BerGenBio

BerGenBio

INTERIM REPORT THIRD QUARTER 2019

BerGenBio

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Richard Godfrey
Chief Executive Officer of BerGenBio

"During the quarter we have continued working to expand our proof of concept trials in AML and NSCLC. Our goal is to confirm the addition of our selective AXL inhibitor bemcentinib can substantially improve patient outcomes across both these indications. This will inform our clinical strategy and position for late stage clinical development, and we remain committed to progressing bemcentinib through to regulatory approval.

We were delighted that the FDA has approved Fast Track Designation for bemcentinib for the treatment of elderly patients with acute myeloid leukaemia (AML) whose disease has relapsed. There are currently no marketed drugs specifically approved for relapsed AML patients, representing a significant unmet medical need. BerGenBio has ongoing phase 2 trials in this indication and plans to seek regulatory advice from the FDA and European Medicines Agency (EMA) to determine the optimal regulatory path for bemcentinib in relapsed AML.

Bemcentinib met the primary and secondary end points in the first cohort of our NSCLC trial investigating bemcentinib in combination with Merck's anti PD-1 therapy Keytruda in lung cancer patients. We have also had the opportunity to present our clinical and translational data at a number of prestigious scientific congresses, including the World Conference on Lung Cancer, the European Society of Medical Oncology and most recently at the Society for Immunotherapy of Cancer (SITC)."

We are delighted, not only by the continued significant patient benefit from bemcentinib in combination with Keytruda, but also by our improved ability to identify patients with durable clinical benefit with a refined composite AXL tumor immune score, an important development for our AXL targeting clinical programs. To date we have assessed data from the first of three cohorts where we are evaluating this combination in previously treated lung cancer patients and I look forward to reporting data from these additional cohorts in the coming months."

Q3 2019 (including post-period end) HIGHLIGHTS

BerGenBio

FDA granted Fast Track Designations for 2L Acute Myeloid Leukaemia (AML)

High impact oral presentation of 2L NSCLC clinical data at SITC

Met primary and secondary end points in Non-Small Cell Lung Cancer (NSCLC) Phase II clinical trial in previously treated patients post chemotherapy (cohort A)

Proprietary composite AXL tumor immune score (cAXL) identified patients that have shown very durable response and significantly prolonged median Progression Free Survival (mPFS)

Proprietary gene signature selected 2L NSCLC patients that reported durable benefit and is independent of PD-L1

Phase Ib/II interim safety data with bemcentinib in combination with pembrolizumab or BRAF/MEK inhibitors in 1L Melanoma confirmed the combinations are well tolerated by patients, presented at ESMO

Cash and Cash equivalents at end of Q3 2019 NOK 289.5 million.

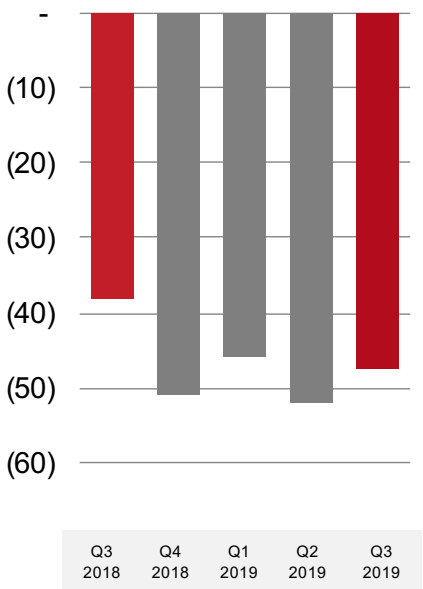
Operating loss of NOK 47.5 million in Q3 2019 (NOK 38.1 in Q3 2018) and NOK 145.3 million YTD 2019 (NOK 143.6 YTD 2018)

