BerGenBio

INTERIM REPORT THIRD QUARTER 2021

BerGenBio

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Martin Olin
Chief Executive Officer at BerGenBio
CEO Statement

"It is my great pleasure to provide an update on BerGenBio's progress over the last quarter, my first since joining the Company as CEO in September 2021. Since my appointment, I have been working alongside the senior management team and the Board to review the business with a view to progress our promising pipeline of clinical stage AXL inhibitors to benefit those in need of improved treatment options as well as to deliver value to shareholders in the best possible way.

I believe we are well positioned to deliver on our potential. BerGenBio has established itself as the market leader in exploring the unique and multiple mechanisms of action of AXL as a target in several diseases including cancer and respiratory infectious. We have made significant progress in demonstrating the great potential of AXL inhibition as a therapeutic modality.

A rigorous data driven approach of connecting a consistent scientific rationale, pre-clinical and clinical data to high unmet medical needs will enable us to define the best possible path to registration as well as unlocking significant potential. Through our BerGenBio and investigator-sponsored trials covering over 400 patients, we have accumulated a valuable understanding of the indications and patient subgroups which appear most likely to benefit from treatment with our lead drug candidate bemcentinib and our focus will be to prioritise the clinical development of bemcentinib within oncology and respiratory infections.

While several additional AML treatments have been approved in recent years; there remains a high unmet medical need in relapsed and refractory second line patients,

many of whom are elderly and unable to tolerate intensive chemotherapy therapy. We have a strong scientific rationale underpinning the use of bemcentinib, pre-clinical validation and promising early clinical data in relapsed patients from our Phase 2 (BGBC003) trial.

We have received valuable input from the FDA on its evolving view of the establishment of dose selection for oncology therapies which we are incorporating into our development plans. We are in a good position to address requirements, having collected and modelled extensive data on dosing and have a favourable benefit:risk profile of bemcentinib in the treatment of AML.

Martin Olin
Chief Executive Officer at BerGenBio

CEO Statement

Our next step will with regulatory alignment be to undertake a confirmatory randomized placebo-controlled trial to investigate bemcentinib in a relapsed 2L AML population unsuitable for intensive chemotherapy. We anticipate first patients in such a trial will be dosed in H2 2022.

Turning to our NSCLC programme, we are enrolling the final eligible patients into our BGBC008 trial as a result of previous patients being ineligible for assessment and we now expect readout in H1 2022. NSCLC is a rapidly changing treatment landscape, which is increasingly focused on immunotherapy and therapies that specifically address specific molecular drivers. Such therapies include Tagrisso (EGFR mutations) and Xalkori (ALK) having global annual sales of USD 4.3 billion and USD 0.5 billion respectively pointing to the significant opportunity of molecular driven therapies in 1L NSCLC.

Recent pre-clinical data presented at SITC and clinical data from our BGB008 trial suggest that 1L NSCLC patients harbouring STK11 mutations may benefit from treatment of bemcentinib in combination with anti-PD1/PDL-1 therapies. Pre-clinical data suggest that bemcentinib restores sensitivity to anti-PD1/PD-L therapies and STK11 mutant patients in our BGBC008 trial showed encouraging clinical benefit. Patients harbouring STK11 mutations are reported to have poor prognosis and do not respond well to treatment with anti-PD1 and PD-L1 therapies.

STK11 mutations are reported to be prevalent in up to 20% of NSCLC patients and thus represents a large identifiable subgroup which may respond to treatment of bemcentinib.

I am pleased to announce that we are in the process of securing an exclusive Intellectual Property license which provide us with valuable rights in the pursuit of treating 1L NSCLC STK11 mutated patients. The next step is to conduct a Phase 1b trial in NSCLC patients harbouring STK11 mutations and we are exploring partnering opportunities in the conduct of such trial.

The COVID-19 pandemic is evolving rapidly with several approved therapies but we believe there remains a clear unmet medical need for hospitalized patients requiring oxygen. The scientific rationale combined with our pre-clinical and clinical data suggest a clear beneficial role of inhibition of AXL by bemcentinib which is known to accumulate in the lung. Our intention is to build on the positive data generated so far, by validating our COVID-19 clinical data through a confirmatory randomized placebo-controlled trial supported by a major, multinational collaboration that provides access to a large number of sites across Europe and established infrastructure at significantly reduced cost to BerGenBio. We anticipate this study to commence in H1 2022.

