BerGenBio

BerGenBio

INTERIM REPORT FOURTH QUARTER 2021

BerGenBio

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Martin Olin
Chief Executive Officer at BerGenBio
CEO Statement

"In the fourth quarter of 2021 we continued to make significant progress in defining our strategy and priorities to advance our development candidates to potential treatment modalities for severe diseases. Our lead development candidate, bemcentinib, a potentially first-in-class selective AXL inhibitor currently undergoing Phase II clinical trials in NSCLC, AML and COVID-19 (respiratory disease), is well positioned for further advancement in areas of high unmet needs.

Our strategy and priorities are anchored within a rigorous data-driven framework, where the scientific rationale, pre-clinical and clinical data define a compelling rationale for advancing our development candidates toward potential treatment modalities addressing high unmet medical needs.

Through our BerGenBio and investigator-sponsored trials covering over 600 patients, we have accumulated a valuable understanding of the indications and patient subgroups which appear most likely to benefit from treatment with bemcentinib. Based on this understanding, we will prioritise the clinical development of bemcentinib within oncology and respiratory infections providing us with three attractive "shots on goal".

Firstly, in non-small cell lung cancer (NSCLC), the largest oncology indication, a specific population harbouring STK11 mutations (up to 20% of NSCLC) are reported to have poor prognosis and do not respond well to treatment with anti-PD1/PD-L1 therapies. Currently there are no effective therapies specifically directed toward this large, identifiable sub-group of NSCLC patients.

Preclinical data suggest that bemcentinib restores sensitivity to anti-PD1/L1 immune checkpoint therapies and STK11 mutant patients in our BGBC008 trial (combining anti-PD1 treatment and bemcentinib) showed encouraging clinical benefit. We received FDA Fast Track designation for bemcentinib in combination with an anti-PD-(L)1 agent as a treatment for patients with STK11 altered advanced/metastatic NSCLC without actionable mutations. In the pursuit of this significant opportunity, we look to aggressively advance our research and clinical activities while also evaluating partnering opportunities to further expand our work in this promising area.

Martin Olin
Chief Executive Officer at BerGenBio
CEO Statement

Secondly, despite recent approvals to 1st line AML treatments, the unmet medical need for 2nd line AML patients who are unable to tolerate intensive chemotherapy remains high. Bemcentinib has shown promising early clinical data in relapsed AML patients in our Phase II (BGBC003) AML trial and data from this trial continues to mature. As previously reported, we will subject to mature data, look to undertake a confirmatory randomised placebo-controlled trial to investigate bemcentinib in a relapsed 2nd line AML population unfit for intensive chemotherapy during the second half of 2022.

Finally, we aim to continue the investigation of bemcentinib as a potential therapy for the treatment of acute respiratory infections, initially within COVID-19. To this end we were pleased to announce our participation in the EU-SolidAct trial, part of EU-RESPONSE, a pan-European research project involved with the rapid and coordinated investigation of medications to treat COVID-19. As part of this Phase II adaptive, multi-centre trial, bemcentinib will be studied in up to 500 hospitalised COVID-19 patients.

The EU-SolidAct platform provides BerGenBio with a unique opportunity to rapidly study the effectiveness of bemcentinib and to evaluate the promising signals of efficacy that were observed in the hospitalised patients requiring oxygen in earlier studies. We hope that the resultant data will be useful in helping us assess the potential of AXL inhibition in a broad range of acute respiratory indications, beyond COVID-19.

With a clear strategy in place, based on three distinct shots on goal, I believe BerGenBio is well positioned to progress and deliver on its potential. As we move into 2022, I look forward to providing you with further updates on our progress.

Finally, our cash position of NOK 436.6m by the end of 2021 provides a good spring board for executing our strategic priorities as we head into 2022. "

Martin Olin
CEO

Q4 2021 (including post-period end) HIGHLIGHTS

Operational Highlights Q4 2021

COVID-19

- Post period end, bemcentinib to be investigated in the sponsored EU-SolidAct Phase II adaptive, multi-centre trial. Bemcentinib will be studied in up to 500 hospitalised COVID-19 patients.

NSCLC

- Exclusively in-licensed key intellectual property rights from UT Southwestern Medical Center, which strengthened the intellectual property estate for the treatment of NSCLC patients harbouring STK11 mutations.

- Granted Fast Track designation by the FDA for bemcentinib in combination with an anti-PD1/L1 agent as treatment for patients with STK11 altered advanced/metastatic NSCLC patients without actionable mutations.

- Presented pre-clinical and clinical data on bemcentinib in STK11-positive NSCLC at SITC Annual Meeting 2021, suggesting that bemcentinib restored response to anti-PD-1 treatments in NSCLC patients harbouring STK11 mutations.

AML

- Presented updated data from Phase II study (BGBC003) of bemcentinib in combination with low dose cytarabine (LDAC) in older, relapsed and refractory AML patients at the 63rd Annual American Society of Hematology (ASH) Meeting.

Other

- Post period end, Anders Tullgren appointed as Chairman of the Board, bringing over 35 years of global experience in both large pharmaceutical and small/mid-size biotechs.