Q3 2019 FINANCIAL HIGHLIGHTS

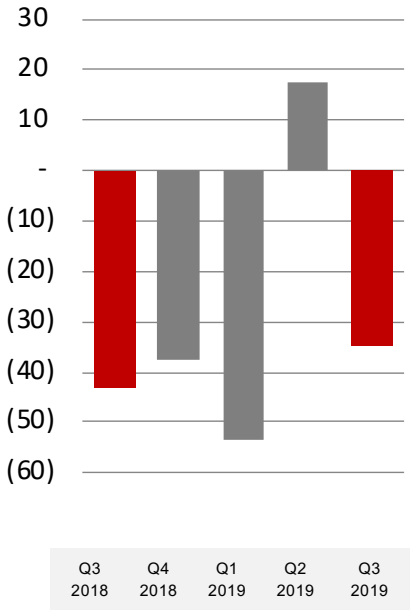
Key financial figures

(NOK million)	Q3 2019	Q3 2018	YTD 2019	YTD 2018	FY 2018
Operating revenues	0	0	8,7	0	2,3
Operating expenses	47,5	38,1	154,0	143,6	196,9
Operating profit (-loss)	-47,5	-38,1	-145,3	-143,6	-194,5
Profit (-loss) after tax	-44,6	-37,7	-141,7	-140,7	-191,7
Basic and diluted earnings (loss) per share (NOK)	-0.73	-0.69	-2.57	-2.66	-3.60
Net cash flow in the period	-34,9	-43,1	-70,9	27,8	-9,9
Cash position end of period	289,5	398,2	289,5	398,2	360,4

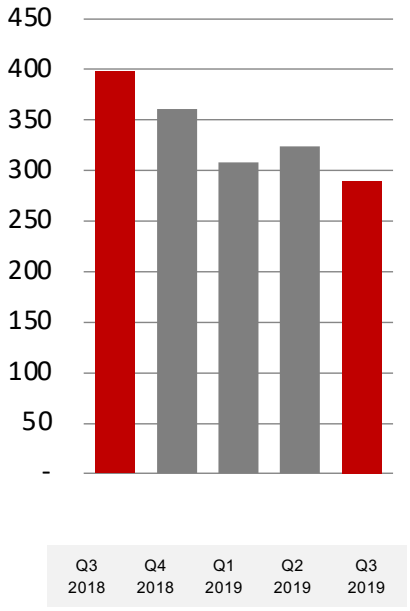
Operating loss



Cash flow



Cash position



OVERVIEW & OUTLOOK

Q3 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

- In November the Company reported that Cohort A of the Phase II clinical trial (BGBC008) evaluating bemcentinib in combination with KEYTRUDA in patients with NSCLC had met its primary endpoint. The primary endpoint of Overall Response Rate (ORR) was met, with 33% ORR in Composite AXL (cAXL) positive patients; five times the response rate of cAXL negative patients (7%), as measured by Response Evaluation Criteria in Solid Tumors (RECIST). This is three times greater than that seen with Keytruda monothearpy reported in earlier clinical trials in similar patients.

- A secondary endpoint of median Progression Free Survival (mPFS) reported significant 3-fold improvement in cAXL positive vs negative patients, 8.4 months in cAXL positive patients, significantly surpassing by more than three fold the duration, what has been shown historically in second line treatment with Keytruda. The data were presented at the prestigious High Impact Clinical Trial session at the Society for Immunotherapy of Cancer (6-10 November 2019) conference in Washington DC.

- A proprietary composite AXL tumor immune Score (cAXL), identifies with increasing confidence, patients that are AXL positive in both their tumor and immune cells and these patients report significantly improved clinical benefit from bemcentinib combination with Keytruda.

- During the quarter, data from Cohort A of BGBC008 was also presented in an oral presentation at the 2019 World Conference on Lung Cancer (WCLC) and as a poster the European Society of Medical Oncology Congress (ESMO).

- 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.

- The clinical trial BGBC008 is ongoing in two additional cohorts; B) in Check Point Inhibitor refractory patients and C) in CPI/chemotherapy combination refractory patients. Preliminary data read out is anticipated in the first half of 2020.

AML Acute Myeloid Leukaemia

- In October we were pleased to announce that the U.S Food and Drug Administration (FDA) had granted bemcentinib Fast Track Designation for the treatment of elderly patients with AML whose disease has relapsed.

