BerGenBio

INTERIM REPORT SECOND QUARTER AND HALF YEAR 2019

BerGenBio

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Richard Godfrey
Chief Executive Officer of BerGenBio

"We are pleased to report a period of continued encouraging clinical development and validation of our lead candidate bemcentinib in our AML and NSCLC programmes. Our focus is now on entering late stage clinical programs in these indications, as we continue to leverage our significant scientific and R&D leadership to develop this potentially transformative therapy. We are committed to progressing bemcentinib through to regulatory approval and, in turn, addressing the significant unmet need among AML and NSCLC patients in order to improve outcomes for these patients and create value for stakeholders."

Q2 2019 (including post-period end) HIGHLIGHTS

Preliminary Phase II clinical data from AML (BGBC003) presented at EHA 24 and ASCO 2019

Promising efficacy for bemcentinib in combo with low-intensity chemo in elderly AML patients unfit for intensive therapy

New clinical data from BGB324 in NSCLC presented at ASCO 2019

Combo of bemcentinib and pembrolizumab (KEYTRUDA®) in advanced lung cancer patients post chemotherapy continues to show promising clinical activity, particularly in patients with AXL positive tumours including those with low or no PD-L1 expression. The combination is overall well-tolerated

Recruitment completed for second stage Phase II bemcentinib and KEYTRUDA® combo trial in patients with advanced NSCLC (BGB008)

Private placement completed, raising gross proceeds of NOK 74.2 million

Cash and Cash equivalents at end of Q2 2019 NOK 324.4 million

Operating loss of NOK 52.0 million in Q2 2019 (NOK 50.7 in Q2 2018) and NOK 97.8 million in H1 2019 (NOK 105.5 H2 2018)

CLINICAL & BUSINESS HIGHLIGHTS

BerGenBio

NSCLC
Non-Small Cell Lung Cancer

Preliminary Phase II clinical data from AML trial (BGBC003) presented at EHA 24 and ASCO 2019

- Phase II trial evaluating bemcentinib in combination with low-intensity chemotherapy in elderly AML patients unfit for intensive therapy shows promising efficacy
- 6 out of 13 patients receiving LDAC combination achieved an Overall Response Rate (ORR) of 46%, with encouraging duration of response - this data is still maturing.
- ORR significantly higher than previously observed/historical benchmarks with single-agent low dose cytarabine
- Encouraging safety profile continues to be seen in LDAC combination
- Initiated preparation of expansion cohort to confirm the clinical signal from bemcentinib in combination with LDAC in elderly relapse AML patients.

AML
Acute Myeloid Leukaemia

New clinical data from BGB324 in NSCLC presented at ASCO 2019

- Completed recruitment for second stage of Phase II trial evaluating bemcentinib and KEYTRUDA® in previously treated NSCLC patients post chemotherapy (NCT03184571 (BGB008, cohort A)
- First stage previously met efficacy endpoint, and reported encouraging median overall survival of 12.2 months
- Preliminary Overall Response Rate of 40% continues to be seen in patients with AXL positive tumours including those with weak or no PD-L1 expression
- Encouraging safety profile continues to be seen in combination

Initiation of additional cohort in combination with KEYTRUDA® in previously treated NSCLC patients post immunotherapy
(NCT03184571, BGB008, cohort B)

Completed private placement, raising gross proceeds of NOK 74 million

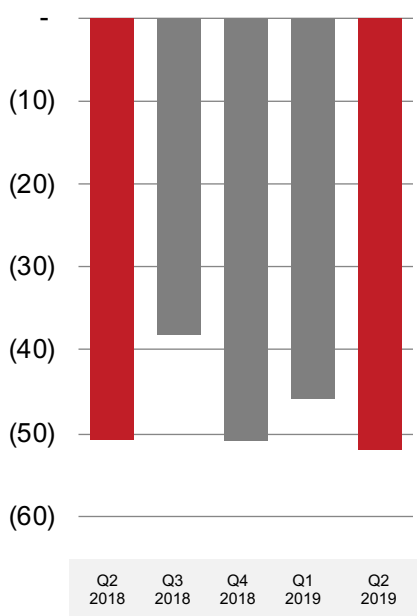
- Net proceeds from the Private Placement to be used to advance the Company's clinical programs in AML and lung cancer, as well as for general corporate purposes
- Arctic Securities AS and Carnegie AS acted as Joint Bookrunners and H.C. Wainwright & Co., LLC acted as Financial Advisors
- The Private Placement, completed via an accelerated book build, attracted strong interest from existing shareholders and new institutional investors