Financial Highlights Q4 2021

- Decreased operating loss compared to previous quarter, Q4 operating loss at NOK 67.3 million (Q4 2020: NOK 71.8 million)

- A strong cash position of NOK 436.6 million at end of Q4 2021.

FY 2021 HIGHLIGHTS

Operational Highlights FY 2021

COVID-19

- Encouraging bemcentinib data from Phase II COVID-19 studies presented at European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) in July.

- Bemcentinib COVID-19 data in late-breaking abstract presentation at ECCMID in November demonstrate encouraging evidence for effect of bemcentinib in hospitalised patients receiving steroids ± remdesivir.

NSCLC

- Updated data from the Phase II bemcentinib combination study (BGBC008) in refractory NSCLC presented at the annual World Conference on Lung Cancer (WCLC) in January.

- Bemcentinib granted Fast Track designation by the FDA for bemcentinib in combination with an anti-PD-(L)1 agent as treatment for NSCLC patients in June and for bemcentinib in combination with an anti-PD1/L1 agent as treatment for patients with STK11 altered advanced/metastatic NSCLC without actionable mutations in November.

AML

- Encouraging updated preliminary data from Phase II relapsed AML study presented at European Hematology Association (EHA) in June.

Financial Highlights FY 2021

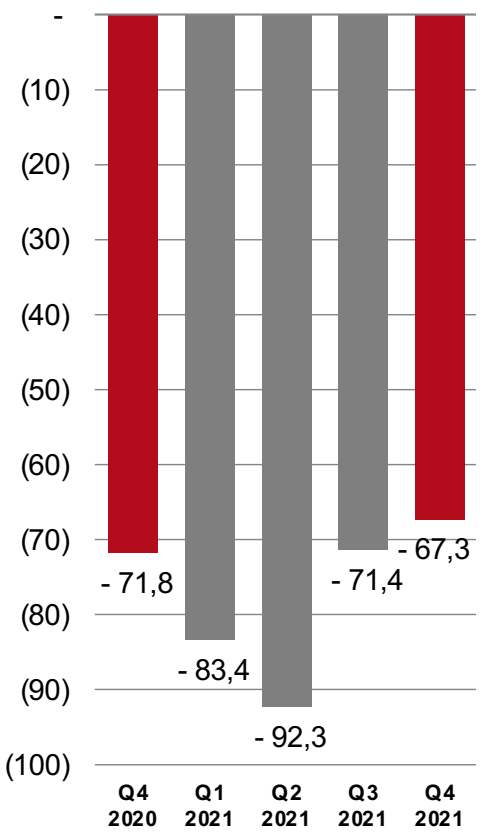
- Increased operating loss compared to 2020, operating loss at NOK 314.5 million (2020: NOK 261.1 million).

Q4 2021 FINANCIAL HIGHLIGHTS

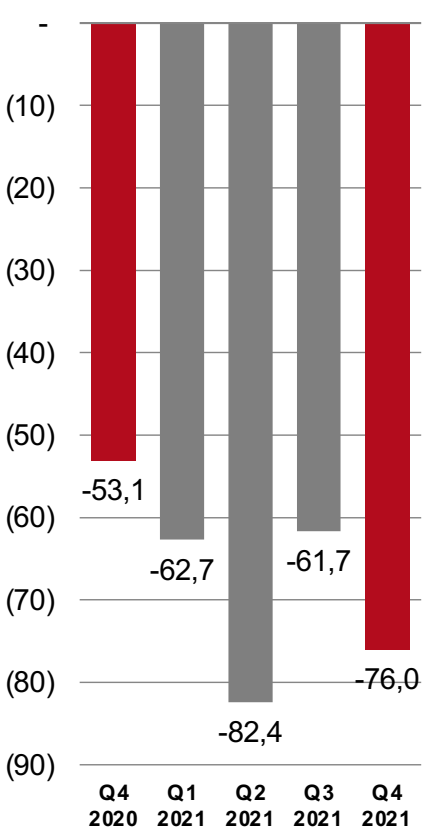
Key financial figures

(NOK million)	Q4 2021	Q4 2020	FY 2021	FY 2020
Operating revenues	0,8	0,6	0,8	0,6
Operating expenses	68,1	72,4	315,2	261,7
Operating profit (-loss)	-67,3	-71,8	-314,5	-261,1
Profit (-loss) after tax	-68,8	-73,9	-309,4	-257,0
Basic and diluted earnings (loss) per share (NOK)	-0.78	-0.85	-3.52	-3.43
Net cash flow in the period	-76,0	-53,1	-284,2	468,8
Cash position end of period	436,6	721,6	436,6	721,6

