are acceptable. The company secured in total NOK 740 million in new equity funding during 2020. Cash position at end of Q4 2022 was NOK 151 million. In addition, the Company secured a shareholder loan facility of up to NOK 100 million. The cash position combined with the shareholder loan facility fund the planned activities through 2023 on a going concern basis. Additional financing options will need to be sought in 2023. The interim financial statements are prepared under the going concern assumption.

Note 3 Payroll and related expenses

(NOK 1000)	Q4 2022	Q4 2021	FY 2022	FY 2021
Salaries	8,182	10,370	49,768	58,910
Social security tax	2,370	1,299	7,864	7,728
Pension expenses	889	1,072	4,095	4,344
Short term incentive	8,748	4,466	8,748	4,466
Other remuneration and employee expenses	202	171	790	855
Government grants 1)	-4,095	-4,746	-5,122	-6,374
Total payroll and other employee related cost	**16,296**	**12,632**	**66,143**	**69,929**
Share option expense employees	1,503	2,166	3,466	7,113
Change in accrued social security tax on share options	-228	99	-920	-2,997
Total employee share option cost	**1,274**	**2,265**	**2,546**	**4,116**
Total employee benefit cost	**17,570**	**14,897**	**68,689**	**74,045**
Average number of full time equivalent employees	29	45	36	45

1) See also note 5 for government grants

Note 4

Employee share option program

The Group has a Long-Term Incentive Program for employees, a share option program. Each option gives the right to acquire one share in BerGenBio at exercise.

The program ensures focus and aligns the Group's long-term performance with shareholder values and interest. Most of the employees in the Group take part in the option program. The program also serves to attract and retain senior management.
The exercise price for options granted is set at the market price of the shares at the time of grant of the options. In general, for options granted after 2012 the options expire eight years after the date of grant.

Primarily the options vest annually in equal tranches over a three-year period following the date of grant.

Total options	FY 2022		FY 2021	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Balance as of 1 January	3,560,897	22.96	4,209,232	18.45
Granted during the period	2,114,230	7.59	1,379,871	28.55
Exercised during the period	-205,277	15.68	-1,195,272	13.91
Forfeited and cancelled	-1,250,005	24.61	-832 934	22.43
Balance as of 31 December	**4,219,845**	**15.13**	**3,560,897**	**22.96**

2,114,230 options were granted in the twelve months period ended 31 December 2022 and 1.379.871 options were granted in the twelve months period ended 31 December 2021.

Vested options	FY 2022	FY 2021
Options vested as of 1 January	1,541,168	1,887,201
Exercised and forfeited in the period	-1,003,946	-1,195,272
Vested in the period	1,077,844	849,239
Options vested as of 31 December	**1,615,066**	**1,541,168**
Total outstanding number of options	4,219,845	3,560,897

The options are valued using the Black-Scholes model.

The risk free interest rates are based on rates from Norges Bank and Oslo Børs on the Grant Date (bonds and certificates) equal to the expected term of the option being valued. Where there is no exact match between the term of the interest rates and the term of the options, interpolation is used to estimate a comparable term.

The vesting period is the period during which the conditions to obtain the right to exercise must be satisfied. The Group has estimated an expected vesting date and this date is used as basis for the expected lifetime. The Group expects the options to be exercised earlier than the expiry date. For Options granted earlier than 2014, the mean of the expected vesting date and expiry date has been used to calculate expected lifetime due to the lack of exercise pattern history for the Group and experience from other companies in combination with the relatively long lifetime of these options (up to 8 years).

For valuation purposes 55,81 % expected future volatility has been applied

For the twelve months period ending 31 December the value of the share options expensed through the profit or loss amounts to NOK 3.5 million (for the same period in 2021: NOK 7.1 million). In addition, a change in provision for social security contributions on share options of NOK -0.9 million (for the same period in 2021: NOK - 3.0 million). The provision for social security contribution is calculated on the difference between the share price and exercise price on exercisable option as at the end of the period.