Q2 2019 FINANCIAL HIGHLIGHTS

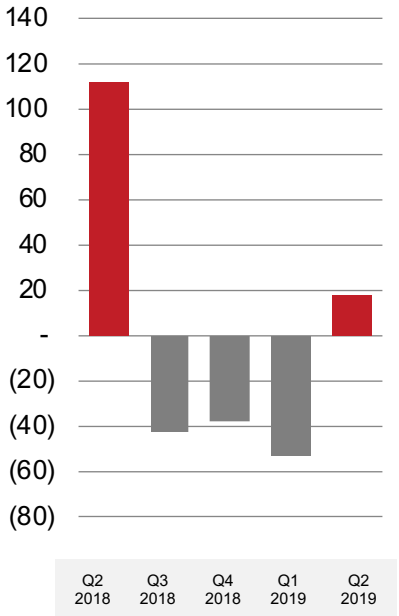
Key financial figures

(NOK million)	Q2 2019	Q2 2018	YTD 2019	YTD 2018	FY 2018
Operating revenues	0	0	8,7	0	2,3
Operating expenses	52,0	50,7	106,5	105,5	196,9
Operating profit (-loss)	-52,0	-50,7	-97,8	-105,5	-194,5
Profit (-loss) after tax	-52,8	-49,2	-97,1	-103,0	-191,7
Basic and diluted earnings (loss) per share (NOK)	-0,95	-0,92	-1,76	-1,99	-3,60
Net cash flow in the period	17,7	112,0	-36,0	70,9	-9,9
Cash position end of period	324,4	441,3	324,4	441,3	360,4

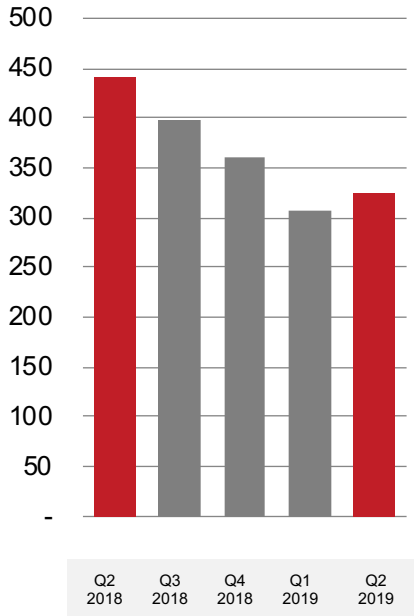
Operating loss



Cash flow



Cash position



OVERVIEW & OUTLOOK

Q2 Business Overview

BerGenBio continued to progress the phase II clinical development of lead candidate bemcentinib, a potentially first-in-class, highly selective, potent, oral, small-molecule AXL inhibitor. Bemcentinib has demonstrated clinical proof-of concept as a monotherapy in acute myeloid leukaemia (AML) and in combination with Keytruda® in non-small cell lung cancer (NCSLC).

NSCLC
Non-Small Cell Lung Cancer

- At the start of the second quarter the Company announced the initiation of an expansion cohort in relapse NSCLC patients in a combination trial with KEYTRUDA® in patients with advanced NSCLC (BGB008). The additional cohort (Cohort B) of the BGBC008 trial, being run in collaboration with Merck (known as MSD outside the US and Canada), will extend eligibility to include patients with previously treated advanced NSCLC whose disease has progressed on immunotherapy.
- Data from Cohort A of the BGBC008 study was presented at the American Society of Clinical Oncology (ASCO) 2019. Data showed that promising clinical activity continues to be seen, particularly in patients with AXL positive tumours including those with low or no PD-L1 expression. A response rate of 40% was achieved in AXL positive patients, irrespective of the patient's PD-L1 score; and an overall response rate of 29% was achieved. The median Overall Survival (mOS) rate of 12.2 months was reported from cohort A, significantly surpassing historical second line mOS rates with PD-1 inhibitor monotherapy.
- These data, which suggest that bemcentinib has the potential to enhance patient responses and overall survival, when treated in combination with a PD-1 inhibitor, particularly in patients with no or limited expression of PD-L1, represent a very significant and encouraging development.

AML
Acute Myeloid Leukaemia

- In April, BerGenBio reported that bemcentinib had met the first efficacy endpoint in a Phase II trial evaluating bemcentinib in combination with low-intensity chemotherapy in AML patients unfit for intensive therapy. Clearing the efficacy threshold for bemcentinib in combination with LDAC is encouraging, particularly as responses have been observed in a less fit, elderly AML patient population who are considered to have unfavourable prognosis after the failure of first-line therapies, or those with high risk cytogenetics.
- Data from this 13-patient study showed an overall response rate (ORR) of 46%, including 31% CR/Cri among elderly AML patients (>70 years) and was presented at ASCO 2019 and the 2019 annual congress of the European Hematology Association (EHA).