In summary I believe BerGenBio is in a strong position, with a promising pipeline underpinned by good data and sufficient resources in place to progress our near term goals. With a number of exciting milestones expected, I look forward to providing further updates on our progress "

Martin Olin
CEO

Q3 2021 (including post-period end) HIGHLIGHTS

Operational Highlights

- Martin Olin appointed Chief Executive Officer, bringing 20 years of executive experience in the pharmaceutical and biotechnology industry. Previous roles include CEO of Symphogen
- Post-period end, NSCLC data presented at SITC, highlighting bemcentinib's potential in NSCLC patients harbouring STK11 mutations
- AML data presented at EHA indicate bemcentinib/LDAC combination is active and well tolerated in relapsed elderly AML patients unfit for intensive chemotherapy
- COVID-19 data in late-breaking abstract presentation at ECCMID demonstrate encouraging evidence for effect of bemcentinib in hospitalised patients receiving steroids ± remdesivir

Financial Highlights

- Decreased operating loss compared to previous quarters, Q3 operating loss at NOK 70.5 million (Q3 2020: NOK 67.3 million)
- A strong cash position of NOK 509.4 million at end of Q3 2021.

BUSINESS OVERVIEW

Q3

Corporate update

BerGenBio is pleased to announce that Gayle Mills has joined the leadership team as Chief Business Officer. Gayle brings a significant track record of executing R&D collaborations and M&A transactions within the pharmaceutical and biotech industry.

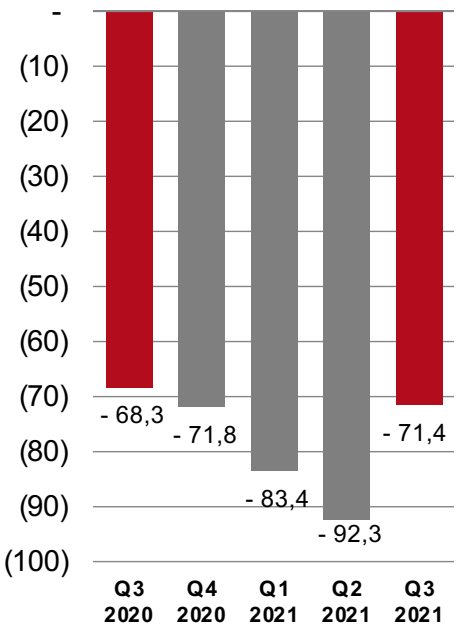
BerGenBio's Senior leadership team now consists of Martin Olin (CEO), Rune Skeie (CFO), Nigel McCracken (CSO), James Barnes (COO), Debbie Molyneux (CPO), Gayle Mills (CBO), Alison Messom (Director of Clinical Operations) and Gwyn Thomas (Head of Clinical Development).

Q3 2021 FINANCIAL HIGHLIGHTS

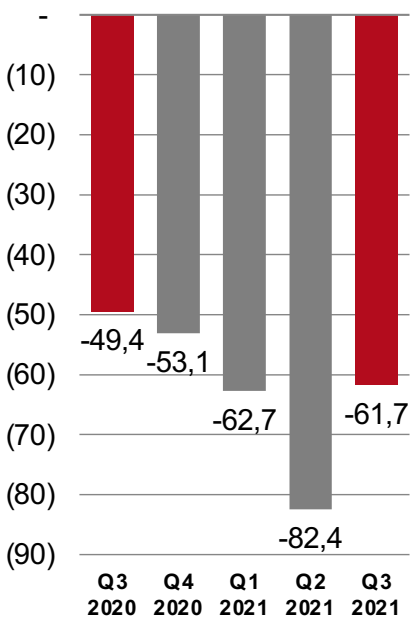
Key financial figures

(NOK million)	Q3 2021	Q3 2020	YTD 2021	YTD 2020	FY 2020
Operating revenues	0,0	0,0	0,0	0,0	0,6
Operating expenses	71,4	68,3	247,1	189,3	261,7
Operating profit (-loss)	-71,4	-68,3	-247,1	-189,3	-261,1
Profit (-loss) after tax	-70,5	-67,3	-240,6	-183,2	-257,0
Basic and diluted earnings (loss) per share (NOK)	-0.80	-0.77	-2.74	-2.51	-3.43
Net cash flow in the period	-61.7	-49,4	-208,2	521,8	468,8
Cash position end of period	509,4	777,9	509,4	777,9	721,6

