



**INTERIM REPORT  
THIRD QUARTER 2018**

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BerGenBio (OSE:BGBIO) is a clinical-stage biopharmaceutical company developing innovative drugs for aggressive diseases, including immune evasive, drug resistant and metastatic cancers.



# RESULTS FOR THE THIRD QUARTER 2018

## Highlights – third quarter 2018 and post-period

### **Bemcentinib/KEYTRUDA® combination in advanced non-small cell lung cancer delivers highly promising phase II clinical results**

- 40% overall response rate & 70% clinical benefit rate observed in AXL-positive, previously treated NSCLC patients, including PD-L1 negative patients, (data presented at World Conference on Lung Cancer (WCLC))
- 5.9 months median progression-free-survival (PFS) in AXL positive vs. 3.3 months in AXL negative patients presented as late breaking abstract at Society Immunotherapy of Cancer congress (SITC, post-period)
- Efficacy endpoint met and stage two of the trial actively enrolling

### **Additional lung cancer phase II trials show promise for bemcentinib in combination with chemo- and targeted agents**

- Median PFS of NSCLC patients receiving the bemcentinib/TARCEVA® combination in first line has surpassed that of TARCEVA monotherapy (data presented at WCLC)
- Encouraging efficacy reported for bemcentinib in combination with docetaxel chemotherapy in patients who had exhausted all available therapy options (data presented at WCLC)

### **Tissue- and blood-based biomarkers with potential for development as companion diagnostics**

- Novel biomarkers identified and qualified across multiple clinical trials with bemcentinib, presented as poster discussion at European Society for Medical Oncology meeting (ESMO) and SITC 2018 (post period)

### **Arbitration process with Rigel Pharma. Inc.**

- The Company is seeking clarification of interpretation and application of certain provisions of the 2011 bemcentinib license agreement

### **Anticipated data and news flow in the coming months**

- AML and MDS mono- and combination therapy at ASH 2018
- Stage 2 of bemcentinib/KEYTRUDA combination trial in H1 2019
- IND filed for BGB149, first in class AXL function blocking antibody (post period)

### **Richard Godfrey, Chief Executive Officer of BerGenBio, commented:**

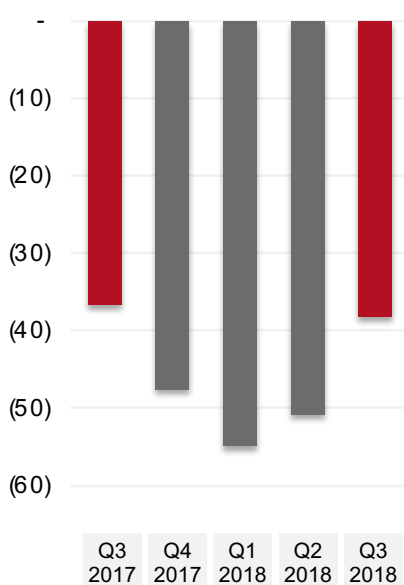
*“We are pleased with the progress of our phase II clinical development programme with our selective AXL inhibitor bemcentinib, particularly in NSCLC. The observed correlation between patient response and positive AXL status in our combination trial with KEYTRUDA gives us confidence in bemcentinib’s proposed mode of action and its broad appeal as a promising new agent treating aggressive cancer. The next six to nine months will be an exciting time for the company as we anticipate further clinical data from our phase II trials, particularly in NSCLC and acute myeloid leukaemia.”*



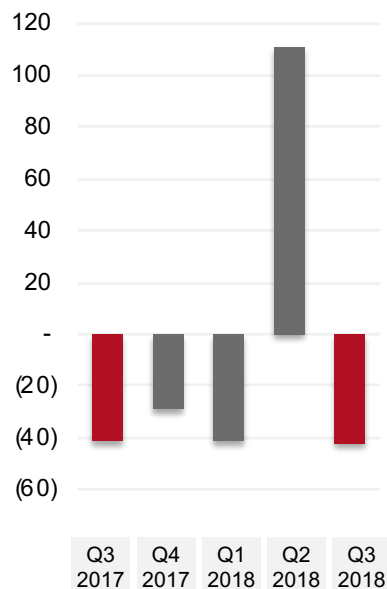
## Key financial figures

(NOK million)	Q3 2018	Q3 2017	YTD 2018	YTD 2017	FY 2017
Operating revenues	-	-	-	-	-
Operating expenses	38.1	36.6	143.6	136.2	183.7
Operating profit (loss)	-38.1	-36.6	-143.6	-136.2	-183.7
Profit (loss) after tax	-37.7	-35.4	-140.7	-134.6	-182.2
Basic and diluted earnings (loss) per share (NOK)	-0.69	-0.71	-2.66	-3.06	-4.01
Net cash flow in the period	-42.1	-41.1	27.8	237.3	208.5
Cash position end of period	398.2	399.2	398.2	399.2	370.3

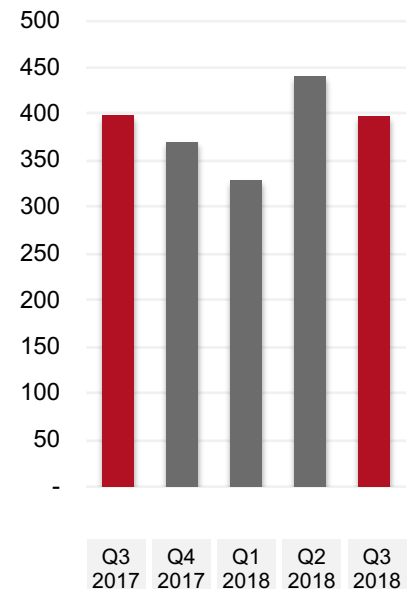
### Operating loss



### Cash flow



### Cash position



## Overview

BerGenBio is a clinical stage biopharmaceutical company focusing on developing novel medicines for aggressive diseases, including advanced, treatment-resistant cancers.

The company's lead drug candidate, bemcentinib, is a highly selective, potent, oral, first-in-class AXL inhibitor, currently being evaluated as a potential cornerstone of future cancer therapy in a broad phase II clinical programme.