Strategic Priorities

- Continuing to advance the bemcentinib clinical development programme towards late stage clinical trials in AML and NSCLC
- Developing companion diagnostics to enrich future clinical trials and improve chances of regulatory success
- Advancing the clinical development of our anti Axl monoclonal antibody (BGB149)
- Securing additional pipeline opportunities for the company's AXL inhibitors in oncology and non-oncology indications

Outlook

BerGenBio has a clear strategy to progress its lead asset, bemcentinib, in AML and NSCLC and is focused on meeting its operational, regulatory and clinical goals.

The Company continues to deliver promising data from its clinical development programme with bemcentinib. The Board's view is that these encouraging results in AML and NSCLC have established sufficient clinical proof-of concept to warrant initiation of late stage clinical development in these indications.

BerGenBio maintains complete strategic flexibility for bemcentinib's future development and commercialisation, aimed at creating maximum value for shareholders, including potential partnering and go-to-market strategies in selected indications and territories.

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 depending 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 achieving 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 has chosen not to hedge its operational performance as the Group's cash flow is denominated in several currencies that change depending on where clinical trials are run. In 2019 the risk management of foreign exchange have been changed by increasing the holding of 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 2019 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 NOK 74 million gross in June 2019.

Non-financial risks

Technology risk

The Group's lead product candidate, bemcentinib (BGB324), is currently in Phase II clinical trials. This is regarded as an early stage of development 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.

Market 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 REVIEW

Financial Results

(Figures in brackets = same period 2018 unless stated otherwise)

Revenue for the second quarter 2019 and the six months ended 30 June 2019 respectively amounted to NOK 0 million (NOK 0 million) and NOK 8.7 million (NOK 0 million). The revenue was received from ADCT as a clinical milestone payment.

Total operating expenses for the second quarter and the six months ended 30 June 2019 respectively amounted to NOK 52.0 million (NOK 50.7 million) and NOK 106.5 million (NOK 105.5 million). Employee expenses in the second quarter were NOK 8.7 million (NOK 6.3 million) and NOK 16.2 million (NOK 22.0 million) for the six months ended 30 June. The decrease in the six months ended 30 June was mainly due to reduction in provisions for social security tax on employee options.

Other operating expenses amounted to NOK 43.0 million (NOK 44.4 million) for the quarter and NOK 89.9 million (NOK 83.4 million) for the six months ended 30 June. Operating expenses are driven by the expansion of ongoing clinical trials and preparations for new clinical trials. The Company incurs costs when clinical trials meet specific milestones of progress, and as recruitment of patients to the clinical trials has progressed costs have increased proportionately and in-line with management's forecasts.

The operating loss for the quarter came to NOK 52.0 million (NOK 50.7 million) and NOK 97.8 million (NOK 105.5 million) for the six months ended 30 June, reflecting the level of activity related to the clinical trials BerGenBio is conducting.

Net financial loss amounted to NOK 0.8 million (profit of NOK 1.5 million) for the quarter and a profit of NOK 0.7 million (NOK 2.5 million) for the six months ended 30 June. The loss in Q2 2019 was primarily due a change in the foreign exchange strategy.

Losses after tax for the quarter were NOK 52.8 million (NOK 49.2 million) and for the six months ended 30 June NOK 97.1 million (NOK 103.0 million).

Financial Position

Total assets at 30 June 2019 increased to NOK 349.0 million (NOK 336.1 million at 31 March 2019), mainly due to the capital raise from the private placement completed in June 2019 raising gross NOK 74.2 million and reflecting the operational loss in the period.

Total liabilities were NOK 33.5 million at 30 June 2019 (NOK 40.9 million at 31 March 2019).

Total equity as of 30 June 2019 was NOK 315.3 million (NOK 295.2 million at 31 March 2019), corresponding to an equity ratio of 90.3% (87.8%).

Cash Flow

Net cash flow from operating activities was negative by NOK 109.1 million for the six months ended 30 June (NOK 106.0 million), mainly driven by the level of activity in the clinical trials.

Net cash flow for investing during the six months ended 30 June was NOK 0.0 million (NOK 0.0 million).

Net cash flow from financing activities was NOK 73.1 million (NOK 177.0 million) for the six months ended 30 June.

Cash and cash equivalents increased to NOK 324.4 million (NOK 306.7 million at 31 March 2019).

RESPONSIBILITY STATEMENT

Responsibility Statement

The board today consider and approved the condensed, consolidated financial statement for the six months ending 30 June 2019 for BerGenBio. The half year report has been prepared in accordance with IAS 34 Interim Financial Reporting as endorsed by the EU and additional Norwegian regulation.