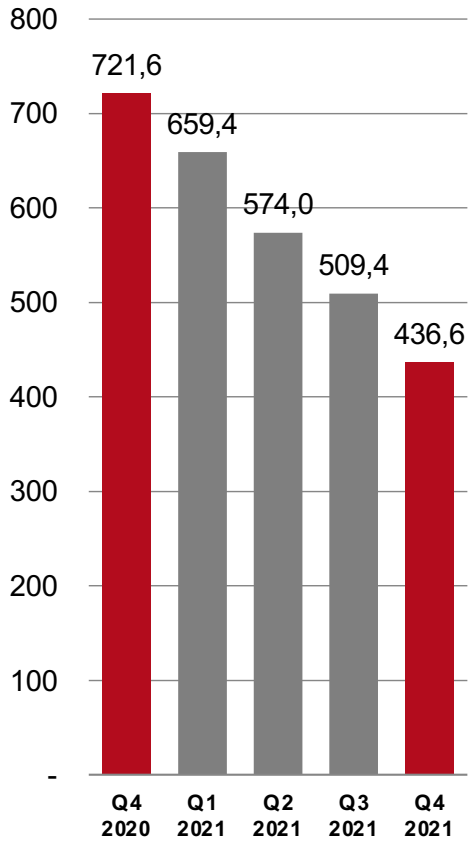
Operating loss



Cash flow



Cash position



OVERVIEW & R&D PIPELINE

Respiratory Disease

COVID-19

We believe that the mechanism of action of bemcentinib limits progression of acute lung injury caused by respiratory infections and facilitates tissue healing, positioning it as a treatment modality for acute respiratory diseases. Importantly, bemcentinib accumulates very well in lung tissue and this further supports its potential within respiratory diseases

While we are expanding our understanding of this broader potential in pre-clinical models, we have also been advancing the potential of bemcentinib in COVID-19 through a large randomized Phase II trial.

BerGenBio has completed two COVID-19 bemcentinib studies, ACCORD2 and BGBC020 in 2021. Combined data from the total 179 patients enrolled showed encouraging survival benefit with fewer deaths within 29 days of enrolment in bemcentinib treated patients versus standard of care. A post-hoc analysis of the data from both studies identified a sub-group of patients with higher disease severity in whom evidence of a treatment benefit with bemcentinib was observed.

Although several treatment modalities have been rapidly developed and adopted during the pandemic, we believe that there is still a need for better in-hospital oral treatments to improve patient outcomes. Significantly, pre-clinical and clinical data on bemcentinib confirms the mechanism of action of reducing viral entry into cells in viral diseases generally.

As a next step, we are continuing our development in COVID-19 by participating in the EU-SolidAct clinical trial platform where bemcentinib will be studied in a randomised confirmatory trial in up to 500 hospitalised COVID-19 patients. The platform provides access to a large number of sites across Europe and an established infrastructure at significantly reduced cost to BerGenBio and we expect this trial to commence in H1 2022.

NSCLC

Non-Small Cell Lung Cancer

Bemcentinib is being investigated as a potential combination treatment to improve the effectiveness of checkpoint inhibitor (CPI) drugs in refractory NSCLC patients. The Phase II clinical trial BGBC008 assessing bemcentinib in combination with pembrolizumab (anti-PD-1 therapy) continues with ongoing patient recruitment. Having previously fully enrolled the Cohort C1 of the study, the Company subsequently learned that several patients were not evaluable. As a result, these patients have been replaced in the study. We now expect the data from BGBC008 to mature in H1 2022.

Preclinical and clinical data has identified a potentially large patient population who may benefit from treatment with bemcentinib, NSCLC patients with mutations in STK11. The latest data announced at SITC in November. In pre-clinical NSCLC mouse models harbouring STK11 mutations, sensitivity to PD-1 blockade was evaluated in the absence and presence of bemcentinib. Systemic inhibition of AXL with bemcentinib resulted in the expansion of tumor-associated T cells and restored therapeutic response to anti-PD-1 check point inhibition.

In parallel, data from our Phase II bemcentinib and pembrolizumab combination study (BGBC008) in advanced NSCLC showed that 3 of 3 evaluable patients with identified STK11 mutations demonstrated objective clinical response / clinical benefit to the combination of bemcentinib and pembrolizumab.

In November 2021, we received FDA Fast Track designation for bemcentinib in combination with an anti-PD1/L1 agent as treatment for patients with STK11 altered advanced/metastatic NSCLC without actionable mutations. We have recently signed an exclusive license to intellectual property covering the treatment of STK11 patients, which enables us to advance exploration of bemcentinib in this population with valuable rights. We intend to initiate a safety and efficacy combination trial assessing bemcentinib in combination with anti PD-L1 immunotherapy and chemotherapy in first line NSCLC.

OVERVIEW & R&D PIPELINE

AML & MDS

Acute Myeloid Leukaemia and Myelodysplastic Syndromes

BerGenBio is investigating bemcentinib as a potential treatment for Acute Myeloid Leukaemia (AML) and Myelodysplastic Syndromes (MDS). The US FDA has granted bemcentinib Fast Track Designation and Orphan Drug status for the treatment of AML in patients unfit for intensive chemotherapy.

We have completed recruitment of Phase Ib/II study of bemcentinib in patients with AML or MDS. We believe there is a strong scientific rationale underpinning the use of bemcentinib in patients who relapse after first line treatment in AML.

Although not yet matured, data from our BGBC003 Phase II trial suggests meaningful clinical benefits (CR, ORR and OS) for AML patients who cannot tolerate intensive chemotherapy. We believe that these data support the immune system modulatory effect of bemcentinib which, when taking into consideration comprehensive PK/PD modelling and dose administration data supports bemcentinib as a therapeutic modality in AML.