The company is investigating bemcentinib in several solid and haematological tumours, in combination with current and emerging therapies (including immunotherapies, targeted therapies and chemotherapy), and as a single agent.

AXL expression is linked with poor prognosis in most cancers, it allows cancer to become aggressive and has immune-suppressive effects. AXL inhibition with bemcentinib, therefore, has potential value as a monotherapy and in combination with other drugs, addressing significant unmet medical needs and multiple high-value market opportunities.

### **The Company is focused on executing the following strategic priorities:**

- **Completing the phase II clinical trial programme with bemcentinib with particular focus in NSCLC and AML:** Positive results will establish clinical proof-of-concept for bemcentinib treatment. It will also inform further clinical development and route-to-market strategies.
- **Developing companion diagnostics to enrich future clinical trials:** To be able to predict if a patient will respond to bemcentinib enhances the chances of regulatory approval. It will also enable the company to adopt a precision medicine approach for commercialisation.
- **Starting clinical testing of BGB149, an anti-AXL antibody:** to expand the opportunity for AXL inhibitors addressing new indications.

- **Investigating additional opportunities for the company's AXL inhibitors:** AXL plays a key role in progression of other aggressive diseases, for example fibrosis.

## Outlook

BerGenBio's broad phase II clinical development programme with bemcentinib, pipeline of AXL inhibitors and robust financial position, together provide a strong foundation to create and deliver significant value for shareholders.

The Board considers that the results emerging from the clinical development programmes, particularly in NSCLC and AML, are providing valuable information to inform the future development strategy for bemcentinib. Further clinical data will be reported at future medical congresses and are expected to represent multiple value inflection events.

In retaining global rights to bemcentinib, BerGenBio maintains complete strategic flexibility for its future development and commercialisation. It is anticipated that the high novelty of bemcentinib plus its promising therapeutic profile will make it (and future pipeline candidates) attractive targets for partnering. A "go-to market" strategy may also be considered in select indications in discrete territories.



# OPERATIONAL REVIEW

## Updated phase II clinical data with bemcentinib highlights its potential in NSCLC

Non-small cell lung cancer (NSCLC) is the lead indication for bemcentinib, this disease is the focus of three ongoing phase II clinical trials covering its use with the three mainstays of current therapy for specific NSCLC populations with unmet medical needs. The trials are investigating bemcentinib in combination with the major drug classes that are in use to treat the majority of patients with advanced disease - immunotherapy, targeted therapy and chemotherapy :

- KEYTRUDA (pembrolizumab), the leading anti-PD-1 immunotherapy (trial code BGBC008)
- TARCEVA (erlotinib) a targeted therapy directed against the epidermal growth factor receptor (EGFR), which is frequently mutated and causes approx. 15% of NSCLC (trial code BGBC004), and
- Docetaxel chemotherapy (trial code BGBIL005), increasingly used in the second and later line setting.

Each of these drugs are currently used as a first- or second-line treatment option for NSCLC patients. Patients who relapse after receiving immunotherapy, targeted therapies or platinum-based chemotherapy in the first line, meaning the tumour has become treatment resistant, will often receive docetaxel chemotherapy in second or later line of treatment.

During 2018, BerGenBio has presented interim favourable results from each of these phase II trials in NSCLC; the data is very encouraging and in support of bemcentinib's proposed mode of action, in particular as these responses are correlated with proprietary biomarkers relevant to the pathway. Predictive biomarker candidates may in future be used to predict outcomes to treatment with bemcentinib.

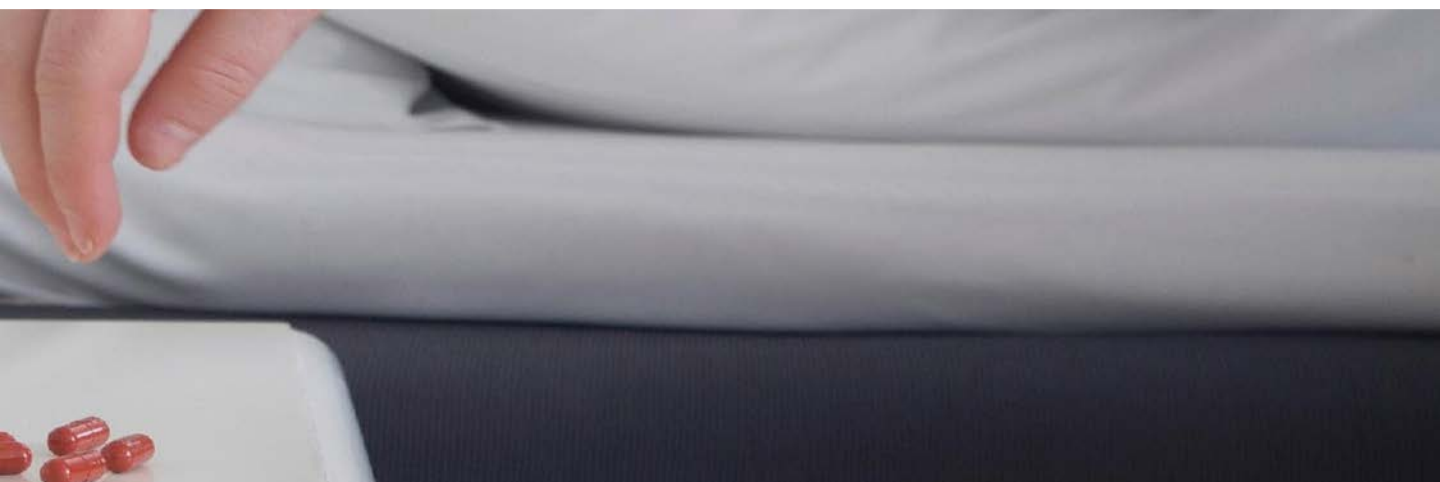
Supportive clinical and biomarker data were presented at the 19<sup>th</sup> Annual World Conference on Lung Cancer (WCLC) in September, the European Society for Medical Oncology meeting (ESMO) in October and the annual meeting of the Society for Immunotherapy of Cancer (SITC) in November.

