

**BerGenBio** 

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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. BerGenBio is based in Bergen, Norway with a subsidiary in Oxford, UK



# **Chairman's statement**

# **Dear Shareholders**

BerGenBio delivered on important scientific objectives in 2018. Published results from clinical trials have confirmed the mode of action and provided clinical proof-of-concept for our AXL targeting approach with the main product candidate bemcentinib.

The proof applies to multiple cancers. It is still early days, but two therapeutic areas of particular interest have emerged. In lung cancer (NSCLC), the largest cancer killer worldwide, the standard of care has been evolving rapidly, but while results are improving, treatments are still suboptimal. We see a strong rationale for combination therapy with bemcentinib as a cornerstone, and clinical results generated in 2018 from a trial evaluating the combination of bemcentinib and KEYTRUDA, the market-leading checkpoint inhibitor, are compelling.

Leukaemia (AML and MDS) is a rarer disease and is very hard to treat in elderly patients, who are in great need of new therapeutic options. Our trials with bemcentinib as a monotherapy have shown promising efficacy.

Clinical trials in both areas are expected to complete in 2019. We anticipate that the mature data sets from these trials will both further validate the clinical basis of and support the commercial future for bemcentinib in these therapeutic areas. The company's focus in 2019 therefore will be to advance bemcentinib into the next phase of clinical development – randomised Phase II trials – in NSCLC and AML/MDS.

To support the multiple activities underway and planned at BerGenBio, we are building a team with first-class competence and experience in the required disciplines to ensure we make qualified strategic decisions and are able to execute these strategies to reach our goals. The process of building the team will continue in 2019.

These are the priorities for Board and Management and provide a solid starting point as we look forward to an exciting 2019.

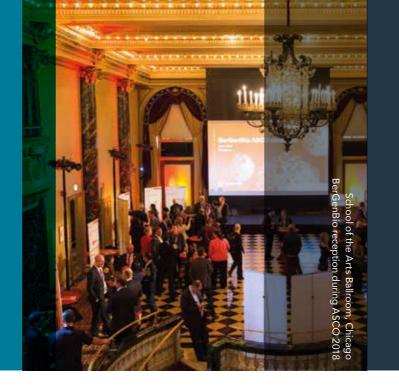
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**Stein Holst Annexstad**Chairman of the Board



# Highlights 2018

The year 2018 constituted a period of clinical trial execution and clinical read-outs for BerGenBio – delivering important initial clinical proof-of-concept for bemcentinib's efficacy and promise in aggressive, immune evasive and therapy resistant cancers



# **Our Vision**

BerGenBio (OSE:BGBIO) is a clinical stage

Lung cancer and leukaemia, two indications representing both high unmet medical need and large market potential, delivered particularly favourable signals for bemcentinib when given as a monotherapy or in combination with targeted, immuno- or chemotherapies

# Our year in review

# 09 January

BerGenBio meets first efficacy endpoint in Phase II trial with selective AXL inhibitor bemcentinib in NSCLC

# January

Bemcentinib is adopted by the WHO as official generic name for BerGenBio's oral selective AXL inhibitor, formerly known as BGB324

# 29 January

Encouraging clinical data with bemcentinib as a monotherapy (AML) and in combination with KEYTRUDA (NSCLC, melanoma) are presented at leading immunooncology congress ASCO-SITC 2018 in San Francisco, CA

# 19 February

BerGenBio completes recruitment into first stage of Phase II breast cancer trial with bemcentinib combined with KEYTRUDA

# 5 March

BerGenBio appoints Rune Skeie as Chief Financial Officer

# 10 April

BerGenBio completes recruitment into first stage of Phase II NSCLC trial with bemcentinib in combination with KEYTRUDA

# 13 April

BerGenBio announces successful NOK 187.5 million (USD 24 million) private placement of new shares - increasing geographical and sector diversity of investor base

# 13 April

Promising pre-clinical data supporting BerGenBio's pipeline to be published and presented at upcoming leading conferences including AACR 2018

# 3 June

BerGenBio provides interim update on all of its Phase II clinical trials with bemcentinib during **ASCO 2018** 

# 26 June

Selective AXL inhibitor bemcentinib meets prespecified efficacy endpoint in stage 1 of NSCLC Phase Il combination trial with KEYTRUDA

# 25 September

WCLC 2018: Updated Phase II clinical data with selective AXL inhibitor bemcentinib strengthens its potential to improve NSCLC patient

# 22 October

BerGenBio announces interim biomarker and Phase II clinical data with bemcentinib presented at **ESMO 2018** 

# 6 November

BerGenBio reports ~80% improvement in PFS of AXLpositive vs AXL-negative NSCLC patients in bemcentinib + KEYTRUDA Phase II combination trial at SITC 2018

# 21 November

BerGenBio appoints cancer drug development specialist Alan Barge MD as interim Chief Medical Officer

# 3 December

BerGenBio reports 43% response rate with bemcentinib monotherapy in AXL positive R/R AML/MDS patients at ASH 2018

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# **Key achievements**

BerGenBio started 2018 with a broad Phase II development programme and an objective to deliver clinical data to support the further development of bemcentinib. Key proof-of-concept clinical readouts have been provided over the year and confirm the company's focus on NSCLC & AML

Priority	Targeted Milestone	
Bemcentinib clinical progress	Clinical updates were presented at all major cancer congresses and indicate that bemcentinib efficacy correlates with presence of AXL biomarkers, supporting its proposed mode of action	<b>~</b>
	PoC clinical data confirms focus on NSCLC and AML	<b>V</b>
	Data generated paving the way to randomised trials (expected in H2 2019)	<b>~</b>
	Phase II development programme read-outs according to plan, further updates in H1 2019  • AML/MDS monotherapy: efficacy reported at ASCO, EHA and ASH  • NSCLC bemcentinib + KEYTRUDA: readouts at ASCO, WCLC and SITC  • NSCLC bemcentinib + TARCEVA: readouts at ASCO reception, WCLC  • NSCLC bemcentinib + docetaxel: readouts at ASCO reception, WCLC  • TNBC bemcentinib + KEYTRUDA: readout at ASCO reception  • Melanoma bemcentinib + KEYTRUDA / TAFINLAR+MEKINIST: readouts at ASCO and ESMO	> > > >
Companion diagnostics development	& glioblastoma planned or started  Research and identification of suitable biomarker candidates is on track, AXL on tissue as detected by IHC or in plasma (sAXL) as detected by liquid biopsy has been reported to correlate with patient benefit at ASCO, ESMO, SITC and ASH	<b>~</b>
BGB149 clinical	MoA and efficacy demonstrated in pre-clinical studies	<b>~</b>
progress	Robust, scalable manufacturing route established, drug product demonstrated to be stable over extended periods of time	~
	CTA to start clinical trials approved	<b>~</b>
	First-in-Man Phase I trial initiated	<b>~</b>



Priority	Targeted Milestone	
Organisational development	BerGenBio has continued to build out the organisation in preparation for the next phase of development and made key strategic, medical, clinical operational and regulatory hires	<b>~</b>
Financial management	A successful private placement completed in April diversified the investor base	<b>~</b>
	Disciplined management with cash runway until 2020	<b>~</b>

# **Key financial figures**

Increasing operating loss over the past years has been in line with increased R&D expenditure and progress of the clinical programmes with bemcentinib and BGB149 as well as growth of the organisation to support the expansion of the pipeline.





# **Chief Executive's statement**

Looking back on 2018, I can reflect on a tremendously successful year in which we have met all our operational milestones and made important progress establishing Phase II clinical proof-of-concept for our lead drug candidate bemcentinib, as well as advancing BGB149, a first-in-class, wholly owned, therapeutic AXL-antibody into the clinic.

During 2018, we were focussed on investigating bemcentinib, which is a novel once-a-day, oral administered, highly selective AXL inhibitor, in a broad Phase II clinical development programme, giving bemcentinib as a monotherapy and in combination with existing standard of care medicines, including immuno-, targeted and chemotherapies, to patients with several different cancers.

This clinical development strategy was designed to identify proof-of-concept efficacy signals to confirm that bemcentinib when administered alone or added to other therapies could increase tumour shrinkage and clinical benefit for patients, when compared to existing therapies.

In parallel, we also completed biomarker studies to measure AXL in the patient's tumour or blood and to correlate those findings with the clinical responses seen. During 2018, we have reported clear evidence that clinical efficacy correlates with AXL biomarker expression, as detected by our proprietary biomarker tests. This will be an important feature of our future clinical development and commercialisation strategy.

It is very encouraging to be able to continue to report that bemcentinib is very well tolerated by cancer patients, when taken as a monotherapy, and also when administered in combination with existing therapies.

The results reported in 2018 provide us with sufficient confidence to confirm our future focus for bemcentinib's forward clinical and regulatory development strategy in patients with non-small cell lung cancer (NSCLC) and acute myeloid leukaemia (AML).

All these data sets were presented at multiple leading international medical congresses during the year, and in some cases have been highlighted by key opinion leaders as data of significant interest.

In the NSCLC trial, we reported strong data that bemcentinib can improve the clinical response to KEYTRUDA (the leading immune checkpoint inhibitor marketed by Merck & Co. Inc.) in patients with no or very low PD-L1 expression – these patients are not expected to respond well or at all to KEYTRUDA alone. Patients whose tumours expressed AXL did particularly well compared to those lacking AXL. This is a very exciting finding, albeit in a small number of patients, that potentially opens a large patient population to treatment benefit with this combination. The observed efficacy triggered expansion of the study into a second stage, top line results of which will be reported in the first half of 2019.

In the AML trial, we were pleased to report that bemcentinib was active as a monotherapy and was very well tolerated in the predominantly elderly and frail patient population. Similarly, the clinical activity was correlated with AXL biomarker expression. We view this data as very encouraging and it forms the basis of a possible first registration path.

Meanwhile, our clinical development programme with bemcentinib in other aggressive cancers continues to advance and expand through collaborations with leading cancer research physicians around the world. We anticipate that data from these trials will provide new opportunities for bemcentinib in the future.

Furthermore, we maintained our development plan for BGB149, our wholly owned anti-AXL therapeutic antibody, and initiated the first human clinical trial at the end of 2018. This strengthens our leadership position in AXL targeting therapeutics, and we see clear and distinct strategic opportunities for this drug candidate. We look forward to reporting progress and data from this study as it advances.

Looking more broadly at the role of AXL in aggressive diseases other than cancer, we reported on very interesting preclinical data that highlight the potential of an anti-AXL approach in fibrosis and liver diseases, such as non-alcoholic steato-hepatitis (NASH) and idiopathic pulmonary fibrosis (IPF). While staying focussed on executing our oncology clinical trials with bemcentinib, we intend to monitor this research closely with a view to secure additional opportunities to capitalise on our expertise in AXL inhibition in the context of aggressive disease.

Having met all our operational milestones in 2018 and delivered promising data in NSCLC and AML that have informed and focused our near term strategy, our outlook for 2019 is very exciting.

We look forward to beginning our late stage clinical trial programme and to continue growing the company so that we are well-positioned to maximise and capture the value we generate.

I would like to thank all employees at BerGenBio and our collaborators worldwide, for their outstanding efforts and commitment, and our shareholders for their support.

We look forward to an exciting year ahead.

Richard Godfrey

CEC



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Having met all our operational milestones in 2018 and delivered promising data in NSCLC and AML that have informed and focused our near term strategy, our outlook for 2019 is very exciting





**Lung Cancer:** 

40%

response rate reported in previously treated NSCLC in combination with KEYTRUDA



Clinical portfolio of first-inclass AXL therapeutics

Leaders in developing selective AXL inhibitors

Two clinical assets: bemcentinib (Phase 2), AXL-antibody BGB149 (Phase 1)

AXL is a novel oncology target to overcome immune evasion, therapy resistance & spread

Pipeline opportunities in multiple cancers and fibrosis



Phase 2 data in NSCLC & AML with selective AXL inhibitor bemcentinib

Monotherapy and combinations with immuno-, targeted and chemotherapies

Biomarker correlation across programme, parallel CDx development

AXL positive patients: 40% ORR in 2L NSCLC (KEYTRUDA combo) 43% ORR in R/R AML/MDS (monotherapy)

Randomised, late stage trial programme expected to start in H2 2019



Resourced to deliver significant milestones

Clinical trial collaborations with Merck and leading academic centres

AXL ADC outlicensed to ADC Therapeutics SA

38 staff at two locations: HQ & R&D in Bergen, Norway; Clinical Development in Oxford, UK

Cash to milestones: Phase 2 bemcentinib, Phase 1 BGB149

Bemcentinib's clinical development is focussed on lung cancer and leukaemia with randomised, late stage trials planned to start in 2019. Internal clinical development is supported by a broad Investigator-Initiated-Trial (IIT) programme.

BGB149, a wholly owned anti-AXL antibody and the company's second clinical candidate, is currently undergoing Phase 1 testing. 77

I think it is extremely motivating to be part of a team that uses knowledge obtained from basic research to develop new drugs and translate these into treatments that can help patients with cancer. I am proud to be part of such achievements



Associate Director of Preclinical Biology, BerGenBio

Gausdal moved to Bergen in 1993 to initiate studies in microbiology at the University of Bergen. After her Masters studies, she moved on to obtain her PhD degree investigating mechanisms of drug induced cell death and resistance in leukaemia. Gausdal did her PostDoc training at the MD Andersen Cancer Center in Houston and at the University of Bergen.

In 2013, Gausdal started working as a senior researcher in BerGenBio with a focus on the effects of AXL inhibition in leukaemia to support clinical translation of bemcentinb. In 2014, she became a team leader and moved into her current position in 2015 where she is now responsible for the preclinical research performed in house and with academic collaborators worldwide.



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# What we do

BerGenBio is a clinical-stage biopharmaceutical company focused on developing innovative drugs inhibiting AXL, a protein involved in aggressive diseases including immune evasive, drug resistant and metastatic cancers



BerGenBio's headquarters are in Bergen, Norway, where the company was founded in 2007

A well established clinical development and R&D team is also located in Oxford, UK,

The company has successfully translated its world-leading research of AXL's biological role and function into two first-in-class clinical development candidates: the highly selective, oral small molecule AXL inhibitor bemcentinib and the novel, wholly owned anti-AXL monoclonal antibody (mAb) BGB149

Bemcentinib, formerly known as BGB324, is in Phase II clinical testing with a focus on lung cancer and leukaemia, whereas BGB149, a wholly owned therapeutic anti-AXL antibody, has recently entered Phase I testing in healthy volunteers.

Phase II clinical data generated with bemcentinib thus far confirms its utility as a monotherapy in patients with relapsed AML and MDS and shows that it may enhance outcomes when combined with immunotherapy in NSCLC. The data was particularly compelling in patient subsets with evidence of AXL activation. Taken together these data form the basis of BerGenBio's randomised late stage clinical strategy for bemcentinib which will be laid out in the first half of 2019.

Additional therapeutic opportunities for bemcentinib are being explored through the framework of Investigator-Initiated-Trials (IITs) in parallel to the company's own clinical programme.

The ability to predict which patients may benefit most from treatment with a selective AXL inhibitor is an important success factor in clinical trials, as well as for registration and later reimbursement of these novel drugs. This insight underpins BerGenBio's strategy of extensive biomarker discovery and development of a companion diagnostic in parallel to the clinical programme. Results obtained thus far in parallel to the Phase II programme with bemcentinib are highly compelling.

BerGenBio furthermore leverages its leadership position in understanding the AXL biology as it relates to aggressive disease by building value through high profile partnerships such as Merck & Co. with whom BerGenBio have multiple clinical trial collaboration agreements as well as a multitude of leading academic research institutions globally.

BGB149, a therapeutic anti-AXL antibody discovered, developed and wholly owned by BerGenBio, will enter First-in-Patient trials in the second half of 2019 pending results from Phase I testing. At that point, the further clinical strategy for this first-in-class anti-AXL antibody will be disclosed.

At pre-clinical stage, BerGenBio has previously also outlicensed an AXL antibody for antibody-drugconjugate (ADC) development to ADC Therapeutics SA.

Relapsed/refractory AML/MDS: Previously treated NSCLC:

monotherapy response rate in AXL positive patients

response rate to bemcentinib with KEYTRUDA in AXL positive patients Progression free survival:

O months

in AXL positive NSCLC patients treated with bemcentinib + KEYTRUDA



H1 2019

H2 2019

H2 2020

# Bemcentinib - selective AXL inhibitor

Complete PoC Phase IIa programme in NSCLC & AML/MDS Start randomised late stage programme

Interim data expected from randomised programme

# BGB149 - therapeutic AXL function blocking antibody

Complete First-in-Man clinical trial

Advance into disease indications Interim data expected from First-in-Patient trial

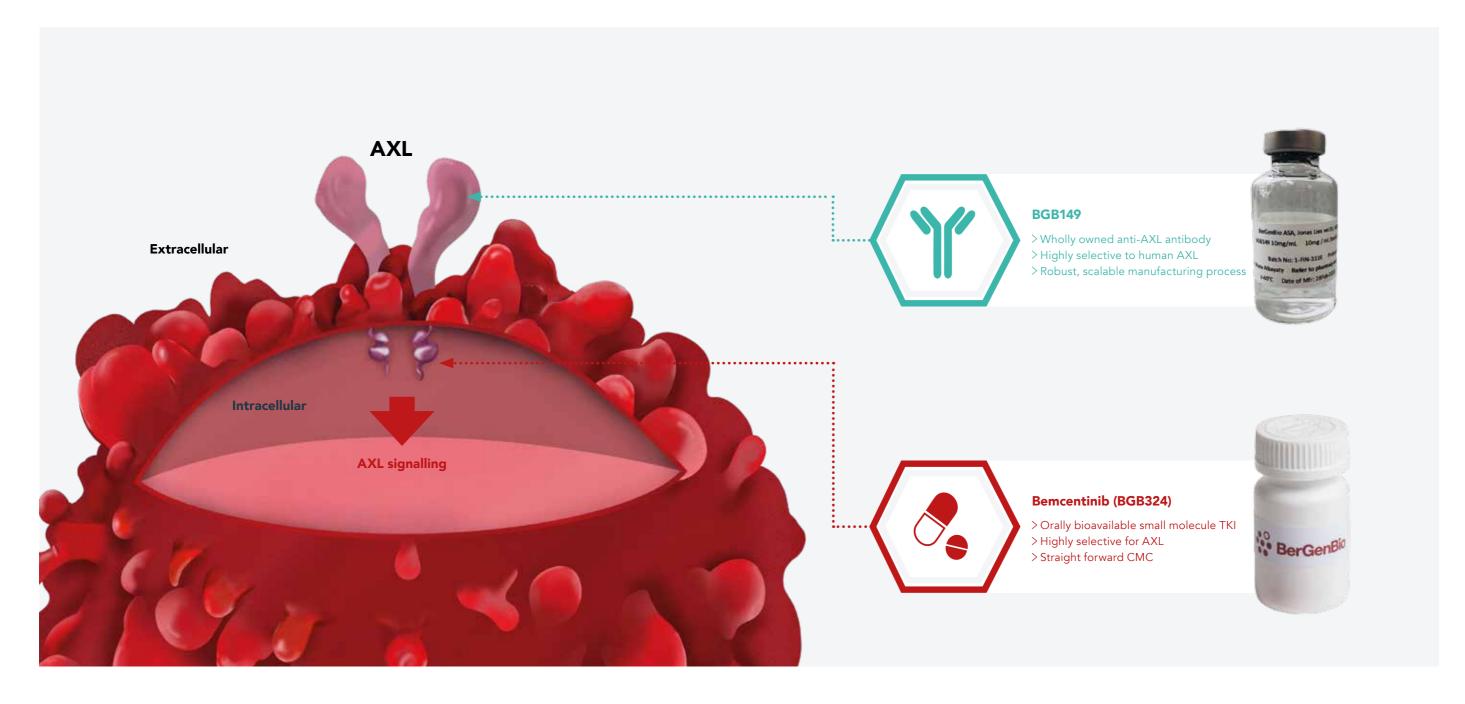
# Our business model

BerGenBio intends to develop its drug candidates itself and through strategic partnerships in multiple indications, and retains all options for the future commercialisation of its products.