We have received valuable input from the FDA on its evolving view of the establishment of dose selection for oncology therapies. As a result, we have established data which we believe further support bemcentinib as a potential therapy with a favourable benefit:risk profile. Bemcentinib distributes well in tissue and accumulates by a factor of 10 in bone marrow tissue further supporting its activity in AML.

Subject to mature clinical data, we will look to conduct a randomized placebo-controlled confirmatory trial in 2nd line AML patients unfit for intensive chemotherapy. The trial is expected to be initiated in H2 2022.

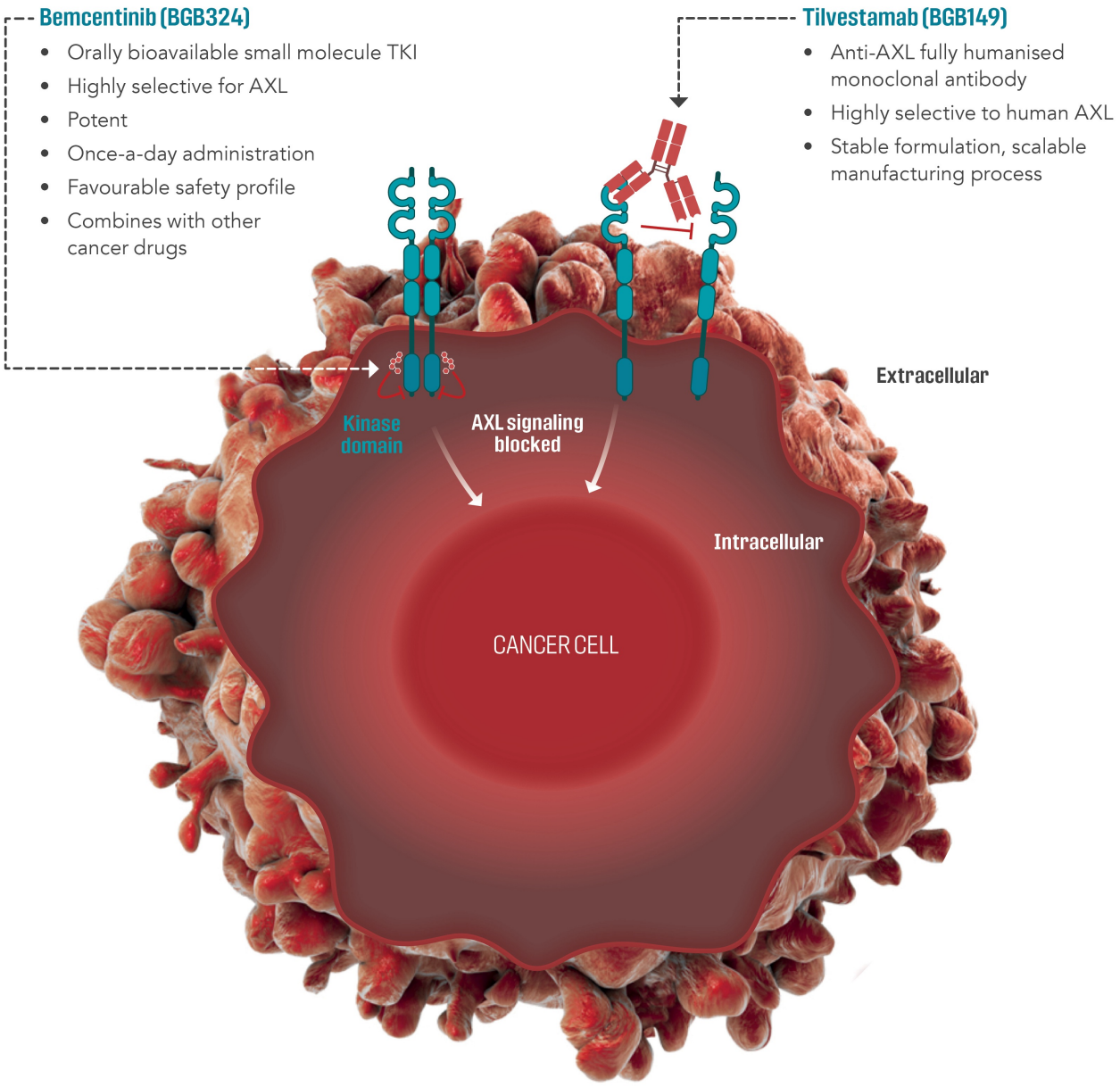
BerGenBio's AXL expertise

BerGenBio is a world leader in understanding AXL biology and its role in mediating aggressive disease.

AXL is a cell surface receptor tyrosine kinase, that when upregulated in response to stress factors in the tumour microenvironment renders cancers highly aggressive, immune-evasive and resistant to therapy with conventional drugs. Furthermore, it has recently been discovered that AXL has a unique dual role in facilitating host cell entry by envelope viruses, including Sars-Cov-2, and dampening of the body's immune response to viral infection.

The Company has successfully translated its world-leading research of AXL's biological role and function into two first-in-class clinical development candidates: the highly selective, potent oral small molecule AXL inhibitor bemcentinib, and a novel, wholly-owned anti-AXL humanised functionally blocking monoclonal antibody (mAb): tilvestamab.