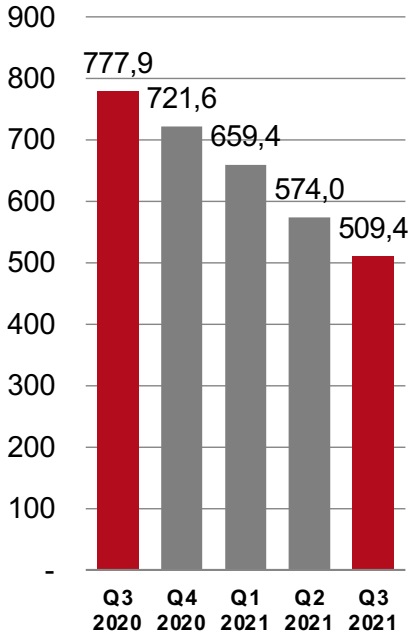
Operating loss



Cash flow



Cash position



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 a 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 and early promising clinical data in patients who relapse after first line treatment in AML.

Although not yet matured, data from our BGBC003 Phase II trial suggests encouraging clinical benefits including OS for AML patients who cannot tolerate intensive chemotherapy. We believe that these data support the immune system modulatory effect of bemcentinib.

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 support bemcentinib as a potential therapy with a favourable benefit:risk profile. Bemcentinib distributes well in tissue and accumulates in bone marrow tissue further supporting its activity in AML.

The next step is to conduct a randomized placebo-controlled confirmatory trial in 2L relapsed AML patients unfit for intensive chemotherapy. The trial is expected to be initiated in H2 2022.

NSCLC

Non-Small Cell Lung Cancer

Bemcentinib is being investigated as a potential combination treatment to improve the effectiveness of immune checkpoint inhibitors (CPI) drugs in refractory non-small cell lung cancer (NSCLC) patients. The Phase II clinical trial BGBC008 assessing bemcentinib in combination with pembrolizumab (anti-PD-1 therapy) continues with patient recruitment ongoing. 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 combination treatment with bemcentinib and anti-PD-1/PD-L1 therapy. 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 clinical benefit (PR, SD) to the combination of bemcentinib and pembrolizumab.

In November 2021, we received FDA Fast Track designation for bemcentinib in combination with an anti-PD-(L)1 agent as treatment for patients with STK11 altered advanced/metastatic NSCLC without actionable mutations. We are in the process of securing 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 Phase 1b trial assessing bemcentinib in combination with anti PD-L1 immunotherapies and chemotherapy in first line NSCLC.

OVERVIEW & R&D PIPELINE

Infectious Disease

COVID-19

BerGenBio has completed two Phase 2 COVID-19 studies, ACCORD2 and BGBC020. 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. We plan to continue development in COVID-19, by possibly employing government and consortium studies to advance the program. Significantly, pre-clinical and clinical data on bemcentinib confirms the mechanism of action of reducing viral entry into cells.

As a next step, we plan to validate earlier COVID-19 clinical data in a confirmatory randomized placebo-controlled trial under a potential collaboration that provides access to a large number of sites across Europe and established infrastructure at significantly reduced cost to BerGenBio and we expect such a trial to commence in H1 2022.