While the research and development strategy is designed in-house, the company leverages its network of external contract research organisations ("CROs") to execute its development strategy. BerGenBio also collaborates with academic institutions to extend research in areas of interest of the company. This approach allows the BerGenBio to react quickly and nimbly to industry changes.

Two AXL targeting drug candidates in clinical development

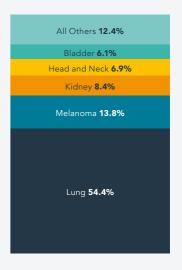




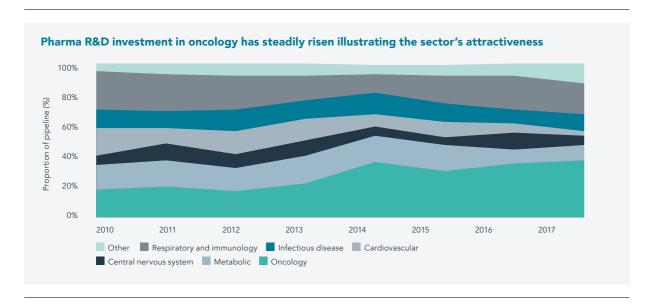
# PD-1 and PD-L1 inhibitor treated patients by tumour type in the United States

Patients treated in 2017 with PD-1 and PD-L1 medicines; total = 147,699

Source: IQVIA Oncology Anonymized Patient Level Data (APLD) sourced from longitudinally linked medical and pharmacy healthcare claims. Feb 2018: IQVIA Institute Apr 2018



Cancer remains one of the most pressing healthcare challenges accounting for the second most common cause of death. The oncology vertical attracts the most interest within the pharmaceutical industry and enjoys the highest rate of innovation. Among 59 novel medicines that the FDA approved in 2018, 17 – almost 30% – were innovative oncology drugs. This therapy area also makes up the vast majority of big pharma's drug development efforts and attracts the most VC funding



These efforts have led to significant and ground-breaking innovation over the past two decades. While chemotherapy was the mainstay of cancer care up until the 90s, the 2000s have marked the beginning of precision medicine with the emergence of the so-called targeted therapies and accompanying diagnostics identifying patients who are most likely to benefit from therapy.

The pace of innovation and approval of practice changing new oncology medicines in the recent past have been unprecedented. Only during the last five years, two completely new treatment paradigms have been introduced: One consisting of CAR-T therapy (a gene- and cell therapy in one) and immune checkpoint inhibitors.



Among these novel immunooncology drugs, it is particularly the checkpoint inhibitors that have seen broad uptake across many tumour types. Agents inhibiting the PD-1 checkpoint (by blocking PD-1 or its ligand PD-L1) for example are now approved in over 23 different cancer indications.

Novel therapies tend to be introduced first in later lines, however checkpoint inhibitors are now already rapidly moving into first line treatment paradigms for a multitude of indications – creating a need

for novel and effective follow-on treatments as well as combinations that further increase initial responses in the first line setting.

The main indications for checkpoint inhibitors are lung cancer and melanoma with over half of all PD-(L)1 inhibitor treated patients being lung cancer patients.

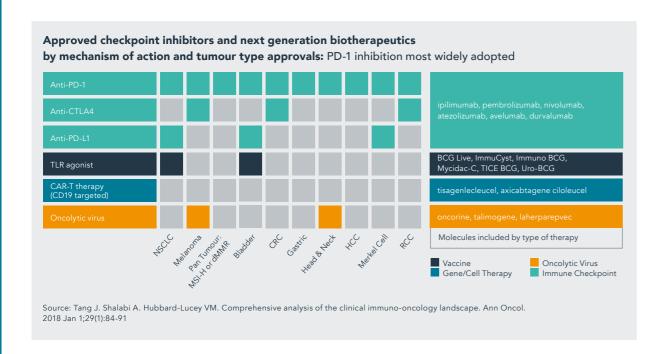
Among immunotherapy mechanisms of action, blockade of the PD-1 checkpoint is the predominant class of therapy in use with approvals across all major tumour types. Prominent PD-1 inhibitors

are KEYTRUDA (pembrolizumab) marketed by Merck and Co. (known as MSD outside the US) and OPDIVO (nivolumab) marketed by BMS.

In their third quarter 2018 report, Merck and Co announced that KEYTRUDA brought in sales of almost 1.9 billion USD in the quarter thus surpassing BMS' OPDIVO and rendering KEYTRUDA the market leader.

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# **Industry context** continued



# Immunotherapies turn cancer into a chronic disease with increasing prevalence, driving growth prospects

In January 2016, an estimated 15.5 million cancer survivors were alive in the US alone - almost 5% of the population – and it is projected that this number will rise to over 26 million by 2040<sup>1</sup>.

Indeed, thanks to novel immunotherapies cancer might just be turning into a chronic disease rather than a rapid death sentence - says Professor Julien Mazière, a leading thoracic oncologist involved in the development of atezolizumab, a PD-L1 blocker marketed by Roche, in a recent press release<sup>2</sup>:

"With immunotherapy we now have a new type of patient: long-term survivors with lung cancer who can go back to normal life."

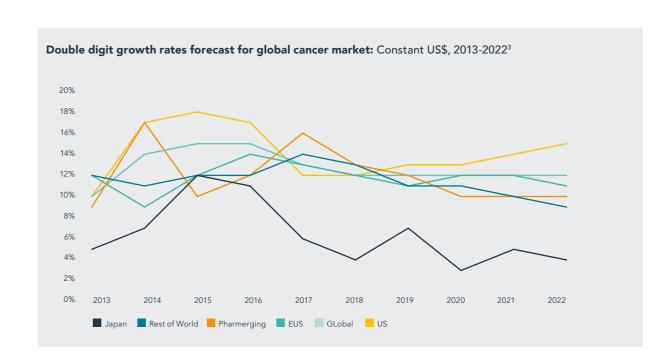
While the number of new cancer cases is mostly stable or even decreasing, the number of patients living with cancer – the disease prevalence – is bound to rise due to increased longevity thanks to novel medicines and an overall trend of populations that are aging and doing so more healthily.

List prices of innovative cancer drugs have steadily risen over the past decade starting with novel targeted therapies and now immunotherapies. New cancer drugs launched in 2017 had a median annual price tag of over USD 150,000, compared to USD 79,000 in 2013.

The oncology therapeutics market is thus projected to continue to expand to reach as much as USD 200 billion by 2022, averaging low double digit growth over the next five years.

# Personalised medicine and rational combination approaches to improve outcomes

Herceptin, a targeted therapy for breast cancer launched in 1998, was the first oncology drug that was approved in a biomarker restricted patient population as defined by an FDA approved companion diagnostics test which formed part of the Herceptin label. Since then, the use of predictive biomarker tests has enjoyed rapid uptake. For example, the vast majority of lung cancer patients are now being tested routinely when presenting



with advanced disease in order to determine the most appropriate treatment strategy.

The ability to predict which patients will respond to a certain therapy spares patients for unnecessary rounds of treatments and ultimately reduces the economic burden of healthcare.

Particularly for immunotherapies and combinations thereof, effective biomarkers remain an area of large need. The director of the Center for Cancer Research at the US National Cancer Institute (NCI) recently commented on a large biomarker study4:

"We know that immunotherapy works, but we do not understand well why a particular therapy will work for some patients but not for others. (..) this challenge is of practical importance for patients."

Although immunotherapies can lead to dramatic and long-lasting responses, only a small subset of patients are likely to see such benefit. The effectiveness of these novel medicines has been shown to be a function of an individual cancer's preexisting immune contexture - in other words, it is more likely that checkpoint by a market for biomarkers and inhibitors work if a patient's immune system has already tried to launch an immune reaction against that particular tumour.

A well-known biomarker to predict such responsiveness to checkpoint inhibitor therapy is the protein PD-L1 – the higher the proportion of a patient's tumour that is positive for PD-L1, the more likely a patient will respond to checkpoint inhibitor therapy. Conversely, if a tumour lacks PD-L1 completely, in almost all the cases there will be no response to treatment.

Research around additional potential biomarkers for response to immune checkpoint inhibitors and other modes of therapy therefore is an area of intense research and an important driver of differentiation for companies hoping to develop a novel therapy. This is also illustrated diagnostics which itself is predicted to see double digit growth over the coming decades nearing USD 6 billion over the next several years according to Informa research.

The identification of a predictive biomarker is also an immense advantage during development as this can greatly shorten the path to registration and improve chances for success.

<sup>1</sup> Bluethmann SM, Mariotto AB, Rowland, JH. Anticipating the "Silver Tsunami": Prevalence Trajectories and Comorbidity Burden among Older Cancer Survivors in the United States. Cancer Epidemiol Biomarkers Prev. 2016;25:1029-1036.

<sup>2</sup> https://www.esmo.org/Press-Office/Press-Releases/Evidence-Immunotherapy-Long-term-Survival-Benefit-Lung-Cancer-Patients, accessed Feb 15 2019

<sup>3</sup> IQVIA Institue: Global Oncology Trends 2018, May 2018

<sup>4</sup> https://www.nih.gov/news-events/news-releases/nih-led-research-team-develops-predictor-immunotherapy-response-melanoma, accessed Feb 15 2019

# **Industry context** continued



**NSCLC** 

Although the rate of new cases of lung cancer continues to decrease along with the smoking rate.

lung cancer is still the second most common cancer

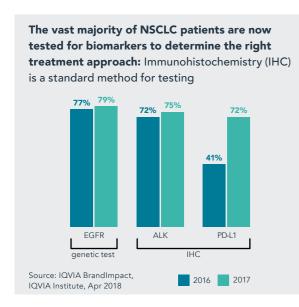
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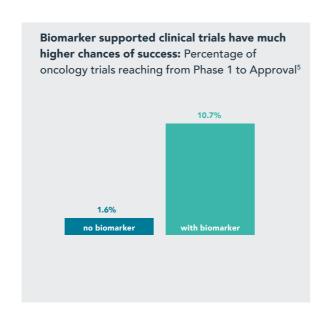
In a 2018 publication, researchers from the MIT Computer Science and Artificial Intelligence Laboratory analysed 406,038 entries of clinical trial data for over 21,143 compounds from January 1, 2000 to October 31, 2015 and found that while oncology drugs have the overall lowest chance of success – only 3.4% compared to over 25% for cardiovascular drugs this rate is greatly improved in the presence of a biomarker: Comparing oncology drugs developed in the absence of a biomarker vs those with a biomarker showed an almost sevenfold dichotomy. Without a biomarker, only 1.6% of oncology drugs can hope to make it all the way to approval vs 10.7% of those with a biomarker.

When combining novel drugs it is particularly important to identify biomarkers for each of the modalities in order to be able to discern the contribution of each component.

BerGenBio's development strategy for bemcentinib encompasses both combining with immunotherapy for which AXL expression is a known resistance mechanism as well as aiming at identifying patients most likely to respond to therapy by testing for AXL biomarkers.

The development of a companion diagnostic is a key strategic priority for the business in light of the immense advantages such a marker entails for patients and the business alike.





# Lung cancer remains the largest cancer killer

Despite improvements in public health, lung cancer remains an extremely common cancer that is very poorly served by current pharmacologic interventions. It is the second most common cancer in men and women and the deadliest of cancer causing more fatalities than breast, prostate, colon and pancreatic cancer combined. Most cases of lung cancer are diagnosed at advanced stage when the cancer has become unresectable or started spreading and treatment options thus are limited.

85% of lung cancer is of socalled non-small cell (NSCLC) histology which further divides into adenocarcinoma (just over half of NSCLC) and squamous cell carcinoma.

A fraction of adenocarcinoma cases are caused by known and targetable genetic alterations that allow the tumour to grow uncontrollably. A mutation in the epidermal growth factor receptor (EGFR) gene, prevalent in about 15% of adenocarcinomas, is among the best understood amongst such driver mechanisms.

While chemotherapy has been the only systemic therapy option for NSCLC for a long time, considerable innovation has happened over the past two decades offering novel targeted therapy options for the still relatively small fraction of lung cancer with actionable genetic drivers.

# Immunotherapy offers a chance of long term survival for the majority of lung cancer patients

Immunotherapy, more specifically immune checkpoint inhibitors, however have more recently brought about a tidal shift for most lung cancer patients today.

Professor Garrido, head of the Thoracic Tumour Section in Spain's largest hospital pronounced in a recent press release<sup>6</sup>:

"Immunotherapy has rapidly become a first line treatment option in NSCLC."

Checkpoint inhibitors have only recently entered the clinics and oncology practices thus data on their ability to increase long-term survival for lung cancer patients is still being collected. Nevertheless, leading scientists are convinced that a shift from palliative to curative treatment

has begun – Professor Solange
Peters, the President of the European
Society for Medical Oncology
(ESMO) for example recently
commented that we now have
a strong argument that every
patient with advanced NSCLC
should receive immunotherapy<sup>7</sup>:

"In the nivolumab<sup>8</sup> Phase I trial 15% of patients were alive at five years, which in cancer is usually considered being cured. We should offer all patients this one in six chance of five-year survival."

# Lung cancer remains the largest cancer killer: causes more fatalities than prostate, pancreas, colon & breast combined (number of fatalities per year, US only)



- 6 https://www.esmo.org/Press-Office/Press-Releases/Mystic-immunotherapy-nsclc-rizvi, accessed Feb 15 2019
- https://www.eurekalert.org/pub\_releases/2018-04/esfm-ipI040518.php, accessed Feb 15 2019
- 8 Nivolumab is a anti-PD-1 checkpoint inhibitor marketed by BMS

# **NSCLC** continued

# **Lung cancer**

remains one of the most common cancers and thus a large healthcare burden

# 85% of lung cancer

Non-small cell lung cancer (NSCLC) constitutes 85% of all lung cancer and a large healthcare burden

# 200,000 new cases

In the US alone, it is expected that 200,000 new cases of NSCLC will be diagnosed this year

# 70% diagnosed late

As the disease often progresses without distinct symptoms, NSCLC tends to be diagnosed at a late stage. Once advanced, surgery alone is not enough to control the disease and systemic therapeutic intervention is needed

# 80% don't respond

to novel immunotherapies when given as a second line. In particular patients lacking the immunotherapy biomarker PD-L1 do not yet benefit from these innovative treatments

# > 8bn USD

Estimated market size for immunotherapies in NSCLC in 2018 (based on sales of approved PD-(L)1 inhibitors in NSCLC)

# Immunotherapies often do not work on their own - drug combinations are needed to unlock the full potential of these novel therapies

Checkpoint inhibitors when given on their own, have the largest effect in patients whose lung cancers are more than 50% positive for the PD-L1 biomarker (see above). This however is only a small fraction of all lung cancer patients leaving much room for improvement.

In the past few years, the pharmaceutical industry has put increased emphasis on rational drug combinations to change the immune contexture of an individual cancer such that it becomes more susceptible to immune attack. This approach is particularly relevant for those patients with low or no expression of the PD-L1 biomarker.

In lung cancer, combining the checkpoint inhibitor KEYTRUDA (marketed by Merck & Co,) or TECENTRIQ (marketed by Roche) with chemotherapy are novel approaches that have gained recent approval due to their extraordinary effectiveness compared to just chemo- or immunotherapy alone.

Indeed, combination therapies are the current focus for pushing the frontier further in improving outcomes for the many lung cancer patients while reducing side effects and enhancing quality of life. Roger Perlmutter, the executive vice president of Merck and Co., the leader of checkpoint inhibitors in the treatment of NSCLC, suggested in a recent interview9:

"You're not going to see much monotherapy anymore, except perhaps in an adjuvant setting.

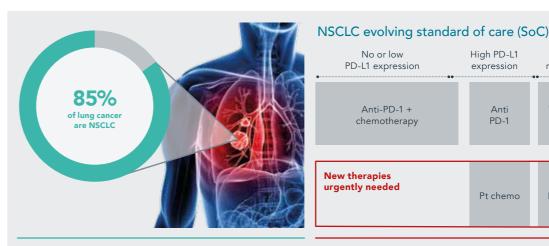
In first-line [treatment of] lung cancer, which is obviously the biggest market, 70 percent of patients are [eligible for] Keytruda plus chemo, and it'll be more later. My expectation is that Keytruda will be foundational in the treatment of the majority of malignancies, and the question will be Keytruda plus what? It's going to be Keytruda plus X, where X is going to be a large set of different things, and it will be much more personalised, depending on the tumour type."

Rational combinations of immunotherapies aim at increasing a tumour's immunogenicity, ie. its ability to be recognised by the immune system, while counteracting immunosuppression and resistance to immunotherapies.

AXL inhibition is thought to have the potential to increase the effectiveness of immunotherapy as signalling of the AXL kinase is central to all of these processes:

AXL is a negative regulator of innate immunity as it decreases the activity of natural killer (NK)10 and dendritic cells<sup>11</sup>, which are important for the detection and destruction of metastases and presentation of antigens, respectively. Similarly, tumour cells that over-express AXL are less likely to be killed via T-cell mediated attack and thus immune destruction, whereas inhibition of AXL with bemcentinib is able to reverse this effect and thus enhance the efficacy of the immune system<sup>12</sup>.

Lastly, data from patients show that when comparing responders to PD-1 immune checkpoint blockade with those that fail to respond, AXL is the number one distinguishing factor found in those patients who did not benefit from the immunotherapy<sup>13</sup>.



The largest cancer killer, most patients depend on drug therapy

More than 1.76 million lung cancer deaths/yr worldwide

Rapidly emerging SoC creates opportunities for effective, chemo free combinations

High PD-L1

expression

Anti

PD-1

Pt chemo

mutations

Targeted

therapy

Pt chemo

Most patients will start on anti-PD-1 + chemo in first line

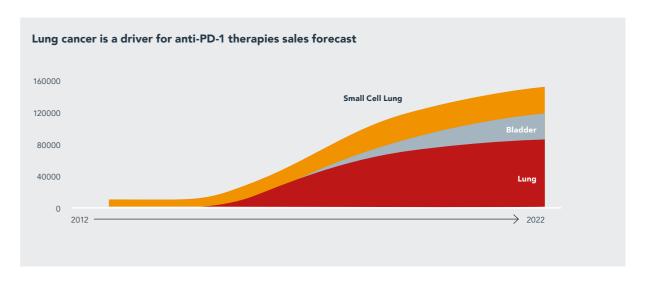
# The lung cancer market is poised for growth driven by checkpoint inhibitors

Checkpoint inhibitors alone or in combination are now approved for first-line treatment of all advanced NSCLC (adeno- and squamous cell carcinoma) apart from the comparably small fraction of adenocarcinoma patients harbouring a driver mutation who still derive most benefit from targeted therapy as a first option.

Consequently, it is expected that the lung cancer market is poised to grow driven primarily by increased uptake of checkpoint inhibitors and novel combinations thereof.

The global lung cancer market is estimated to grow at a CAGR of c. 13% and already in 2018, it is estimated that approved PD-(L)1 inhibitors have brought in over 8 billion USD in lung cancer alone.

