



INTERIM REPORT FIRST QUARTER 2022



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Martin Olin

Chief Executive Officer at BerGenBio

CEO Statement

"I am pleased to provide an update to shareholders on our main activities and achievements during the 1st quarter of 2022.

Earlier this month, we provided an update on the Company's strategy. BerGenBio's mission remains unchanged, and we believe that the announced focus provides an optimal path to unlock the potential of AXL inhibition as a transformative treatment modality for severe diseases.

By focusing the development of our lead asset bemcentinib on two key areas, STK11 mutated (STK11m) 1st line non-small cell lung cancer (NSCLC) and COVID-19, we believe we have defined the path to efficiently advance BerGenBio's clinical and commercial potential. Both indications represent significant unmet medical needs and our defined plans for each of these indications provides a strong foundation for bringing new drugs to market with the aim of achieving better outcomes for patients and the generation of significant value for our shareholders.

Lung cancer of which NSCLC accounts for approx. 85% is the biggest cancer killer in both women and men. Each year more than 200.000 people are diagnosed and more than 150.000 die from lung cancer. Although, treatment with immune checkpoint inhibitors (ICIs) has transformed the outcome for many patients a large portion of NSCLC patients do not benefit from treatment with ICIs due to resistance or molecular drivers.



A mutation in the STK11/LBK1 gene represents such a driver mutation and is present in up to 20% of NSCLC patients – showing poor response to standard of care therapy with ICI. We believe bemcentinib potentially offers a transformative treatment modality for this significant unmet medical need. Bemcentinib has been shown to restore the activity of ICIs in preclinical studies and we have early clinical data in STK11m patients indicating response to bemcentinib in combination with the immune checkpoint inhibitor pembrolizumab.

Martin Olin

Chief Executive Officer at BerGenBio

CEO Statement

We are in an advantageous strategic position. Bemcentinib is the only selective AXL inhibitor in development for STK11m patients and has been granted Fast Track status by the FDA. With STK11 recognized as a predictor of poor outcome in NSCLC patients, with no specific therapeutic approaches available today, we believe there is a potential for an accelerated approval pathway. Additionally, we are continuing our collaboration with UT Southwestern Medical Center (Texas) to further enhance the understanding of bemcentinib role and mode of action relevant to the STK11 mutation. The exclusive license to inventions relevant for bemcentinib in STK11 mutations provides us with a strong position in pursuing this significant opportunity.

We are currently preparing to initiate a Phase Ib/2a study in STK11m NSCLC patients in the second half of 2022.

COVID-19 is a novel variant of SARS-COV-2 leading to severe implications for some patients being infected. Despite the success of vaccine programs and recent approvals of new therapies more than three million deaths have been reported due to COVID-19 in the last twelve months and we believe that a medical need for effective treatments for hospitalized patients remains.

We are encouraged by the strong efficacy signal of bemcentinib recently reported from the ACCORD2 study of hospitalized COVID-19 patients. We believe that bemcentinib has potential as a treatment with broad variant coverage, with a mode of action likely to be unaffected by future viral mutations.

Bemcentinib had been accepted into the EUSolidAct platform where it will be assessed in up to 500 hospitalized COVID-19 patients. If the positive results from the ACCORD2 trial are replicated in the larger EU-SolidAct study, the Company believes that this could warrant Emergency Use Authorizations, based on precedents.

We have recently strengthened the senior leadership team with the appointment of Cristina Oliva as our new Chief Medical Officer. Cristina has extensive leadership experience leading oncology drug development programs across big pharma, biotech and CRO environments.

Tilvestamab and other potential indications for bemcentinib such as 2nd line NSCLC, 2nd line AML and MDS, will in accordance with the priorities described be de-prioritized for the time being.

With a focused strategy and rightsized organization, I believe we are well positioned to unlock significant potential value related to the two indications selected and define the path to market.”