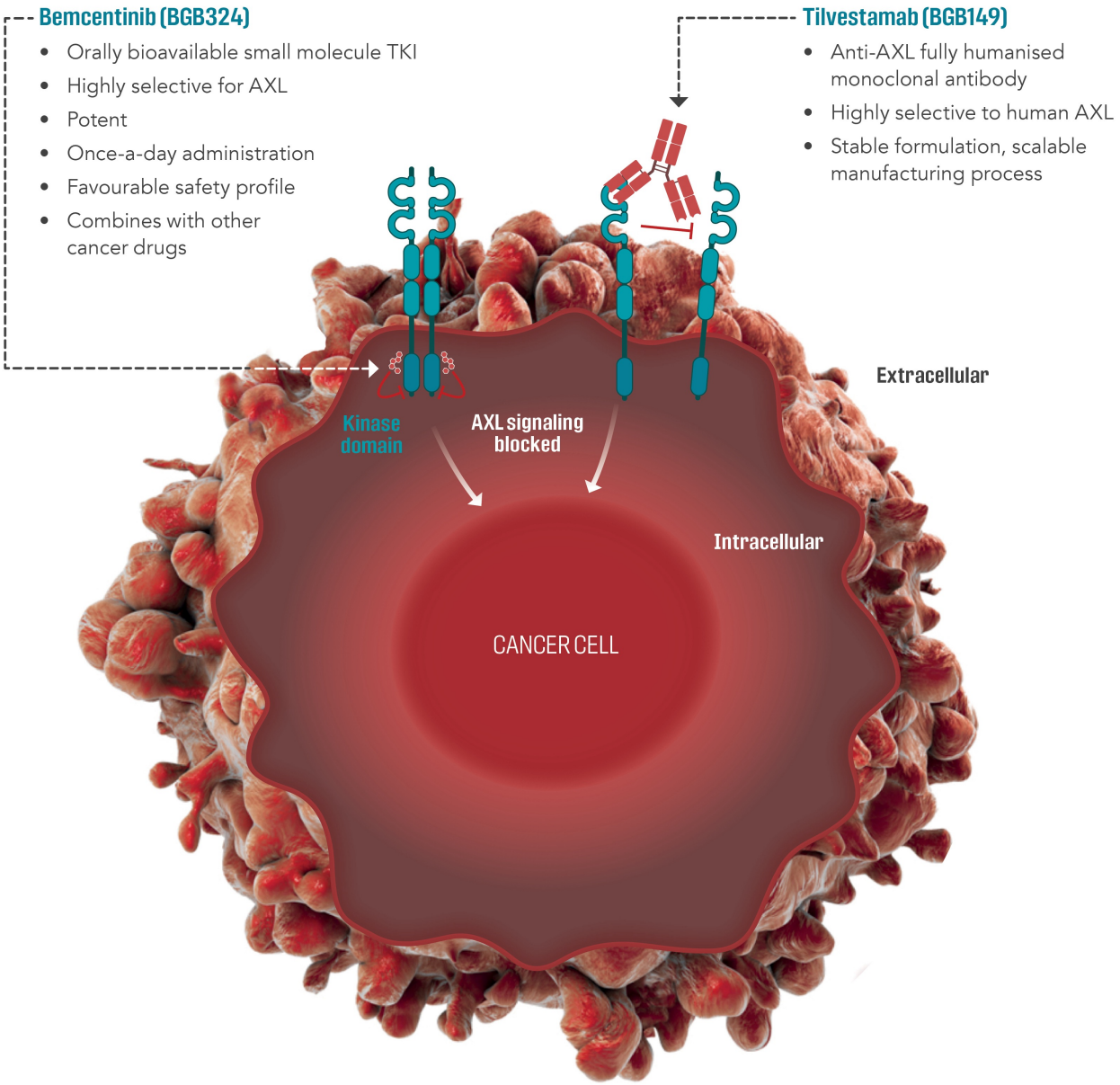
BerGenBio's AXL expertise

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:

- Pursue the unmet medical need in 2L relapsed AML through a confirmatory randomized placebo-controlled trial in patients unfit for intensive chemotherapy
- Aggressively pursue the 1L NSCLC opportunity for patients harbouring STK11 mutations through additional pre-clinical work and the conduct of a Phase 1b trial
- Through a platform sponsored confirmatory randomized placebo-controlled trial position bemcentinib as a treatment modality in hospitalised COVID patients
- Progressing the clinical development of tilvestamab
- Securing additional opportunities for the Company's AXL inhibitors in oncology and non-oncology indications including COVID-19

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 as a second line treatment of AML, with a view to initiating a randomized placebo-controlled confirmatory study in H2 2022. The clinical development of the NSCLC program continues, and a Phase 1b trial investigating bemcentinib in patients with STK11 altered advanced/metastatic NSCLC is scheduled to be initiated in H1 2022.

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 third quarter 2021 amounted to NOK 0.0 million (NOK 0 million) and year to date (YTD) 2021 NOK 0 million (NOK 0 million).