It can be reasonably expected that providing combination agents that further increase the effectiveness of checkpoint inhibitor blockade - either by increasing the number of responders, the time on treatment or both - will lead to additional increases in sales which will likely be captured, at least in part, by the developers of the combination therapies.



- https://xconomy.com/national/2019/01/16/merck-and-the-future-of-immuno-oncology-a-chat-with-roger-perlmutter/, accessed Feb 15 2019
- 10 Paolino et al. Nature: 507 (2014)
- 11 Kurowska-Stolarska et al Nature Communications: 8 (2017)
- 12 Davidsen et. AACR 2018
- 13 Hugo et al. Cell: 165 (2016)

BerGenBio

# Acute Myeloid Leukaemia and Myelodysplastic Syndromes



# Aggressive diseases typically affecting older patients

Acute Myeloid Leukaemia (AML) is the most common acute leukaemia in adults and describes a heterogeneous group of cancers of blood cells that are generated by clonal expansion of malignant hematopoietic precursor cells.

Because they proliferate in the bone marrow, the leukaemic cells in turn interfere with the production of normal blood cells causing cytopenias – the consequences are weakness, infection, bleeding and other complications.

AML is generally rapidly lethal if left untreated.

The median age at diagnosis is 65 years old.

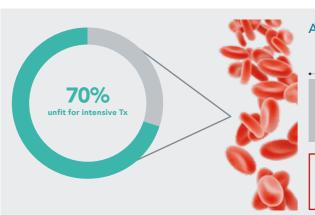
Similarly, Myelodysplastic Syndromes (MDS) encompass a series of hematologic conditions which are more prevalent in older patients and are characterised by chronic cytopenias accompanied by abnormal cellular maturation.

As a result, patients with MDS are at risk for symptomatic anaemia, infection, and bleeding. Patients with unfavourable prognosis tend to progress to AML more frequently and are thus called "high-risk". Notwithstanding this fraction of patients transforming to AML, most MDS cases lead to death due to bone marrow failure illustrating the dire need to address this disease.

# Treatment options beyond chemotherapy still limited

The primary goal of AML treatment is the initial induction of complete remission, ie. the eradication of leukaemic cells. Once such remission is achieved, it typically has to be stabilised by follow-on treatment, so-called post-remission therapy. Patients who do not achieve initial remission are called refractory, those whose diseases recur despite initial remission are referred to as relapsed.

In younger or particularly fit patients, induction and post-remission therapy typically consist of intensive chemotherapy regimens ("7 + 3" chemotherapy combination regimens) and potentially a stem cell transplant which eventually leads to cure in about a third of these patients<sup>14</sup>.



# AML & MDS – difficult to treat malignancies, predominantly elderly frail patient population

~ 20,000 new cases diagnosed and >10,000 deaths (2018, U.S.)\*

# AML evolving standard of care (SoC)

Younger fit patients

>75 yo / unfit for intensive therapy

Induction chemotherapy +/- FLT3 inhibitor low dose chemo / nypomethylating agents / best supportive care

New therapies needed for patients w/o actionable mutations

# Treatment options beyond chemotherapy still limited

Urgent need particularly in older and R/R patients

\* SEER

For older or less fit patients who are not deemed candidates for intensive therapy, treatment options are more limited particularly in the relapsed or refractory (R/R) setting, ie. once initial therapy has failed.

However, after more than 40 years with limited advances, there have been several recent new drug approvals for a proportion of patients with R/R AML. These include a new chemotherapy formulation and therapies directed at the FLT3 (c. 25% of patients) and IDH mutations (c. 10 – 15% of patients).

For newly diagnosed patients, focus has been on improving the effectiveness of treatment regimens with lower intensity for older patients and those not deemed fit enough to tolerate high intensity treatments. A very recent approval in this setting is that of VENCLEXTA (marketed by AbbVie & Genentech) which can now be used in combination with hypomethylating agents or low-dose chemotherapy as a first line treatment in the elderly patient population.

# The need for novel medicines for patients with AML and MDS

Despite recent progress, there still aren't any approved standard treatment options for a large proportion of older, less fit patients in the relapsed/refractory setting and treatment in the first line depends on chemotherapies and is encumbered by severe side effects.

Similarly, for many years, blood transfusions and the use of erythropoiesis stimulating agents were the only therapy available for patients with MDS. More recently, chemotherapy agents directed at the underlying disorder have been developed and continue to be studied. However, due to the advanced age of most patients, the chronicity of the disease, and frequent comorbidities, supportive care remains central to the treatment of all patients with MDS.

AXL has been demonstrated to drive leukaemic proliferation and shown to be an independent prognostic factor in patients with AML, whereas bemcentinib had the ability to reverse the disease in animal models and patient cell cultures<sup>15</sup>. This makes selective AXL inhibition via bemcentinib a promising approach to be investigated in this setting.

The global blood cancer market was valued at USD 24 billion in 2017 and is projected to grow with an CAGR of 11% on the years leading up to 2025<sup>16</sup>.

# Acute Myeloid Leukaemia

is the most common acute leukaemia in adults

## Less than 30%

of AML patients survive beyond 5 years after diagnosis, prospects are particularly grim in elderly, more frail patients

# Up to 70% of patients

may not tolerate intensive induction therapy and thus need novel, well tolerated therapies

# 20,000

new cases of AML are estimated to have been diagnosed in the US alone in 2018

# 40,000

new cases of myelodysplastic syndrome (MDS), a severe bone marrow neoplasm often diagnosed in older patients. In a fraction of – high risk – patients, MDS progresses to a particularly aggressive form of AML

<sup>14</sup> https://www.uptodate.com/contents/overview-of-acute-myeloid-leukemia-in-adults

<sup>15</sup> Ben-Batalla et al. Blood (2013)

<sup>16</sup> Polaris Market research: Global Blood Cancer Drugs Market: Market Size & Forecast, 2017 – 2025; April 2018



# Sites across Europe & USA:

Pipeline overview BerGenBio is a clinical-stage biopharmaceutical company focused on developing innovative drugs inhibiting AXL a protein involved in aggressive diseases including immune evasive, drug resistant and metastatic cancers

Patients:

350

2019

Late stage

programme:

The company has successfully translated its world-leading research of AXL's biological role and function into two first-in-class clinical development candidates: the highly selective, oral small molecule AXL kinase inhibitor bemcentinib and the novel anti-AXL therapeutic monoclonal antibody (mAb) BGB149.

**BerGenBio** 

Additional pre-clinical immunomodulatory small molecule programmes are in discovery stage and an AXL antibody has been outlicensed for ADC development (ADCT-601).

During 2018, BerGenBio's extensive Phase II clinical development programme provided initial clinical

proof-of-concept that bemcentinib and AXL inhibition can increase the efficacy of immunotherapy, targeted and chemotherapy; particularly in patients whose tumours are rich in AXL. A range of additional oncology indications for bemcentinib are also being pursued externally, through the mechanism of investigator initiated trials.

Meanwhile, BerGenBio's internal clinical development is focused on lung cancer and leukaemia where Phase II data was particularly strong in combination with KEYTRUDA and as a monotherapy, respectively. Randomised, late stage trials in these indications will be initiated during the year 2019.

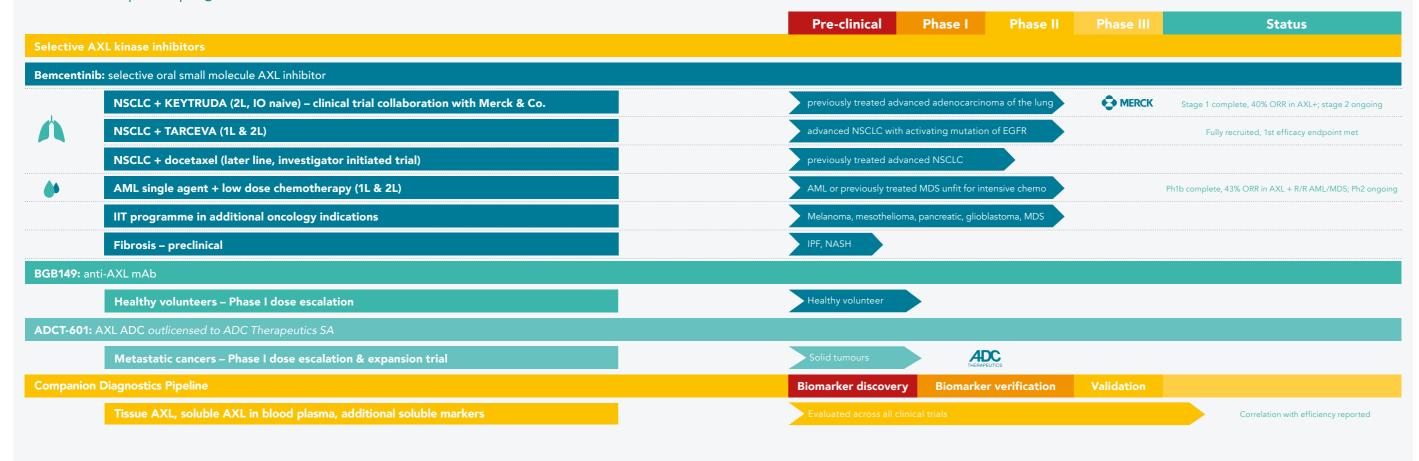
BGB149, a proprietary, therapeutic anti-AXL antibody, is BerGenBio's second clinical asset and has entered Phase I testing in healthy volunteers. First-in-Patient trials in a strategically independent indication are expected to start in 2019.

ADCT-601 is a partnered anti-AXL ADC, and is being developed by ADC Therapeutics SA, a Swiss

biotech company with world class antibody drug conjugate technology.

In parallel with the clinical development programme, BerGenBio pursues a broad companion diagnostics programme in order to support a personalised medicine approach for the company's AXL inhibitors.

# Clinical development programmes of AXL inhibitors



30



# Overview of trials

# **♥** Bemcentinib Company Sponsored Studies

Indication/phase	Treatment	Patients*	Status
NSCLC Phase II	Bemcentinib + KEYTRUDA	48	Ongoing
NSCLC Phase II	Bemcentinib + TARCEVA	66	Completed
AML/MDS Phase II	Bemcentinib + low dose chemotherapy	75	Ongoing
TNBC Phase II	Bemcentinib + KEYTRUDA	56	Completed

# **♥** Bemcentinib Investigator Initiated Trial (IIT) Programme

Clinical development overview

Indication/phase	Treatment	Patients*	Status
NSCLC Phase II	Bemcentinib + docetaxel	30	Ongoing
Melanoma randomised Phase II	KEYTRUDA or TAFINLAR/MEKINIST +/- bemcentinib	92	Ongoing
Pancreatic Cancer randomised Phase II	Triple chemotherapy combination +/- bemcentinib	74	Ongoing
MDS Phase II	Bemcentinib single agent	43	Ongoing

# **♥** BGB149

Indication/phase	Treatment	Patients*	Status
Healthy volunteer Phase I	BGB149 single agent	36	Ongoing

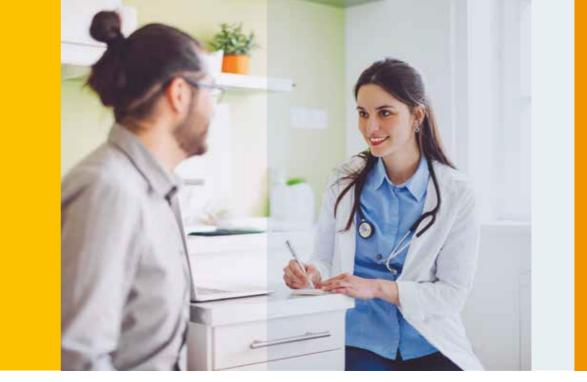
# **♥** BGB601/ADCT-601

Indication/phase	Treatment	Patients*	Status
Solid tumours Phase I	ADCT-601 single agent	75	Ongoing



**BerGenBio** 







# Focussed on **AXL**



# At a glance:

- AXL is a negative prognostic factor in a multitude of aggressive diseases including immune evasive, therapy resistant cancers
- AXL is a cell surface receptor tyrosine expressed on cancer cells and cells of the innate immune system
- When activated on immune cells, AXL suppresses the immune response; on cancer cells it allows for immune escape, therapy resistance and spread

AXL receptor tyrosine kinase is expressed on aggressive cancer cells and on cells of the innate immune system where it acts as a negative immune checkpoint.

AXL helps aggressive tumours escape detection by the immune system and destruction by therapy through its dual action of switching off the innate immune response and allowing cancer cells to enter a state of survival by becoming resistant to therapy, less susceptible to immune attack and able to spread throughout the body.

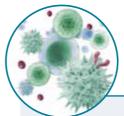
AXL has been established as an independent negative prognostic factor in a multitude of diseases including AML and NSCLC.

While seldom mutated, AXL becomes epigenetically unregulated in response to an anti-cancer immune

attack or tumour therapy – it has been demonstrated to correlate with lack of response to checkpoint inhibitor therapy, impaired T-cell mediated killing of cancer cells and reduced activity of dendritic and natural killer cells<sup>17, 18, 19, 20</sup>.

More recently, AXL has also been reported to be implicated in lifethreatening fibrotic conditions.

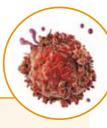
# AXL receptor tyrosine kinase drives aggressive disease including therapy resistant, immune-evasive tumours



Key suppressor of innate immune response

- AXL is an innate immune checkpoint: • M1 to M2 macrophage polarisation
- Decreased antigen presentation by DCs
- Immunosuppressive cytokine profile

Drives tumour cell plasticity: non-genetic resistance mechanism



AXL drives features of aggressive cancer:

- Acquired therapy resistance
- Immune escape
- Metastasis

very low expression under healthy **physiological conditions** (AXL knockout mouse phenotypically normal)

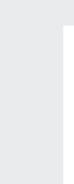


overexposed in response to hypoxia, immune reaction, cellular stress / therapy



overexpression correlates with worse prognosis in most cancers





AXL IHC identifies NSCLC pts with improved outcomes to bemcentinib + KEYTRUDA

Approximately half of previously treated NSCLC patients had AXL positive disease

Biomarker at screen	AXL pos	AXL neg
ORR	40%	9%
CBR	70%	45%
mPFS	5.9 months	3.3 months
(stage 1, n = 21 pts e	evaluable for	AXL status)

Soluble AXL levels identify R/R AML & MDS pts with improved outcomes to monotherapy



Plasma shed AXL (sAXL) levels are inversely correlated with receptor activity

Biomarker at screen	sAXL low	sAXL high
ORR	43%	0%
CBR	64%	45%

(part A, n = 20 pts evaluable for sAXL status)

Additional predictive soluble and tissue markers identified and under investigation



# Bemcentinib, Phase II - preparing for late stage development

First-in-class highly selective AXL inhibitor

# At a glance:

- First-in-class, highly selective and potent oral small molecule AXL inhibitor to treat aggressive cancer
- Phase II clinical development in AML/MDS and solid tumours including NSCLC
- as a monotherapy and in combination, respectively
- Randomised, late stage clinical trials to start in 2019



# Key results to date:

Bemcentinib, a highly selective small molecule AXL inhibitor is being tested as a monotherapy and in combination with immuno-, targeted and chemotherapy in leukaemia and solid tumours. Bemcentinib is taken once daily orally, has reported activity both as a monotherapy and in combination, AXL biomarker correlation has been observed and treatment is generally well tolerated.

The company focusses on NSCLC and AML/MDS in several company sponsored trials.

In 2018, these trials delivered important and highly promising results for bemcentinib as a monotherapy in AML/MDS (43% response rate in AXL biomarker positive patients, evidence of immune activation and clonal stabilisation) and NSCLC in combination with KEYTRUDA (40% response rate in AXL and six months median PFS in AXL positive

patients). These results form the basis for the company's plans for a randomised, late stage clinical trial programme to start in 2019.

In addition, BerGenBio supports a large portfolio of investigator initiated trials which are sponsored by leading patient facing physicians in indications with strong scientific rationale and potential for future label extension.



# **BerGenBio Companion Diagnostics**

Tissue and plasma markers to identify patients most likely to respond

### At a glance:

- Probability of success for a drug development programme is greatly improved in the presence of a biomarker
- Common technologies used during diagnosis of cancer patients include tissue-based procedures such as immunohistochemistry (IHC) which typically require a biopsy
- Liquid biopsies are also particularly attractive options as they promise a more convenient and cost-effective patient experience
- The company uses established and cutting edge technology in its CDx programme with a view to clinically validate relevant markers and seek regulatory approval for their use in the clinic future use in the clinic.

#### Key results to date:

#### AXL IHC

- Proprietary AXL IHC method has been developed
- Approximately half of advanced NSCLC patients in BerGenBio's BGBC008 Phase II clinical study of bemcentinib in combination with KEYTRUDA (NCT03184571) were found to stain positive for tumour AXL
- AXL positive patients reported superior response (40% vs 9%) and median progression free survival (PFS, c. 6 months vs 3.3 months) compared to AXL negative patients

# Soluble AXL

- When the AXL receptor is not in use, it is shed into the plasma, levels of soluble AXL (sAXL) are thus inversely correlated with AXL signalling activity
- Approximately half or relapsed / refractory AML and MDS patients were found to exhibit low sAXL plasma levels indicative of increased AXL signalling activity in the company's BGBC003 Phase I/II bemcentinib monotherapy clinical study (NCT02488408)
- Patients with low sAXL / high AXL signalling reported superior response (43% vs 0%) compared to those with high levels of sAXL



Overview of results: BerGenBio sponsored studies

Focus: AML and Lung Cancer



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# Monotherapy / Chemo combo 1L & 2L AML

Increase rate of remission as monotherapy and in combo with low dose chemo

20,000 new cases annually\*

**Results** in R/R patients unfit for intensive therapy

- 43% CR/CRi/CRp-rate to monotherapy in AXL biomarker positive patients
- Responses included patients with poorer prognosis
- Bemcentinib + decitabine 1L cohort fully recruited

#### Context

 Venetoclax, now approved in combo w/ chemo, has shown 19% ORR in R/R AML as a monotherapy

**Clinical Trial Identifier:** NCT02488408

# KEYTRUDA combo 2L NSCLC

Increase response rate - including in PD-L1 negative

200,000 new cases annually\*

**Results** in advanced previosuly treated patients

- Stage 1 complete: Predominantly PD-L1 negative / low patient population
- 40% ORR in AXL positive patients
- Median PFS 5.9 months in AXL positive patients
- Stage 2: open and recruiting

#### Context

- KEYTRUDA monotherapy or combination with chemotherapy is current standard of care
- ORR in PD-L1 negative / low patients is 8–14%, with 2 months PFS<sup>21</sup>

Clinical Trial Identifier: NCT03184571

# TARCEVA combo 1L & 2L NSCLC

Reverse (2L) and prevent resistance (1L) to EGFR targeted therapy

20,000 new cases annually\*

# Results (trial complete)

- 2L: Tumour responses and disease stabilisation observed in T790M neg TARCEVA progressors
- 1L: further deepening of responses in patients who were stable or in response to TARCEVA, combined PFS exceeded that reported for TARCEVA monotherapy

### Context

- TARCEVA & newer generation EGFR inhibitors are widely used in this patient population
- Responses are initially high, but almost all responders develop resistance over time

Clinical Trial Identifier: NCT02424617

BerGenBio designed a broad Phase II programme with a view to identify the most promising indications for selective AXL inhibition to progress into late stage clinical development.

In anticipation of a correlation of efficacy with biomarker expression, particularly the bemcentinib target AXL, a comprehensive biomarker programme was rolled out alongside the clinical trials.

Based on the Phase II clinical data reported in 2018 in conjunction with biomarker findings, the company was able to confirm its focus for late stage clinical trials in NSCLC and AML.