The ability to identify which patients may benefit most from treatment with a selective AXL inhibitor could be an important success factor in clinical trials, as well as for registration and later reimbursement of these novel drugs. This insight underpins BerGenBio's strategy of extensive biomarker discovery, and development of a companion diagnostic, in parallel to the clinical programme. Results obtained thus far in parallel to the Phase II programme with bemcentinib are encouraging and suggest bemcentinib could yield greater clinical benefit in patients that can be identified by these biomarkers and companion diagnostic tests.



STRATEGIC PRIORITIES & OUTLOOK

Strategic Priorities

In the pursuit of the potential of our two clinical stage AXL inhibitors the priorities are:

- Aggressively pursue the 1st line NSCLC opportunity for patients harbouring STK11 mutations through additional pre-clinical work and the completion of a Phase 1b trial
- Pursue the potential within acute respiratory disease initially through the EU-SolidAct sponsored platform to conduct a confirmatory randomized placebo-controlled trial to position bemcentinib as a treatment modality in hospitalised COVID patients
- Pursue the unmet medical need in 2nd line AML through a confirmatory randomized placebo- controlled trial in relapsed patients unfit for intensive chemotherapy
- Progress the clinical development of tilvestamab
- Secure additional pipeline opportunities for the Company's AXL inhibitors in oncology and non-oncology indications (respiratory disease)

In retaining global rights to bemcentinib, BerGenBio maintains complete strategic flexibility for its future development and commercialisation. It is anticipated that the high novelty of bemcentinib plus its promising therapeutic profile, particularly in combination with existing therapies, could make it and future pipeline candidates attractive targets for partnering. A go-to market strategy may also be considered in selected indications in discrete territories, where greater value for shareholders could be created.

Outlook

The Board's aim is to continue its work towards a number of upcoming milestones, to be achieved across its oncology and infectious diseases pipeline.

Having completed a strategic review of operations following the appointment of Martin Olin as CEO, the Company has reiterated its focus on the clinical development of bemcentinib within NSCLC, acute respiratory diseases (initially COVID-19) and AML. Each of the therapeutic areas represents attractive commercial opportunities.

The Company remains well-funded 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.

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. The long term impact of the COVID-19 crisis remains unclear although no greater for BerGenBio than any other business in the sector.

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 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 to some extent 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. The Group's interest rate risk is therefore 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 the 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 2021 and the Group considers its credit risk as low.

Liquidity risk
Liquidity is monitored on a continued 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. Management considers the Group's liquidity situation to be satisfactory. The Group secured equity funding of total NOK 740 million in 2020.

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.

Financial Results

(Figures in brackets = same period 2020 unless stated otherwise)

Revenue for the fourth quarter 2021 amounted to NOK 0.8 million (NOK 0.6 million) and for the twelve months ended 31 December 2021 NOK 0.8 million (NOK 0.6 million).

Total operating expenses for the fourth quarter 2021 amounted to NOK 68.1 million (NOK 72.4 million) and for the twelve months ended 31 December 2021 NOK 315.2 million (NOK 261.7 million).

Employee expenses in the fourth quarter were NOK 14.9 million (NOK 16.9 million) and for the twelve months ended 31 December NOK 74.0 million (NOK 60.2 million). Payroll expenses decreased in Q4 mainly due to the effect of share option costs. Payroll expenses increased for the full year compared to 2020 due to increased headcount as part of organizational development in preparation for the next phase of clinical trials, including transfer of contractors to employees, in addition to cost related to change of CEO, including severance payment to departing CEO.

Other operating expenses amounted to NOK 52.9 million (NOK 55.4 million) for the fourth quarter and NOK 239.9 million (NOK 200.8 million) for the twelve months ended 31 December 2021. The increased costs year on year are related to increase clinical trials activities with a significant number of patient recruited in 1H 2021. Some of these trials have completed recruitment during 2021.

The operating loss for the quarter came to NOK 67.3 million (NOK 71.8 million) and for the twelve months ended 31 December 2021 NOK 314.5 million (NOK 261.1 million). The decrease in Q4 is reflective of the fact that some of BerGenBio's key clinical trials have completed patient recruitment and have or are preparing for study readout. The increase of the cost for the year is due to overall increase of activity related to clinical trials and patient recruitment in the first half year 2021.

Net financial items amounted to a loss of NOK 1.4 million (loss of NOK 2.0 million) for the fourth quarter.

For the twelve months ended 31 December 2021 the net financial items amounted to a gain of NOK 5.1 million (gain of NOK 4.1 million) which represent a results from interest income on bank deposits and money market fund.

Losses after tax for the fourth quarter were NOK 68.8 million (NOK 73.9 million) and for the twelve months ended 31 December 2021 NOK 309.4 million (NOK 257.0 million).

Financial Position

Total assets as of 31 December 2021 decreased to NOK 450.2 million (NOK 515.0 million as of 30 September 2021) mainly due to the operational loss in the period.

Total liabilities were NOK 65.8 million as of 31 December 2021 (NOK 64.9 million 30 September 2021).