- The FDA's Fast Track program is designed to facilitate the development and expedite regulatory review of drugs to treat serious conditions and fill an unmet medical need. A drug granted Fast Track Designation may be eligible for several benefits, including more frequent meetings and communications with the FDA and, if relevant criteria are met, the potential for Accelerated Approval, Priority Review or Rolling Review of a Biologics License Application (BLA) or New Drug Application (NDA).

- Phase IIa clinical trial data has shown that bemcentinib in combination with low-intensity chemotherapy (LDAC) in elderly AML patients is well tolerated and efficacious. In data presented earlier in 2019, preliminary responses were reported in 43% of evaluated patients, with complete responses in a substantially higher percentage of patients compared to previously observed/historical benchmarks in single-agent cytarabine. This trial has been expanded to include an additional 28 patients to verify these early proof of concept, preliminary data from this expanded trial will be available in the first half of 2020.

Strategic Priorities

The Company remains well placed to deliver its stated strategic priorities, specifically:

- 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 the development and commercialisation of bemcentinib, aimed at creating maximum value for shareholders, including potential partnering and go-to-market strategies in selected indications and territories.
The Company continues to deliver promising clinical outcomes and increasingly robust translational biomarker data from its bemcentinib development programme. The Board's view is that these encouraging results in AML and NSCLC have established increasing clinical proof-of concept and the Company is focused on meeting its operational, regulatory and clinical goals.

Recent announcements from emerging competitors reaffirm the Company's leadership position in developing Axl inhibitors, and has heightened industry awareness of their potential value.

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 has chosen not to hedge its operational costs 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 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 third quarter 2019 and the nine months ended 30 September 2019 respectively amounted to NOK 0 million (NOK 0 million) and NOK 8.7 million (NOK 0 million). The revenue was received in Q1 2019 from ADCT as a clinical milestone payment .

Total operating expenses for the third quarter and the nine months ended 30 September 2019 respectively amounted to NOK 47.5 million (NOK 38.1 million) and NOK 154.0 million (NOK 143.6 million).

Employee expenses in the third quarter were NOK 6.5 million (NOK 9.3 million) and NOK 22.7 million (NOK 31.3 million) for the nine months ended 30 September. The decrease in the nine months ended 30 September was mainly due to reduction in provisions for social security tax on employee options.

Other operating expenses amounted to NOK 40.9 million (NOK 28.8 million) for the quarter and NOK 130.7 million (NOK 112.2 million) for the nine months ended 30 September. 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.
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 47.5 million (NOK 38.1 million) and NOK 145.3 million (NOK 143.6 million) for the nine months ended 30 September, reflecting the level of activity related to the clinical trials BerGenBio is conducting.

Net financial profit amounted to NOK 2.9 million (NOK 0.5 million) for the quarter and a profit of NOK 3.6 million (NOK 3.0 million) for the nine months ended 30 September.

Losses after tax for the quarter were NOK 44.6 million (NOK 37.7 million) and for the nine months ended 30 September NOK 141.7 million (NOK 140.7 million).

Financial Position

Total assets at 30 September 2019 decreased to NOK 310.2 million (NOK 378.8 million at year end 2018), mainly due to the operational loss in the period and reflecting the private placement completed in June 2019 raising gross NOK 74.2 million.

Total liabilities were NOK 33.7 million at 30 September 2019 (NOK 41.5 million at year end 2018).

Total equity as of 30 September 2019 was NOK 276.5 million (NOK 337.3 million at year end 2018), corresponding to an equity ratio of 89.1% (89.0%).

Cash Flow

Net cash flow from operating activities was negative by NOK 39.2 in the quarter and 148.3 million for the nine months ended 30 September (negative by 43.1 in Q3 2018 and NOK 149.1 million YTD 2018), mainly driven by the level of activity in the clinical trials.

Net cash flow for investing during the quarter and the nine months ended 30 September was NOK 0.0 million (NOK 0 in Q3 2018 and NOK 0.1 million YTD 2018).

Net cash flow from financing activities was NOK 4.3 million for the quarter and 77.4 million for the nine months ended 30 September (NOK 0 in Q3 2018 and NOK 177.0 million YTD 2018).