Meanwhile, the BGBC007 study of bemcentinib in combination with KEYTRUDA in TNBC (NCT03184558) was completed in 2018. A planned interim readout after completion of the first stage concluded that the first efficacy threshold was not met and progression into the second stage was not warranted. The combination was well tolerated, however, unexpectedly few patients were found to express AXL, the target for bemcentinib. In line with this finding, the combination of bemcentinib and KEYTRUDA was not seen to improve efficacy over monotherapy in this particular cohort of TNBC patients.



Docetaxel combo in 2nd & later line NSCLC

Increase response rate

150,000 cases annually\*

90,000 new cases annually\*

**MEKINIST/TAFINLAR** 

or KEYTRUDA combo in

metastatic melanoma

Increase response rate

### Results

- Bemcentinib + docetaxel shows promising activity in previously-treated patients with advanced NSCLC, including patients who failed on immunotherapy
- 8 patients reported clinical benefit including 2 partial responses out of 11 evaluable patients

# Context

- Docetaxel increasingly used as 2L therapy
- Docetaxel monotherapy ORR: 8 14% <sup>22</sup>

Clinical Trial Identifier: NCT02922777

### Results

- Confirmed recommended Phase II dose of bemcentinib in combination with MEKINIST/ TAFINLAR, all combinations continue to be well tolerated
- 18 out of 23 radiographically evaluated patients reporting clinical benefit including complete responses

#### Context

- MEKINIST/TAFINLAR and KEYTRUDA are standard of care in advanced melanoma
- AXL expression is associated with resistance to these therapies

Clinical Trial Identifier: NCT02872259

BerGenBio has established broad investigator initiated trial (IIT) support for its internal clinical development programme.

Investigator-initiated clinical trials are clinical trials proposed by front-line patient-facing physicians who act as the regulatory sponsor and are supported by industry in bespoke clinical development partnerships.

The industry partner does not assume the role of sponsor according to European or US regulatory guidelines but may offer support in a variety of different ways, such as providing investigational medicinal product at no cost.

As such, IITs are a cost effective way to secure additional pipeline opportunities for bemcentinib while raising the company's profile among the scientific and clinical community who will ultimate be prescribing bemcentinib to patients should it be approved.

IITs with bemcentinib are ongoing or planned in the following indications: metastatic melanoma, mesothelioma (NCT03654833), pancreatic cancer (NCT03649321), glioblastoma and MDS (NCT03824080).

Updated results from these studies will be presented at future clinical congresses as appropriate.



<sup>\*</sup> US only, https://seer.cancer.gov, accessed Feb 15 2019

<sup>22</sup> Garon EB, Ciuleanu TE, Arrieta O, et al: Ramucirumab plus docetaxel versus placebo plus docetaxel for second-line treatment of stage IV nonsmall- cell lung cancer after disease progression on platinum-based therapy (REVEL): a multicentre, doubleblind, randomised Phase 3 trial. Lancet 384:665-73, 2014





# **BGB149, Phase I**

First-in-class therapeutic AXL antibody

# At a glance:

- First-in-class therapeutic AXL function blocking antibody
- Discovered, developed and wholly owned by BerGenBio
- Robust, scalable manufacturing process established
- Phase I healthy volunteer clinical trial ongoing, First-in-Patient trials planned in 2019



BGB149 is a fully humanised AXL function blocking antibody discovered and wholly owned by BerGenBio. The antibody is produced at scale and currently undergoes a placebo controlled healthy volunteer Phase I clinical trial (NCT03795142) to confirm its safety, tolerability, pharmacokinetics and pharmacodynamics prior to testing its efficacy in patients later in 2019.

Antibodies are proteins that our bodies produce to mark pathogens for recognition by the immune system and that as such play a vital part in building immunity. Antibodies are characterised by extremely high specificity and can be produced by biological systems such as specialised cells within our

These characteristics captured the biotechnology industry's interest several decades ago: Instead of using chemical synthesis generating chemical structures (so-called "small molecules") it is now possible to engineer highly specific proteins ("large molecules") that either

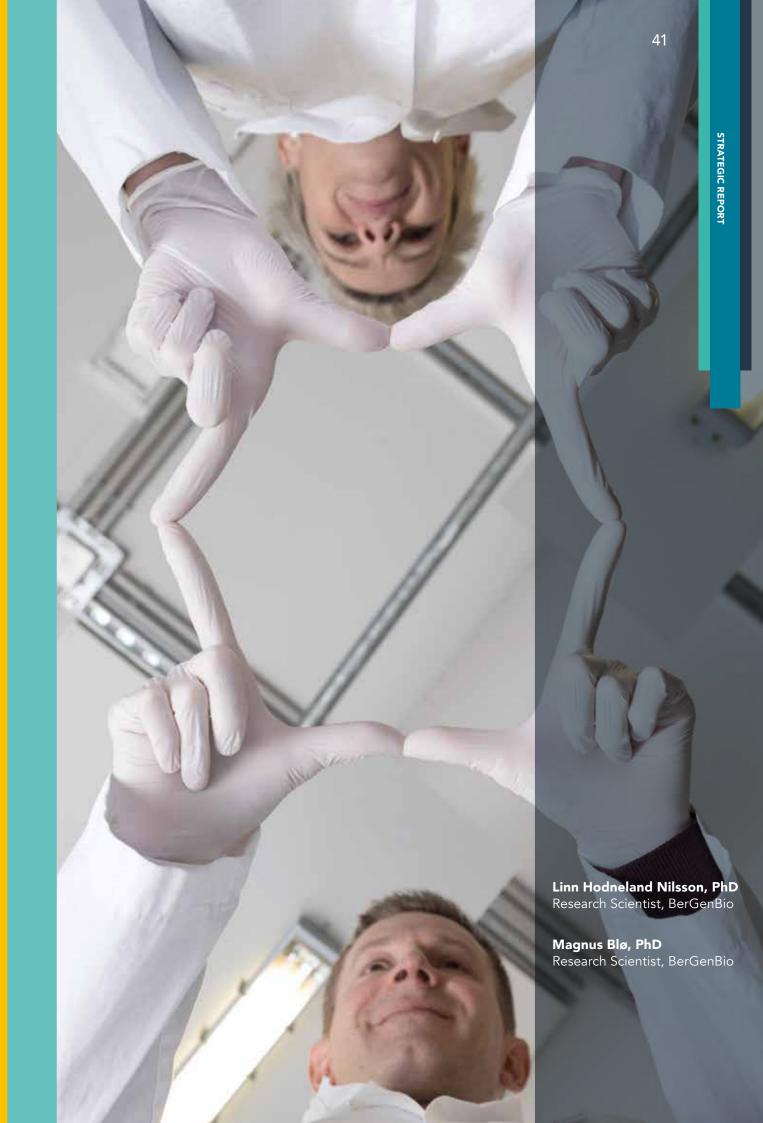
receptor's signal (as for example the immune checkpoint inhibitor antibodies). Antibodies now form a vital part of modern medicine as they can be engineered with high specificity to a certain target and function thus inducing a desired therapeutic effect.

BGB149 is an antibody that binds the extracellular portion of the AXL receptor and blocks its signal. BGB149 is fully humanised and is selective for human AXL; it is manufactured by specialised cells that are kept in a bioreactor in a process that has been optimised to reproducibly yield the antibody at high quantity. Therapeutic activate or antagonise a cell surface antibodies like BGB149 are

most commonly administrated intravenously (bemcentinib on the other hand, a small molecule, is taken orally).

A Phase I placebo controlled healthy volunteer trial with BGB149 (NCT03795142) was initiated in the end of 2018 and the company reported dosing of the first patient in January 2019. Pending readout of this First-in-Human trial, the company will commence First-in-Patient trials in the second half of

BGB149 and bemcentinib while both blocking the AXL signal are being developed in strategically different indications.



# **AXL's role in fibrosis**

Several high-profile pre-clinical reports indicate an important role for AXL also in non-oncology indications such as fibrosis. The group of Professor Cory Hogaboam, PhD, from the Cedars Sinai Center in Los Angeles, published important work on blocking AXL by virtue of bemcentinib in mouse models of idiopathic pulmonary fibrosis (IPF). We spoke to Professor Hogaboam about his thoughts on AXL's role in this severe disease.

# the role of AXL in fibrotic diseases, more specifically in IPF?

C.H.: Our hypothesis is that AXL and its ligand Gas6 are part of a vicious cycle in IPF driving the activation of a special type of support cell - the so-called fibroblast - into a myofibroblast (literally a fibroblast expressing the contractile protein called alpha smooth muscle actin).

While fibroblasts are important for the integrity and repair of all of our tissues under physiological circumstances, activated fibroblasts or myofibroblasts (particularly those isolated from the lungs of IPF patients) are in a sort of hyper-activated state, and remain active long after the tissue injury has been repaired.

These IPF myofibroblasts then take over by continuously laying down extracellular matrix, which you could think of as a process of never-ending scarring. Also, these cells do not stay in one place but rather move into normal areas of the IPF patient's lungs and produce collagen as they move.

This form of aberrant fibroblast function is called fibrosis and ultimately prevents the lung from functioning normally.

By targeting AXL, which we think may be integral to the differentiation of fibroblasts into disease-inducing myofibroblasts, we may be able to help preserve lung function by reversing the activation of the fibroblasts that are to blame for the unrelenting scarring process in IPF.

# What evidence have you seen so far to support this rationale?

**C.H.:** Data directly from IPF patient tissues – as opposed to normal lungs - show that AXL is highly expressed and highly active in the affected lungs, particularly in patients with the fast progressing variation of IPF.

What is the hypothesis regarding These data provide some initial evidence for a potential role of AXL in IPF while also indicating that AXL levels may serve as a biomarker to identify patients with a poor prognosis.

> Consistent with the proposed pathological role of AXL in fibrosis and the observations from IPF patient lung samples, we have seen that selective inhibition of AXL using bemcentinib (BGB324) impacted IPF fibroblast functions and slowed and/or stopped the development of fibrosis in pre-clinical models.

By blocking the AXL pathway we reversed fibroblast to myofibroblast transition, altered the migration of these cells, and ultimately prevented the development of fibrosis.

# What is the medical need in IPF and how important could AXL inhibition be as a new therapeutic modality for IPF?

C.H.: IPF is a chronic, and at times, rapidly progressive respiratory disease leading to respiratory failure and is lethal within 3 years if left untreated. The disease has a profound clinical and economic impact and the incidence is increasing worldwide particularly in the baby boomer generation since IPF is usually diagnosed in the 6th or 7th decade of life.

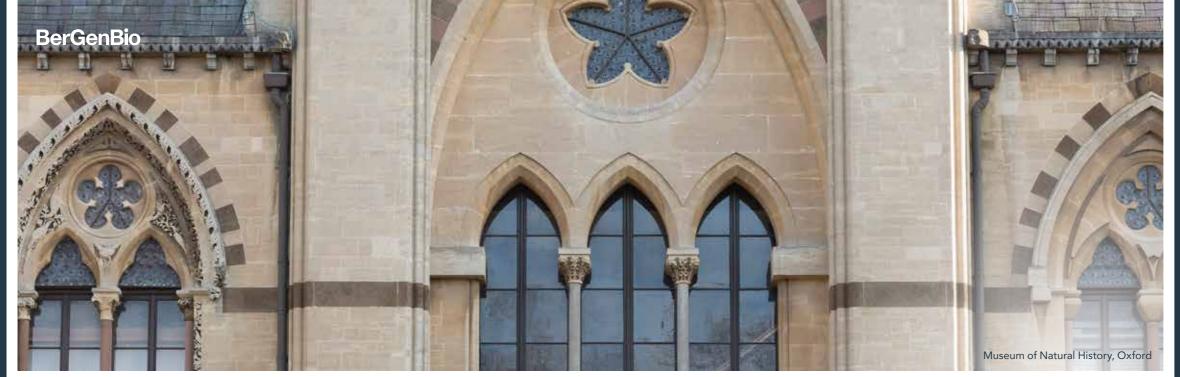
Approved IPF drugs may slow down the loss of respiratory function over time, but these treatments have limitations as ultimately, they are not disease modifying and poorly tolerated by the majority of IPF patients. Consequently, most patients are still dependent on oxygen therapy, pulmonary rehabilitation, and/or lung transplant.

If the hypothesis that AXL receptor activity contributes to the underlying cause of IPF holds true, AXL inhibition may play a key role in future treatment strategies.



Approved IPF drugs (...) have limitations as ultimately, they are not disease modifying and poorly tolerated by the majority of IPF patients





# Governance

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# **Interview with David Micklem**

#### **David Micklem**

Director Biomarkers & Assay Development

David is one of BerGenBio's co-founders. He moved from Cambridge to Bergen in 2004 where he worked as a Senior Post Doc at the University of Bergen. He has a BA in Biochemistry from the University of Oxford and a PhD in Developmental Biology and Genetics from the University of Cambridge.

# How come you moved to Bergen?

My wife is from Stord, which is an island south of Bergen. When we were living in Cambridge, she got a permanent job in Bergen and I too was invited to an interview and booked a flight. However, before I even got to Bergen, I received a message from a guy called James Lorens saying: "Hey, I've heard that you're in Bergen – can we talk?". That is how I first met James.

# Was the meeting successful?

We hit it off pretty much immediately. James was a professor at the University of Bergen and wanted to understand how branching occurred in blood vessels, which I had an interest in from before – by the time I went for the interview I came for in the first place, I had already decided that I was going to work with James.

#### What did you and Jim work on?

I worked for James for four years during which I spent a lot of time developing a new technology for knocking down genes. Later we used that technology to establish AXL's role in cancer development and as a result we started BerGenBio.

# How did BerGenBio develop as a start-up?

In the beginning we used the developed technology to validate candidate targets for other companies, using AXL as a "star demonstration". This was done to pay for the internal research and to push BerGenBio's own targets forward. That was when we got the opportunity to in-license bemcentinib, a selective AXL inhibitor that was at an early preclinical stage. We decided to focus on developing our own targets and bring bemcentinib into the clinic. And that's what we have done.

# What are you working on now?

I am organising a lot of the research and responsible for preclinical biomarker research and assay development – I have always been technology oriented and interested in developing new ways of doing things. We are currently putting a lot of effort in exploring patient samples in relation to biomarkers to understand which patients may respond best to bemcentinib.

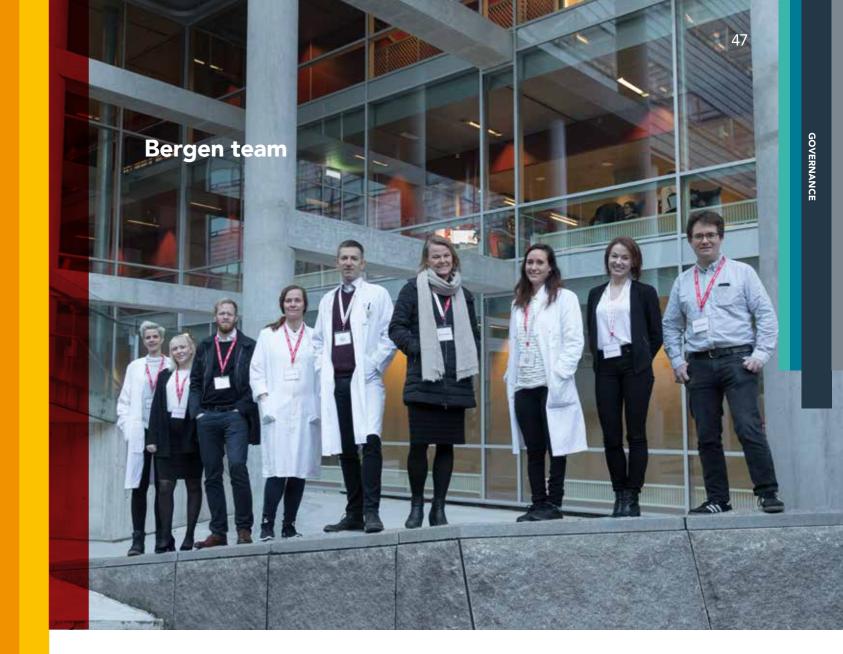
# Any thoughts from the journey?

We have moved a very long way in terms of what we have been working on, the fact that we were able to work on AXL and develop multiple drug candidates targeting it is pretty cool! It is an interesting job with plenty of experimentation where we can discover new things.



I worked for James for four years during which I spent a lot of time developing a new technology for knocking down genes. Later we used that technology to establish AXL's role in cancer development and as a result we started BerGenBio





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It is fascinating to be part of an extremely ambitious BerGenBio team that has the power to do incredible things. My role as the Quality Manager is focused on ensuring regulatory compliance and providing confidence that internal and external requirements will be fulfilled in achieving organisational excellence



ayesh Samani

Quality and Clinical Support Manager, BerGenBio

Jayesh is a Qualified Pharmacist having more than 10 years of diverse experience in a multi-disciplinary setting of the pharmaceutical industry. He has also received MBA from the University of Leicester. Jayesh joined BerGenBio in October 2016.



#### **Stein Holst Annexstad**

Mr. Annexstad holds a BA in Commerce from the Norwegian School of Economics (1969). He has senior industry experience, both at executive and Board levels. He is former executive of Dyno Industrier AS (fine chemicals), and became the CEO of the pharmaceutical firm Nycomed AS (subsequently merged with Amersham Plc and thereafter merged with GE). He was head of AS Isco Group, an Executive Search and Corporate Advisory Group. Mr. Annexstad was in 1996 a co-founder of NorgesInvestor AS, an Oslo-based Private Equity firm, and was in 2008 the first Chairman of Investinor AS (the VC of the Norwegian State). At the same time he was Chairman of Algeta ASA, the pharmaceutical startup that successfully developed Xofigo (prostate cancer drug) and was acquired by Bayer Health Care in 2014. Other previous Chairman positions comprise commercial banking, business school, public and various industrial enterprises.

Mr Annexstad was appointed Chair of the Board of Directors on 1 February 2016. He is a Norwegian citizen and resides in Norway. He attended 16 Board meetings in 2018.

#### Jon Øyvind Eriksen (CFA)

**Non-Executive Director** 

Jon Øyvind Eriksen is an Investment Director and head of the Tech Sector investment area at Investinor AS, a Norwegian government funded venture capital company, and a CFA Charterholder. He is currently Non-Executive Director at Boostcom Group, Northern.tech, Novelda, Signicat, Swarm64 and Unacast. Mr Eriksen is a serial entrepreneur and previously served as CEO of several tech companies, including Mogul Technology and Kantega. He studied Biotechnology at the Norwegian University of Science and Technology (NTNU), from where he obtained an MSc, and has been awarded an MBA with Distinction from London Business School

Mr Eriksen joined the Board of Directors on 30 January 2012. He is a Norwegian citizen and resides in Norway. He attended 16 Board meetings in 2018.

# Hilde Furberg

Non-Executive Director

Hilde Furberg has broad senior leadership experience, coming from her 35 years in sales, marketing, strategy and general management roles in pharmaceuticals and biotechnology. Her experience is in different areas of specialty care, and from small to large global companies. Hilde is a professional Board member and an independent consultant. Hilde has worked in companies like Baxter and Genzyme, and she was most recently the European Head of Rare Diseases for Sanofi Genzyme. Hilde has previously been a Board member of Probi, Pronova, Clavis and Algeta. She is currently a Board member of Calliditas and Tappin, and Chairman of the Board for Blueprint Genetics. Hilde is also an industrial advisor to Investinor. Hilde has a Master of Science from the University of Oslo, Norway.