We confirm, to the best of our knowledge that the financial statements for the period 1 January to 30 June 2018 have been prepared in accordance with current applicable accounting standards, and give a true and fair view of the assets, liabilities, financial position and profit or loss of the entity and the group taken as a whole.

We also confirm that the Board of Directors' Report includes a true and fair view of the development and performance of the business and the position of the entity and the group, together with a description of the principal risks and uncertainties facing the entity and the group.

Bergen, 18 August 2019
Board of Directors and CEO of BerGenBio ASA

Sveinung Hole, Chairman
Pamela A. Trail
Stener Kvinnsland
Grunde Eriksen
Debra Barker
Richard Godfrey, CEO

Condensed consolidated statement of profit and loss and other comprehensive income

(NOK 1000) Unaudited	Note	Q2 2019	Q2 2018	YTD 2019	YTD 2018	FY 2018
Revenue		0	0	8,682	0	2,335
Expenses						
Employee benefit expenses	3, 10	8,728	6,300	16,187	21,972	38,012
Depreciation	2	196	54	392	108	204
Other operating expenses	6	43,041	44,378	89,885	83,433	158,658
Total operating expenses		**51,965**	**50,732**	**106,465**	**105,513**	**196,874**
Operating profit		**-51,965**	**-50,732**	**-97,783**	**-105,513**	**-194,539**
Finance income		1,509	1,622	3,270	2,668	4,857
Finance expense		2,331	128	2,585	172	2,065
Financial items, net		**-822**	**1,495**	**685**	**2,496**	**2,792**
Profit before tax		**-52,787**	**-49,238**	**-97,098**	**-103,017**	**-191,747**
Income tax expense		0	0	0	0	0
Profit after tax		-52,787	-49,238	-97,098	-103,017	-191,747
Other comprehensive income						
Items which will not be reclassified over profit and loss						
Actuarial gains and losses on defined benefit pension plans		0	0	0	0	0
Total comprehensive income for the period		-52,787	-49,238	-97,098	-103,017	-191,747
Earnings per share:						
- Basic and diluted per share	7	-0.95	-0.92	-1.76	-1.99	-3.60

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Condensed consolidated statement of financial position

(NOK 1000) Unaudited	Note	30 JUN 2019	30 JUN 2018	31 DEC 2018
ASSETS				
Non-current assets				
Property, plant and equipment	2	1,367	518	581
Total non-current assets		**1,367**	**518**	**581**
Other current assets	5, 8	23,259	14,135	17,831
Cash and cash equivalents		324,379	441,263	360,413
Total current assets		**347,637**	**455,398**	**378,245**
TOTAL ASSETS		**349,004**	**455,917**	**378,826**
EQUITY AND LIABILITIES				
Equity				
Paid in capital				
Share capital	9	6,054	5,471	5,471
Share premium	9	285,489	398,521	309,791
Other paid in capital	4, 9	23,743	20,687	22,018
Total paid in capital		**315,286**	**424,679**	**337,280**
Total equity		**315,286**	**424,679**	**337,280**
Non-current liabilities				
Long term debt	2	248	0	0
Total non-current liabilities		248	0	0
Current liabilities				
Accounts payable		25,977	16,646	23,939
Other current liabilities		6,977	5,443	12,875
Provisions		516	9,150	4,732
Total current liabilities		**33,470**	**31,238**	**41,546**
Total liabilities		**33,718**	**31,238**	**41,546**
TOTAL EQUITY AND LIABILITIES		**349,004**	**455,917**	**378,826**

Condensed consolidated statement of changes in equity

(NOK 1000) Unaudited	Note	Share capital	Share premium	Other paid in capital	Total equity
Balance at 1 January 2019		**5,471**	**309,791**	**22,018**	**337,280**
Loss for the period			-97,098		-97,098
Other comprehensive income (loss) for the period, net of income tax			0		0
Total comprehensive income for the period		**0**	**-97,098**	**0**	**-97,098**
Recognition of share-based payments	3, 4			1,725	1,725
Issue of ordinary shares	9	583	77,672		78,255
Paid in, not registed capital raise	9				0
Share issue costs			-4,875		-4,875
Balance at 30 June 2019		**6,054**	**285,489**	**23,743**	**315,286**

(NOK 1000) Unaudited	Note	Share capital	Share premium	Other paid in capital	Total equity
Balance at 1 January 2018		**4,992**	**325,018**	**20,340**	**350,350**
Other comprehensive income (loss) for the period, net of income tax			0		0
Total comprehensive income for the period		0	**-103,017**	**0**	**-103,017**
Recognition of share-based payments	3, 4			347	347
Issue of ordinary shares	9	479	190,047		190,525
Paid in, not registed capital raise	9				0
Share issue costs			-13,527		-13,527
Balance at 30 June 2018		**5,471**	**398,521**	**20,687**	**424,678**