***Bemcentinib + KEYTRUDA (BGBC008): First stage (of two) met efficacy endpoint - superior anti-tumour effect and progression-free survival (PFS) observed in AXL-positive patients – trial advances to second stage***

The BGBC008 study is investigating whether adding bemcentinib to KEYTRUDA in previously treated, PD-L1 unselected and immunotherapy naive patients with advanced NSCLC is well tolerated and improves patient outcomes. The study also assesses the combination in the subset of PD-L1 negative patients for whom KEYTRUDA monotherapy is not indicated.

The two-stage study will recruit a total of 48 patients; the first stage is fully enrolled (n=24 patients). The key results presented at WCLC are:





- Approximately half of the patients (10 of 21 evaluable for AXL expression) were AXL positive; the studied patient population was predominantly PD-L1 negative (11 of 20 evaluable for PD-L1) or weakly positive (7 of 20) for whom KEYTRUDA monotherapy has limited effect.
- 40% overall response rate (ORR) was reported in AXL-positive patients with a disease control rate (DCR) of 70%
- Median progression-free-survival (PFS) was 5.9 months in AXL-positive patients, compared to 3.3 months in AXL-negative patients
- Treatment with the bemcentinib/KEYTRUDA combination was well tolerated

The clinical efficacy endpoint\* was met in the first stage and this triggered the start of the second stage of the trial and BerGenBio announced that the first patient had been dosed in this stage in October.

The second stage will enrol 24 patients in total at sites in Norway, Spain, UK and the US, and aims to confirm the safety and clinical efficacy of the combination seen in the first part. Comprehensive exploratory studies will continue to evaluate biomarkers in tumour and blood indicative of AXL expression and immune modulation. Preliminary results from stage two of the trial are expected during 1H 2019.

***Bemcentinib + TARCEVA (BGBC004): Median PFS rate in first-line combination therapy has surpassed that of TARCEVA monotherapy – patient recruitment complete***

TARCEVA is indicated for NSCLC that is driven by a mutation in the EGFR gene, the most common mutation in NSCLC.

Although response rates to TARCEVA are high initially, nearly all patients develop resistance over time. The BGBC004 study is designed to test if adding bemcentinib to TARCEVA in first- or second-line EGFR mutation-driven NSCLC may prevent or reverse acquired resistance to TARCEVA, respectively.

Patient recruitment into BGBC004 is complete; updated results from all arms of the study were presented at WCLC:

- Arms A and B have previously met their objectives in demonstrating safety of the combination and ability to reverse resistance in a subset of patients, respectively. Arm B met its first primary endpoint, with tumour shrinkage and objective response observed in patients who had progressed on first generation EGFR inhibitors but who were negative for the T790M resistance mutation and thus not eligible for any approved targeted therapy (ORR of 20% and a DCR of 40% including 1 PR and 1 SD out of five T790M negative patients).

\* defined as at least four patients achieving clinical responses (complete response – CR, or partial response – PR as measured by RECIST – Response Evaluation Criteria in Solid Tumors) in the first 22 patients

- Arm C is designed to evaluate the ability of bemcentinib to prevent acquired resistance to TARCEVA and improve outcomes in patients who had been responding/stable to first-line TARCEVA therapy for at least 12 weeks. Arm C reported additional tumour shrinkage when adding bemcentinib to TARCEVA in 6 of 9 patients (67%). Importantly, median progression-free survival (PFS), while not mature, had already surpassed median PFS of ca. 10 months for TARCEVA monotherapy given as a first-line treatment, suggesting an enhanced clinical response through the addition of bemcentinib to treatment.
- Importantly, a predictive soluble biomarker candidate was identified across all three arms common to all patients who showed clinical benefit from bemcentinib treatment.

Preliminary results from the fully recruited BGB004 trial are expected in 1H 2019.

### ***Bemcentinib + docetaxel chemotherapy (BGBIL005): Superior response rates to docetaxel chemotherapy in NSCLC patients who have exhausted all treatment options***

Docetaxel is emerging as a key second- and third-line option in patients progressing on approved therapy regimens containing immune-, targeted and / or platinum-containing chemotherapy. Around 10% of patients show responses to docetaxel single-agent chemotherapy with a median PFS of 3-4 months commonly reported. The investigator-sponsored study BGBIL005 is designed to evaluate if combining bemcentinib with docetaxel chemotherapy is safe and can improve outcomes in up to 30 NSCLC patients who have failed up to three lines of therapy.

Patient recruitment into the study is progressing and, in September, an update of clinical findings from 11 patients evaluated was presented at WCLC. The results so far show that the bemcentinib/docetaxel combination was generally well tolerated, with 2 PRs (18%) and 6 SDs (55%) reported. Most patients had received and progressed on or after at least one prior immunotherapy regimen.

## **Pipeline Update**

### ***Investigator-sponsored trials: exploring the broader opportunity for bemcentinib based on the universal role of AXL in aggressive cancers***

BerGenBio continues to expand its broad bemcentinib clinical development programme by supporting Investigator Sponsored Trials with scientific and regulatory input, provision of bemcentinib and often a biomarker research programme. World-leading cancer research physicians are investigating patient treatment with bemcentinib in several indications where there is strong scientific evidence that increased AXL expression is driving the disease. The company has announced several of these studies as having begun and where appropriate, presented preliminary results.

New studies are also beginning or being prepared to start with an overall objective to assess, in a cost-effective and efficient way, the potential benefit bemcentinib could bring across multiple cancer indications with high unmet need and to identify indications for future label extension.

At the European Society for Medical Oncology (ESMO) annual congress in October, results were presented from an investigator-sponsored phase Ib/II trial designed to explore whether bemcentinib added to standard of care therapies improves overall response rates in patients with metastatic melanoma (BGBIL006).