Net cash flow in the quarter was negative with NOK 34.9 million. Cash and cash equivalents decreased to NOK 289.5 million (NOK 360.4 at end of Q2 2019 and NOK 398.2 million at year end 2018).

The board today considered and approved the condensed, consolidated financial statement of the nine months ending 30 September 2019 for BerGenBio.

Bergen 18 November 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	Q3 2019	Q3 2018	YTD 2019	YTD 2018	FY 2018
Revenue		0	0	8,682	0	2,335
Expenses				0	0	
Employee benefit expenses	3, 10	6,482	9,285	22,669	31 257	38,012
Depreciation	2	196	59	589	167	204
Other operating expenses	6	40,861	28,773	130,746	112,206	158,658
Total operating expenses		**47,539**	**38,116**	**154,004**	**143,630**	**196,874**
Operating profit		**-47,539**	**-38,116**	**-145,323**	**-143,630**	**-194,539**
Finance income		4,226	974	7,496	3,642	4,857
Finance expense		1,280	513	3,865	685	2,065
Financial items, net		**2,946**	**461**	**3 631**	**2,957**	**2,792**
Profit before tax		**-44 593**	**-37,656**	**-141,691**	**-140,673**	**-191,747**
Income tax expense		0	0	0	0	0
Profit after tax		**-44,593**	**-37,656**	**-141,691**	**-140,673**	**-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		**-44,593**	**-37,656**	**-141,691**	**-140,673**	**-191,747**
Earnings per share:						
- Basic and diluted per share	7	-0.73	-0.69	-2.57	-2.66	-3.60

BerGenBio

Condensed consolidated statement of financial position

(NOK 1000) Unaudited	Note	30 SEP 2019	30 SEP 2018	31 DEC 2018
ASSETS				
Non-current assets				
Property, plant and equipment	2	1,171	460	581
Total non-current assets		**1,171**	**460**	**581**
Other current assets	5, 8	19,522	21,868	17,831
Cash and cash equivalents		289,503	398,166	360,413
Total current assets		**309,025**	**420,034**	**378,245**
TOTAL ASSETS		**310,196**	**420,494**	**378,826**
EQUITY AND LIABILITIES				
Equity				
Paid in capital				
Share capital	9	6,108	5,471	5,471
Share premium	9	245,373	360,865	309,791
Other paid in capital	4, 9	241,972	21,396	22,018
Total paid in capital		**276,452**	**387,731**	**337,280**
Total equity		**276,452**	**387,731**	**337,280**
Non-current liabilities				
Long term debt	2	63	0	0
Total non-current liabilities		**63**	**0**	**0**
Current liabilities				
Accounts payable		14,113	9,373	23,939
Other current liabilities		19,144	15,195	12,875
Provisions		424	8,194	41,732
Total current liabilities		**33,681**	**32,762**	**41,546**
Total liabilities		**33,744**	**32,762**	**41,546**
TOTAL EQUITY AND LIABILITIES		**310,196**	**420,494**	**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			-141,691		-141,691
Other comprehensive income (loss) for the period, net of income tax			0		0
Total comprehensive income for the period		**0**	**-141,691**	**0**	**-141,691**
Recognition of share-based payments	3, 4			2,954	2,954
Issue of ordinary shares	9	637	82,148		82,785
Paid in, not registed capital raise	9				0
Share issue costs			-4,875		-4,875
Balance at 30 September 2019		**6,108**	**245,373**	**24,972**	**276,452**

(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**
Loss for the period			-140,673		-140,673
Other comprehensive income (loss) for the period,net of income tax			0		0
Total comprehensive income for the period		**0**	**-140,673**	**0**	**-140 673**
Recognition of share-based payments	3, 4			1,056	1,056
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 September 2018		**5,471**	**360,865**	**21,396**	**387,731**