BerGenBio

Condensed consolidated statement of cash flow

(NOK 1000) Unaudited	Note	YTD 2019	YTD 2018
Cash flow from operating activities			
Loss before tax		-97,098	-103,017
Non-cash adjustments to reconcile loss before tax to net cash flows			
Depreciation of property, plant and equipment		392	108
Share-based payment expense	3, 4	1,725	347
Movement in provisions and pensions		-3,968	6,130
Working capital adjustments:			
Decrease in trade and other receivables and prepayments		-5,427	-705
Increase in trade and other payables		-4,746	-8,878
Net cash flow from operating activities		**-109,122**	**-106,015**
Cash flows from investing activities			
Purchase of property, plant and equipment		0	-70
Net cash flow used in investing activities		**0**	**-70**
Cash flows from financing activities			
Proceeds from issue of share capital	9	73,380	176,998
Debt repayments		-292	0
Net cash flow from financing activities		**73,088**	**176,998**
Net increase/(decrease) in cash and cash equvivalents		-36,034	70,914
Cash and cash equivalents at beginning of period		360,413	370,350
Cash and cash equivalents at end of period		**324,379**	**441,263**

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. 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 sixt-months period ended 30 June 2019 and were approved for issue by the Board of Directors on 18 August 2019.

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 2018, except for the adoption of new standards and interpretations effective as of 1 January 2019.

The new and amended standards and interpretations from IFRS that were adopted by the EU with effect from 2019 did not have any significant impact on the reporting for Q2 2019.

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

IFRS 16 Leases

The company has implemented IFRS 16 Leases from 1.1.2019.

IFRS 16 replaces IAS 17, Leases and related interpretations. IFRS 16 from a lessee viewpoint eliminates the classification of leases as either operating leases or finance leases. Instead, all leases are treated in a similar way to finance leases under IAS 17. The standard is effective for accounting periods beginning on or after 1 January 2019 and adopted by the company from the same date.

IFRS 16 allows various adoption approaches. The company applies the modified retrospective approach under which all right-of-use assets (ROU assets) are measured at an amount equal to the lease liability at 1 January 2019. The lease liability in turn is calculated as the discounted present value of remaining lease payments under the leases. The cumulative effect of initially applying the standard as an adjustment to the opening balance on retained earnings is zero. Under this transition approach, the 2018 comparable numbers presented in the first quarter 2019 reporting are not restated as if IFRS 16 was applied in 2018. The presented amounts are calculated based on judgements and interpretations at the time of adopting the new standard.

The company has only lease agreements previously classified as operational leases. Under IFRS 16 these are treated as financial leases.

Implementing effect of adopting the new standard and effect on the income statement for the second quarter and first half year of 2019 are shown in the tables below.

(NOK 1,000 Unaudited)			
Effect on Statement of Financial Position	**31.12.2018**	**IFRS 16 effect**	**1.1.2019**
Non-current assets	581	1,178	1,759
Total assets	378,826	1,178	380,004
Long term debt	0	551	551
Current liabilities	41,546	627	42,173
Total liabilities	41,546	1,178	42,724
Total equity and liabilities	378,826	1,178	380,004

	Q2 2019				YTD 2019		
Effect on Income Statement	**Q2 2019 excl IFRS 16**	**IFRS 16 effects**	**Q2 2019**		**YTD excl IFRS 16**	**IFRS 16 effects**	**YTD 2019**
Total operation revenue	0	0	0		8,682	0	8,682
Depreciation	41	155	196		82	310	392
Other operating expenses	43,203	-162	43,041		90,209	-324	89,885
Total operation expenses	51,972	-7	51,965		106,479	-14	106,465
Operating profit	-51,972	7	-51,965		-97,797	14	-97,783
Financial items, net	-808	-14	-822		717	-32	685
Profit before tax	-52,780	-7	-52,787		-97,080	-18	-97,098

Basis for consolidation

The consolidated financial statements comprise the financial statements of the Company and its subsidiary as of 30 June 2019. 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. A private placement and capital increase of gross NOK 74 million was completed in June 2019, and thus 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

	For the six months ended 30 June	
	2019	2018
Salaries	15,434	12,307
Social security tax	2,459	1,892
Pension expense	1,139	1,018
Share option expense employees	1,725	347
Accrued social security tax on share options	-4,216	6,130
Other remuneration	333	795
Government grants 1)	-686	-518
Total payroll and related expenses	**16,187**	**21,972**
Average number of full time equivalent employees	24	24