Martin Olin
CEO



HIGHLIGHTS

Operational Highlights Q1 2022 (including post-period end)

- Post-period end, business strategy update announced, focusing on two key indications; 1st line STK11m non-small cell lung cancer (NSCLC) and COVID-19.
- Primary endpoint met in hospitalized COVID-19 patients in complete data analysis of ACCORD2 (BGBIL019), a randomized phase II study of bemcentinib in combination with standard of care (SoC) therapy.
- Presented clinical trial data from Phase IIa bemcentinib COVID-19 clinical trial (BCBC020) at 32nd European Congress of Clinical Microbiology and Infectious Diseases (ECCMID).
- Cristina Oliva, MD appointed as Chief Medical Officer, bringing over 20 years of senior clinical development experience across large pharmaceutical, biotechnology and Clinical Research Organizations.
- Publication of a peer-reviewed article entitled “AXL targeting restores PD-1 blockade sensitivity of STK11/LKB1 mutant NSCLC through expansion of TCF1+ CD8+ T cells” in the journal Cell Reports Medicine.
- Announced inclusion of bemcentinib, in the EUSolidAct platform study of hospitalized COVID-19 patients designed to enroll up to 500 patients across European centers participating in the EUSolidAct platform.

Financial Highlights – first quarter 2022

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

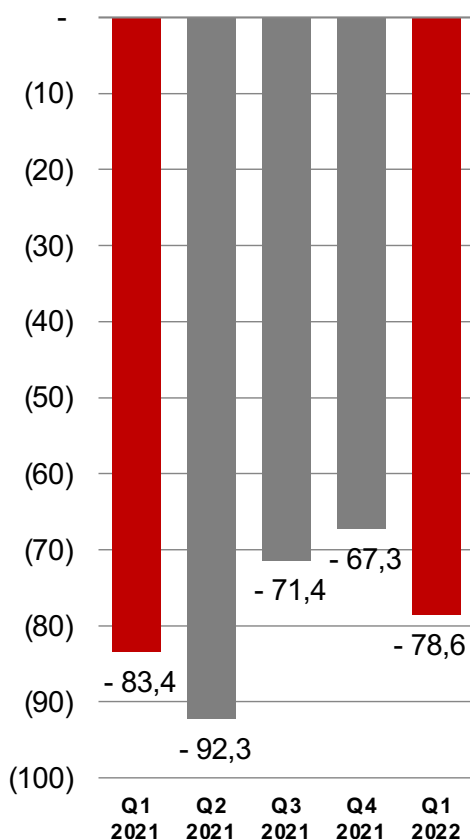
- Revenue amounted to NOK 0.0 million (NOK 0.0 million) for the first quarter 2022
- Total operating expenses for the first quarter were NOK 78.6 million (NOK 83.4 million)
- The operating loss for the first quarter came to NOK 78.6 million (NOK 83.4 million)
- Cash and cash equivalents amounted to NOK 367.8 million at the end of the first quarter 2022 (NOK 436.6 million by end of December 2021)

Q1 2022 FINANCIAL HIGHLIGHTS

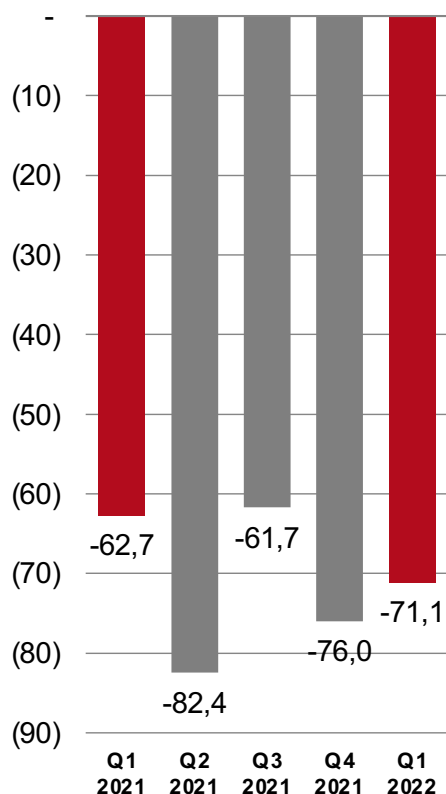
Key financial figures

(NOK million)	Q1 2022	Q1 2021	FY 2021
Operating revenues	0,0	0,0	0,8
Operating expenses	78,6	83,4	315,2
Operating profit (-loss)	-78,6	-83,4	-314,5
Profit (-loss) after tax	-81,1	-81,2	-309,4
Basic and diluted earnings (loss) per share (NOK)	-0.92	-0.93	-3.52
Net cash flow in the period	-71,1	-62,7	-284,2
Cash position end of period	367,8	659,4	436,6