Total operating expenses for the third quarter 2021 amounted to NOK 71.4 million (NOK 68.3 million) and YTD 2021 NOK 247.1 million (NOK 189.3 million).

Payroll and other employee related cost in the third quarter were NOK 26.7 million (NOK 12.8 million) and YTD 2021 NOK 57.3 million (NOK 35.6 million). The increase in the quarter and YTD is related to the increased headcount as the Company prepares for the next phase of clinical trials, including transfer of contractors to permanent employees in addition to cost related to change of CEO, including severance payment to departing CEO.

Employee share option costs in the third quarter were NOK – 0.6 million (NOK 0.8 million) and YTD 2021 NOK 1.9 million (NOK 7.7 million). The decrease in Q3 2021 compared to Q3 2020 is a non-cash effect due to the reduction in social security tax provision on share options driven by a decrease in share price.

Other operating expenses amounted to NOK 45.0 million (NOK 54.5 million) for the third quarter and NOK 187.0 million (NOK 145.4 million) YTD. Operating expenses are driven by activities in the development program.

The operating loss for the third quarter came to NOK 71.4 million (NOK 68.3 million) and YTD 2021 NOK 247.1 million (NOK 189.3 million), reflecting the level of activity related to the clinical trials BerGenBio is conducting.

Net financial items amounted to a profit of NOK 0.9 million (profit of NOK 1.0 million) for the third quarter related to foreign exchange rates. YTD 2021 the net financial items amounted to a profit of NOK 6.5 million (profit of NOK 6.1 million).

Losses after tax for the third quarter were NOK 70.5 million (NOK 67.3 million) and YTD 2021 NOK 240.6 million (NOK 183.2 million).

Financial Position

Total assets as of 30 September 2021 decreased to NOK 515.0 million (NOK 584.8 million as of 30 June 2021) mainly due to the operational loss in the period.

Total liabilities were NOK 64.9 million as of 30 September 2021 (NOK 69.9 million as of 30 June 2021).

Total equity as of 30 June 2021 was NOK 450.1 million (NOK 514.9 million as of 30 June 2021), corresponding to an equity ratio of 87% (88% as of 30 June 2021).

Cash Flow

Net cash flow to operating activities was NOK 67.2 million in the third quarter (NOK 68.8 million) and NOK 223.8 million YTD 2021 (NOK 177.9 million), mainly driven by the level of activity in the clinical trials.

Net cash flow from investing during the third quarter was NOK 0.4 million (NOK 0 million) and YTD 2021 NOK 0.6 million (NOK 0.2 million).

Net cash flow from financing activities in the third quarter 2021 was NOK 5.1 million (NOK 19.4 million) and YTD 2021 NOK 15.0 million (NOK 699.6 million). The variance year-on-year is related to the private placement completed in the first quarter 2020 at gross NOK 220.0 million and second quarter 2020 at gross NOK 500.0 million.

Cash and cash equivalents decreased to NOK 509.4 million by 30 September 2021 (NOK 574.0 by 30 June 2021 and NOK 777.9 by 30 September 2020).

The Board today considered and approved the condensed, consolidated financial statement of the nine months ending 30 September 2021 for BerGenBio.

Bergen 15 November 2021

Board of Directors and CEO of BerGenBio ASA

Sveinung Hole, Chairman	Sally Bennett
Stener Kvinnsland	François Thomas
Debra Barker	Martin Olin, CEO

Condensed consolidated statement of profit and loss and other comprehensive income

(NOK 1000) Unaudited	Note	Q3 2021	Q3 2020	YTD 2021	YTD 2020	FY 2020
Revenue		**0**	**0**	**0**	**0**	**601**
Expenses						
Payroll and other related employee cost	3, 10	26,669	12,797	57,297	35,594	48,832
Employee share option cost	3	-562	782	1,851	7,668	11,346
Depreciation	2	335	196	1,005	589	726
Other operating expenses	6	44,977	54,539	186,990	145,419	200,788
Total operating expenses		**71,419**	**68,314**	**247,143**	**189,269**	**261,692**
Operating profit (-loss)		**-71,419**	**-68,314**	**-247,143**	**-189,269**	**-261,091**
Finance income		3,028	4,478	11,966	16,511	19,499
Finance expense		2,107	3,488	5,420	10,402	15,437
Financial items, net		**920**	**990**	**6 545**	**6,108**	**4,062**
Profit (-loss) before tax		**-70,498**	**-67,324**	**-240,598**	**-183,161**	**-257,029**
Income tax expense		0	0	0	0	0
Profit (-loss) after tax		**-70,498**	**-67,324**	**-240,598**	**-183,161**	**-257,029**
Other comprehensive income						
Items which will not be reclassified over profit and loss						
		0	0	0	0	0
Total comprehensive income (-loss) for the period		**-70,498**	**-67,324**	**-240,598**	**-183,161**	**-257,029**
Earnings per share:						
- Basic and diluted per share	7	-0.80	-0.77	-2.74	-2.51	**-3.43**