Total equity as of 31 December 2021 was NOK 384.4 million (NOK 450.1 million 30 September 2021), corresponding to an equity ratio of 85.4 % (87.4% 30 September 2021).

Cash Flow

Net cash flow from operating activities was negative by NOK 79.5 million in the fourth quarter (negative by 56.4 million) and negative by NOK 303.3 million for the twelve months ended 31 December 2021 (negative by 234.3 million), mainly driven by the level of activity in the clinical trials.

Net cash flow from investing during the fourth quarter was NOK 2.6 million (NOK 3.4 million) and for the twelve months ended 31 December 2021 NOK 3.1 million (NOK 3.5 million).

Net cash flow from financing activities in fourth quarter 2021 was positive by NOK 1.0 million (negative NOK 0.1 million) and positive for the twelve months ended 31 December 2021 NOK 16.0 million (positive NOK 699.5 million) representing the private placements completed in the first half 2020 at gross NOK 738.0 million.

Cash and cash equivalents decreased to NOK 436.6 million as of 31 December 2021 (NOK 509.4 million 30 September 2021).

The Board today considered and approved the condensed, consolidated financial statement of the three months ending 31 December 2021 for BerGenBio.

Bergen 15 February 2022

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 2021	Q4 2020	FY 2021	FY 2020
Revenue		**774**	**601**	**774**	**601**
Expenses					
Payroll and other related employee cost	3, 10	12,632	13,238	69,929	48,832
Employee share option cost	3	2,265	3,677	4,116	11,346
Depreciation	2	307	137	1,312	726
Other operating expenses	6	52,890	55,370	239,880	200,788
Total operating expenses		**68,094**	**72,422**	**315,237**	**261,692**
Operating profit (-loss)		**-67,320**	**-71,821**	**-314,464**	**-261,091**
Finance income		4,027	2,988	15,993	19,499
Finance expense		5,473	5,035	10,894	15,437
Financial items, net		**-1,446**	**-2,047**	**5,100**	**4,062**
Profit (-loss) before tax		**-68,766**	**-73,868**	**-309,364**	**-257,029**
Income tax expense		0	0	0	0
Profit (-loss) after tax		**-68,766**	**-73,868**	**-309,364**	**-257,029**
Other comprehensive income					
Items that may be reclassified to profit and loss in subsequent periods					
Translation effects		-112	0	-112	0
Total comprehensive income (-loss) for the period		**-68,878**	**-73,868**	**-309,476**	**-257,029**
Earnings per share:					
- Basic and diluted per share	7	**-0.78**	**-0.85**	**-3.52**	**-3.43**

BerGenBio

Condensed consolidated statement of financial position

(NOK 1000) Unaudited	Note	31 DEC 2021	31 DEC 2020
ASSETS			
Non-current assets			
Property, plant and equipment		1,191	2,332
Total non-current assets		1,191	**2,332**
Other current assets	5, 8	12,398	14,228
Cash and cash equivalents		436,646	721,641
Total current assets		**449,045**	**735,869**
TOTAL ASSETS		**450,236**	**738,200**
EQUITY AND LIABILITIES			
Equity			
Paid in capital			
Share capital	9	8,846	8,726
Share premium	9	335,195	628,231
Other paid in capital	4, 9	40,386	33,272
Total paid in capital		**384,426**	**670,229**
Total equity		**384,426**	**670,229**
Non-current liabilities			
Long term debt		942	1,367
Total non-current liabilities		**942**	**1,367**
Current liabilities			
Accounts payable		26,726	22,550
Other current liabilities		37,172	38,046
Provisions		969	6,008
Total current liabilities		**64,868**	**66,604**
Total liabilities		**65,810**	**67,971**
TOTAL EQUITY AND LIABILITIES		**450,236**	**738,200**

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 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**

(NOK 1000) Unaudited	Note	Share capital	Share premium	Other paid in capital	Total equity
Balance as of 1 January 2020		**6,108**	**187,786**	**25,860**	**219,754**
Loss for the period			-257,029		-257,029
Other comprehensive income (loss) for the period, net of income tax			0		0
Total comprehensive income for the period		**0**	**-257,029**	**0**	**-257,029**
Recognition of share-based payments	3, 4			7,412	7,412
Issue of ordinary shares	9	2,618	738,234		740,852
Share issue costs	9		-40,760		-40,760
Transactions with owners		2,618	697,474	7,412	707,504
Balance as of 31 December 2020		**8,726**	**628,231**	**33,272**	**670,229**