The results demonstrated that bemcentinib in combination with the targeted therapies dabrafenib/trametinib or the immunotherapy pembrolizumab (KEYTRUDA) were well tolerated in patients with no increase in toxicity compared to either therapeutic approach alone. Biomarker candidates predicting treatment benefit were also explored. Further investigation of safety and efficacy as well as biomarkers is ongoing.

Two new investigator-sponsored trials in mesothelioma and pancreatic cancer, respectively are being planned and further details are available on [clinicaltrials.gov](https://www.clinicaltrials.gov): <https://www.clinicaltrials.gov/ct2/results?term=bg324>. Updates on investigator-sponsored trials will be made as they are initiated and when data is presented at conferences.

**First in human trials with BGB149, a potentially first in class anti-AXL antibody, on track to begin in Q4 2018**

BerGenBio continues the development of BGB149, an anti-AXL antibody, anticipating first clinical trials during 2018. BGB149 shows high affinity and selectivity for AXL and a strong inhibitory effect, and presents an opportunity to address additional and different medical conditions.

**Tissue- and blood-based biomarkers show promise for development as companion diagnostics**

In parallel with its clinical trials, BerGenBio continues to investigate biomarkers that are predictive of a clinical response to bemcentinib, for development as companion diagnostics. Such diagnostics could allow patient selection for future clinical trials and ultimately support the registration process for bemcentinib.

The company presented a review of its biomarker studies across its clinical development programme at ESMO in October and SITC in November. The key findings are:

- A standardised AXL immunohistochemistry (IHC) assay, carried out on a tumour biopsy, has reported strong correlation with patient response to bemcentinib + pembrolizumab (KEYTRUDA) treatment. IHC is the most common method for tumour diagnosis and classification.
- Blood-based biomarkers continue to show correlation with patient response to bemcentinib treatment with particularly encouraging results in relapsed or refractory (R/R) AML and MDS. This state-of-the-art technique is expected to be more convenient, minimally invasive, less expensive than biopsy-based diagnoses and suitable for primary care diagnosis.

*Note that all phase II trials are ongoing and results discussed are preliminary and subject to change as the trials progress to completion. Updated data will be presented at future clinical congresses.*



## **Corporate update: Arbitration with Rigel Pharmaceuticals, Inc.**

In September, BerGenBio served Notice of Arbitration to Rigel pursuant to a License Agreement for bemcentinib made and entered into as of 29 June 2011. The arbitration aims to resolve a dispute between the companies with respect to the interpretation and application of certain provisions of the Agreement, particularly as they relate to the rights and obligations of the parties in the event of the licensing or sale of bemcentinib by BerGenBio.

## **Risks and uncertainties**

The Company 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 Company, 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.

BerGenBio has no interest-bearing debt. Financial risk is primarily related to fluctuations in interest rates on bank deposits which are placed in various banks.

BerGenBio undertakes various transactions in foreign currencies and is consequently exposed to fluctuations in exchange rates. The exposure arises largely from research expenses in USD, EUR and GBP.

BerGenBio's credit risk is limited, primarily associated with receivables from governmental grants.

Cash flow is monitored closely from both long and short-term perspectives through planning and reporting.

Management will continue to focus on efficient operations, good planning and close monitoring of the liquidity situation and maintaining a clear business development strategy.



# FINANCIAL REVIEW

(Figures in brackets = same period 2017 unless stated otherwise)

## Financial Results

Total operating expenses for the third quarter and the nine months ending 30 September 2018, respectively, amounted to NOK 38.1 million (NOK 36.6 million) and NOK 143.6 million (NOK 136.2 million). Employee expenses were NOK 9.3 million (NOK 6.3 million) for the quarter and NOK 31.3 million (NOK 18.5 million) for the nine months ending September 2018. The increase mainly due to increase in staff and increase in provisions for social security tax on employee options as a result of increase of the share price.

Other operating expenses amounted to NOK 28.8 million (NOK 30.2 million) for the quarter. For the first nine months other operating expenses amounted to NOK 112.2 million (117.5 million). A significant element of the operating expenses in the first nine months ending September 2017 related to a phase II milestone payment to Rigel Pharmaceuticals Inc., amounting to NOK 27.8 million. Furthermore, the third quarter of 2018 decrease in other operating expenses is mainly caused by the NSCLC study in combination with Keytruda met its clinical efficacy endpoint in Q2, the study had a cool down period in Q3 and prepared to enter second stage in Q4.

The operating loss for the quarter came to NOK 38.1 million (NOK 36.6 million) and NOK 143.6 million (NOK 136.2 million) for the first nine months of the year, reflecting the level of research and development activities described above.

Net financial items were NOK 0.5 million (NOK 1.1 million) for the third quarter and NOK 3.0 million (1.6 million) for the first nine months of the year.

Losses after tax for the third quarter were NOK 37.7 million (NOK 35.4 million) and NOK 140.7 million (NOK 134.6 million) for the first nine months of the year.

## Financial Position

Total assets at 30 September 2018 increased to NOK 420.0 million (NOK 384.3 million at year-end 2017), mainly due to the capital raise from the private placement completed in April 2018.

Total liabilities were NOK 32.8 million (NOK 34.0 million at year-end 2017).

Total equity as of 30 September 2018 was NOK 387.7 million (NOK 350.4 million at year-end 2017), corresponding to an equity ratio of 92.2% (91.2%).

In April 2018, BerGenBio raised NOK 187.5 million through a private placement. BerGenBio is in a good financial position.

## Cash Flow

Net cash flow from operating activities was negative by NOK 149.1 million for the first nine months of the year (NOK 137.9 million), mainly driven by the ongoing development and research activities.

Net cash flow used in investing activities during the first nine months of the year was NOK 0.1 million (NOK 0.2 million).

Net cash flow from financing activities was NOK 177.0 million (NOK 375.2 million), reflecting the share issue in April 2018 in relation to the private placement and fund raise of gross NOK 187.5 million. In the first nine months of 2017 the Company completed a successful IPO and fund raised a gross NOK 400 million.

Cash and cash equivalents increased to NOK 398.2 million (NOK 370.4 million at year-end 2017).