Members of senior management participating in the option program

Option holder	Position	Number of options outstanding 31 Dec 2022	Weighted Average Strike Price 2022	Number of options outstanding 31 Dec 2021	Weighted Average Strike Price 2021
Martin Olin	Chief Executive Officer	950,000	7.59	0	
Rune Skeie	Chief Financial Officer	397,097	18.90	297,097	22.71
Cristina Oliva	Chief Medical Officer	200,000	7.59	0	
Nigel McCracken	Chief Scientific Officer	275,000	7.59	0	
James Barnes	Chief Operating Officer	411,522	16.57	301,522	19.85
		2,233,619		**598,619**	

Government grants

Government grants have been recognised in the profit and loss as a reduction of related expense with the following amounts:

(NOK 1000)	Q4 2022	Q4 2021	FY 2022	FY 2021
Employee benefit expenses	4 095	4 746	5 122	6 373
Other operating expenses	1 229	5 184	5,298	6 914
Total	**5,324**	**9,929**	**10,420**	**13,287**

Grants **receivable** as of 31 December are detailed as follows:

	31 Dec 2022	31 Dec 2021
Grants from Research Council, BIA	172	755
Grants from Research Council, PhD	496	519
Grants from SkatteFunn	4,750	4,750
Grants R&D UK	7,958	4,224
Total grants receivable	**13,375**	**10,248**

BIA grants from the Research Council of Norway:

Company currently had one grant from the Research Council, program for user-managed innovation arena (BIA) in 2022.

The BIA grant ("AXL as a therapeutic target in fibrosis; biology and biomarkers") has been awarded from 2019 and amount up to NOK 10.7 million. The Group has recognized NOK 0.3 million YTD 2022 (2021: NOK 2.3 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses

PhD grants from the Research Council of Norway:

BerGenBio has been awarded two grants supporting industrial PhD's in 2020. The fellowship covers 50 % of the established current rates for doctoral research fellowships and an operating grant to cover up to 50 % of additional costs related to costly laboratory testing connected with the research fellow's doctoral work.
The Group has recognized NOK 1.6 million YTD 2022 (2021 : NOK 1.6 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses.

Innovation Norway:

BerGenBio has been awarded a NOK 24 million (USD 2.85m) grant from Innovation Norway to support the clinical development of BGB324 in combination with Merck & Co.'s KEYTRUDA® (pembrolizumab) in patients with advanced lung cancer.
The grant from Innovation Norway is an Industrial Development Award (IFU). The IFU program is directed to Norwegian companies developing new products or services in collaboration with foreign companies.
BerGenBio has by end of 2020 recognized and received the total grant of NOK 24 million. The grant may be withdrawn under certain circumstances.

SkatteFunn:

R&D projects have been approved for SkatteFunn, a Norwegian government R&D tax incentive program designed to stimulate R&D in Norwegian trade and industry, for the period from 2021 until the end of 2023. The Group has recognized NOK 4.8 million YTD 2022 (2021: NOK 4.8 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses.

R&D tax grants UK:

BerGenBio Limited, a 100% subsidary of BerGenBio ASA, has been granted R&D tax grants in UK from 2017. R&D grants are approved retrospect by application. The Group has in 2022 recognized NOK 3.7 million (2021: NOK 4.2 mill) classified as reduction of payroll and related expenses.