Mrs Furberg is the former Chair of the Board of Directors of BerGenBio, having joined the Board on 1 June 2015. She is a Norwegian citizen and resides in the Netherlands. She attended 11 Board meetings in 2018.

#### Kari Grønås

**Non-Executive Director** 

Kari Grønås (M. Sc. Pharm) has more than 25 years of experience in drug development and the commercialisation of new products including securing regulatory approvals. She has significant management experience including leadership of cross functional and governance teams. She was SVP Operations at Algeta ASA, and has had leading positions in both Photocure ASA and Nycomed/Amersharm Health. She holds a non-executive directorship at Lytix Biopharma AS, is Chairman of the Board of the Norwegian Pharmaceutical Society, and is currently working as a consultant within biotech.

Mrs Grønås joined the Board of Directors on 1 February 2016. She is a Norwegian citizen and resides in Norway. She attended 15 Board meetings in 2018.

# Stener Kvinnsland (MD, PhD)

**Non-Executive Director** 

Dr. Stener Kvinnsland has more than 30 years of experience in oncology. He is Chair of Board, Oslo University Hospital. Among Dr. Kvinnsland's previous roles, he of Board positions amongst others at was Chief Executive Officer of the Bergen Hospital Trust (Helse Bergen), Head of the Department of Oncology and Medical Physics at Haukeland University Hospital, Professor of Medicine (Oncology) at the University of Bergen and Director Clinical R&D, Oncology for Pharmacia & Upjohn

Dr Kvinnsland joined the Board of Directors on 22 February 2015. He is a Norwegian citizen and resides in Norway. He attended 12 Board meetings in 2018.

#### **Sveinung Hole**

**Non-Executive Director** 

Sveinung Hole is the CEO of Trond Mohn Foundation and Stiftelsen Kristian Gerhard Jebsen. Hole holds a number Tromsø Research Foundation, Sarsia Seed AS. Nordic and Europe Health Invest AS, PE Helse AS and Prophylix Pharma AS. Formerly he was the CEO of the investment fund Sarsia Seed AS, Board Member of Norwegian Venture Capital association, Bergen Hospital Trust (Helse Bergen) and Director of Anesthesia and Intensive Care at Haukeland University Hospital. Hole has also held various top management positions at Telenor Corporation and been Regional Managing Director/Director of Global Strategies at the Berlitz Corporation. Hole holds a Master of International Management from BI Norwegian Business School.

Mr Hole joined the Board of Directors on 1 September 2010. He is a Norwegian citizen and resides in Norway. He attended 14 Board meetings in 2018.



# **Richard Godfrey**

**Chief Executive Officer** 

Richard Godfrey joined BerGenBio as Chief Executive Officer in 2008. He has more than 25 years' industry experience leading many international drug development and commercialisation partnerships. Formerly he served as Chief Executive Officer of Aenova Inc., a specialist biopharmaceutical company. Prior to this he was the Managing Director of DCC Healthcare Ltd and previously he held positions of increasing responsibility at Catalant, Eli Lilly and Reckitt Benckiser in R&D and commercial roles. He qualified as a Pharmacist from Liverpool University and received his M.B.A. from Bath

# **Dr Alan Barge**

Dr Alan Barge joined

as interim Chief Medical

**Chief Medical Officer, interim** 

BerGenBio in 2018 and serves

Officer. He is a board-certified

oncologist and haematologist,

with more than 25 years of

experience in cancer drug

development, spent primarily

at AstraZeneca and Amgen.

AstraZeneca, where he was

and Infection, during which

time he was responsible for

the development of Iressa®

(gefitinib) for non-small cell

lung cancer (NSCLC) and the

translational research that

resulted in the successful

strategy for AZ. Prior to AZ,

Dr Barge was European and

Global Medical Director at

Amgen, at which he was

responsible for European

therapies. More recently,

Dr Barge has been actively involved in the biotech sector in both CMO and non-executive positions including CMO of Carrick Therapeutics (UK and Ireland) and SVP Oncology at ASLAN Pharmaceuticals (Singapore). Dr Barge is a UK citizen and resides in UK.

approval and label extensions

for several of Amgen's cancer

personalised medicine

He spent over 12 years at

VP and Head Oncology

**Chief Scientific Officer** 

**Anthony Brown** 

Dr Anthony Brown joined BerGenBio as Research Director in October 2015 and was promoted to CSO in 2018. He has over 25 years of experience in the drug discovery of both small molecules and biological therapeutics. He has managed strategic alliances with Pharma and Biotech and led several novel programmes in Oncology, from early research through to clinical studies. Previously he has held Senior Management and Director level positions at British

Biotech, OSI Pharmaceuticals,

Piramed Pharma, Cancer

Research Technology and

more recently at CellCentric.

He completed his doctorate

from the University of Oxford

in 1993 and MBA from Oxford

Dr Brown is a UK citizen and resides in the UK.

Brookes University in 2008.

# **Tone Bjaaland**

**Director of Clinical** Operations

Tone Bjaaland joined BerGenBio in 2018 and serves as Director of Clinical Operations, based in Oxford, UK. She brings over 25 years of experience from a successful track record of directing Clinical R&D in global Pharmaceutical, Start-up and CRO companies. She has extensive clinical operations and management experience across Phase I-IV studies in multiple indications, including oncology. She holds a BSc (Hons) in Biology and gained her PhD in Physiology from Kings College London.

Dr Bjaaland is a UK citizen and resides in UK.

# Rune Skeie

**Chief Financial Officer** 

Rune Skeie joined BerGenBio Dr Julia Schoelermann in 2018 as CFO. He has joined BerGenBio in 2015. over 20 years of financial She has held positions of management, corporate increasing responsibility development, corporate at the company and is now governance and advisory leading BerGenBio's Business experience with public and Development, Partnering and private companies across communications activities. multiple industry sectors. Originally a trained scientist, Julia has had an academic The majority of his career was spent at EY (formerly Ernst career during which she & Young), where he held the supervised several research role of Executive Director, projects and academic before joining REMA Franchise theses as well as authored a Norge AS, the multinational multitude of peer-reviewed supermarket business, as research articles. She holds a BSc and MSc in molecular biotechnology and biophysics from the University of Heidelberg, Germany (2008),

# Julia Schölermann

**Director BD and Partnering** 

Dr Endre Kjærland joined BerGenBio in 2011 and is now head of intellectual property, quality systems and contracts. Prior to joining BerGenBio, he has gained more than 10 years of experience in academic science and supervision. He completed a MSc in molecular biology and PhD in biochemistry from the University of Bergen. Dr Kjærland is a Norwegian citizen

**Endre Kjærland** 

and Contracts

**Associate Director of IP** 

and resides in Norway.

# **Mike Rogers**

HR Director, interim

Mike Rogers joined BerGenBio as a Interim HR Director in 2018. He is a Strategic HR professional with a depth of experience gained over the past 20 years supporting the development of successful organisations within a range of emerging life sciences and medical diagnostic businesses such as Oxford Asymmetry International (Evotec), Oxford Immunotec, Genzyme Therapeutics, and most recently Silence Therapeutics Plc in the RNAi field. Mike has an MA In Economics from Edinburgh University and is a Member of the Chartered Institute of Personnel Development.

Mr Rogers is a UK citizen and resides in UK.

CFO. Mr Skeie is a Registered Accountant and a State Authorised Public Accountant. Mr Skeie is a Norwegian citizen and resides in Norway.

> Dr Schölermann is a German citizen and resides in Norway.

a PhD in cell biology from the

University of Bergen, Norway

(2012), and a dual-degree

Madrid, Spain (2017).

MBA from Brown University,

USA, and ie business school in

University. Mr Godfrey is a UK citizen and resides in Norway.

# **Remuneration report 2018**

Prepared by: BerGenBio Remuneration Committee

#### Section 1 – Introduction

This statement regarding remuneration of the management of BerGenBio ASA has been adopted by the Board of Directors of BerGenBio ASA pursuant to section 6-16a of the Norwegian Public Limited Companies Act.

The BerGenBio Remuneration Committee has reviewed the remuneration policies for the executive management as summarised in this statement to the Annual General Meeting.

BerGenBio is an expansive company with several potential drugs in clinical development operating in a competitive international market. As such, it is important to be able to attract and retain the necessary expertise.

The Committee has reviewed the composition of BerGenBio's peer group companies and updated the comparative market remuneration data to ensure competitiveness towards the market.

BerGenBio's remuneration principles and policies including compensation models, elements and levels have been reviewed.

Annual bonuses are used to award short-term performance. Share options are used to retain, attract, incentivise and align employees with shareholders.

Restricted Stock Units and Performance Shares have been evaluated as alternatives to share options in the Long Term Incentive Plan.

The Committee has concluded that based on comparison peer companies, BerGenBio's remuneration package as a whole is well balanced and should provide the required foundation to serve its purposes.

#### **Sveinung Hole**

Chairman of the Remuneration Committee 20 February 2019

# Section 2 – Remuneration Committee Activity

#### The Remuneration Committee

The Board of Directors with the support of the Remuneration Committee determines the remuneration policy for BerGenBio. The applied remuneration practices must continue to support the strategic aims of the business and enable the recruitment, motivation and retention of senior executives. At the same time, BerGenBio's practices must take account of the views of governance bodies and the expectations of shareholders and the wider employee population.

The Board of Directors approves the total remuneration of the CEO and the total remuneration of the CEO is communicated to the shareholders through the annual accounts. The Board of Directors has final approval of the remuneration of the senior management, based on recommendation from the Remuneration Committee.

In 2018, the Committee has not taken paid advice in association with the assignment. The Committee is appointed by the Board of Directors and consists of members of the Board of Directors. The members in 2018 were:

- Stein H. Annexstad
- Hilde Furberg
- Sveinung Hole, Chairman

The Committee met six times in 2018. The CEO and the CFO attended specific meetings. The CEO and CFO have given input to levels of remuneration and performance, but have not participated in final conversations regarding their own levels of remuneration.

The following matters were covered by the Committee during the year:

- Reviewed feedback received from shareholders regarding remuneration policies and practices.
- Reviewed and adapted the composition of BerGenBio's Peer Group companies in accordance with the development of BerGenBio.
- Updated the comparative market remuneration data from the Peer Group.
- Reviewed BerGenBio's remuneration principles and policies, including compensation models, elements and levels with regards to market standards.
- Evaluated the use of Restricted Stock Units or Performance Shares as alternatives to Share Options in the Long Term Incentive Plan.
- Prepared recommendations to the Board of Directors for the grant of share options as part of the Long Term Incentive Plan.
- Prepared recommendation to the Board of Directors for the yearly salary adjustment of the CEO and reviewed the recommendations made by the CEO for the other members of the executive management team.
- Prepared recommendation to the Board of Directors for objectives and Bonus Plan for CEO and Bonus Principles for the management team for 2018
- Quarterly reviewed CEO performance according to the 2018 Bonus Plan.

# Remuneration report 2018 continued

# Section 3 – Overview of the Remuneration Policy

#### The Remuneration Policy

**BerGenBio** 

The current remuneration policies for BerGenBio are based on the principles summarised below:

Principle	Summary		
Market competitive remuneration	BerGenBio offers competitive reward opportunities to enable the company to attract retain and motivate the talent needed to achieve the vision and business objectives.		
	BerGenBio shall balance the need to provide competitive levels of reward against a desire to be cost effective when determining reasonable and responsible reward outcomes.		
Pay for performance	An appropriate proportion of the reward package is performance-based to ensure the linking of reward to the achievement of key financial and non-financial objectives with a balance of short and long-term performance components.		
Transparency	Remuneration programmes are designed and communicated in a manner that reinforces the linkage between business objectives, vision and culture.		
Business alignment and consistency	Remuneration decisions are made to ensure local practices are aligned and consistent with BerGenBio's principles and policies.		
	The remuneration practices will remain flexible enough to evolve as BerGenBio's business priorities change.		
Shareholder alignment	The remuneration programmes will align the interests of all employees in driving value creation for shareholders.		

A key component of the policy review is to establish an appropriate peer group of companies in order to verify the market competitiveness of the remuneration package and assess market practice for bonus and equity incentive programs.

The selection of the peer companies is based on industry sector, commercial status, products, number of employees, revenue and, where applicable, market capitalisation. This has led to the selection of a comparator Peer Group, which, reflecting the structure of BerGenBio, covers both Nordic and UK companies.

After the 2018 revision, the BerGenBio Comparator Peer Group consists of 21 companies from the Nordic countries (10) and the UK (11) with number of employees, revenue, R&D expense and market capitalisation spanning from well below to well above the relevant metrics for BerGenBio. The Peer Group is used for a benchmarking of the executive management team to assess the market positioning of the remuneration packages.

The remuneration arrangements for the BerGenBio executive management team comprise the following elements:

- Base salary
- Short-term incentive
- Share options
- Benefits
- Pension

Base salary

CEO







The chart below shows, as a proportion of the 2018 total remuneration package, the % value split between salary, annual bonus and share option grants across the executive management team.

The Committee considers the below structure, with a considerable proportion of the remuneration being equity based, to be necessary and appropriate at the present stage of development for the company.



## Section 4 – Remuneration Policy for each element

The Committee reviews base salaries for individual members of the executive management team annually. The salaries are set by taking into consideration the scope of the role, the level of experience of the individual, the geographical location of the role, internal relativity, and external economic environment. The Committee also makes reference to the mid-point of the market range for equivalent roles in peer companies. The Committee receives a proposal from the CEO for total annual base salary increase. This is presented latest in February, for final Board approval in March and will be retroactive effective from 1 January. The base salary for the CEO has over the last two years been adjusted according to the median benchmark salary for the Peer Group.

The overall performance, employee potential and current remuneration competitiveness are combined to assess any proposed salary revision.

# **Short-term incentive scheme**

All members of the executive management team are eligible to participate in an annual short-term incentive (STI) scheme. The scheme is linked to individual performance measures, which focus on the achievement of key performance indicators for the business area relevant for individual executives, as well as some overall objectives common for all in the executive team. The individual objectives of the CEO and the overall objective for the executive team are set by the Board. The Committee, in discussion with the CEO, reviews the level of performance achieved and the amount of STI earned by the members of the executive management team. The CEO will share the recommendation to the Committee in February. Latest in March the recommendation from the Committee is shared with the Board, which finally approves this and any STI award to the CEO.

# Remuneration report 2018 continued

#### Section 4 - Remuneration Policy for each element continued

Each individual has a number of measures, which are grouped into the following categories

Category	Measures cover				
Execution of bemcentinib	Opening of IND approved trials				
development plan	Clinical trial progress				
	<ul> <li>CMC / chemistry, manufacturing and controls, objectives</li> </ul>				
	Publications in peer reviewed journals and at conferences				
Finance management	Financial strategy formulation				
	Adherence to budget				
	Investor relations and equity analyst coverage				
Business development and footprint	Progress in development of BGB149				
	R&D agreements				
	Bemcentinib positioning				

In order to be consistent with the principles of pay for performance and competitive remuneration, a stretch bonus target has been introduced to reward exceptional performance and results.

Category	Target bonus in % of base salary (2018)	Maximum bonus in % of salary, inc. stretch (2018)
Chief Executive	50%	75%
All other executives	30%	45%

The Committee may, at its discretion, review the operation of the STI scheme and make recommendations to the Board for approval. Any review will take into account the overall impact of the remuneration package, the mix between fixed and variable pay and between short and long-term performance measurement.

BerGenBio operates with a share option plan (Long-term Incentive Plan – LTP). The purpose of the LTP is to ensure that a proportion of the remuneration package is based on the long-term performance of the company and therefore aligned directly with the interests of the shareholders. Share options may be granted when employees join the company. Share option grants are not subject to performance-based vesting conditions, and are hence geared towards employee retention and recruitment, which at BerGenBio's current stage is paramount to success.

Share options may also be granted to selected consultants and Board members to attract and retain the individuals with the skill, international acumen and industry competence the company requires. Use of share options for Board members is not in compliance with The Norwegian Corporate Governance Board ("NCGB" or "NUES") recommendation on corporate governance for Companies listed in Norway (30 October 2014). If options are recommended to Board members, the Nomination Committee will argue the separate cases based on specific considerations.

The use of share options reflects practice in the sector.

Relevant surveys shows more than 70% of LTPs employ the use of share options. The Committee has reviewed the profile of the total remuneration package and given consideration to the use of other equity vehicles such as restricted stock and performance shares. The Committee's conclusion is that none of the alternatives to the use of share options results in significantly more favourable consequences regarding the handling of risk, value or dilution - over time. The transaction costs of converting to an alternative regime of LTP is hence found to outweigh the potential benefits.

The Board of Directors has been authorised by the General Meeting of BerGenBio ASA 14 May 2018 to have up to 5,471,140 shares outstanding as part of the share option plan. At the end of 2018, 3,181,514 share options are outstanding, of which 2,598,333 were vested and exercisable at year end 2018.

The Board of Directors will decide if share options are to be granted to the executive team and forward recommendation to the Annual General Meeting. When granted, share options will be awarded relative to a % of base salary, with the option value set to 50% of market value at the time of the grant, which is in line with practice for biotech share options without performance conditions and compliant with IFRS2.

Category	Share option value of base salary (2017)
Chief Executive	0–100%
All other executives	0–50%

Under the current plan, until 2016, share options have been granted to all employees upon joining the company with vesting subject to performance conditions. Additional grants have been made to senior employees on a discretionary basis taking into account overall performance, competitiveness of terms, work responsibility, importance of retention, organisation level and position. Granted share options vest over a three- year period, with a 1/3 of the options vested per year. Options expire eight years after the grant date. For Board members the granted options vest over two years in line with the period for which they are elected.

In the case of termination of employment, the employee will not vest further share options beyond notice of termination. The terminated employee can, as a rule, exercise vested share options for maximum six months post termination. Board members must as a rule be a member of the Board at the time of exercise. All deviations must be decided by the Board of Directors.

Vested share options can be exercised partly or fully at four specified points per year at least. In addition, the Board may allow exercise at other suitable times during the year. The exercise price for any new options granted is set at the market price of the shares at the time of grant of the options.

The Board of BerGenBio seeks authorisation from shareholders at the Annual General Meeting to issue a maximum number of share options in total for all grants. This authorisation is sought every year and at the Annual General Meeting in May 2018, the Board was authorised to issue up to 5,471,140 share options, constituting a maximum 10% of outstanding shares. In 2018 the total amount of outstanding share options increased with 0.47%, from 5.35% to 5.82% – well below most of BerGenBio's peer companies.

By the end of 2018, Board members held 307,500 share options and the senior management held 2,306,423 share options. The remaining 567,591 share options are held by other employees. Please see Note 5 and 6 of the consolidated financial statements for 2018 for an overview of options granted per 31 December 2018.

#### **Pension**

BerGenBio ASA has a defined contribution pension plan according to the mandatory requirements in the Norwegian Law. BerGenBio Limited has a defined contribution pension plan according to the requirements in UK. The executive management is included in these pension plans, which applies to all employees of BerGenBio ASA and BerGenBio Limited.

#### Other benefits

Benefits to senior management may comprise certain other items such as healthcare, accident insurance, limited car allowance, etc. on customary terms.

The type of benefit provision, the level of cover and the coverage will be reviewed when deemed relevant. No review is planned for 2019.

#### Severance payment

The CEO of BerGenBio ASA, Richard Godfrey, has the right to receive 12 months' salary and benefits in the case of involuntary termination of his employment.

In the event that the employment agreement is terminated within 18 months of a change of control in the company the CEO is entitled to compensation of 18 months' salary and the buy back of his shares of fair market value at his sole discretion.