BerGenBio

Condensed consolidated statement of cash flow

(NOK 1000) Unaudited	Note	Q3 2019	Q3 2018	YTD 2019	YTD 2018
Cash flow from operating activities					
Loss before tax		-44,593	-37,656	-141,691	-140,673
Non-cash adjustments to reconcile loss before tax to net cash flows					
Depreciation of property, plant and equipment		196	59	589	167
Share-based payment expense	3, 4	1,229	709	2,954	1,056
Movement in provisions and pensions		-93	-956	-4,246	5,174
Working capital adjustments:					
Decrease in trade and other receivables and prepayments		3,737	-7,732	-1,691	-8,438
Increase in trade and other payables		363	2,480	-4,197	-6,398
Net cash flow from operating activities		**-39,160**	**-43,097**	**-148,283**	**-149,112**
Cash flows from investing activities					
Purchase of property, plant and equipment		0	0	0	-70
Net cash flow used in investing activities		**0**	**0**	**0**	**-70**
Cash flows from financing activities					
Proceeds from issue of share capital	9	4,530	0	77,910	176,998
Debt repayments		-245	0	-537	0
Net cash flow from financing activities		**4,285**	**0**	**77,373**	**176,998**
Net increase/(decrease) in cash and cash equvivalents		-34,875	-43,097	-70,910	27,817
Cash and cash equivalents at beginning of period		324,379	441,263	360,413	370,350
Cash and cash equivalents at end of period		**289,503**	**398,166**	**289,503**	**398,166**

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 nine-months period ended 30 September 2019 and were approved for issue by the Board of Directors on 18 November 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 Q3 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

	Q3 2019				YTD 2019		
Effect on Income Statement	**Q3 2019 excl IFRS 16**	**IFRS 16 effects**	**Q3 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		124	465	589
Other operating expenses	41 023	-162	40 861		131 232	-486	130 746
Total operation expenses	47 546	-7	47 539		154 025	-21	154 004
Operating profit	-47 546	7	-47 539		-145 344	21	-145 323
Financial items, net	2,959	-13	2 946		3 676	-45	3 631
Profit before tax	-44 587	-6	-44 593		-141 667	-24	-141 691

Basis for consolidation

The consolidated financial statements comprise the financial statements of the Company and its subsidiary as of 30 September 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 nine months ended 30 September	
	2019	2018
Salaries	21,197	20,282
Social security tax	3,809	2,764
Pension expense	1,706	1,549
Share option expense employees	2,954	1,056
Accrued social security tax on share options	-4,309	5,174
Other remuneration	563	1,461
Government grants 1)	-3,251	-1,031
Total payroll and related expenses	**22,669**	**31,257**
Average number of full time equivalent employees	26	24

1) See also note 5 for government grants

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	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	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
	1 813,881			

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
Granted in April 2019	784,629			25,00
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	-451,975			36,65
Exercised in 2019	870,000			9,89
Total	**2 644,168**			

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 nine months ended 30 September 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	-870,000	9,89	-160,000	19,01
Forfeited and cancelled	-451,975	27,73		
Balance at 30 September	**2,644,168**	**21,32**	**3,150,027**	**17,93**

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

Vested options	For the nine months ended 30 September 2019	2018
Options vested at 1 January	2,598,334	2,891,667
Exercised and forfeited in the period	-1,018,562	-160,000
Vested in the period	83 927	0
Options vested at 30 September	**1,663,699**	**2,731,667**
Total outstanding number of options	2,644,168	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 conditions. 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 nine months period ending 30 September 2019 the value of the share options expensed through the profit or loss amounts to NOK 3.0 million (for the same period in 2018: NOK 1.1 million). In addition a provision for social security contributions on share options of NOK - 4.3 million (for the same period in 2018: NOK 5.2 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:

	Q3 2019	Q3 2018	YTD 2019	YTD 2018
Employee benefit expenses	2,564	513	3,251	1,031
Other operating expenses	8,485	8,363	15,984	14,890
Total	**11,049**	**8,876**	**19,234**	**15,921**

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

	30 Sep 2019	30 Sep 2018
Grants from Research Council, BIA	2,949	574
Grants from Innovation Norway	0	5,400
Grants from SkatteFunn	13,455	12,311
Total grants receivable	**16,404**	**18,286**

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 Q3 2019 (Q3 2018: NOK 2.2 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 3.0 million in Q2 2019 (Q2 2018: NOK 3.0 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 recognised NOK 2.6 million in Q3 2019 (Q3 2018: NOK 0.0 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses.