Note 6 Other operating expenses

(NOK 1000)	Q4 2022	Q4 2021	FY 2022	FY 2021
Program expenses, clinical trials and research	48,053	44,881	194,063	193,076
Office rent and expenses	632	830	3,331	2,447
Consultants R&D projects	2,654	2,413	8,340	12,744
Patent and licence expenses	3,474	1,921	8,101	7,491
Other operating expenses	5,525	8,029	27,915	31,035
Government grants	-1,229	-5,184	-5,298	-6,914
Total	**59,109**	**52,890**	**236,451**	**239,880**

Note 7 Earnings per share

	Q4 2022	Q4 2021	FY 2022	FY 2021
Loss for the period (NOK 1,000)	-77,189	-68,766	-302,122	-309,364
Average number of outstanding shares during the period	88,660,532	88,418,000	88,636,493	87,956,563
Earnings (loss) per share - basic and diluted (NOK)	**-0.87**	**-0.78**	**-3.41**	**-3.52**

Share options issued have a potential dilutive effect on earnings per share. No dilutive effect has been recognized as potential ordinary shares only shall be treated as dilutive if their conversion to ordinary shares would decrease earnings per share or increase loss per share from continuing operations. As the Group is currently loss-making an increase in the average number of shares would have anti-dilutive effects.

Note 8 Other current assets

(NOK 1000)	31 Dec 2022	31 Dec 2021
Government grants	13,375	10,248
Refundable VAT	290	676
Prepaid expenses	1,804	701
Other receivables	390	774
Total	**15,860**	**12,398**

Note 9 Share capital and shareholder information

As of 31 December	Number of shares	Nominal value (NOK)	Book value (NOK)
Ordinary shares 2022	88,660,532	0.10	8,866,053.20
Ordinary shares 2021	88,247,755	0.10	8,824,775.50

Changes in the outstanding number of shares	FY 2022	FY 2021
Ordinary shares as of 1 January	88,455,255	87,259,983
Issue of ordinary shares	205,277	1,195,272
Ordinary shares as of 31 December	**88,660,532**	**88,455,255**

Ownership structure 31 12 2022:

Shareholder		Number of shares	% share of total shares
METEVA AS		24,139,650	27.2 %
INVESTINOR DIREKTE AS		7,270,780	8.2 %
FJARDE AP-FONDEN		4,487,493	5.1 %
SARSIA SEED AS		2,117,900	2.4 %
J.P. Morgan SE	NOMINEE I	1,726,731	1.9 %
BERA AS		1,712,426	1.9 %
VERDIPAPIRFONDET NORDEA AVKASTNING		1,510,174	1.7 %
SARSIA DEVELOPMENT AS		1,175,000	1.3 %
VERDIPAPIRFONDET NORDEA NORGE PLUS		901,260	1.0 %
VERDIPAPIRFONDET NORDEA KAPITAL		881,920	1.0 %
VERDIPAPIRFONDET NORDEA NORGE VERD		864,688	1.0 %
MOHN MARIT		850,000	1.0 %
MARSTIA INVEST AS		850,000	1.0 %
VERDIPAPIRFONDET KLP AKSJENORGE IN		574,309	0.6 %
NORDA ASA		519,614	0.6 %
MOHN LOUISE		509,676	0.6 %
J.P. Morgan SE	NOMINEE II	422,541	0.5 %
HØSE AS		383,111	0.4 %
MP PENSJON PK		372,783	0.4 %
NORDNET LIVSFORSIKRING AS		371,168	0.4 %
Top 20 shareholders		**51,641,224**	**58.2 %**
Total other shareholders		37,019,308	41.8 %
Total number of shares		88,660,532	100.0 %

The Board of Directors has been granted a mandate from the general meeting held on 28 April 2022 to increase the share capital with up to NOK 883,605 by subscription of new shares. The power of attorney was granted for the purpose of issuance of new shares in accordance with the Company's share incentive program and is valid until the earlier of the annual general meeting in 2023 and 30 June 2023. See note 4 for more information about the share incentive program and number of option granted.

The Board of Directors has been granted a mandate from the general meeting held on 28 April 2022 to increase the share capital with up to NOK 1,773,210 by subscription of new shares. The proxy is valid until the earlier of the annual general meeting in 2023 and 30 June 2023.