1) See also note 5 for government grants

BerGenBio

Members of management and Board of Directors participating in the option program

Option holder	Number of options outstanding	Grant date	Expiry date	Exercise price (NOK)
Richard Godfrey	50,000	1-Sep-10	31-Dec-19	5.65
	100,000	27-May-11	31-Dec-19	7.56
	75,000	21-Jun-12	31-Dec-19	10.62
	150,000	3-Sep-13	3-Sep-21	10.62
	75,000	13-Jun-13	13-Jun-21	10.62
	120,000	11-Jun-14	11-Jun-22	11.15
	275,000	22-May-15	22-May-23	16.01
	100,000	1-Jan-16	1-Jan-24	24.00
	122,484	23-May-18	23-May-26	45.70
	50,000	31-Oct-18	31-Oct-26	28.50
	236,800	17-Apr-19	17-Apr-27	25.00
James B Lorens	50,000	10-Sep-10	31-Dec-19	5.65
	25,000	27-May-11	31-Dec-19	7.56
	75,000	21-Jun-12	31-Dec-19	10.62
	55,000	3-Sep-13	3-Sep-21	10.62
	100,000	13-Jun-13	13-Jun-21	10.62
	70,000	11-Jun-14	11-Jun-22	11.15
	275,000	22-May-15	22-May-23	16.01
	50,000	1-Jan-16	1-Jan-24	24.00
	10,707	23-May-18	23-May-26	46.70
	7,000	31-Oct-18	31-Oct-26	28.50
	20,800	17-Apr-19	17-Apr-27	25.00
Rune Skeie	24,090	23-May-18	23-May-26	46.70
	20,000	31-Oct-18	31-Oct-26	28.50
	52,000	17-Apr-19	17-Apr-27	25.00
	2,188,881			

In the annual general meeting on the 22nd of March 2017 it was resolved a split of the shares so that 1 share with a nominal value of NOK 10 was split into 100 shares with a nominal value of NOK 0.10. The overview above takes into account the share split.

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 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 retain and attract 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.

Primarlily the options vest at the earlier of an IPO or annually in equal tranches over a three-year period following the date of grant.

The following equity incentive schemes were in place in the current year:

	Number of options	Grant date	Expiry date	Exercise price
Granted in September 2010	225,000	Sep 2010	Dec 2017/2019	5.65
Granted in May 2011	175,000	May 2011	Dec 2017/2019	7.56
Granted in June 2012	285,000	Jun 2012	Dec 2017/2019	10.62
Granted in June 2012	225,000	Jun 2012	Jun 2020	10.62
Granted in June 2013	360,000	Jun 2013	Jun 2021	10.62
Granted in September 2013	400,000	Sep 2013	Sep 2021	10.62
Granted in June 2014	280,000	Jun 2014	Jun 2022	11.15
Granted in May 2015	650,000	May 2015	May 2023	16.01
Granted in September 2015	260,000	Sep 2015	Sep 2021	16.01
Granted in January 2016	400,000	Jan 2016	Jan 2024	24.00
Granted in February 2016	122,500	Feb 2016	Feb 2024	24.00
Granted in December 2017	50,000	Dec 2017	Dec 2025	22.00
Granted in May	385,027	May 2018	May 2026	46.70
Granted in October 2018	277,000	Oct 2018	Oct 2026	28.50
Forfeited in 2015	-7,500			10.62
Forfeited in 2016	-50,000			16.01
Forfeited and cancelled in 2017 *	-220,000			12.33
Exercised in 2017	-230,000			9.98
Exercised in 2018	-160,000			19.01
Forfeited in 2018	-245,513			26.27
Cancelled in 2019 *	-332,865			36.65
Exercised in 2019	-330,000			12.33
Total	**3,303,278**			

In the annual general meeting on the 22nd of March 2017 it was resolved a split of the shares so that 1 share with a nominal value of NOK 10 was split into 100 shares with a nominal value of NOK 0.10. The overview above takes into account the share split.

** The exercise price is calculated as the weighted average exercise price of the forfeited and cancelled options.*

Total options	For the six months ended 30 June			
	2019		2018	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Balance at 1 January	3,181,514	18.20	2,925,000	14.20
Granted during the period	784,629	25.00	385 027	46.70
Exercised during the period	-330,000	12.33	-160 000	19.01
Forfeited and cancelled	-332,865	28.69		
Balance at 31 March	**3,303,278**	**19.34**	**3,150,027**	**17.93**

784,629 options were granted in the six months ended 30 June 2019 and 385,027 options were granted in the six months period ended 30 June 2018.