BerGenBio

Condensed consolidated statement of cash flow

(NOK 1000) Unaudited	Note	Q4 2021	Q4 2020	FY 2021	FY 2020
Cash flow from operating activities					
Loss before tax		-68,878	-73,868	-309,476	-257,029
Adjustments for:					
Depreciation of property, plant and equipment		307	137	1,312	726
Share-based payment expense	3, 4	2,166	1,749	7,113	7,411
Movement in provisions and pensions		-33	1,928	-5,039	3,934
Currency gains not related to operating activities		-3,219	3,163	779	710
Net interest received		-2,572	-3,463	-3,130	-3,614
Working capital adjustments:					
Decrease in trade and other receivables and prepayments		-8,312	2,741	1,830	1,590
Increase in trade and other payables		1,036	11,227	3,270	11,982
Net cash flow from operating activities		**-79,505**	**-56,385**	**-303,340**	**-234,290**
Cash flows from investing activities					
Net interest received		2,572	3,463	3,130	3,614
Purchase of property, plant and equipment			-67		-67
Net cash flow from investing activities		**2,572**	**3,396**	**3,130**	**3,548**
Cash flows from financing activities					
Proceeds from issue of share capital	9	1,050	0	16,629	740,852
Share issue costs	9	-32	0	-70	-40,760
Repayment of lease liabilities		-66	-67	-565	-585
Net cash flow from financing activities		**953**	**-67**	**15,995**	**699,507**
Effects of exchange rate changes on cash and cash equivalents		3,219	-3,163	-779	-710
Net increase/(decrease) in cash and cash equivalents		-75,799	-53,055	-284,216	468,765
Cash and cash equivalents at beginning of period		509,408	777,858	721,641	253,586
Cash and cash equivalents at end of period		**436,646**	**721,641**	**436,646**	**721,641**

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, treatment-resistant cancers and COVID-19.

BerGenBio ASA is a limited public liability company incorporated and domiciled in Norway. The address of the registered office is Jonas Lies vei 91, 5009 Bergen, Norway.

The condensed interim financial information is unaudited. These interim financial statements cover the three-months period ended 31 December 2021 and were approved for issue by the Board of Directors on 15 February 2022.

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 2020.

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 2021.

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 2021. 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 2021 was NOK 436 million, and the Board of Directors has reasonable expectation that the Group will maintain adequate resources to continue in operational existence for the foreseeable future. The interim financial statements are prepared under the going concern assumption.

Note 3 Payroll and related expenses

	Q4 2021	Q4 2020	FY 2021	FY 2020
Salaries	10,370	11,107	58,910	37,364
Social security tax	1,299	1,325	7,728	5,840
Pension expense	1,072	900	4,343	3,075
Short term incentive	4,466	2,562	4,466	6,062
Other remuneration and employee expenses	171	914	855	1,291
Government grants 1)	-4,746	-3,571	-6,373	-4,800
Total payroll and other employee related cost	**12,632**	**13,238**	**69,929**	**48,832**
Share option expense employees	2,166	1,749	7,113	7,412
Change in accrued social security tax on share options	99	1,928	-2,997	3,934
Total employee share option cost	**2,265**	**3,677**	**4,116**	**11,346**
Total employee benefit cost	**14,897**	**16,915**	**74,045**	**60,177**
Average number of full time equivalent employees			45	39

1) See also note 5 for government grants

Note 4

Employee share option program

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

The program ensure focus and align 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 2021		FY 2020	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Balance as of 1 January	4,209,232	18,45	2,569,547	21,07
Granted during the period	1,379,871	28,55	2,026,663	15,00
Exercised during the period	-1,195,272	13,91	-102,500	11,15
Forfeited and cancelled	-832,934	22,43	-284,478	20,14
Balance as of 31 December	**3,560,897**	**22,96**	**4,209,232**	**18,45**

1.379.871 options were granted in the twelve months period ended 31 December 2021 and 2.026.663 options were granted in the twelve months period ended 31 December 2020.

Vested options	FY 2021	FY 2020
Options vested as of 1 January	1,887,201	1,701,981
Exercised and forfeited in the period	-1,195,272	-163,552
Vested in the period	849,239	348,772
Options vested as of 31 December	**1,541,168**	**1,887,201**
Total outstanding number of options	3,560,897	4,209,232

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 66,54 % 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 7.1 million (for the same period in 2020: NOK 7.4 million). In addition, a change in provision for social security contributions on share options of NOK -3.0 million (for the same period in 2020: NOK 3.9 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 2021	Weighted Average Strike Price 2021	Number of options outstanding 31 Dec 2020	Weighted Average Strike Price 2020
Rune Skeie	Chief Financial Officer	297,097	22,71	242,757	21,40
James Barnes	Chief Operating Officer	301,522	19,85	237,400	17,50
Alison Messom	Director of Clinical Operations	169,068	19,89	108,000	15,00
		767,687		**588,157**	

Government grants

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

	Q4 2021	Q4 2020	FY 2021	FY 2020
Employee benefit expenses	4,746	3,571	6,373	4,800
Other operating expenses	5,184	7,983	6,914	16,616
Total	**9,929**	**11,554**	**13,287**	**21,417**

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

	31 Dec 2021	31 Dec 2020
Grants from Research Council, BIA	755	2,551
Grants from Research Council, PhD	519	591
Grants from SkatteFunn	4,750	4,750
Grants R&D UK	4,224	4,243
Total grants receivable	**10,248**	**12,135**

BIA grants from the Research Council of Norway:

The Company currently has one grants from the Research Council, programs for user-managed innovation arena (BIA) in 2021. One additional grant ended in December 2020.

The BIA grant ("Investigator-Initiated Trials for AXL driven cancers with high unmet clinical need") totals to NOK 15.1 million and covers the period from February 2017 to January 2021. The Group has recognised NOK 0.0 million in Q4 2021 (Q4 2020: NOK 3.2 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses.