The remuneration for the Board of Directors comprises an annual fee for acting as a Director, which takes into account the Director's experience, Chairmanship and Committee chairmanship or membership. The Annual General

Post IPO, the company has not granted share options to members of its Board, thereby complying with the recommendation on corporate governance for Companies listed in Norway.

# Section 5 – Remuneration tables for 2017 and 2018

See Notes 5 and 6 to the group financial statements.

# Corporate governance report 2018

# 1. Corporate Governance in BerGenBio

BerGenBio ASA considers good corporate governance to be a prerequisite for value creation and trustworthiness, and for access to capital. In order to secure strong and sustainable corporate governance, it is important that BerGenBio ensures good and healthy business practices, reliable financial reporting and an environment of compliance with legislation and regulations.

BerGenBio is incorporated and registered in Norway and is subject to Norwegian law. The company's shares are listed on Oslo Børs, and thus subject to the requirement to prepare an annual statement of its principles and practices for corporate governance. The company endorses the Norwegian Code of Practice for Corporate Governance, issued by the Norwegian Corporate Governance Board, most recently revised on 17 October 2018 (the "Code"). Compliance with the Code is based on the "comply or explain" principle, which means that the company must either comply with the individual items in the Code or explain why they have chosen an alternative solution.

### Implementation and reporting of corporate governance

BerGenBio has governance documents setting out principles for how business should be conducted. References to more specific policies are included in this corporate governance report where relevant. The BerGenBio governance regime is approved by the Board of Directors in the company.

BerGenBio believes good corporate governance involves openness and trustful cooperation between the company and all its stakeholders. By practicing good corporate governance, the company's Board of Directors and management will contribute to achieving the company's objectives of openness, independence, equal treatment, and control and management.

The following sections provide a discussion of the company's corporate governance in relation to each section of the Code. According to the company's own evaluation, the company deviates from the Code on the following points:

- Formulation of company takeover policy (section 14)
- Formulation of guidelines for use of the auditor for services other than auditing (section 15)

#### Values and ethical policies

BerGenBio has not defined any corporate values, but the company's main values and ethical principles form the basis for the company's corporate social responsibility policy. The CSR policy is distributed to all employees, management and Board members, and published on the company's website.

The company's ethical and corporate social responsibility rules set forth the basic principles for business practices and personal behaviour for BerGenBio and apply to all employees, as well as persons/entities related to the company, including hired consultants acting on behalf of the Group. They comprise the company's main principles on issues such as human and labour rights, health and safety, business ethics, legal compliance, insider trading, whistle-blowing and other relevant issues related to the company's operations.

Material breaches of the ethical guidelines may result in termination of employment.

#### 2. Business

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

The company's operations comply with the business objective set forth in its articles of associations 3: "The company's objective is to undertake research and development in biotechnology with a focus on new pharmaceutical therapeutics".

The company has developed clear goals and strategies which are further described in the Annual Report for 2018.

#### 3. Equity and Dividends

# Capital adequacy

BerGenBio's total equity at 31 December 2018 was NOK 337.3 million, corresponding to an equity ratio of 89.0%. The Board of Directors considers this to be an adequate level relative to the risk and scope of operations based on the company's internal estimated capital

The company's capital situation is continuously monitored, and the Board of Directors will take adequate steps to capitalise the company if deemed necessary.

# **Dividend policy**

BerGenBio has not developed any dividend policy. The company is focusing on the development of novel pharmaceutical products and does not anticipate paying any cash dividend until sustainable profitability is achieved. The company has not previously distributed any dividends to its shareholders.

#### **Authorisations to the Board of Directors**

At the company's annual general meeting, held on 14 May 2018, the Board of Directors was granted the following authorisation:

• Authorisation to increase the company's share capital by up to NOK 547,114 in connection with its existing share option scheme. The authorisation is effective until the earlier of the AGM in 2019 and 30 June 2019.

For supplementary information on the authorisations, reference is made to the minutes of the annual general meeting held on 14 May 2018, available from the company's website and www.newsweb.no.

At the company's extraordinary general meeting, held on 9 March 2018, the Board of Directors was granted the following authorisation:

• The Board of Directors is granted an authorisation to increase the share capital with up to NOK 499,222 by subscription of up to 4,992,220 new shares, which constitute 10% of the company's outstanding shares. The purpose of the authorisation is to permit the issue of new shares to strengthen the company's equity and to increase the liquidity and/or to broaden the company's shareholder base with domestic and international investors that may include healthcare specialist investors.

On 13 April the Board of Directors issued 4,629,246 shares under this authorisation. For supplementary information on the authorisations, reference is made to the minutes of the annual general meeting held on 9 March 2018, available from the company's website and www.newsweb.no.

# 4. Equal treatment of Shareholders and transactions with close associates

BerGenBio has only one class of shares. Each share in the company carries one vote, and all shares carry equal rights, including the right to participate in general meetings. All shareholders shall be treated on an equal basis, unless there is just cause for treating them differently.

# Share issues without preferential rights for existing shareholders

In the event of a share capital increase through the issue of new shares, a decision to waive the existing shareholders' preferential rights to subscribe for shares shall be justified. Where the Board of Directors resolves to issue shares, and waive the preferential rights of existing shareholders pursuant to an authorisation granted to the Board of Directors by the general meeting, the justification will be publicly disclosed in a stock exchange announcement issued in connection with the shares issuance.

In 2018 the company issued 4,629,246 new shares on 13 April where the existing shareholders preferential rights where waived. The Board assessed this private placement in light of the equal treatment requirement, balanced the considerations that speak for and against carrying out the private placement and concluded that the waiver of the preferential rights inherent in a private placement was considered necessary in the interest of time and successful completion in the common interest of the company and its shareholders, as well as being in accordance with the stated purpose of the authorisation from the extraordinary general meeting to the Board to increase the share capital.

# Transactions in treasury shares

Any transactions in treasury shares shall be carried out through Oslo Børs, and in any case to prevailing stock exchange prices. In the event that there is limited liquidity in the company's shares, the company will consider other ways to cater for equal treatment of shareholders. There were no such transactions in 2018.

# Approval of agreements with shareholders and close associates

For transactions that are considered to be not immaterial between the company and its closely related parties, the Board of Directors will arrange for an independent thirdparty valuation. Members of the Board of Directors and executive personnel are required to notify the Board of Directors when such members have any significant, direct or indirect, interest in a transaction carried out by the company. There were no such transactions in 2018.

# 5. Freely Negotiable Shares

The shares of the company are freely negotiable, and the company's articles of association do not place any restrictions on the negotiability of shares.

# Corporate governance report 2018 continued

### 6. General Meetings

The general meeting is open to all shareholders, and BerGenBio encourages all shareholders to participate and exercise their rights in connection with the company's general meetings. The right to participate and vote at the general meeting can only be exercised for shares registered in the shareholders' register by the fifth business day prior to the day of the general meeting.

Notice of a general meeting and any supporting documents, including the recommendation by the Nomination Committee and other information on the resolutions to be considered, shall be made available on the company's website no later than 21 days prior to the date of the general meeting. In accordance with the company's articles of association, documents that are to be considered by the general meeting are not required to be sent to the shareholders if they have been made available on the company's website. The deadline for registration will be set as close to the meeting as possible, and all the necessary registration information will be described in the notice.

Shareholders unable to attend may vote by proxy. Whenever possible, the company will prepare a proxy form that will allow separate votes for the items that are to be considered in the general meeting.

The agenda for the annual general meeting is stipulated by the articles of association, and the main topics to be considered include the approval of the annual accounts and the Director's report, including distribution of dividend, and remuneration of leading personnel.

The Board Chairman is normally the chairperson for the general meeting. If there is disagreement on individual items for which the Board chairman belongs to one of the fractions, or is not regarded as being impartial for other reasons, another chairperson will be appointed to ensure consisted of seven members, whereof three women: impartiality regarding the items to be considered.

The Board Chairman and the CEO will be present at general meetings, together with representatives of the Board. Representatives of the Nomination Committee, the Remuneration Committee and the Audit Committee, as well as the auditor, should be present at general meetings where matters of relevance for such committees/persons are on the agenda.

Minutes from the general meetings will be published in accordance with the stock exchange regulations.

In 2018, BerGenBio held its annual general meeting on 14 May. One extraordinary general meeting was held on 9 March.

# 7. Nomination Committee

The Nomination Committee of BerGenBio consists of three members, elected pursuant to section 9 of the company's articles of association.

The Nomination Committee is responsible for recommending candidates for the election of members and Chairman of the Board of Directors, candidates for the election of members and Chairman of the Nomination Committee, and remuneration of the Board of Directors, Board subcommittees and the Nomination Committee.

The objectives, responsibilities and functions of the Committee are further described in the "Instructions for the Nomination Committee", which were adopted by the general meeting at the AGM in 2017. The instructions are available from the company's website.

The current Nomination Committee was elected at the general meeting, held on 22 March 2017, and consists of:

- Ann-Tove Kongsnes (Chair)
- Hans Peter Bøhn
- Masha P.N Le Gris Strømme

The members were elected with a term until the annual general meeting in 2019. All members are considered independent of the company's Board of Directors and executive management.

All shareholders are entitled to nominate candidates to the Board, and contact information for proposing candidates can be found on the company's website.

# 8. Board of Directors; Composition and Independence

Pursuant to the articles of association section 5, the company's Board of Directors shall consist of three to seven members. At 31 December 2018, the Board of Directors

- Stein Holst Annexstad (Chair)
- Hilde Furberg
- Susan Foden
- Kari Grønås
- Stener Kvinnsland
- Sveinung Hole
- Jon Øyvind Eriksen

All members are elected for a term of two years and may

Effective from 1 January 2019 Susan Foden, for personal reasons, decided to step down from her position as member of the Board of Directors.

The composition of the Board of Directors is in compliance with the independence requirements of the Norwegian Code of Practice for Corporate Governance, (the "Corporate Governance Code"), meaning that (i) the majority of the shareholder-elected Board Members are independent of the company's executive management and material business contacts, (ii) at least two of the shareholder-elected Board Members are independent of the company's main shareholders (shareholders holding more than 10% of the Shares in the company), and (iii) no members of the company's Management serve on the Board of Directors. Furthermore, pursuant to the Norwegian Public Limited Companies Act, if the Board of Directors of a Norwegian public limited liability company consists of six to eight members, then each gender shall be represented by at least three members.

Except for Jon Øyvind Eriksen and Sveinung Hole, all Board Members are independent of the company's significant business relations and large shareholders (shareholders holding more than 10% of the Shares in the company) and of the Management.

Board members are encouraged to own shares in BerGenBio. Prior to the listing of BerGenBio on Oslo Børs, the company has granted share options to its Board members as set out in the table below. This practice ended in connection with the IPO and adoption of the Code.

Name	Position	Considered independent	Served since	Term expires	Board Meeting Attendance 2018	Shares	Share options
Stein Holst Annexstad <sup>1</sup>	Chair	Yes	01.02.2016	AGM 2020	16	7,539	0
Susan Elizabeth Foden	Board member	Yes	08.09.2011	01.01.2019	13	6,700	267,500
Hilde Furberg <sup>2</sup>	Board member	Yes	01.06.2015	AGM 2020	11	3,769	25,000
Kari Grønås³	Board member	Yes	01.02.2016	AGM 2020	15	4,522	15,000
Stener Kvinnsland	Board member	Yes	22.02.2015	AGM 2020	12	0	0
Sveinung Hole	Board member	No	01.09.2010	AGM 2020	14	0	0
Jon Øyvind Eriksen	Board member	No	31.01.2012	AGM 2020	16	0	0

- 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 Borkenholm 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.

## 9. The Work of the Board of Directors

The Board of Directors is responsible for the management of the company, including the appointment of Chief Executive Officer (CEO), convening and preparing for general meetings and supervising the daily management and the activities of the company in general.

The Board of Directors has implemented instructions for the Board and the executive management, with focus on allocation of internal responsibilities and duties. The objectives, responsibilities and functions of the Board of Directors and the CEO are in compliance with rules and standards applicable to the company and are described in the company's "Instructions for the Board of Directors" and "Instructions for the CEO".

The Board of Directors will produce an annual schedule for its work, with particular focus on objectives, strategy and implementation. The CEO is responsible for keeping the Board of Directors informed and provides monthly reports to the Board of Directors about the company's activities, position and financial and operational developments. During 2018, the Board of Directors held 16 meetings.

# Corporate governance report 2018 continued

#### 9. The Work of the Board of Directors continued

The Board of Directors' consideration of material matters in which the Chairman of the Board is, or has been, personally involved, shall be chaired by another member of the Board.

The Board of Directors shall annually evaluate its performance and expertise in the previous year. The evaluation is made available to the Nomination Committee.

#### **Audit Committee**

The Board of Directors established an Audit Committee on 28 February 2017, which is a sub committee of the Board of Directors. Its main duties are to assess the company's financial reporting and systems for internal control. The Audit Committee also supports the Board in the administration and exercise of its responsibility for supervision in accordance with applicable rules and legislations. The company's Audit Committee is governed by the Norwegian Public Limited Liability Companies Act and a separate instruction adopted by the Board of Directors. The Audit Committee has held four meetings in 2018, and met with the Auditor, EY, separately without the executive management present.

The members of the Audit Committee are elected by and amongst the members of the Board of Directors for a term of up to two years. The current members of the Audit Committee are:

- Jon Øyvind Eriksen (Chair)
- Kari Grønås
- Stein Holst Annexstad

# **Remuneration Committee**

The Board of Directors has established a Remuneration Committee as a preparatory and advisory committee for the Board of Directors in questions relating to remuneration of the company's executive management.

The duties are described in the company's "instructions for the Remuneration Committee". The main duties include the responsibility to review the remuneration and benefits strategy of the members of the executive management; review the performance of the executive management vs. the adopted objectives and recruitment policies, career planning and management development plans; and prepare matters related to other material employment issues in respect of the executive management. The Remuneration Committee meets as often as deemed necessary, but normally two to three times a year.

The members of the Remuneration Committee are elected by and amongst the members of the Board of Directors for a term of up to two years and shall be independent of the company's executive management. The current members of the Remuneration Committee are:

- Sveinung Hole (Chair)
- Stein Holst Annexstad
- Hilde Furberg

# 10. Risk Management and Internal Control

The Board of Directors of BerGenBio are responsible for ensuring that the company has sound and appropriate risk management and internal control systems in accordance with the regulations that apply to its business activities.

The company has implemented a comprehensive set of relevant corporate manuals and procedures, which provide detailed descriptions of procedures covering all aspects of managing its operations, including the development of clinical data and financial performance. The procedures and manuals are continuously revised to reflect best practice derived from experience or adopted through regulations. In connection with the implementation of the General Data Protection Regulation (GDPR), BerGenBio have undergoing a comprehensive risk assessment related to employee data management.

The Board of Directors receives reports from the management on developments and results related to strategy, finance, KPIs, risk management, clinical studies, challenges and plans for the coming periods. In addition, quarterly and annual reports are prepared in accordance with the listing requirements and recommendations of Oslo Børs, and they are reviewed by the Audit Committee prior to the Board meeting and subsequent publication.

BerGenBio prepares its financial accounts in accordance with the international accounting standard IFRS, which aims to provide a true and fair overview of the company's assets, financial obligations, financial position and operating profit. For information on the company's financial risk and risk management, reference is made to the Board of Directors' report and Note 20 in the 2018 annual report.

# 11. Remuneration of the Board of Directors

The remuneration of the Board of Directors is determined by the shareholders at the annual general meeting of the company based on the proposal from the Nomination Committee. The level of the remuneration is based on remuneration of Board members for comparable companies and reflects the Board of Directors' responsibility, expertise, the complexity of the company, as well as time spent and the level of activity in both the Board of Directors and any Board Committees.

The remuneration of Board members is not linked to the company's performance and does not contain option elements. Prior to the listing of BerGenBio on Oslo Børs, the company has granted share options to its Board members as set out in section eight above. This practice ended in connection with the IPO and adoption of the Code. Board members who participate in the Audit Committee or Remuneration Committee receive separate compensation for this.

Detailed information on the remuneration of the Board of Directors can be found in Note 5 to the financial accounts in the annual report for 2018.

Members of the Board of Directors, or companies with which they are associated, should not engage in specific assignments for the company in addition to their appointment as members of the Board, but if they do, this shall be fully disclosed to the Board of Directors. The remuneration for such additional duties will be approved by the Board of Directors and specifically identified in the annual report.

# 12. Remuneration of Executive Personnel

The main principles for BerGenBio's executive remuneration policy are that the management should be offered terms that are competitive when salary, benefits, bonus and pension plans are seen as a whole. The executive remuneration guidelines are described in the company's annual report and have been presented to and adopted by the general meeting.

The company has a share option scheme for employees, which is linked to the company's long-term performance with shareholder values and interest. Details regarding the programme are available in Note 6 to the financial accounts in the annual report for 2018.

#### 13. Information and Communications

BerGenBio complies with Oslo Børs' Code of Practice for IR. The Board of Directors has adopted an investor relations policy, to clarify roles and responsibilities related to financial reporting and regulate contact with shareholders and the investor market and ensure that the principles of openness and equal treatment of market participants are followed. The IR policy is available from the company's website. In addition, the Board has adopted separate instructions for financial reporting and handling of inside information.

The company will each year publish a financial calendar, providing an overview of the dates for major events such as its ordinary general meeting and publication of interim reports. Interim reports are published on a quarterly basis, in line with Oslo Børs' recommendations. The company will give open presentations in connection with its interim reporting.

All financial and other IR information is provided in English. All information is distributed to the company's shareholders by postings on the company's website at the same time as it is sent to Oslo Børs through its information system www.newsweb.no.

#### 14. Take-Overs

There are no defence mechanisms against take-over bids in the company's articles of association, nor have other measures been implemented to specifically hinder acquisitions of shares in the company.

In the event of a take-over process, the Board of Directors and the executive management will ensure that the company's shareholders are treated equally and that the company's activities are not unnecessarily interrupted. The Board of Directors has a special responsibility in ensuring that the shareholders have sufficient information and time to assess the offer. In addition to complying with relevant legislation and regulations, the Board of Directors will seek to comply with the recommendations in the Code, including a valuation from an independent third-party. On this basis, the Board of Directors will make a recommendation as to whether the shareholders should accept the bid.

The Board of Directors has not established any other written guidelines for procedures to be followed in the event of a take-over bid, as such situations normally are characterised by specific and one-off situations which makes guidelines challenging to prepare.

# Corporate governance report 2018 continued

#### 15. Auditor

**BerGenBio** 

The company's auditor is EY and is regarded as independent in relation to BerGenBio ASA. The Board of Directors receives an annual confirmation from the auditor that the requirements regarding independence and objectivity have been satisfied.

The auditor prepares an annual plan for carrying out the auditing work, which is made known to the Audit Committee. The Board of Directors have annual meetings with the auditor to discuss the annual accounts, accounting principles, assessment of any important accounting estimates and matters of importance on which there has been disagreement between the auditor and the company's executive management. At least once per year, the auditor will present to the Audit Committee a review of the company's internal control procedures, including identification of weaknesses and proposals for improvement. These meetings will also be held with an opportunity for a review with the auditor, without the company's day to day management being present. No separate guidelines have been prepared for use of the auditor for services other than auditing.

The Board of Directors will disclose the remuneration paid to the auditor to the shareholders at the annual general meeting, including a break-down of the fee paid for audit work and fees paid for other specific assignments, if any. The Audit Committee has reviewed the work of the auditor and recommend to the General Meeting to retain EY as the company's auditor.

The auditor will participate at the annual general meeting.