Vested options	For the six months ended 30 June	
	2019	2018
Options vested at 1 January	2,598,334	2,891,667
Exercised and forfeited in the period	-379,063	-160,000
Vested in the period	83,927	0
Options vested at 30 June	**2,303,198**	**2,731,667**
Total outstanding number of options	3,303,278	3,150,027

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. Most of the options vest dependent on certain condition. 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 Gropup and experience from other companies in combination with the relatively long lifetime of these options (up to 8 years).

For valuation purposes 43% expected future volatility has been applied. As the Group recently went public it has limited history of volatility in its share price, therefore the historical volatility of similar listed companies has been used as a benchmark for expected volatility.

For the six month period ending 30 June 2019 the value of the share options expensed through the profit or loss amounts to NOK 1.7 million (for the same period in 2018: NOK 0.35 million). In addition a provision for social security contributions on share options of NOK - 4.2 million (for the same period in 2018: NOK 6.1 million) is recognised based on the difference between the share price and exercise price on exercisable option as at the end of the period

Note 5
Government grants

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

	For the six months ended 30 June	
	2019	2018
Payroll and related expenses	686	518
Other operating expenses	7,499	6,527
Total	**8,186**	**7,045**

Grants receivable as at 30 June are detailed as follows:

	For the six months ended 30 June	
	2019	2018
Grants from Research Council, BIA	1,567	1,148
Grants from Innovation Norway	6,597	3,600
Grants from SkatteFunn	12,022	6,958
Total	**20,185**	**11,707**

BIA grants from the Research Council:

The Company currently has three grants from the Research Council, programs for user-managed innovation arena (BIA).

The first BIA grant ("Axl targeting therapeutics to treat fibrotic diseases") totals to NOK 12.0 million and covers the period from April 2015 to April 2019. The Group has recognised NOK 0.9 million in Q2 2019 (Q2 2018: NOK 1.4 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses.

The second 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 2.0 million in Q2 2019 (Q2 2018: NOK 2.0 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses.

The third 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 not recognised any of this grant in Q2 2019 or in 2018.

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 2019. The Group has recognised NOK 4.1 million in Q2 2019 (Q 2018: NOK 0.0 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses.

Innovasjon Norge:

BerGenBio has been awarded a NOK 24 million (USD2.85m) grant from Innovasjon Norge to support the clinical development of BGB324 in combination with Merck & Co.'s KEYTRUDA® (pembrolizumab) in patients with advanced lung cancer.
The grant from Innovasjon Norge 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 received NOK 7.2 million in Q4 2017 of this grant. The grant may be withdrawn under certain circumstances.The Group has recognised NOK 1.2 million in Q2 2019 (Q2 2018: NOK 3.6 million) classified as cost reduction of other operating expenses.

Note 6 Other operating expenses

	For the three months ended 30 June	
	2019	2018
Program expenses, clinical trials and research	68,296	67,478
Office rent and expenses	702	1,040
Consultants R&D projects	7,857	4,784
Patent and licence expenses	1,430	1,509
Other operating expenses *	19,100	15,148
Government grants	-7,499	-6,527
Total	**89,885**	**83,433**

Note 7 Earnings per share

	For the six months ended 30 June	
	2019	2018
Loss for the period (NOK 1,000)	-97,098	-103,017
Average number of outstanding shares during the year	55,128,774	51,833,944
Earnings (loss) per share - basic and diluted (NOK)	**-1.76**	**-1.99**

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 June 2019	30 June 2018
Government grants	20,185	11,707
Refundable VAT	1,334	363
Prepaid expenses	798	532
Other receivables	941	1,534
Total	**23,259**	**14,135**

Note 9 Share capital and shareholder information

As of 30 June	Number of shares	Nominal value (NOK)	Book value (NOK)
Ordinary shares 2019	60,536,590	0.10	6,053,659.00
Ordinary shares 2018	54,711,446	0.10	5,471,144.60

Changes in the outstanding number of shares	For the six months ended 30 June	
	2019	2018
Ordinary shares at 1 January	54,711,446	49,922,200
Issue of ordinary shares	5,825,144	4,789,246
Ordinary shares at 30 June	**60,536,590**	**54,711,446**