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 recognised NOK 2.3 million YTD 2021 (2020: NOK 4.5 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 recognised NOK 1.6 million YTD 2021 (2020: NOK 1.2 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 2.85 million) 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 recognised 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 2018 until the end of 2020. The Company has applied for SkatteFunn from 2021 to 2023 and the application was approved in Q4 2021. The Group has recognised NOK 4.8 million in Q4 2021 (Q4 2020: 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% subsidiary 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 2021 recognised NOK 4.2 (2020: NOK 2.9 mill) classified as reduction of payroll and related expenses for the year 2021.

BerGenBio

Note 6 Other operating expenses

	Q4 2021	Q4 2020	FY 2021	FY 2020
Program expenses, clinical trials and research	44,881	48,340	193,076	163,442
Office rent and expenses	830	659	2,447	2,364
Consultants R&D projects	2,413	6,412	12,744	21,792
Patent and licence expenses	1,921	1,782	7,491	6,041
Other operating expenses	8,029	6,160	31,035	23,766
Government grants	-5,184	-7,983	-6,914	-16,616
Total	**52,890**	**55,370**	**239,880**	**200,788**

Note 7 Earnings per share

	FY 2021	FY 2020
Loss for the period (NOK 1,000)	-309,476	-257,029
Average number of outstanding shares during the year	87,956,563	74,919,830
Earnings (loss) per share - basic and diluted (NOK)	**-3,52**	**-3,43**

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

	31 Dec 2021	31 Dec 2020
Government grants	10,248	12,135
Refundable VAT	676	772
Prepaid expenses	701	720
Other receivables	774	601
Total	**12,398**	**14,228**

Note 9 Share capital and shareholder information

As of 31 December	Number of shares	Nominal value (NOK)	Book value (NOK)
Ordinary shares 2021	88,455,255	0.10	8,845,525.50
Ordinary shares 2020	87,259,983	0.10	8,725,998.30

Changes in the outstanding number of shares	FY 2021	FY 2020
Ordinary shares as of 1 January	87,259,983	61,076,590
Issue of ordinary shares	1,195,272	26,183,393
Ordinary shares as of 31 December	**88,455,255**	**87,259,983**

Ownership structure 31 12 2021:

Shareholder		Number of shares	% share of total shares
METEVA AS		23,798,564	26,9 %
INVESTINOR DIREKTE AS		7,270,780	8,2 %
FJARDE AP-FONDEN		4,487,493	5,1 %
SARSIA SEED AS		2,117,900	2,4 %
BERA AS		1,712,426	1,9 %
VERDIPAPIRFONDET NORDEA AVKASTNING		1,510,174	1,7 %
VERDIPAPIRFONDET NORDEA KAPITAL		1,504,740	1,7 %
VERDIPAPIRFONDET KLP AKSJENORGE		1,440,000	1,6 %
SARSIA DEVELOPMENT AS		1,175,000	1,3 %
J.P. MORGAN BANK LUXEMBOURG S.A.	NOM	1,088,228	1,2 %
VERDIPAPIRFONDET NORDEA NORGE PLUS		909,260	1,0 %
VERDIPAPIRFONDET NORDEA NORGE VERD		864,688	1,0 %
MOHN, MARIT		850,000	1,0 %
MARSTIA INVEST AS		850,000	1,0 %
NORDNET LIVSFORSIKRING AS		660,469	0,7 %
MOHN, LOUISE		509,676	0,6 %
J.P. MORGAN BANK LUXEMBOURG S.A.	NOM	430,541	0,5 %
ZAIM, KEVIN		374,000	0,4 %
Nordnet Bank AB	NOM	359,581	0,4 %
RO INVEST AS		350,000	0,4 %
Top 20 shareholders		**52,263,520**	**59,1 %**
Total other shareholders		36,191,735	40,9 %
Total number of shares		**88,455,255**	**100,0 %**

The Board of Directors has been granted a mandate from the general meeting held on 19 March 2021 to increase the share capital with up to NOK 872,599.80 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 2022 and 30 June 2022. From 19 March 2021 to end of December 2021 there has been issued 633,673 new shares under this proxy at a nominal value of NOK 63,367.30. 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 19 March 2021 to increase the share capital with up to NOK 1,745,199.50 by subscription of new shares. The proxy is valid until the earlier of the annual general meeting in 2022 and 30 June 2022.

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

	Position	Served since	31 Dec 2021	31 Dec 2020
Sveinung Hole 1)	Chairman	September 2010	107,394	107,394
Stener Kvinnsland 2)	Board Member	February 2015	104,444	104,444
Total shares held by members of the Board of Directors			**211,838**	**211,838**

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.
2) Stener Kvinnsland resigned from the board 6 January 2022 but remains in an observer position.

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.
Cytarabine	A chemotherapy agent used mainly in the treatment of cancers of white blood cells such as acute myeloid leukaemia (AML).
DCR	Disease control rate
Decitabine	A cancer treatment drug used for acute myeloid leukaemia (AML).
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
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.
LDAC	Low-dose chemotherapy
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, currently completed Phase 1a.
UKRI	UK Research and Innovation
WCLC	World Conference on Lung Cancer

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