The board today considered and approved the condensed, consolidated financial statement of the nine months ending September 30, 2018 for BerGenBio.

**Bergen 12 November 2018**  
**Board of Directors and CEO of BerGenBio ASA**

Stein H. Annexstad, Chairman

Susan Foden

Sveinung Hole

Jon Øyvind Eriksen

Hilde Furberg

Kari Grønås

Stener Kvinnsland

Richard Godfrey, CEO

## Condensed consolidated statement of profit and loss and other comprehensive income

(NOK 1000) Unaudited	Note	Q3 2018	Q3 2017	YTD 2018	YTD 2017	Full year 2017
<b>Revenue</b>		0	0	0	0	0
<b>Expenses</b>						
Employee benefit expenses	3	9,285	6,336	31,257	18,525	28 827
Depreciation		59	51	167	152	193
Other operating expenses	6	28,773	30,174	112,206	117,519	154 686
<b>Total operating expenses</b>		<b>38,116</b>	<b>36,561</b>	<b>143,630</b>	<b>136,197</b>	<b>183 707</b>
<b>Operating profit</b>		<b>-38,116</b>	<b>-36,561</b>	<b>-143,630</b>	<b>-136,197</b>	<b>-183 707</b>
Finance income		974	1,596	3,642	3,256	4 168
Finance expense		513	461	685	1,634	2 668
<b>Financial items, net</b>		<b>461</b>	<b>1,135</b>	<b>2,956</b>	<b>1,622</b>	<b>1 500</b>
<b>Profit before tax</b>		<b>-37,656</b>	<b>-35,426</b>	<b>-140,673</b>	<b>-134,574</b>	<b>-182 207</b>
Income tax expense		-	0	-	0	0
<b>Profit after tax</b>		<b>-37,656</b>	<b>-35,426</b>	<b>-140,673</b>	<b>-134,574</b>	<b>-182,207</b>
<b>Other comprehensive income</b>						
<i>Items which will not be reclassified over profit and loss</i>						
Actuarial gains and losses on defined benefit pension plans		-	0	-	0	0
<b>Total comprehensive income for the period</b>		<b>-37,656</b>	<b>-35,426</b>	<b>-140,673</b>	<b>-134,574</b>	<b>-182 207</b>
<b>Earnings per share:</b>						
<b>- Basic and diluted per share</b>	7	-0.69	-0.71	-2.66	-3.06	-4.01





## Condensed consolidated statement of financial position

(NOK 1000) Unaudited	Note	30 SEP 2018	30 SEP 2017	31 DEC 2017
<b>ASSETS</b>				
<b>Non-current assets</b>				
Property, plant and equipment		460	416	557
<b>Total non-current assets</b>		<b>460</b>	<b>416</b>	<b>557</b>
<b>Current assets</b>				
Other current assets	5, 8	21,868	18,466	13,430
Cash and cash equivalents		398,166	399,152	370,350
<b>Total current assets</b>		<b>420,034</b>	<b>417,618</b>	<b>383,780</b>
<b>TOTAL ASSETS</b>		<b>420,494</b>	<b>418,034</b>	<b>384,336</b>
<b>EQUITY AND LIABILITIES</b>				
<b>Equity</b>				
<b>Paid in capital</b>				
Share capital	9	5,471	4,976	4,992
Share premium	9	360,865	371,063	325,018
Other paid in capital	4, 9	21,396	20,237	20,340
<b>Total paid in capital</b>		<b>387,731</b>	<b>396,276</b>	<b>350,350</b>
<b>Total equity</b>		<b>387,731</b>	<b>396,276</b>	<b>350,350</b>
<b>Non-current liabilities</b>				
Pension liability	10	0	0	0
<b>Total non-current liabilities</b>		<b>0</b>	<b>0</b>	<b>0</b>
<b>Current liabilities</b>				
Accounts payable		9,373	13,751	21,575
Other current liabilities		15,195	4,917	9,391
Provisions		8,194	3,091	3,020
<b>Total current liabilities</b>		<b>32,762</b>	<b>21,759</b>	<b>33,986</b>
<b>Total liabilities</b>		<b>32,762</b>	<b>21,759</b>	<b>33,986</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>420,494</b>	<b>418,034</b>	<b>384,336</b>