BerGenBio

Condensed consolidated statement of financial position

(NOK 1000) Unaudited	Note	30 SEP 2021	30 SEP 2020	31 DEC 2020
ASSETS				
Non-current assets				
Property, plant and equipment		1,498	386	2,332
Total non-current assets		**1,498**	**386**	**2,332**
Other current assets	5, 8	4,086	16,970	14,228
Cash and cash equivalents		509,408	777,858	721,641
Total current assets		**513,494**	**794,828**	**735,869**
TOTAL ASSETS		**514,992**	**795,214**	**738,200**
EQUITY AND LIABILITIES				
Equity				
Paid in capital				
Share capital	9	8,825	8,726	8,726
Share premium	9	400,875	702,099	628,231
Other paid in capital	4, 9	38,219	31,524	33,272
Paid in, not registered capital		2,201	0	0
Total paid in capital		**450,120**	**742,348**	**670,229**
Total equity		**450,120**	**742,348**	**670,229**
Non-current liabilities				
Long term debt		1,016	0	1,367
Total non-current liabilities		**1,016**	**0**	**1,367**
Current liabilities				
Accounts payable		22,283	23,444	22,550
Other current liabilities		40,572	25,342	38,046
Provisions		1,002	4,079	6,008
Total current liabilities		**63,857**	**52,865**	**66,604**
Total liabilities		**64,872**	**52,865**	**67,971**
TOTAL EQUITY AND LIABILITIES		**514,992**	**795,214**	**738,200**

Condensed consolidated statement of changes in equity

(NOK 1000) Unaudited	Note	Share capital	Share premium	Other paid in capital	Paid in not reg. capital	Total equity
Balance as of 1 January 2021		**8,726**	**628,231**	**33,272**	**0**	**670,229**
Loss for the period			-240,598			-240,598
Other comprehensive income (loss) for the period, net of income tax			0			0
Total comprehensive income for the period		**0**	**-240,598**	**0**	**0**	**-240,598**
Recognition of share-based payments	3, 4			4,947		4,947
Issue of ordinary shares	9	99	13,279			13,378
Share issue costs	9		-38			-38
Paid in, not registered capital					2,201	2,201
Transactions with owners		99	13,241	4,947	2,201	20,489
Balance as of 30 September 2021		**8,825**	**400,875**	**38,219**	**2,201**	**450,120**

(NOK 1000) Unaudited	Note	Share capital	Share premium	Other paid in capital	Paid in not reg. capital	Total equity
Balance as of 1 January 2020		**6,108**	**187,786**	**25,860**	**0**	**219,754**
Loss for the period			-183,161			-183,161
Other comprehensive income (loss) for the period, net of income tax			0			0
Total comprehensive income for the period		**0**	**-183,161**	**0**	**0**	**-183,161**
Recognition of share-based payments	3, 4			5,663		5,663
Issue of ordinary shares	9	2,618	738,234			740,852
Share issue costs	9		-40,760			-40,760
Paid in, not registered capital						0
Transactions with owners		2,618	697,474	5,663	0	705,755
Balance as of 30 September 2020		**8,726**	**702,099**	**31,524**	**0**	**742,348**