# **Board of Directors' report 2018**

#### Strategy

BerGenBio ASA ("the company") and its subsidiary (together "the Group") is a biopharmaceutical company developing novel medicines for aggressive diseases, including advanced, immune-evasive and treatmentresistant cancers. The company has a portfolio of multiple • Develop companion diagnostics to enrich future clinical clinical assets targeting the receptor tyrosine kinase AXL and is focused on developing a pipeline of first-inclass AXL kinase inhibitors as a potential cornerstone of combination cancer therapy. The company is a world leader in understanding the essential role of AXL kinase in mediating cancer spread, immune evasion and drug resistance in multiple aggressive solid and haematological cancers.

The company's lead drug candidate, bemcentinib, is a highly selective, potent, oral, first-in-class small-molecule AXL inhibitor, currently being evaluated as a potential cornerstone of future cancer therapy in a Phase II clinical programme focussed on mono- and combination therapies in AML and lung cancer.

AXL expression is linked with poor prognosis in most cancers, it allows tumours to become aggressive and resistant to therapy while having immune-suppressive effects. AXL inhibition with bemcentinib, therefore, has potential value as a monotherapy and in combination with other drugs.

The company is investigating bemcentinib in lung cancer and AML/MDS, in combination with current and emerging therapies (including immunotherapies, targeted therapies and chemotherapy), and as a single agent. A broad investigator-initiated trial programme is exploring the wider potential of bemcentinib in disease indications with high scientific rationale, Key Opinion Leaders (KOL) support and high unmet medical need with a view to develop future pipeline opportunities.

BerGenBio's second clinical asset is BGB149, a first-inclass anti-AXL antibody, currently in Phase I studies in healthy volunteers.

The company is focused on executing the following strategic priorities:

- Advance clinical development programme with bemcentinib towards late stage clinical trials in AML
- trials and improve chances of regulatory success
- Advance the clinical development of BGB149
- Secure additional pipeline opportunities for the company's AXL inhibitors in oncology and nononcology indications

# Operational review

# Important progress in 2018: encouraging clinical data support potential of bemcentinib and confirm focus for next stages of development

During 2018, BerGenBio provided clinical readouts on all its ongoing Phase II monotherapy and combination trials confirming that bemcentinib is generally well tolerated and efficacy correlates with AXL biomarkers supporting the proposed mode of action. The company views the data generated in combination with KEYTRUDA in lung cancer and as a monotherapy in AML/MDS as particularly promising.

The encouraging data generated have enabled the company to confirm its focus for the next stages of bemcentinib's development with randomised Phase II studies in NSCLC and in AML/MDS being planned with start during 2019. Accelerated routes to approval will be pursued where appropriate.

To support this next phase of development BerGenBio has further strengthened its operations, in particular the medical and regulatory teams, during 2018.

BerGenBio is focused on further maximising the value from its leadership position in understanding AXL biology driving aggressive disease: (i) investigator-sponsored studies at leading cancer centres around the world explore additional promising cancer indications for bemcentinib, (ii) the company expands its pipeline with new AXL inhibitors, such as BGB149, a novel and proprietary anti-AXL antibody, which entered first-in-human studies in January 2019, and (iii) AXL targeting in the context of non-cancer indications with good scientific rationale, such as fibrosis, is being evaluated through translational and pre-clinical research with a view of potential future clinical trials.

# Board of Directors' report 2018 continued

### Operational review continued

BerGenBio's licence partner ADC Therapeutics SA has advanced ADCT-601, a novel AXL-targeting ADC, into clinical development in patients with advanced solid tumours.

The company ended 2018 with a cash position of NOK 360 million and is positioned to execute its strategy for bemcentinib and BGB149.

#### **Clinical Trial Progress: Bemcentinib**

The company progressed all of its company sponsored clinical trials and provided readouts at or in connection with leading oncology congresses in 2018:

- BGBC003 bemcentinib monotherapy in AML and MDS
- BGBC004 bemcentinib combination therapy with TARCEVA in NSCLC
- BGBC007 bemcentinib combination therapy with KEYTRUDA in TNBC
- BGBC008 combination therapy with KEYTRUDA in NSCLC

In summary, the BGBC003 study showed encouraging monotherapy efficacy and favourable safety in the very frail patient population of relapsed/refractory AML and MDS, particularly in patients who exhibit low levels of circulating AXL (sAXL), an indicator of AXL activity. These results warrant further exploration and the trial continues to enrol AML patients receiving bemcentinib in combination with low intensity therapy.

The BGBC004 study has completed enrolment and met its interim efficacy threshold in demonstrating that combining bemcentinib with TARCEVA in NSCLC patients who have become resistant to TARCEVA monotherapy can induce further benefit in some patients. Combining bemcentinib with TARCEVA in the first line setting showed further benefit from TARCEVA therapy indicating a synergistic effect and bemcentinib's potential to prevent or delay resistance to targeted therapy.

The BGBC007 study of bemcentinib in combination with KEYTRUDA in TNBC is completed. A planned interim readout after completion of the first stage concluded that the first efficacy threshold was not met and progression into the second stage was not warranted. The combination was well tolerated, however, unexpectedly few patients were found to express AXL, the target for bemcentinib. In line with this finding, the combination of bemcentinib and KEYTRUDA was not seen to improve efficacy over monotherapy in this particular cohort of patients.

The BGBC008 study of bemcentinib in combination with KEYTRUDA in NSCLC met its primary efficacy threshold to proceed into stage 2 with continued enrolment. Highly encouraging activity was reported for the combination particularly in AXL positive patients - or approximately half of the studied patient population. These findings warrant further exploration of the combination of bemcentinib with immune checkpoint inhibitors in this indication.

BGB149 is BerGenBio's second clinical candidate and a first-in-class therapeutic anti-AXL antibody. During 2018, a robust and scalable manufacturing route has been established and preparations for clinical testing were completed. The first-in-human clinical trial testing BGB149 in healthy volunteers was initiated on schedule and the first subject was confirmed dosed at the beginning of 2019.

#### **Progress: Companion Diagnostics Programme**

The availability of a predictive biomarker test significantly enhances the chances of regulatory success and later reimbursement, in general and particularly for high-value oncology drugs.

The development of a Companion Diagnostics test is therefore a strategic priority for the company. Consistently, bemcentinib efficacy alone or in combination has scaled with AXL biomarker expression and several candidates continue to be explored and evaluated for progression into forward development of a clinically validated Companion Diagnostics assay.

The company supports its own clinical development programme with a broad portfolio of investigator sponsored clinical trials of high scientific value, commercial interest and key opinion leader endorsement. This is considered a cost-effective strategy to explore opportunities for potential future label extension for bemcentinib.

Similarly, pre-clinical academic collaborations exploring AXL's role in driving additional oncology or non-oncology indications are sought or supported where appropriate.

Encouraging results from such clinical and pre-clinical collaborations have been published at major congresses throughout 2018, increasing the knowledge of selective AXL inhibition as a promising drug target and contributing positively to BerGenBio newsflow.

# **Corporate highlights**

# Clinical operations teams strengthened and other organisational changes

During 2018, the company has further strengthened its operations, particularly the medical and regulatory capabilities, as it expands its pipeline and prepares to advance bemcentinib to the next stages of clinical development.

Alan Barge MD was appointed as Interim Chief Medical Officer and member of the leadership team in November. Dr Barge is a board-certified oncologist and haematologist, with more than 25 years of experience in cancer drug development, spent primarily at AstraZeneca and Amgen. He spent over 12 years at AstraZeneca. during which time he was responsible for the development of Iressa® (gefitinib) for NSCLC and the translational research that resulted in the successful personalised medicine strategy for AZ. More recently, Dr Barge was CMO of Carrick Therapeutics (UK and Ireland) and SVP Oncology at ASLAN Pharmaceuticals (Singapore).

Further, Dr Tone Bjaaland joined as Director of Clinical Operations. She brings more than 25 years' experience in clinical research and further strengthens the team. At the end of 2018, the company had 21 employees and contractors in clinical operations based out of its Oxford,

In December, Dr Susan Foden decided, for personal reasons, to stand down from her position as a Nonexecutive Director and left the Board of Directors at the end of December 2018

## Successful private placement strengthens financial position

In April, the company announced it had raised NOK 187.5 million (USD 24 m) in gross proceeds through an oversubscribed private placement. The placement was directed towards institutional investors primarily in the US including those specialising in the biotechnology sector, bringing added geographical diversity and increased sector specialism to the company's shareholder base.

At the end of 2018, BerGenBio had a cash position at NOK 360 million to support its clinical development strategy.

# Arbitration with Rigel Pharmaceuticals, Inc.

In September, BerGenBio served Notice of Arbitration to Rigel pursuant to a License Agreement for bemcentinib 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 Group operates in a highly competitive industry sector with many large players and may be subject to rapid and substantial technological change.

BerGenBio is currently in a development phase involving activities that entail exposure to various risks. BerGenBio's lead product candidate bemcentinib is currently in Phase II clinical trials. This is regarded as an early stage of development and the clinical studies may not prove to be successful. Timelines for completion of clinical studies are to some extent depending on external factors outside the control of the Group, including resource capacity at clinical trial sites, competition for patients, etc.

The financial success of BerGenBio and / or its commercial partners requires obtaining marketing authorisation and achieving an acceptable reimbursement price for its drugs. There can be no guarantee that the drugs will obtain the selling prices or reimbursement rates foreseen.

BerGenBio and / or its commercial partners will need approvals from the US Food & Drug Administration (FDA) to market its products in the US, and from the European Medicines Agency (EMA) to market its products in Europe, as well as equivalent regulatory authorities in other worldwide jurisdictions to commercialise in those regions. The future earnings are likely to be largely dependent on the timely marketing authorisation of bemcentinib for various indications.

#### **Financial risks**

# Interest rate risk

The Group holds cash and cash equivalents and does not have any borrowings. The Group's interest rate risk is therefore in the rate of return of its cash on hand. Bank deposits are exposed to market fluctuations in interest rates, which affect the financial income and the return on cash.

# Board of Directors' report 2018 continued

#### Risks and uncertainties continued

# Exchange rate risk

**BerGenBio** 

The value of non-Norwegian currency denominated costs will be affected by changes in currency exchange rates or exchange control regulations. The Group undertakes various transactions in foreign currencies and is consequently exposed to fluctuations in exchange rates. The exposure arises largely from the clinical trials and research expenses. The Group is mainly exposed to fluctuations in euro (EUR), pounds sterling (GBP) and US dollar (USD). The Group has chosen not to hedge its operational performance as the Group's cash flow is denominated in several currencies that change depending on where clinical trials are run. 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 2018 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 187 million gross in April 2018.

#### Non-financial risks

# Technology risk

The Group's lead product candidate, bemcentinib (BGB324), is currently in Phase II clinical trials. This is regarded as an early stage of development and the Group's clinical studies may not prove to be successful.

# Competitive technology

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

#### Market risks

The financial success of the Group requires obtaining marketing authorisation and achieving an acceptable reimbursement price for its drugs. There can be no guarantee that the Group's drugs will obtain the selling prices or reimbursement rates foreseen by the Group.

The Group will need approvals from the US Food and Drug Administration (FDA) to market its products in the US, and from the European Medicines Agency (EMA) to market its products in Europe, as well as equivalent regulatory authorities in other worldwide jurisdictions to commercialise in those regions. The Group's future earnings are likely to be largely dependent on the timely marketing authorisation of bemcentinib for various indications.

#### Financial review

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

#### **Accounting policies**

The financial statements of BerGenBio Group have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU on 31 December 2018. Figures is for the Group and for the parent company BerGenBio ASA labelled ASA below).

#### Financial results

# Operating revenues

Revenue for the fourth quarter and full year 2018 amounted to NOK 2.3 million (0.0 million) for the Group and ASA. The revenue represents a preclinical milestone from an out-license agreement with ADCT.

### Operating expenses

Total operating expenses for 2018 for the Group amounted to NOK 196.9 million (NOK 183.7 million), and NOK 197.5 million (NOK 179.6 million) for ASA. Employee costs in the Group were NOK 38.0 million (NOK 28.8 million), and NOK 24.1 million (NOK 21.3 million) for ASA for the full year 2018.

For the full year 2018 other operating costs for the Group amounted to NOK 158.7 million (NOK 154.7 million), and 173.2 million (158.1 million) for ASA. The increase in operating costs is driven by expansion of clinical trials and preparations for new clinical trials. Costs are triggered when clinical trials meet specific milestones of progress, and as recruitment of patients to the clinical trials have progressed, costs have increased proportionately, in keeping with forecasts.

The Group and ASA has recognised government grants for a total of NOK 20.2 million (NOK 22.5 million) for the full year 2018. Payroll expenses has been reduced by NOK 1.4 million (NOK 2.5 million) and operating expenses by NOK 18.9 million (NOK 20.0 million) as a result of these government grants.

The operating loss for the Group in 2018 was NOK 194.5 million (NOK 183.7 million) and NOK 195.1 million (NOK 179.6 million) for ASA, reflecting the increased level of activity related to the many clinical trials BerGenBio is conducting and progress made to trigger milestone payment.

Net financial profit for the Group was NOK 2.8 million (NOK 1.5 million) and NOK 2.9 million (NOK 1.5 million) for ASA for the full year 2018.

Losses after tax for the Group was NOK 191.7 million (NOK 182.2 million) and NOK 192.2 million (NOK 178.1 million) for the full year 2018.

# **Financial position**

Total assets at 31 December 2018 for the group decreased to NOK 378.8 million (384.3 million at year-end 2017) for the Group and to NOK 381.4 (NOK 392.5 million at year-end 2017) for ASA, mainly due to the cash spent on operating activities adjusted for the capital raise completed in April 2018.

Total liabilities was NOK 41.5 million (NOK 34.0 million at year-end 2017) for the Group and NOK 40.5 million (NOK 38.0 million at year-end 2017) for ASA.

Total equity as of 31 December 2018 was NOK 337.3 million (NOK 350.4 million at year-end 2017) for the Group and NOK 340.9 million (NOK 354.5 million at year-end 2017) for ASA, corresponding to an equity ratio of 89.0% (91.2%) for the Group and 89.4% (90.3%) for ASA.

#### Cash flow

Net cash flow from operating activities was negative by NOK 186.7 million (NOK 168.1 million) for the Group and negative by NOK 185.1 million (NOK 169.0 million) for ASA for the full year 2018, mainly driven by the increased level of activity related to the clinical trials the Group is conducting as well as milestone payments related to progress made.

Net cash flow used in investing activities during the full year 2018 was negative by NOK 0.3 million (NOK -0.3 million) for the Group and NOK 0.0 million (NOK -0.3 million) for ASA.

Net cash flow from financing activities was NOK 177.0 million (NOK 377.0 million) for the Group and NOK 177.0 million (NOK 377.0 million) for ASA for the full year 2018, reflecting the share issue in April 2018 in relation to the completion of the private placement.

Cash and cash equivalents decreased to NOK 360.4 (NOK 370.4 million) for the Group and NOK 361.4 million (NOK 369.4 million) for ASA.

#### Research and development

While the research and development strategy are designed in-house in BerGenBio, the Group leverages its network of external contract research organisations ("CROs") in order to execute its development strategy. BerGenBio also collaborates with academic institutions to extend the research in areas of interest of the Group.

The Group has employed experienced personnel that are capable of directing work that is performed by the CROs. This approach to product development allows the Group to quickly change research directions and efforts when needed and to quickly bring in new technologies and expertise when necessary.

Uncertainties related to the regulatory approval process and results from ongoing clinical trials generally indicate that the criteria for capitalisation of R&D cost are not met until market authorisation is obtained from relevant regulatory authorities. The Group has currently no development expenditure that qualifies for recognition as an asset under IAS 38.

## Board of Directors' report 2018 continued

#### Going concern

The Board stated that the annual accounts represent a true and fair view on the Group's financial position at the turn of the year. According to the Norwegian Accounting Act §3-3 (a), the Board of Directors confirmed that the financial statements have been prepared under the assumption of going concern.

#### Corporate social responsibility

BerGenBio's mission is to create value for patients, the society, and its shareholders by discovering and develop novel medicines to treat aggressive diseases, including advanced, treatment resistant cancers.

To ensure that patients, research and development partners, employees, shareholders and other stakeholders feel confident about its commitment to operate this business in accordance with responsible, ethical and sound corporate and business principles, the Group has established a set of ethical guidelines that are presented in its policy for corporate social responsibility (CSR policy). These guidelines provide a framework for what BerGenBio considers as responsible conduct, and defines the individual responsibilities of employees through a combination of broad principles and specific requirements.

The CSR policy apply to all employees and board members in the Group, and is available from the Group's website. By agreement, the ethical guidelines it may also apply to independent consultants, intermediaries or others acting on behalf of BerGenBio. Material breaches of the ethical guidelines may result in termination of employment.

BerGenBio is subject to corporate social responsibility reporting requirements under section 3-3c of the Norwegian Accounting Act. The Group is still in a precommercial phase, with a strong focus on activities aiming to achieve regulatory approval of its drug candidates. The implementation of specific goals, strategies or action plans related to CSR has thus not yet been prioritised but will be developed along with the continuous development of BerGenBio's products and operations.

#### Health, safety and working environment

BerGenBio promotes an open and strong corporate culture, with a healthy, safe and fair work environment in accordance with applicable laws and regulations. BerGenBio will not use force of any form or involuntary labour or employ any persons below the legal minimum age.

At year end, BerGenBio employed 25 people (26 people), of which 16 in Bergen and 9 in Oxford. The working environment in the Group is regarded as good.

Absence due to illness for the year for BerGenBio ASA totalled 247 working days (172 working days), which corresponds to 6,68 per cent (4,32 per cent) of total working days. No work-related incidents or accidents were registered in 2018 (0).

BerGenBio promotes a productive and inclusive working environment, free from harassment, discrimination and disrespectful behaviour. All employees are offered equal opportunities with regards to hiring, compensation, training, promotion, termination or retirement, regardless of gender, age, ethnic and national origin, religion, sexual orientation, social background or other distinguishing characteristics. The Group has traditionally recruited from environments where the number of women and men is relatively equally represented. At the end of the year, two out of eight executives in the management team were women. Among the Board of Directors, three out of seven board members are women.

BerGenBio seeks to offer competitive remuneration to all employees, reflecting their education, experience responsibility and professional qualifications. The Group has also implemented a share option programme for its employees to promote mutually long-term interests between employees, the Group and its shareholders. The programme also serves to attract and retain senior management. Further information can be found in note 6 to the 2018 annual financial statements.

#### **Business ethics and anti-corruption**

BerGenBio follows existing principles, regulations and guidelines to ensure the highest ethical standards in its research. BerGenBio also work to minimize the risk that volunteers and patients are exposed to. All employees as well as external contractors are required to strictly adhere to the Group's guidelines for Ethics in Research & Development.

The Group takes a zero tolerance stands towards corruptions, money laundering and insider trading. All employees are encouraged to report any breaches of Group regulations. No incidents were reported in 2018.

#### **Environmental impact**

BerGenBio strives to minimise its impact on the environment, and its activities are subject to strict requirements in terms of quality, safety and impacts on personal health and the environment.

The Group does not pollute the external environment to a greater extent than is normal for this industry. All production and distribution are outsourced to carefully selected qualified vendors.

#### Share information

As of 31 December 2018, there were 54,711,446 ordinary shares outstanding, up from 49,922,200 shares at year end 2017, following the private placement in April 2018.

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

The company had more than 3,000 shareholders at 31 December 2018.

The result for 2018 show a loss of NOK 192,233,987. The board of director propose the loss to be covered by share premium.