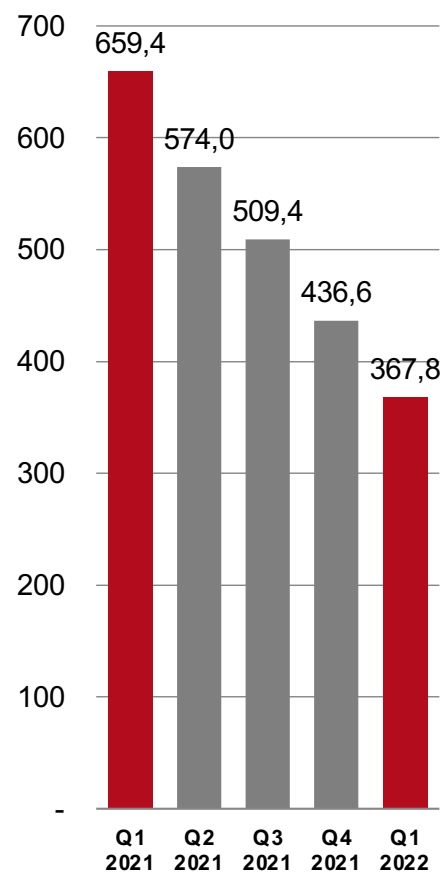
Operating loss



Cash flow



Cash position





In May 2022 BerGenBio announced an updated strategy based on two key indications; 1st line non-small cell lung cancer (NSCLC) and COVID-19, which the Company believes offer the optimal path towards translating BerGenBio's strong scientific foundation into significant value generation.

Oncology

Non-Small Cell Lung Cancer (NSCLC)

Lung cancer of which NSCLC accounts for 85% is the largest cancer indication with more than 200.000 patients diagnosed each year and more than 150.000 deaths annually. While ICIs have transformed the treatment of NSCLC (and other cancers) a large subset of NSCLC patients do not benefit from the treatment with ICIs due to resistance and/or molecular drivers. STK11 mutations represent such a molecular driver / resistance situation and is present in up to 20% of NSCLC cases. STK11 mutations have been reported by multiple sources to be a poor prognostic factor, showing little or no benefit of ICI treatment.

Preclinical and clinical data has identified the patients with STK11 mutation as a population who may benefit from treatment with bemcentinib. In March a peer-reviewed article in the journal Cell Reports Medicine identified AXL as a critical targetable driver of immune suppression in STK11/LKB1 mutated NSCLC. The latest data was announced at SITC in November. In pre-clinical NSCLC mouse models harboring 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 secured an exclusive license to intellectual property covering the treatment of STK11 patients with bemcentinib and plan to initiate a safety and efficacy combination trial assessing bemcentinib in combination with anti PD-L1 immunotherapy and chemotherapy in first line NSCLC.



Respiratory Disease

COVID-19

Although several treatment modalities have been rapidly developed and adopted during the pandemic, there is still a large number of hospitalized patients that remain in need of improved therapeutic options for COVID-19 and we believe that there is still a need for better in-hospital oral treatments to improve patient outcomes.

We believe that the mechanism of action of bemcentinib limits progression of acute lung injury caused by respiratory infections such as COVID-19 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.

In January 2022 BerGenBio and Oslo University Hospital announced that bemcentinib will be studied as part of the EU funded EUSolidAct trial in hospitalized covid-19 patients.

The EU-SolidAct trial is a multi-center, randomized, adaptive Phase II and III platform trial, the master protocol of which has been developed to evaluate potential treatments in hospitalized patients with COVID-19. Under the trial, bemcentinib will be studied in up to 500 hospitalized COVID-19 patients. In support of the trial, BerGenBio will provide bemcentinib drug material and incremental funding of costs related to the bemcentinib sub-protocol. The platform will provide 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.