BerGenBio

Condensed consolidated statement of cash flow

(NOK 1000) Unaudited	Note	Q3 2021	Q3 2020	YTD 2021	YTD 2020	FY 2020
Cash flow from operating activities						
Loss before tax		-70,498	-67,324	-240,598	-183,161	-257,029
Adjustments for:						
Depreciation of property, plant and equipment		335	196	1,005	589	726
Share-based payment expense	3, 4	433	2,187	4,947	5,663	7,412
Movement in provisions and pensions		-1,437	-1,406	-5,006	2,005	3,934
Currency gains not related to operating activities		2,935	1,090	3,998	-2,453	710
Net interest received		-419	0	-558	-151	-3,614
Working capital adjustments:						
Decrease in trade and other receivables and prepayments		4,823	-1,536	10,142	-1,151	1,590
Increase in trade and other payables		-3,352	-2,008	2,234	755	11,982
Net cash flow from operating activities		**-67,179**	**-68,801**	**-223,835**	**-177,905**	**-234,290**
Cash flows from investing activities						
Net interest received		419	0	558	151	3,614
Purchase of property, plant and equipment		0	0	0	0	-67
Net cash flow from investing activities		**419**	**0**	**558**	**151**	**3,548**
Cash flows from financing activities						
Proceeds from issue of share capital	9	5,292	20,032	15,579	740 852	740,852
Share issue costs	9	0	-472	-38	-40 760	-40,760
Repayment of lease liabilities		-221	-197	-499	-518	-585
Net cash flow from financing activities		**5 071**	**19 363**	**15,043**	**699 574**	**699,507**
Effects of exchange rate changes on cash and cash equivalents		-2,935	-1,090	-3,998	2,453	-710
Net increase/(decrease) in cash and cash equivalents		-61,689	-49,438	-208,235	521,819	468,765
Cash and cash equivalents at beginning of period		574,033	828,386	721,641	253,586	253,586
Cash and cash equivalents at end of period		**509,408**	**777,858**	**509,408**	**777,858**	**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 nine-months period ended 30 September 2021 and were approved for issue by the Board of Directors on 15 November 2021.

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 Q3 2021.

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

Basis for consolidation

The consolidated financial statements comprise the financial statements of the Company and its subsidiary as of 30 September 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 Q3 2021 was NOK 509 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

			First nine months	
	Q3 2021	Q3 2020	2021	2020
Salaries	22,827	11,044	48,540	29,757
Social security tax	3,263	1,444	6,429	4,515
Pension expense	1,210	780	3,272	2,174
Short term incentive	0	0	0	0
Other remuneration and employee expenses	139	170	684	377
Government grants 1)	-870	-641	-1,628	-1,229
Total payroll and other employee related cost	**26,569**	**12,797**	**57,297**	**35 594**
Share option expense employees	433	2,187	4,947	5,663
Change in accrued social security tax on share options	-996	-1,406	-3,096	2,005
Total employee share option cost	**562**	**782**	**1,851**	**7,668**
Total employee benefit cost	**26,007**	**13,579**	**59,048**	**43,262**
Average number of full time equivalent employees			46	37

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 Group has a share option program to 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	First nine months 2021		First nine months 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	-1,125,272	13,84	-102,500	11,15
Forfeited and cancelled	-760,065	22,62	-86,175	28,67
Balance as of 30 September	**3,703,766**	**22,76**	**4,407,535**	**18,36**

1.379.871 options were granted in the nine months period ended 30 September 2021 and 2.026.663 options were granted in the nine months period ended 30 September 2020.
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Vested options	First nine months	
	2021	2020
Options vested as of 1 January	1,887,201	1,701,981
Exercised and forfeited in the period	-1,153,195	-153,552
Vested in the period	847,160	286,443
Options vested as of 30 September	**1,581,166**	**1,834,872**
Total outstanding number of options	3,703,766	4,407,535

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 nine months period ending 30 September the value of the share options expensed through the profit or loss amounts to NOK 4.9 million (for the same period in 2020: NOK 5.7 million). In addition, a change in provision for social security contributions on share options of NOK -3.1 million (for the same period in 2020: NOK 2.0 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 30 Sep 2021	Weighted Average Strike Price 2021	Number of options outstanding 30 Sep 2020	Weighted Average Strike Price 2020
Rune Skeie	Chief Financial Officer	297,097	22,71	242,757	21,40
James Barnes	Director of Operations	301,522	19,85	237,400	17,50
Hani Gabra	Director of Clinical Development	208,000	15,00	208,000	15,00
Gro Gausdal	Director of Research & Bergen Site Leader	175,359	21,84	143,376	20,34
Endre Kjærland	Associate Director of IP and Contracts	161,577	22,90	130,525	21,56
Alison Messom	Director of Clinical Operations	169,068	19,89	108,000	15,00
		1,312,623		**1,070,058**	