Ownership structure 30 06 2019

Shareholder		Number of shares	% share of total shares
METEVA AS		16,458,750	27.2%
INVESTINOR AS		7,270,780	12.0%
SARSIA SEED AS		2,117,900	3.5%
VERDIPAPIRFONDET ALFRED BERG GAMBA		2,086,286	3.5%
KLP AKSJENORGE		1,887,484	3.1%
KOMMUNAL LANDSPENSJONSKASSE		1,328,322	2.2%
VERDIPAPIRFONDET NORDEA KAPITAL		1,275,460	2.1%
MP PENSJON PK		1,229,955	2.0%
VERDIPAPIRFONDET NORDEA AVKASTNING		1,228,174	2.0%
BERA AS		1,204,800	2.0%
SARSIA DEVELOPMENT AS		1,175,000	1.9%
VERDIPAPIRFONDET NORDEA NORGE VERD		943,407	1.6%
VERDIPAPIRFONDET ALFRED BERG NORGE		921,160	1.5%
NORSK INNOVASJONSKAPITAL II AS		806,170	1.3%
ALTITUDE CAPITAL AS		715,000	1.2%
MIDDELBORG INVEST AS		705,000	1.2%
VERDIPAPIRFONDET ALFRED BERG AKTIV		639,296	1.1%
VERDIPAPIRFONDET NORDEA NORGE PLUS		623,060	1.0%
Euroclear Bank S.A./N.V.	NOM	606,750	1.0%
NORDA ASA		536,281	0.9%
Top 20 shareholders		**43,759,035**	**72.4%**
Total other shareholders		16,687,555	27.6%
Total number of shares		60,446,590	**100.0%**

The Board of Directors has been granted a mandate from the general meeting held on 13 March 2019 to increase the share capital with up to NOK 548,514 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 2020 and 30 June 2020. In Q1 2019 there was issued 140,000 new shares under this proxy at a nominal value of NOK 14,000 and in Q2 2019 there was issued 190,000 new shares under this proxy at a nominal value of NOK 19,000.. 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 13 March 2019 to increase the share capital with up to NOK 1,097,028 by subscription of new shares. The proxy is valid until the earlier of the annual general meeting in 2020 and 30 June 2020. In June 2019 there was issued 5,495,144 shares under this proxy at a nominal value of NOK 549,514.40.

Shares in the Group held by the management group

	Position	Employed since	30 Jun 2019	30 Jun 2018
Richard Godfrey 1)	Chief Executive Officer	January 2009	167,815	160,408
James Bradley Lorens	Senior Scientific Adviser	January 2009	250,000	250,000
Total shares held by management			**417,815**	**410,408**

1) Richard Godfrey holds 167,815 shares in the Company through Gnist Holding AS.

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

	Position	Served since	30 June 2019	30 June 2018
Sveinung Hole 1)	Chairman	September 2010	107 394	-
Stener Kvinnsland	Board Member	February 2015	104 444	-
Total shares held by members of the Board of Directors			**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.

Grunde Eirksen (board member) is CEO in Altitude Capital AS. Altitude Capital AS is holding 715,000 shares in BerGenBio ASA at 30 Jun 2019.

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.

As of 1 October 2016, BerGenBio transitioned from a defined benefit scheme to a defined contribution scheme.

MEDICAL AND BIOLOGICAL TERMS

Adenocarcinoma	Cancerous tumour that can occur in several parts of the body and that forms in mucus-secreting glands throughout the body. It can occur in many different places in the body and is most prevalent in the following cancer types; lung cancer, prostate cancer, pancreatic cancer, oesophageal cancer and colorectal cancer. Adenocarcinomas are part of the larger grouping of carcinomas.
ADCT601	BGB601 (ADCT-601) is an antibody drug conjugate (ADC) composed of a humanised IgG1 antibody against human AXL that is linked to a cytotoxin.
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
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 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.
Checkpoint inhibitors	The immune system depends on multiple checkpoint 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.
CR	Complete response
CRO	Contract research organisation.
CTL	Cytotoxic T-lymphocytes. Key effector cells of the body's immune response to cancer.
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.
Erlotinib	A drug used to treat non-small cell lung cancer (NSCLC), pancreatic cancer and several other types of cancer. It is a reversible tyrosine kinase inhibitor, which acts on epidermal growth factor receptor (EGFR).
ESMO	European Society for Medical Oncology
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.
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
Paclitaxel	A medication used to treat a number of types of cancer including ovarian cancer, breast cancer, lung cancer and pancreatic cancer among others.
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
sAXL	Soluble AXL
SITC	Society ImmunoTherapy Cancer
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.
Squamous cell carcinoma	Is an uncontrolled growth of abnormal cells arising in the squamous cells, which compose most of the skin's upper layers. Squamous cell carcinoma is the second most common form of skin cancer.
T790M	Over 50% of acquired resistance to EGFR tyrosine kinase inhibitors is caused by a mutation in EGFR called T790M
WCLC	World Conference on Lung Cancer

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Disclaimer

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