## Condensed consolidated statement of changes in equity

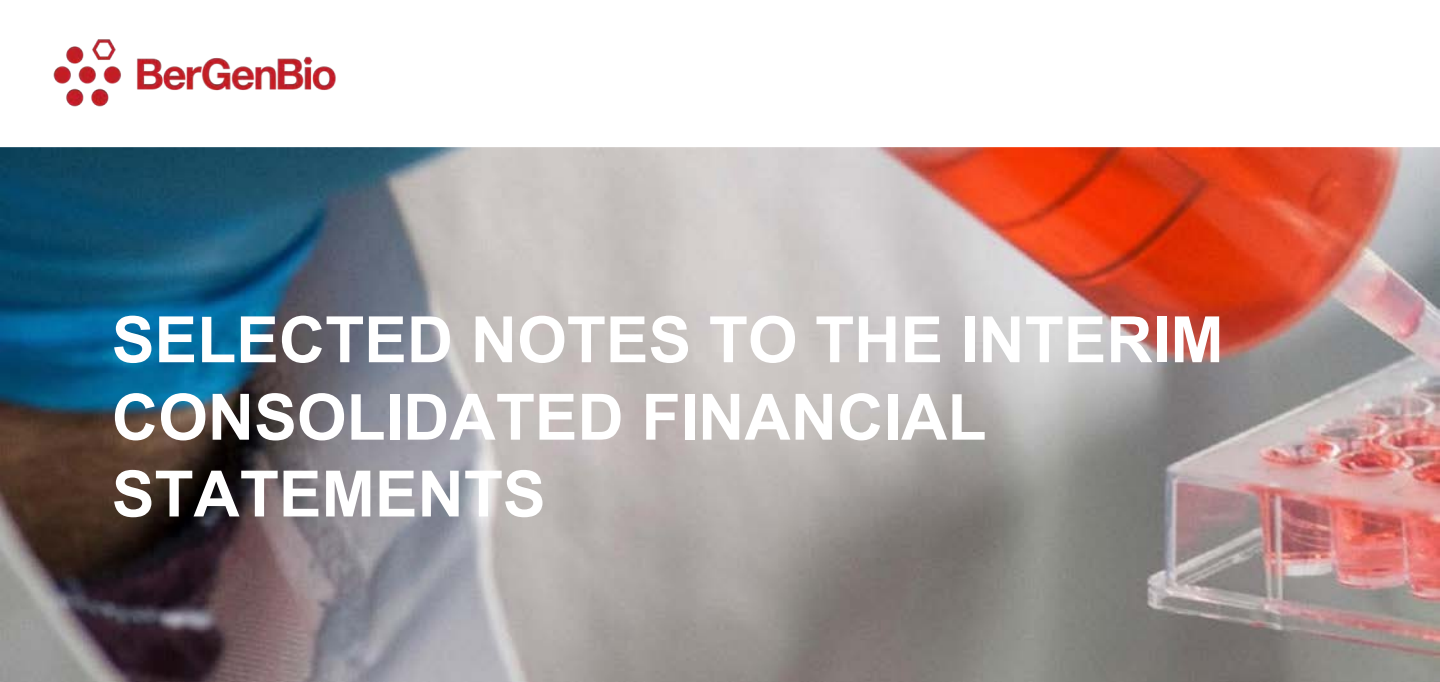
(NOK 1000) Unaudited	Note	Share capital	Share premium	Other paid in capital	Total equity
<b>Balance at 1 January 2018</b>		<b>4 992</b>	<b>325 018</b>	<b>20 340</b>	<b>350 350</b>
Loss for the period			-140 673	-	-140 673
Other comprehensive income (loss) for the period, net of income tax		-	-	-	-
<b>Total comprehensive income for the period</b>		<b>-</b>	<b>-140 673</b>	<b>-</b>	<b>-140 673</b>
Recognition of share-based payments	3, 4			1 056	1 056
Issue of ordinary shares	9	479	190,047		190,525
Paid in, not registered capital raise	9				-
Share issue costs			-13 527		-13 527
<b>Balance at 30 September 2018</b>		<b>5 471</b>	<b>360 865</b>	<b>21 396</b>	<b>387 731</b>

(NOK 1000) Unaudited	Note	Share capital	Share premium	Other paid in capital	Total equity
<b>Balance at 1 January 2017</b>		<b>3 369</b>	<b>131 875</b>	<b>18 026</b>	<b>153 270</b>
Loss for the period		-	-134 574	-	-134 574
Other comprehensive income (loss) for the period, net of income tax		-	-	-	-
<b>Total comprehensive income for the period</b>		<b>-</b>	<b>-134 574</b>	<b>-</b>	<b>-134 574</b>
Recognition of share-based payments	3, 4	-	-	2 212	2 212
Issue of ordinary shares	9	1 607	399 084	-	400 691
Paid in, not registered capital raise	9	-	-		-
Share issue costs		-	-25 322	-	-25 322
<b>Balance at 30 September 2017</b>		<b>4 976</b>	<b>371 063</b>	<b>20 237</b>	<b>396 276</b>



## Condensed consolidated statement of cash flow

(NOK 1000) Unaudited	Note	YTD 2018	YTD 2017
<b>Cash flow from operating activities</b>			
Loss before tax		-140,673	-134,574
Non-cash adjustments to reconcile loss before tax to net cash flows			
Depreciation of property, plant and equipment		167	152
Calculated interest element on convertible loan		0	0
Share-based payment expense	3, 4	1,056	2,212
Movement in provisions and pensions		5,174	-1,752
Working capital adjustments:			
Decrease in trade and other receivables and prepayments		-8,438	-6,164
Increase in trade and other payables		-6,398	2,245
<b>Net cash flow from operating activities</b>		<b>-149,112</b>	<b>-137,882</b>
Cash flows from investing activities			
Purchase of property, plant and equipment		-70	-159
<b>Net cash flow used in investing activities</b>		<b>-70</b>	<b>-159</b>
Cash flows from financing activities			
Proceeds from issue of share capital	9	176,998	375,368
Paid in, not registered capital increase	9	0	
<b>Net cash flow from financing activities</b>		<b>176,998</b>	<b>375,368</b>
Net increase/(decrease) in cash and cash equivalents		27,817	237,328
Cash and cash equivalents at beginning of period		370,350	161,825
<b>Cash and cash equivalents at end of period</b>		<b>398,166</b>	<b>399,152</b>



# 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 three-months period ended 30 September 2018 and were approved for issue by the Board of Directors on 12 November 2018.

## Note 2. Basis for preparation and significant accounting policies

### Basis for preparation and significant accounting policies

The interim condensed consolidated financial statements for the Group have been prepared in accordance with IAS 34 Interim Financial Reporting, as adopted by the EU.

The interim condensed consolidated financial statements do not include all the information and disclosures required in the annual financial statements and should be read in conjunction with BerGenBio’s annual financial statements as at 31 December 2017

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 2017, except for the adoption of new standards and interpretations effective as of 1 January 2018. The accounting policies are also consistent with those followed in preparation of Q1 and Q2 2018.

The new and amended standards and interpretations from IFRS that were adopted by the EU with effect from 2018 did not have any significant impact on the reporting for 2018.