Government grants

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

	Q3 2021	Q3 2020	YTD 2021	YTD 2020
Employee benefit expenses	870	641	1,628	1,229
Other operating expenses	578	3,024	1,730	8,633
Total	**1,447**	**3,664**	**3,358**	**9,862**

Grants **receivable** as of 30 September are detailed as follows:

	30 Sep 2021	30 Sep 2020
Grants from Research Council, BIA	189	634
Grants from Research Council, PhD	130	563
Grants from Innovasjon Norge	0	-272
Grants from SkatteFunn	0	11,596
Grants R&D UK	2,640	1,457
Total grants receivable	**2,959**	**13,978**

BIA grants from the Research Council:

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 Q3 2021 (Q3 2020: NOK 2.4 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 1.7 million YTD 2021 (2020: NOK 3.4 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:

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 1.2 million YTD 2021 (2020: NOK 0.6 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 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 and recognise cost reduction if and when it is approved. The Group has recognised NOK 0.0 million in Q3 2021 (Q3 2020: NOK 3.6 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 2020 recognised NOK 2.9 classified as reduction of payroll and related expenses for the year 2020.

BerGenBio

Note 6 Other operating expenses

	Q3 2021	Q3 2020	First nine months 2021	First nine months 2020
Program expenses, clinical trials and research	29,413	45,095	148,196	115,102
Office rent and expenses	623	576	1,618	1,705
Consultants R&D projects	2,507	5,314	10,330	15,379
Patent and licence expenses	1,496	806	5,570	4,259
Other operating expenses	11,516	5,772	23,006	17,606
Government grants	-578	-3,024	-1,730	-8,633
Total	**44,977**	**54,539**	**186,990**	**145,419**

Note 7 Earnings per share

	2021	First nine months 2020
Loss for the period (NOK 1,000)	-240,598	-183,161
Average number of outstanding shares during the year	87,801,061	73,039,354
Earnings (loss) per share - basic and diluted (NOK)	**-2,74**	**-2,51**

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

	30 Sep 2021	30 Sep 2020
Government grants	2,959	13,978
Refundable VAT	0	491
Prepaid expenses	1,067	999
Other receivables	60	1,501
Total	**4,086**	**16,970**

Note 9 Share capital and shareholder information

As of 30 September	Number of shares	Nominal value (NOK)	Book value (NOK)
Ordinary shares 2021	88 247 755	0.10	8 824 775,50
Ordinary shares 2020	87 259 983	0.10	8 725 998,30

Changes in the outstanding number of shares	First nine months 2021	First nine months 2020
Ordinary shares as of 1 January	87 259 983	61 076 590
Issue of ordinary shares	987 772	26 183 393
Ordinary shares as of 30 September	**88 247 755**	**87 259 983**

Ownership structure 30 09 2021:

Shareholder		Number of shares	% share of total shares
METEVA AS		23 798 564	27,0 %
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 %
MARIT MOHN		850 000	1,0 %
MARSTIA INVEST AS		850 000	1,0 %
NORDNET LIVSFORSIKRING AS		590 097	0,7 %
LOUISE MOHN		509 676	0,6 %
J.P. Morgan Bank Luxembourg S.A.	NOM	430 541	0,5 %
Nordnet Bank AB	NOM	417 591	0,5 %
RO INVEST AS		350 000	0,4 %
VERDIPAPIRFONDET DNB NORGE INDEKS		305 425	0,3 %
Top 20 shareholders		**52 182 583**	**59,1 %**
Total other shareholders		36 065 172	40,9 %
Total number of shares		88 247 755	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 September 2021 there has been issued 563,673 new shares under this proxy at a nominal value of NOK 56,367.30. 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 the management group

	Position	Employed since	30 Sep 2021	30 Sep 2020
Endre Kjærland	Associate director Contracts and IP	July 2011	3,262	3,262
Total shares held by management			**3,262**	**3,262**

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

	Position	Served since	30 Sep 2021	30 Sep 2020
Sveinung Hole 1)	Chairman	September 2010	107,394	107,394
Stener Kvinnsland	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.

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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