In April, BerGenBio presented clinical trial data from its Phase IIa bemcentinib COVID-19 clinical trial (BCBC020) at the 32nd European Congress of Clinical Microbiology and Infectious Diseases (ECCMID). Data showed that bemcentinib treatment (up to 14 days) provides early and sustained protection, limiting clinical deterioration in patients. Bemcentinib treated patients were discharged earlier from the hospital, required less supplementary oxygen, and demonstrated a significant reduction in the need for intubation or ventilation.

In April 2022, BerGenBio reported that the primary efficacy endpoint was met in a complete data analysis of a randomized phase II study of bemcentinib in combination with standard of care (SoC) therapy, ACCORD2 (BGBIL019), in hospitalized COVID-19 patients. 90% of patients treated with bemcentinib + SoC experienced a clinical response by day 29 as defined by either a two-point improvement in World Health Organization (WHO) category from baseline score, or discharge from hospital, whichever arose sooner. This compared to 69% with a clinical response to SoC treatment alone, showing statistical significance. 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.

If the positive results from the ACCORD2 trial are replicated in the larger EU-SolidAct study, the Company believes that this could warrant Emergency Use Authorizations, based on precedents.

STRATEGIC PRIORITIES & OUTLOOK



Strategic Priorities

BerGenBio's aim is to continue its assessment of the potential of the clinical stage AXL inhibitor bemcentinib as a transformative treatment for severe diseases. Our strategic priorities are to:

- Pursue the 1st line NSCLC opportunity for patients harboring STK11 mutations
- Pursue the potential application of bemcentinib as a treatment for COVID-19 and respiratory disease, initially via the EU-SolidAct sponsored platform, through which a confirmatory randomized placebo-controlled trial will be conducted to position bemcentinib as a treatment modality in hospitalized COVID-19 patients

In retaining global rights to bemcentinib, BerGenBio maintains complete strategic flexibility for its future development and commercialization. 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 STK11m and respiratory diseases (initially COVID-19). Each of the therapeutic areas represents attractive commercial opportunities.

The Company remains funded to deliver on its milestones 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.

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 2022 and the Group considers its credit risk as low.

Funding and 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.

Funding of ongoing operations is and will be for some time depending on external sources, mainly equity contributions. Significant changes to financial market conditions, may affect the climate for investor investments.

Management considers the Group's liquidity situation to be satisfactory.

Non-financial risks

Technology risk

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

Competitive technology

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

Patent and IP risks

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

Regulatory & Commercial risks

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

COVID-19

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

FINANCIAL REVIEW



Financial Results

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

Revenue for the first quarter 2022 amounted to NOK 0.0 million (NOK 0.0 million).

Total operating expenses for the first quarter 2022 amounted to NOK 78.5 million (NOK 83.4 million).

Employee expenses in the first quarter were NOK 16.5 million (NOK 16.4 million). Payroll expenses slightly increased and share option cost decreased compared to Q1 2021.

Other operating expenses amounted to NOK 61.8 million (NOK 66.6 million) for the first quarter. The decrease is mainly driven by level of clinical trials and drug development activities.

The operating loss for the quarter came to NOK 78.6 million (NOK 83.4 million).

Net financial items amounted to a loss of NOK 2.5 million (gain of NOK 2.2 million) for the first quarter. Net financial items is driven by change in currency rates on bank deposits in other currencies than NOK.

Losses after tax for the first quarter were NOK 81.1 million (NOK 81.2 million).

Financial Position

Total assets as of 31 March 2022 decreased to NOK 380.6 million (NOK 450.2 million at year end 2021) mainly due to the operational loss in the period.

Total liabilities were NOK 72.6 million as of 31 March 2022 (NOK 65.8 million at year end 2021).

Total equity as of 31 March 2022 was NOK 308.0 million (NOK 384.4 million at year end 2021), corresponding to an equity ratio of 80.9 % (85.4% at year end 2021).

Cash Flow

Net cash flow from operating activities was negative by NOK 74.2 million in the quarter (negative by 70.8 million), mainly driven by the level of activity in the clinical trials and other operating activities.