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

### Basis for consolidation

The consolidated financial statements comprise the financial statements of the Company and its subsidiary as at 30 September 2018. 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 is 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 funding when this is appropriate and when conditions in these markets are acceptable. A private placement and capital increase of gross NOK 187 million was successfully completed in April 2018, 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	
	2018	2017
Salaries	20 282	17 004
Social security tax	2 764	1 616
Pension expense	1 549	1 292
Bonus		
Share option expense employees	1 056	2 212
Accrued social security tax on share options	5 174	-1 752
Other remuneration	1 461	295
Government grants 1)	-1 031	-2 142
<b>Total payroll and related expenses</b>	<b>31 257</b>	<b>18 525</b>
Average number of full time equivalent employees	24	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	50,000	10-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	May 2018	May 2026	46.70
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	May 2018	May 2026	46.70
Anthony Brown	100,000	2-Sep-15	2-Sep-23	16.01
	50,000	1-Jan-16	1-Jan-24	24.00
	26,499	May 2018	May 2026	46.70
Murray Yule	100,000	3-Sep-13	3-Sep-21	10.62
	50,000	1-Jan-16	1-Jan-24	24.00
	40,797	May 2018	May 2026	46.70
Rune Skeie	24,090	May 2018	May 2026	46.70
Susan Foden	100,000	18-Jun-12	18-Jun-20	10.62
	55,000	3-Sep-13	3-Sep-21	10.62
	25,000	20-Jun-13	20-Jun-21	10.62
	50,000	19-Jun-14	19-Jun-22	11.15
	37,500	1-Feb-16	1-Feb-24	24.00
Hilde Furberg	25,000	1-Feb-16	1-Feb-24	24.00
Kari Grønås	15,000	1-Feb-16	1-Feb-24	24.00
	<b>2,477,077</b>			

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 share option scheme for employees. Each option gives the right to acquire one share in BerGenBio on 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.

Primarily 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	June 2012	Dec 2017/2019	10.62
Granted in June 2012	225,000	June 2012	June 2020	10.62
Granted in June 2013	360,000	June 2013	June 2021	10.62
Granted in September 2013	400,000	Sep 2013	Sep 2021	10.62
Granted in June 2014	280,000	June 2014	June 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 2018	385,027		May 2026	46.70
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
<b>Total</b>	<b>3,150,027</b>			

*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			
	2018		2017	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Balance at 1 January	2,925,000	14.20	3,325,000	13.66
Granted during the period	385 027	46.70	-	-
Exercised during the period	-160 000	19.01	-65 000	10.62
Forfeited and cancelled			-170 000	14.29
<b>Balance at 30 September</b>	<b>3,150,027</b>	<b>17.93</b>	<b>3,090,000</b>	<b>13.69</b>

There were no options granted in the period in 2017. There were granted 385 027 options in the period in 2018.

Vested options	For the nine months ended 30 September	
	2018	2017
	Balance at 1 January	2,891,667
Granted during the period	-160,000	-
Exercised during the period	-	839 300
<b>Options vested at 30 September</b>	<b>2,731,667</b>	<b>3,051,200</b>
Total outstanding number of options	3,150,027	3,090,000

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 meeting milestones and is thus dependent on a performance 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 Group and experience from other companies in combination with the relatively long lifetime of these options (up to 8 years).

For valuation purposes 70% 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 month period ending 30 September 2018 the value of the share options expensed through the profit or loss amounts to NOK 1.0 million (for the same period in 2017: NOK 2.2 million). In addition a provision for social security contributions on share options of NOK 5.2 million (for the same period in 2017: NOK -1,8 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 nine months ended 30 September	
	2018	2017
Payroll and related expenses	1 031	2 142
Other operating expenses	14 890	7 572
<b>Total</b>	<b>15 921</b>	<b>9 714</b>

Grants receivable as at 30 September are detailed as follows:

	For the nine months ended 30 September	
	2018	2017
Grants from Research Council, BIA	574	73
Grants from Research Council, PhD		282
Grants from Innovasjon Norge	5 400	
Grants from SkatteFunn	12 311	13 581
<b>Total</b>	<b>18 286</b>	<b>13 936</b>

### BIA grants from the Research Council of Norway:

The Company currently has two grants from the Research Council, programs for user-managed innovation arena (BIA). The first BIA grant ("Novel therapeutics targeting the EMT/AXL pathway in aggressive cancers") totals to NOK 13.2 million and covers the period from May 2014 to April 2017. The Group has recognised NOK 0.0 million (2017: NOK 1.0 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses. The second BIA grant ("AXL targeting therapeutics to treat fibrotic diseases") totals to NOK 12.0 million and covers the period from April 2016 to March 2019. The Group has recognised NOK 2.2 million in Q3 2018 (Q3 2017: NOK 1.8 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses. The third 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 Q3 2018 (Q3 2017: NOK 0.0 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses.

### PhD grants from the Research Council of Norway:

BerGenBio has been awarded four grants supporting Industrial PhDs for the period from September 2010 through July 2017. The fellowship covers 50 % of the established current rates for doctoral research fellowships and an operating grant to cover up to 50 % of additional costs related to costly laboratory testing connected with the research fellow's doctoral work.

The Group has recognised NOK 0.0 million in Q1 2018 (Q2 2017: NOK 0.4 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 2016 until the end of 2017. The Group has also been approved for SkatteFunn from 2018 to 2019. The Group has recognised NOK 5.4 million YTD in Q3 2018 (YTD Q3 2017: NOK 5.9 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. The grant may be withdrawn under certain circumstances. The Group has recognised NOK 5.4 million in Q3 2018 (Q3 2017: NOK 0.0 million) classified as cost reduction of other operating expenses.

## Note 6. Other operating expenses

	For the nine months ended 30 September	
	2018	2017
Program expenses, clinical trials and research	95 870	67 948
Milestone and license payments to Rigel Pharmaceuticals	0	27 921
Office rent and expenses	1 575	1 299
Consultants R&D projects	6 809	9 357
Patent and licence expenses	2 277	3 892
Other operating expenses	20 564	14 675
Government grants	-14 890	-7 572
<b>Total</b>	<b>112 206</b>	<b>117 519</b>

## Note 7. Earnings per share

	For the nine months ended 30 September	
	2018	2017
Loss for the period (NOK 1,000)	-140,673	-134,574
Average number of outstanding shares during the year	52,803,652	44,048,006
<b>Earnings (loss) per share - basic and diluted (NOK)</b>	<b>-2.66</b>	<b>-3.06</b>

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 2018	30 Sep 2017
Government grants	18 286	13 936
Refundable VAT	552	1 897
Prepaid expenses	606	605
Other receivables	2 424	2 028
<b>Total</b>	<b>21 868</b>	<b>18 466</b>

## Note 9. Share capital and shareholder information

The Group has one class of shares and all shares carry equal voting rights.