Shares in the Group held by the management group

	Position	Employed since	31 Dec 2022	31 Dec 2021
Martin Olin	Chief Executive Officer	September 2021	37,100	0
Total shares held by management			**37,100**	**0**

Shares in the Group held by members of the Board of Directors

	Position	Served since	31 Dec 2022	31 Dec 2021
Anders Tullgren	Chairman	January 2022	50,000	0
Sveinung Hole 1)	Board member	September 2010	107,394	107,394
Total shares held by members of the Board of Directors			**157,394**	**107,394**

1) Sveinung Hole holds 104,444 shares in the Company through Svev AS, a wholly owned company of Sveinung Hole, and 2,950 shares directly.

Note 10 Pension

BerGenBio ASA is required to have an occupational pension scheme in accordance with the Norwegian law on required occupational pension ("lov om obligatorisk tjenestepensjon").
The Company has a pension scheme which complies with the Act on Mandatory company pensions.

MEDICAL AND BIOLOGICAL TERMS

ACCORD	Accelerating COVID-19 Research & Development
AML	Acute Myeloid Leukaemia.
Anti-AXL MAb	Anti-AXL Monoclonal antibody. A monoclonal antibody that recognises AXL and binds to the AXL receptor blocking its function.
Antibody	Proteins produced by the B Lymphocytes of the immune system in response to foreign proteins called antigens. Antibodies function as markers, biding to the antigen so that the antigen molecule can be recognized and destroyed.
ASCO	American Society of Clinical Oncology
ASH	American Society of Hematology
AXL	Cell surface expressed receptor tyrosine kinase, being an essential mediator of the EMT programme. AXL is up-regulated in a variety of malignancies and associated with immune evasion, acquired drug resistance and correlates with poor clinical prognosis.
Anti-AXL MAb	AXL Monoclonal antibody. A monoclonal antibody that recognises AXL and binds to the AXL receptor.
Anti-PD-1	Agent that is used to inhibit the PD-1 receptor
Bemcentinib	BerGenBio's lead drug candidate; a highly selective inhibitor of AXL currently undergoing Phase Ib/II clinical trials in a range of aggressive cancers.
Biomarkers	A measurable indicator of some biological state or condition. More specifically, a biomarker indicates a change in expression or state of a protein that correlates with the risk or progression of a disease, or with the susceptibility of the disease to a given treatment.
cAXL	Composite AXL
CDx	Companion diagnostics
Checkpoint inhibitors	The immune system depends on multiple checkpoints to avoid overactivation of the immune system on healthy cells. Tumour cells often take advantage of these checkpoints to escape detection by the immune system. Checkpoint inhibitors, inhibit these checkpoints by "releasing the brakes" on the immune system to enhance an anti-tumour T-cell response.
Clinical Research	The research phases involving human subjects.
Clinical Trials	Clinical Trials are conducted with human subjects to allow safety and efficiency data to be collected for health inventions (e.g., drugs, devices, therapy protocols). There trials can only take place once satisfactory information has been gathered on the quality of the non-clinical safety, and Health Authority/Ethics Committee approval is granted in the country where the trial is taking place.
CPI	Immune checkpoint inhibitor
CR	Complete response
CRi	Complete response with incomplete recovery of peripheral counts
CRO	Contract research organisation.
DCR	Disease control rate
Docetaxel	A clinically well-established anti-mitotic chemotherapy medication that works by interfering with cell division.
EHA	European Hematology Association
Epithelial state	A state of the cell where the cells are stationary, typically forming layers and tightly connected and well ordered. They lack mobility tending to serve their specific bodily function by being anchored in place.
EGFR inhibitors	Epidermal growth factor receptor inhibitors. EGFRs play an important role in controlling normal cell growth, apoptosis and other cellular functions, but mutations of EGFRs can lead to continual or abnormal activation of the receptors causing unregulated EGFR inhibitors are either tyrosine kinase inhibitors or monoclonal antibodies that slow down or stop cell growth.
EMT	Epithelial-mesenchymal transition, a cellular process that makes cancer cells evade the immune system, escape the tumour and acquire drug resistant properties.
EMT inhibitors	Compounds that inhibit AXL and other targets that in turn prevent the formation of aggressive cancer cells with stem-cell like properties.