Net cash flow from investing during the first quarter was NOK 0.1 million (NOK 0.0 million).

Net cash flow from financing activities in first quarter 2022 was positive by NOK 3.0 million (NOK 8.1 million).

Cash and cash equivalents decreased to NOK 367.82 million as of 31 March 2022 (NOK 436.6 million at year end 2021).



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

Bergen 23 May 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	Q1 2022	Q1 2021	FY 2021
Revenue		0	0	774
<u>Expenses</u>				
Payroll and other related employee cost	3, 10	15,077	14,491	69,929
Employee share option cost	3	1,396	1,947	4,116
Depreciation	2	317	335	1,312
Other operating expenses	6	61,776	66,645	239,880
Total operating expenses		78,566	83,419	315,237
Operating profit (-loss)		-78,566	-83,419	-314,464
Finance income		403	4 369	15,993
Finance expense		2,904	2,194	10,894
Financial items, net		-2,501	2,175	5,100
Profit (-loss) before tax		-81,067	-81,244	-309,364
Income tax expense		0	0	0
Profit (-loss) after tax		-81,067	-81,244	-309,364
Other comprehensive income				
<i>Items that may be reclassified to profit and loss in subsequent periods</i>				
Translation effects		41	0	-112
Total comprehensive income (-loss) for the period		-81,026	-81,244	-309,476
Earnings per share:				
- Basic and diluted per share	7	-0.92	-0.93	-3.52

Condensed consolidated statement of financial position

(NOK 1000) Unaudited	Note	31 MAR 2022	31 MAR 2021	31 DEC 2021
ASSETS				
Non-current assets				
Property, plant and equipment		875	2 168	1,191
Total non-current assets		875	2 168	1,191
Other current assets	5, 8	11,896	11,657	12,398
Cash and cash equivalents		367,829	659,388	436,646
Total current assets		379,725	671,045	449,045
TOTAL ASSETS		380,600	673,213	450,236
EQUITY AND LIABILITIES				
Equity				
Paid in capital				
Share capital	9	8,866	8,782	8,846
Share premium	9	257,360	555,251	335,195
Other paid in capital	4, 9	41,814	35,243	40,386
Total paid in capital		308,041	599,276	384,426
Total equity		308,041	599,276	384,426
Non-current liabilities				
Long term debt		796	1,309	942
Total non-current liabilities		796	1,309	942
Current liabilities				
Accounts payable		15,028	32,701	26,726
Other current liabilities		55,848	35,163	37,172
Provisions		887	4,764	969
Total current liabilities		71,763	72,628	64,868
Total liabilities		72,560	73,937	65,810
TOTAL EQUITY AND LIABILITIES		380,600	673,213	450,236



Condensed consolidated statement of changes in equity

(NOK 1000) Unaudited	Note	Share capital	Share premium	Other paid in capital	Total equity
Balance as of 1 January 2022		8,846	335,195	40,386	384,426
Loss for the period			-81,067		-81,067
Other comprehensive income (loss) for the period, net of income tax			41		41
Total comprehensive income for the period		0	-81,026	0	-81,026
Recognition of share-based payments	3, 4			1,429	1,429
Issue of ordinary shares	9	21	3,198		3,218
Share issue costs	9		-7		-7
Transactions with owners		21	3,191	1,429	4,640
Balance as of 31 March 2022		8,866	257,360	41,814	308,041

(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			-81,244		-81,244
Other comprehensive income (loss) for the period, net of income tax			0		0
Total comprehensive income for the period		0	-81,244	0	-81,244
Recognition of share-based payments	3, 4			1,971	1,971
Issue of ordinary shares	9	56	8,279		8,336
Share issue costs	9		-15		-15
Transactions with owners		56	8,264	1,971	10,291
Balance as of 31 March 2021		8,782	555,251	35,243	599,276