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

As of 30 September	Number of shares	Nominal value (NOK)	Book value (NOK)
Ordinary shares 2018	54,711,446	0.10	5,471,144.60
Ordinary shares 2017	49,757,200	0.10	4,975,720.00

### Changes in the outstanding number of shares

	For the nine months ended 30 September	
	2018	2017
Ordinary shares at 1 January	49,922,200	336,922
Issue of ordinary shares, prior to share split		500
Effect of share split (1 to 100) 22 March 2017		33,404,778
Issue of ordinary shares	4,789,246	16,015,000
<b>Ordinary shares at 30 September</b>	<b>54,711,446</b>	<b>49,757,200</b>

## Ownership structure 30 09 2018

Shareholder	Number of shares	Percentage share of total shares	
METEVA AS	14,923,000	27.3%	
INVESTINOR AS	6,609,800	12.1%	
SARSIA SEED AS	2,117,900	3.9%	
VERDIPAPIRFONDET ALFRED BERG GAMBA	1,757,942	3.2%	
DATUM INVEST AS	1,485,467	2.7%	
EUROCLEAR BANK S.A./N.V.	NOM	1,307,305	2.4%
SARSIA DEVELOPMENT AS	1,175,000	2.1%	
VPF NORDEA KAPITAL	1,143,187	2.1%	
VPF NORDEA AVKASTNING	1,125,902	2.1%	
KLP AKSJENORGE	1,119,368	2.0%	
MP PENSJON PK	1,117,455	2.0%	
BERA AS	1,084,800	2.0%	
NORSK INNOVASJONSKAPITAL II AS	856,170	1.6%	
KOMMUNAL LANDSPENSJONSKASSE	819,579	1.5%	
VERDIPAPIRFONDET ALFRED BERG NORGE	801,556	1.5%	
JPMORGAN CHASE BANK, N.A., LONDON	NOM	680,000	1.2%
NORRON SICAV - TARGET	575,000	1.1%	
VERDIPAPIRFONDET ALFRED BERG AKTIV	574,391	1.0%	
NORDA ASA	536,281	1.0%	
VERDIPAPIRFONDET DELPHI NORGE	475,714	0.9%	
<b>Top 20 shareholders</b>	<b>40,285,817</b>	<b>73.6%</b>	
Total other shareholders	14,425,629	26.4%	
<b>Total number of shares</b>	<b>54,711,446</b>	<b>100.0%</b>	

The Board of Directors have been granted a mandate from the general meeting held on 14 May 2018 to increase the share capital with up to NOK 547,114 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 2019 and 30 June 2019.

The Board of Directors have been granted a mandate from the general meeting held on 9 March 2018 to increase the share capital with up to NOK 499,222 by subscription of new shares. In April 2018 there was issued 4,629,246 new shares under this proxy at a nominal value of 462,924.60.

**Shares in the Group held by the management group**

	Position	Employed since	30 Sep 2018	30 Sep 2017
Richard Godfrey 1)	Chief Executive Officer	January 2009	160 408	160 408
James Bradley Lorens	Chief Scientific Officer	January 2009	250 000	250 000
<b>Total shares held by management</b>			<b>410 408</b>	<b>410 408</b>

1) Richard Godfrey holds 160,408 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 2018	30 Sep 2017
Stein H. Annexstad 1)	Chairman	February 2016	7 539	7539
Susan Elizabeth Foden	Board Member	September 2011	6 700	6 700
Hilde Furberg 2)	Board Member	June 2015	3 769	3769
Kari Grønås 3)	Board Member	February 2016	4 522	4522
<b>Total shares held by members of the Board of Directors</b>			<b>22 530</b>	<b>22 530</b>

1) Stein H. Annexstad holds 7,539 shares in the Company through Holstein AS, a closely associated company of Stein H. Annexstad.

2) Hilde Furberg holds 3,769 shares in the Company through J&J Future Invest AS, a closely associated company of Hilde Furberg.

3) Kari Grønås holds 4,522 shares in the Company through K og K AS, a closely associated company of Kari Grønås.

**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, binding to the antigen so that the antigen molecule can be recognized and destroyed.
API	Active pharmaceutical ingredient.
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 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). These 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.





CML	Chronic myelogenous leukaemia.
CMOs	Contract manufacturing organisations.
Comorbidity	The presence of one or more additional disorders (or diseases) co-occurring with a primary disease or disorder.
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.
Epithelial tumour cell	Tumour cells in an epithelial state.
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.
IPF	Idiopathic Pulmonary Fibrosis
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.
NASH	Nonalcoholic Steatohepatitis
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 <sup>-9</sup> 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
TNBC	Triple negative breast cancer.
WCLC	World Conference on Lung Cancer

## **Disclaimer**

This Report contains certain forward-looking statements relating to the business, financial performance and/or results of the Company and/or the industry in which it operates. Forward-looking statements concern future circumstances and results and other statements that are not historical facts, sometimes identified by the words “believes”, “expects”, “predicts”, “intends”, “projects”, “plans”, “estimates”, “aims”, “foresees”, “anticipates”, “targets”, and similar expressions. The forward-looking statements contained in this Report, including assumptions, opinions and views of the Company or cited from other sources are solely opinions and forecasts which are subject to risks, uncertainties and other factors that may cause actual events to differ materially from any anticipated development. None of the Company or any of their parent or subsidiary undertakings or any such person’s officers or employees provides any assurance that the assumptions underlying such forward-looking statements are free from errors nor do any of them accept any responsibility for the future accuracy of the opinions expressed in this Presentation or the actual occurrence of the forecasted developments. The Company assumes no obligation, except as required by law, to update any forward-looking statements or to conform these forward-looking statements to our actual results.

## **Contact us**

### **BerGenBio ASA**

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