ESMO	European Society for Medical Oncology
EU-SolidAct	The EU-SolidAct trial is part of EU-RESPONSE, a pan-European research project involved with rapid and coordinated investigation of new and repurposed medication to treat Covid-19 during the ongoing pandemic. EU-SolidAct is an Adaptive Platform Trial.
FDA	Food and Drug Administration
Glioblastoma	Is the most aggressive of the gliomas, a collection of tumours arising from glia or their precursors within the central nervous system. Gliomas are divided into four grades, grade 4 or glioblastoma multiforme (GBM) is the most aggressive of these and is the most common in humans.
HR-MDS	High Risk Myelodysplastic Syndromes
IHC	Immunohistochemistry
In vivo	Studies within living organisms.
In vitro	Studies in cells in a laboratory environment using test tubes, petri dishes etc.
MAb	Monoclonal antibodies. Monospecific antibodies that are made by identical immune cells that are all clones of a unique parent cell, in contrast to polyclonal antibodies which are antibodies obtained from the blood of an immunized animal and thus made by several different immune cells.
MDS	Myelodysplastic Syndrome
Mesenchymal state	A state of the cell where the cells have loose or no interactions, do not form layers and are less well ordered. They are mobile, can have invasive properties and have the potential to differentiate into more specialised cells with a specific function.
Mesenchymal cancer cells	Cancer cells in a mesenchymal state, meaning that they are aggressive with stem-cell like properties.
Metastatic cancers	A cancer that has spread from the part of the body where it started (the primary site) to other parts of the body.
Myeloid leukaemia	A type of leukaemia affecting myeloid tissue. Includes acute myeloid leukaemia (AML) and chronic myelogenous leukaemia.
NSCLC	Non-small cell lung cancer.
ORR	Overall response rate
PDAC	Pancreatic ductal adenocarcinoma is the most common type of pancreatic cancer and a notoriously lethal disease
PD-1	Programmed death 1
PD-L1	Programmed death-ligand 1
PFS	Progression-free survival
Phase I	The phase I clinical trials where the aim is to show that a new drug or treatment, which has proven to be safe for use in animals, may also be given safely to people.
Phase Ib	Phase Ib is a multiple ascending dose study to investigate the pharmacokinetics and pharmacodynamics of multiple doses of the drug candidate, looking at safety and tolerability.
Phase II	The phase II clinical trials where the goal is to provide more detailed information about the safety of the treatment and its effect. Phase II trials are performed on larger groups than in Phase I.
Phase III	In the phase III clinical trials data are gathered from large numbers of patients to find out whether the drug candidate is better and possibly has fewer side effects than the current standard treatment.
PR	Partial Response
Receptor tyrosine kinase	High-affinity cell surface receptors for many polypeptide growth factors, cytokines and hormones. Receptor tyrosine kinases have been shown not only to be key regulators of normal cellular processes but also to have a critical role in the development and progression of many types of cancer.
RECIST	Response Evaluation Criteria In Solid Tumors, a set of published rules that define when cancer patients improve ("respond"), stay the same ("stable") or worsen ("progression") during treatments.
R/R	Relapsed/Refractory
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
sAXL	Soluble AXL
SITC	Society for Immunotherapy of Cancer
SoC	Standard of care
Small molecule	A small molecule is a low molecular weight (<900 Daltons) organic compound that may help regulate a biological process, with a size on the order of 10^{-9}m.
Tilvestamab	Former BGB149, BerGenBio's AXL inhibitor antibody.
UKRI	UK Research and Innovation
WCLC	World Conference on Lung Cancer

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