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 5.5 million in Q3 2019 (Q3 2018: NOK 5.4 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 (USD2.85m) grant from Innovation Norway to support the clinical development of BGB324 in combination with Merck & Co.'s KEYTRUDA® (pembrolizumab) in patients with advanced lung cancer.
The grant from Innovation Norway is an Industrial Development Award (IFU). The IFU program is directed to Norwegian companies developing new products or services in collaboration with foreign companies. BerGenBio received NOK 7.2 million in Q4 2017 of this grant and further NOK 12 million in Q3 2019. The grant may be withdrawn under certain circumstances. The Group has recognized NOK 5.4 million in Q3 2019 (Q3 2018: NOK 5.4 million) classified as cost reduction of other operating expenses.

Note 6 Other operating expenses

	For the nine months ended 30 September 2019	2018
Program expenses, clinical trials and research	103,592	95,870
Office rent and expenses	1,250	1,575
Consultants R&D projects	13,876	6,809
Patent and licence expenses	2,964	2,277
Other operating expenses	25,048	20,564
Government grants	-15,984	-14,890
Total	**130,746**	**112,206**

Note 7 Earnings per share

	For the nine months ended 30 September 2019	2018
Loss for the period (NOK 1,000)	-141,691	-140,673
Average number of outstanding shares during the year	55,212,180	52,803,652
Earnings (loss) per share - basic and diluted (NOK)	**-2.57**	**-2.66**

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

Note 8 Other current assets

	30 Sep 2019	30 Sep 2018
Government grants	16,404	18,286
Refundable VAT	900	552
Prepaid expenses	754	606
Other receivables	1,463	2,424
Total	**19,522**	**21,868**

Note 9 Share capital and shareholder information

As of 30 September	Number of shares	Nominal value (NOK)	Book value (NOK)
Ordinary shares 2019	61,076,590	0.10	6,107,659,00
Ordinary shares 2018	54,711,446	0.10	5,471,144,60

Changes in the outstanding number of shares	For the nine months ended 30 September 2019	2018
Ordinary shares at 1 January	54,711,446	49,922,200
Issue of ordinary shares	6,365,144	4,789,246
Ordinary shares at 30 September	**61,076,590**	**54,711,446**

Ownership structure 30 09 2019

Shareholder		Number of shares	% share of total shares
METEVA AS		16 458 750	26,9%
INVESTINOR AS		7 270 780	11,9%
SARSIA SEED AS		2 117 900	3,5%
VERDIPAPIRFONDET ALFRED BERG GAMBA		2 086 286	3,4%
KLP AKSJENORGE		1 937 484	3,2%
KOMMUNAL LANDSPENSJONSKASSE		1 378 322	2,3%
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	1,5%
VERDIPAPIRFONDET ALFRED BERG NORGE		921 160	1,5%
NORSK INNOVASJONSKAPITAL II AS		806 170	1,3%
ALTITUDE CAPITAL AS		715 000	1,2%
VERDIPAPIRFONDET ALFRED BERG AKTIV		639 296	1,0%
VERDIPAPIRFONDET NORDEA NORGE PLUS		623 060	1,0%
Euroclear Bank S.A./N.V.	NOM	526 750	0,9%
Morgan Stanley & Co. LLC	NOM	525 000	0,9%
Skandinaviska Enskilda Banken AB	NOM	500 000	0,8%
Top 20 shareholders		**43 562 754**	**71,3%**
Total other shareholders		17 513 836	28,7%
Total number of shares		**61 076 590**	**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. In Q3 2019 there was issued 540,000 new shares under this proxy at a nominal value of NOK 54,000. 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 Sep 2019	30 Sep 2018
Richard Godfrey 1)	Chief Executive Officer	January 2009	215,449	160,408
James Bradley Lorens	Senior Scientific Adviser	January 2009	280,039	250,000
Total shares held by management			**495,488**	**410,408**

1) Richard Godfrey holds 215,449 shares in the Company through Gnist Holding AS.

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

	Position	Served since	30 Sep 2019	30 Sep 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 September 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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