Condensed consolidated statement of cash flow

(NOK 1000) Unaudited	Note	Q1 2022	Q1 2021	FY 2021
Cash flow from operating activities				
Loss before tax		-81,026	-81,244	-309,364
Adjustments for:				
Depreciation of property, plant and equipment		317	335	1,312
Share-based payment expense	3, 4	1,429	1,971	7,113
Movement in provisions and pensions		-82	-1,244	-5,039
Currency gains not related to operating activities		-2,320	-436	667
Net interest received		-85	0	-3,130
Working capital adjustments:				
Decrease in trade and other receivables and prepayments		502	2,571	1,830
Increase in trade and other payables		7,065	7,255	3,270
Net cash flow from operating activities		-74 200	-70,793	-303,340
Cash flows from investing activities				
Net interest received		85	0	3,130
Purchase of property, plant and equipment				
Net cash flow from investing activities		85	0	3,130
Cash flows from financing activities				
Proceeds from issue of share capital	9	3,218	8,336	16,629
Share issue costs	9	-7	-15	-70
Repayment of lease liabilities		-234	-217	-565
Net cash flow from financing activities		2 978	8,104	15,995
Effects of exchange rate changes on cash and cash equivalents		2,320	436	-779
Net increase/(decrease) in cash and cash equivalents		-71,137	-62,689	-284,216
Cash and cash equivalents at beginning of period		436,646	721,641	721,641
Cash and cash equivalents at end of period		367,829	659,388	436,646

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 March 2022 and were approved for issue by the Board of Directors on 23 May 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 2021.

The new and amended standards and interpretations from IFRS that were adopted by the EU with effect from 2021 did not have any significant impact on the reporting for Q1 2022.

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

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

Basis for consolidation

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

Estimates and assumptions

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

Capital markets are used as a source of liquidity when this is appropriate and when conditions in these markets are acceptable. The company secured in total NOK 740 million in new equity funding during 2020. Cash position at end of Q1 2022 was NOK 368 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

	Q1 2022	Q1 2021
Salaries	12,296	12,116
Social security tax	1,750	1,622
Pension expense	1,039	909
Short term incentive	0	0
Other remuneration and employee expenses	334	225
Government grants 1)	-342	-380
Total payroll and other employee related cost	15,077	14,491
Share option expense employees	1,429	1,971
Change in accrued social security tax on share options	-33	-23
Total employee share option cost	1,396	1,947
Total employee benefit cost	16,473	16,439
Average number of full time equivalent employees	43	44
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 ensures focus and aligns the Group's long term performance with shareholder values and interest. Most of the employees in the Group take part in the option program. The program also serves to attract and retain senior management.

The exercise price for options granted is set at the market price of the shares at the time of grant of the options. In general, for options granted after 2012 the options expire eight years after the date of grant.

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

Total options	Q1 2022		Q1 2021	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Balance as of 1 January	3,560,897	22,96	4,209,233	18,45
Granted during the period	0	0,00	0	0,00
Exercised during the period	-205,277	15,68	-561,599	14,84
Forfeited and cancelled	-605,651	29,39	-71,124	22,91
Balance as of 31 March	2,749,969	22,09	3,576,510	18,93

0 options were granted in the three months period ended 31 March 2022 and 0 options were granted in the three months period ended 31 March 2021.

Vested options	Q1 2022	Q1 2021
	Options vested as of 1 January	1,541,168
Exercised and forfeited in the period	-641,088	-589,522
Vested in the period	0	0
Options vested as of 31 March	900,080	1,297,679
Total outstanding number of options	2,749,969	3,576,510

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 three months period ending 31 March the value of the share options expensed through the profit or loss amounts to NOK 1,4 million (for the same period in 2021: NOK 2.0 million). In addition, a change in provision for social security contributions on share options of NOK -0.03 million (for the same period in 2021: NOK - 0.02 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 Mar 2022	Weighted Average Strike Price 2022	Number of options outstanding 31 Mar 2021	Weighted Average Strike Price 2021
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
		598,619		480,157	



Government grants

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

	Q1 2022	Q1 2021
Employee benefit expenses	342	380
Other operating expenses	1,414	575
Total	1,756	955

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

	31 Mar 2022	31 Mar 2021
Grants from Research Council, BIA	154	566
Grants from Research Council, PhD	415	389
Grants from SkatteFunn	5,937	4,750
Grants R&D UK	4,089	4,243
Total grants receivable	10,595	9,948

BIA grants from the Research Council of Norway:

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

The BIA grant ("AXL as a therapeutic target in fibrosis; biology and biomarkers") has been awarded from 2019 and amounts up to NOK 10.7 million. The Group has recognised NOK 0.2 million in Q1 2022 (Q1 2021: NOK 0.6 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 0.4 million in Q1 2022 (Q1 2021 : NOK 0.4 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 2021 until the end of 2023. The Group has recognised NOK 1.2 million in Q1 2022 (Q1 2021: NOK 0.0 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 retrospectively by application. The Group has in 2022 recognized NOK 4.1 (2021: NOK 4.2 mill) classified as reduction of payroll and related expenses for the year 2021.

Note 6 Other operating expenses

	Q1 2022	Q1 2021
Program expenses, clinical trials and research	51,779	53,666
Office rent and expenses	729	386
Consultants R&D projects	2,457	4,149
Patent and licence expenses	829	2,044
Other operating expenses	7,396	6,974
Government grants	-1,414	-575
Total	61,776	66,645

Note 7 Earnings per share

	Q1 2022	Q1 2021
Loss for the period (NOK 1,000)	-81,026	-81,244
Average number of outstanding shares during the year	88,563,039	87,434,703
Earnings (loss) per share - basic and diluted (NOK)	-0,92	-0,93

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 Mar 2022	31 Mar 2021
Government grants	10,595	9,948
Refundable VAT	320	560
Prepaid expenses	951	1,115
Other receivables	30	34
Total	11,896	11,657

Note 9 Share capital and shareholder information

As of 31 March	Number of shares	Nominal value (NOK)	Book value (NOK)
Ordinary shares 2022	88,660,532	0.10	8,866,053.20
Ordinary shares 2021	87,821,582	0.10	8,782,158.20

Changes in the outstanding number of shares	Q1 2022	Q1 2021
Ordinary shares as of 1 January	88,455,255	87,259,983
Issue of ordinary shares	205,277	561,599
Ordinary shares as of 31 March	88,660,532	87,821,582



Ownership structure 31 03 2022:

Shareholder	Number of shares	% share of total shares	
METEVA AS	24,039,650	27,1 %	
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 %	
J.P. MORGAN SE	NOMINEE I	1,538,631	1,7 %
VERDIPAPIRFONDET NORDEA AVKASTNING	1,510,174	1,7 %	
VERDIPAPIRFONDET KLP AKSJENORGE	1,440,000	1,6 %	
SARSIA DEVELOPMENT AS	1,175,000	1,3 %	
NORDNET LIVSFORSIKRING AS	1,140,085	1,3 %	
VERDIPAPIRFONDET NORDEA KAPITAL	1,078,020	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 %	
MOHN, LOUISE	509,676	0,6 %	
J.P. MORGAN SE	NOMINEE II	430,541	0,5 %
RO INVEST AS	350,000	0,4 %	
ZAIM, KEVIN	341,000	0,4 %	
BIRK VENTURE AS	330,000	0,4 %	
Top 20 shareholders	52,945,324	59,7 %	
Total other shareholders	35,715,208	40,3 %	
Total number of shares	88,660,532	100,0 %	

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

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

Shares in the Group held by the management group

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

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

	Position	Served since	31 Mar 2022	31 Mar 2021
Sveinung Hole 1)	Board member	September 2010	107,394	107,394
Anders Tullgren	Chair	January 2022	25,000	0
Total shares held by members of the Board of Directors			132,394	107,394

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

Note 10 Pension

BerGenBio ASA is required to have an occupational pension scheme in accordance with the Norwegian law on required occupational pension ("lov om obligatorisk tjenestepensjon").

The Company has a pension scheme which complies with the Act on Mandatory company pensions.

Note 11 Subsequent events

In May 2022, the Company announced a strategy focusing on NSCLC STK11m and COVID-19 and a rightsizing of the organisation. This decision has not affected any financial items in this Q1 2022 report.



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

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



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