#### Outlook

BerGenBio's broad Phase II clinical development programme with bemcentinib, pipeline of AXL inhibitors and 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, have established proof-of-concept for AXL inhibition as an attractive approach for cancer therapy and are providing valuable information to inform the future development strategy for bemcentinib. As such the company aims to initiate randomised Phase II trials with bemcentinib in NSCLC and AML during 2019. Further clinical data will be reported at future medical congresses and as appropriate by the company.

In retaining global rights to bemcentinib, BerGenBio maintains complete strategic flexibility for its future development and commercialisation. It is anticipated that the high novelty of bemcentinib plus its promising therapeutic profile, particularly in combination with existing therapies, will make it (and future pipeline candidates) attractive targets for partnering. A "goto market" strategy may also be considered in select indications in discrete territories, where greater value for shareholders could be created.

#### Bergen, 20 February 2019, The Board of Directors, BerGenBio ASA



# **Confirmation** from the Board of **Directors and CEO**

We confirm that, to the best of our knowledge, the financial statements for the period from 1 January to 31 December 2018 have been prepared in accordance with IFRS as adopted by EU and the Norwegian Accounting Act and give a true and fair view of the Group and the company's consolidated assets, liabilities, financial position and results of operations, and that the Report of the Board of Directors provides a true and fair view of the development and performance of the business and the position of the Group and the company together with a description of the key risks and uncertainty factors that the company is facing.

Bergen, 20 February 2019, The Board of

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Directors/CEO, BerGenBio ASA

# Income statement and other comprehensive income

1 January – 31 December (NOK 1,000)

Parent 2017	Parent 2018		Note	Group 2018	Group 2017
0	2,335	Revenue	4	2,335	0
21,341	24,054	Employee benefit expenses	5, 7, 10	38,012	28,827
193	204	Depreciation	8	204	193
158,062	173,217	Other operating expenses	7, 9 ,13, 22	158,658	154,687
179,596	197,475	Total operating expenses		196,874	183,708
(179,596)	(195,140)	Operating profit		(194,539)	(183,708)
4,092	4,794	Finance income	11	4,857	4,168
2,599	1,888	Finance expense	11	2,065	2,668
1,492	2,906	Financial items, net		2,792	1,500
(178,104)	(192,234)	Profit before tax		(191,747)	(182,208)
0	0	Income tax expense	12	0	0
(178,104)	(192,234)	Profit after tax		(191,747)	(182,208)
		Other comprehensive income			
		Items which will not be reclassified over profit and loss			
(178,104)	(192,234)	Total comprehensive income for the year		(191,747)	(182,208)
		Earnings per share:			
(3.91)	(3.61)	– Basic and diluted per share	14	(3.60)	(4.01)

# Statement of financial position

31 December (NOK 1,000)

Parent 2017	Parent 2018	Note	Group 2018	Group 2017
		ASSETS		
		Non-current assets		
557	581	Property, plant and equipment 8	581	557
557	581	Total non-current assets	581	557
		Current assets		
22,507	21,430	Other current assets 7, 15, 22	17,831	13,430
369,426	359,403	Cash and cash equivalents 16, 20	360,413	370,350
391,933	380,833	Total current assets	378,245	383,780
392,489	381,414	TOTAL ASSETS	378,826	384,336
		EQUITY AND LIABILITIES		
	•	Equity		
	•	Paid in capital		
4,992	5,471	Share capital 17	5,471	4,992
329,122	313,408	Share premium 17	309,791	325,018
20,340	22,018	Other paid in capital 6, 17	22,018	20,340
354,454	340,897	Total paid in capital	337,280	350,350
354,454	340,897	Total equity	337,280	350,350
		Current liabilities		
25,970	23,692	Accounts payable	23,939	21,575
9,046	12,094	Other current liabilities 18	12,875	9,391
3,020	4,732	Provisions 19	4,732	3,020
38,035	40,517	Total current liabilities	41,546	33,986
38,035	40,517	Total liabilities	41,546	33,986
392,489	381,414	TOTAL EQUITY AND LIABILITIES	378,826	384,336

Bergen 20 February 2019, The Board of Directors, BerGenBio ASA

Richard Godfrey (CEO)

# Statement of changes in equity

(NOK 1,000)

Group 2018	Note	Share capital	Share premium	Other paid in capital	Total equity
Balance at 1 January 2018		4,992	325,018	20,340	350,350
Profit after tax		0	(191,747)	0	(191,747)
Other comprehensive income (loss) for the year, net of income tax		0	0	0	0
Total comprehensive income for the year		0	(191,747)	0	(191,747)
Recognition of share-based payments	5, 6	0	0	1,678	1,678
Issue of ordinary shares	17	479	190,047	0	190,525
Share issue costs	17	0	(13,527)	0	(13,527)
Balance at 31 December 2018		5,471	309,791	22,018	337,280

Group 2017	Note	Share capital	Share premium	Other paid in capital	Total equity
Balance at 1 January 2017		3,369	131,875	18,026	153,270
Profit after tax		0	(182,208)	0	(182,208)
Other comprehensive income (loss) for the year, net of income tax		0	0	0	0
Total comprehensive income for the year		0	(182,208)	0	(182,208)
Recognition of share-based payments	5, 6	0	0	2,314	2,314
Issue of ordinary shares	17	1,623	400,673	0	402,296
Share issue costs	17	0	(25,322)	0	(25,322)
Balance at 31 December 2017		4,992	325,018	20,340	350,350

Parent 2018	Note	Share capital	Share premium	Other paid in capital	Total equity
Balance at 1 January 2018		4,992	329,122	20,340	354,454
Loss for the year		0	(192,234)	0	(192,234)
Other comprehensive income (loss) for the year, net of income tax		0	0	0	0
Total comprehensive income for the year		0	(192,234)	0	(192,234)
Recognition of share-based payments	5, 6	•	•	1 678	1,678
Issue of ordinary shares	17	479	190,047	0	190,525
Share issue costs	17	0	(13,527)	0	(13,527)
Balance at 31 December 2018		5,471	313,408	22,018	340,897

Parent 2017	Note	Share capital	Share premium	Other paid in capital	Total equity
Balance at 1 January 2017		3,369	131,875	18,026	153,270
Loss for the year		0	(178,104)	0	(178,104)
Other comprehensive income (loss) for the year, net of income tax		0	0	0	_
Total comprehensive income for the year		0	(178,104)	0	(178,104)
Recognition of share-based payments	5, 6	0	0	2,314	2,314
Calculated interest element on convertible loan	11, 17	0	0	0	_
Issue of ordinary shares	17	1,623	400,673	0	402,296
Share issue costs	17	0	(25,322)	0	(25,322)
Balance at 31 December 2017		4,992	329,122	20,340	354,454

# Statement of cash flows

1 January – 31 December (NOK 1,000)

Parent 2017	Parent 2018		Note	Group 2018	Group 2017
		Cash flow from operating activities			
(178,104)	(192,234)	Profit before tax		(191,747)	(182,208)
		Non-cash adjustments to reconcile loss before tax to net cash flows			
193	204	Depreciation of property, plant and equipment	8	204	193
2,314	1,678	Share-based payment expense	5	1,678	2,314
(1,823)	1,712	Movement in provisions and pensions	10, 19	1,712	(1,823
		Working capital adjustments:			
(10,205)	1,076	Decrease in trade and other receivables and prepayments		(4,401)	(1,128
18,593	770	Increase in trade and other payables		5,847	14,543
(169,032)	(186,793)	Net cash flow from operating activities		(186,706)	(168,108
		Cash flows from investing activities			
(340)	(228)	Purchase of property, plant and equipment	8	(228)	(340
(340)	(228)	Net cash flow used in investing activities		(228)	(340
		Cash flows from financing activities			
402,296	190,525	Proceeds from issue of share capital	17	190,525	402,296
(25,322)	(13,527)	Share issue cost		(13,527)	(25,322
376,974	176,998	Net cash flow from financing activities		176,998	376,974
207,602	(10,023)	Net increase/(decrease) in cash and cash equivalents		(9,936)	208,525
161,825	369,426	Cash and cash equivalents at beginning of period	16	370,350	161,825
369,426	359,403	Cash and cash equivalents at end of period	16	360,414	370,350

**BerGenBio** 

# FINANCIAL STATEMENTS

## Notes to the financial statements

#### Note 1 – Corporate information

BerGenBio ASA ("the company") as the Parent Company and its subsidiary (together "the Group") is a clinical-stage biopharmaceutical company developing innovative drugs for aggressive diseases, including immune evasive, drug resistant and meastatic cancers.

BerGenBio's lead product, bemcentinib (BGB324), is a selective, potent and orally bio-available small molecule AXL inhibitor in company sponsored Phase II clinical trials in major cancer indications, with read-outs anticipated during 2019. It is the most advanced selective AXL inhibitor in clinical development.

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.

BerGenBio retains strategic flexibility for the further development and commercialisation of its product candidates: it is anticipated that the high novelty of bemcentinib plus its promising therapeutic profile will make it (and later other pipeline candidates) attractive targets for strategic partnering; a "Go-to market" strategy will also be considered in select indications in discrete territories.

The consolidated financial statements and the financial statement for the company cover the year ending 31 December 2018 and were approved for issue by the Board of Directors on 20 February 2019.

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

The principal accounting policies applied in the preparation of these financial statements are set out below. These policies have consistently been applied in all periods presented. Amounts are in Norwegian kroner (NOK) and all values are presented in 1,000 NOK, except when otherwise indicated. The functional currency of the Group and the company is NOK.

#### **Basis for preparation**

The consolidated financial statements for the Group and the company have been prepared in accordance with IFRS as adopted by the EU.

#### **Basis for consolidation**

The consolidated financial statements comprise the financial statements of the company and its subsidiary as at 31 December 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. BerGenBio Limited was incorporated 10 January 2017 with a share capital of NOK 1,044.

#### Going concern

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. An IPO and capital increase of gross NOK 400 million was successfully completed on the 7 April 2017 and a private placement raising gross NOK 187.5 million where successfully completed on the 13 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 financial statements are prepared under the going concern assumption.

#### Summary of significant accounting policies

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.

#### Revenue recognition

Revenue is recognised to the extent that it is probable that the economic benefits will flow to the Group and the revenue can be reliably measured, regardless of when the payment is being made. Revenue is measured at the fair value of the consideration received or receivable, and is recognised excluding taxes or duties.

The Group's products are still in the research and development phase, and have limited revenue from sales of products yet.

The Group have entered into an out licence agreement where development, regulatory and sales-based milestone trigger revenue payment to the Group. Revenue from out licence agreement are recognised in the period when the milestone events occur.

#### **Government grants**

Government grants are recognised where there is reasonable assurance that the grant will be received and all attached conditions will be complied with. The grant is recognised in the income statement in the same period as the related costs, and presented net. Government grants are recognised at the value of the contribution at the

Government grants are normally related to either reimbursements of employee costs and classified as a reduction of payroll and related expenses, or related to other operating activities and thus classified as a reduction of other operating expenses.

#### Research and development costs

Research costs are expensed as incurred. Internal development costs related to the Group's development of products are recognised in the income statement in the year incurred unless it meets the asset recognition criteria of IAS 38 "Intangible Assets". An internally generated asset arising from the development phase of an R&D project is recognised as an intangible asset if the Group can demonstrate:

- Its ability to use or sell the intangible assets
- The technical feasibility of completing the intangible asset so that the asset will be available for use or sale
- Its intention to complete and its ability and intention to use or sell the asset
- How the asset will generate future economic benefits
- The availability of adequate technical, financial and other resources to complete the development and use or sell the asset
- The ability to measure reliably the expenditure during development

Uncertainties related to the regulatory approval process and results from on-going clinical trials, generally indicate that the criteria are not met until the time when marketing authorisation is obtained from relevant regulatory authorities. The Group has currently no development expenditure that qualifies for recognition under IAS 38.

#### Property, plant and equipment

Property, plant and equipment are stated at cost, net of accumulated depreciation and accumulated impairment losses, if any. Acquisition cost includes expenditures that are directly attributable to the acquisition of the individual item. Property, plant and equipment are depreciated on a straight-line basis over the expected useful life of the asset. If significant individual parts of the assets have different useful lives, they are recognised and depreciated separately. Depreciation commences when the assets are ready for their intended use.

Depreciation is calculated over the estimated useful lives of the assets, as follows:

• Computer equipment 5 years • Other equipment 5 years

An item of property, plant and equipment and any significant part initially recognised is derecognised upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss arising on derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the income statement when the asset is derecognised.

The residual values, useful lives and methods of depreciation of the property, plant and equipment are reviewed at each financial year and adjusted prospectively, if appropriate.

#### Note 2 - Basis for preparation and significant accounting policies continued

#### Investment in subsidiaries

Subsidiaries are consolidated in the Group Financial statement. In the company Financial Statement subsidiaries are accounted at cost.

#### Leases

The determination of whether an arrangement is (or contains) a lease is based on the substance of the arrangement at the inception of the lease.

#### The Group as a lessee

A lease is classified at the inception date as a finance lease or an operating lease. A lease that transfers substantially all the risks and rewards incidental to ownership to the Group is classified as a finance lease.

Operating lease payments are recognised as an operating expense in the statement of profit or loss on a straight-line basis over the lease term.

The Group has not entered into any finance lease arrangements.

#### Financial assets

#### Initial recognition and measurement

Financial assets are classified, at initial recognition, as subsequently measured at amortised cost, fair value through other comprehensive income (OCI), and fair value through profit or loss.

Financial assets are recognised initially at fair value plus, in the case of financial assets not recorded at fair value through profit or loss, transaction costs that are attributable to the acquisition of the financial asset.

#### Financial assets at amortised cost

This category is the most relevant to the Group. The Group measures financial assets at amortised cost if both of the following conditions are met:

- The financial asset is held within a business model with the objective to hold financial assets in order to collect contractual cash flows and
- The contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding

Financial assets at amortised cost are subsequently measured using the effective interest (EIR) method and are subject to impairment. Gains and losses are recognised in profit or loss when the asset is derecognised, modified or impaired.

The Group does not have financial assets at fair value through profit and loss.

#### Impairment of financial assets

The Group assesses, at each reporting date, whether there is objective evidence that a financial asset or a group of financial assets is impaired. An impairment exists if one or more events that has occurred since the initial recognition of the asset (an incurred 'loss event'), has an impact on the estimated future cash flows of the financial asset or the group of financial assets that can be reliably estimated. Evidence of impairment may include indications that the debtors or a group of debtors is experiencing significant financial difficulty, default or delinquency in interest or principal payments, the probability that they will enter bankruptcy or other financial reorganisation and observable data indicating that there is a measurable decrease in the estimated future cash flows, such as changes in arrears or economic conditions that correlate with defaults.

The amount of any impairment loss identified is measured as the difference between the asset's carrying amount and the present value of estimated future cash flows (excluding future expected credit losses that have not yet been incurred).

#### Financial liabilities

#### Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, loans and borrowings, payables, or as derivatives designated as hedging instruments in an effective hedge, as appropriate.

All financial liabilities are recognised initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

The Group's financial liabilities include trade and other payables, and loans and borrowings.

The Group does not have financial liabilities at fair value through profit and loss.

#### Derecognition

A financial liability is derecognised when the obligation under the liability is discharged or cancelled or expires.

#### **Share-based payments**

The Group operates an equity-settled, share-based compensation plan, under which the Group receives services from employees and members of the Board as consideration for share-based payments (options).

The cost of equity-settled transactions is determined by the fair value at the date when the grant is made using an appropriate valuation model.

That cost is recognised, together with a corresponding increase in other capital reserves in equity, over the period in which the performance and/or service conditions are fulfilled in employee benefits expense. The cumulative expense recognised for equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and the Group's best estimate of the number of equity instruments that will ultimately vest. The statement of profit or loss expense or credit for a period represents the movement in cumulative expense recognised at the beginning and end of that period and is recognised in employee benefits expense.

The fair value of the options granted is measured using the Black-Scholes model. Measurement inputs include share price on the measurement date, exercise price of the instrument, expected volatility, weighted average expected life of the instruments, expected dividends and the risk-free interest rate.

When the options are exercised, the Group will issue new shares. The proceeds received net of any directly attributable transaction costs are recognised as share capital (nominal value) and share premium reserve.

#### **Taxes**

#### Current income tax

Current income tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted, at the reporting date in the country where the Group operates and generates taxable income.

#### Deferred ta

Deferred tax is provided using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date.

Deferred tax liabilities are recognised for all taxable temporary differences, except:

When the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss

Deferred tax assets are recognised for all deductible temporary differences, the carry forward of unused tax credits and any unused tax losses. Deferred tax assets are recognised to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carry forward of unused tax credits and unused tax losses can be utilised.

#### Note 2 – Basis for preparation and significant accounting policies continued

#### Taxes continued

#### Deferred tax continued

The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilised. Unrecognised deferred tax assets are re-assessed at each reporting date and are recognised to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

Deferred tax relating to items recognised outside profit or loss is recognised outside profit or loss.

Deferred tax items are recognised in correlation to the underlying transaction either in OCI or directly in equity.

#### Foreign currencies

The Group's financial statements are presented in NOK, which is also the parent's functional currency.

The subsidiary BerGenBio Limited's functional currency is NOK and no effect occurred by consolidating into Group.

#### Transactions and balances

Transactions in foreign currencies are recorded at their respective functional currency spot rates at the date the transaction first qualifies for recognition.

Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency spot rates of exchange at the reporting date.

Differences arising on settlement or translation of monetary items are recognised in profit or loss as financial items.

#### Cash and short-term deposits

Cash and short-term deposits in the statement of financial position comprise cash at banks and on hand and shortterm deposits with a maturity of three months or less, which are subject to an insignificant risk of changes in value.

For the purpose of the statement of cash flows, cash and cash equivalents consist of cash and short-term deposits, as defined above. The indirect method is used to prepare the statement of cash flow.

#### **Provisions**

Provisions are recognised when the Group has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation. The expense relating to a provision is presented in the Income Statement and other Comprehensive Income net of any reimbursement.

If the effect of the time value of money is material, provisions are discounted using a current pre-tax rate that reflects, when appropriate, the risks specific to the liability. When discounting is used, the increase in the provision due to the passage of time is recognised as a finance cost.

#### Pensions and other post-employment benefits

As per 1 October 2016, the Group decided to change the defined benefit scheme to a defined contribution scheme. Under the defined contribution scheme, the Group does not commit itself to paying specific future pension benefits, but makes annual contributions to the employees' pension savings.

The Group's payment to the defined contribution scheme amounts to 7% of salary up to 12G and 18.1% of salary between 7.1G and 12G for Norwegian employees and 7% for UK employees (G is Norwegian National Insurance basic amount).

Further details about pensions, and the closing of the defined benefit scheme, are given in Note 10.

#### New and amended standards and interpretations

The standards and interpretations that are issued, but not yet effective, up to the date of issuance of the Group's financial statements are disclosed below.

Note that only the ones that are expected to have material impact on the Group's financial position, performance, and/ or disclosures are discussed. The Group intends to adopt these standards, if applicable, when they become effective.

#### IFRS 16 Leases

IFRS 16 was issued in January 2016 and sets out the principles for the recognition, measurement, presentation and disclosure of leases and requires lessees to account for all leases under a single on-balance sheet model similar to the accounting for finance leases under IAS 17.

The standard includes two recognition exemptions for lessees – leases of 'low-value' assets (e.g., personal computers) and short-term leases (i.e., leases with a lease term of 12 months or less). At the commencement date of a lease, a lessee will recognise a liability to make lease payments (i.e., the lease liability) and an asset representing the right to use the underlying asset during the lease term (i.e., the right-of-use asset). Lessees will be required to separately recognise the interest expense on the lease liability and the depreciation expense on the right-of-use asset.

Lessees will be also required to remeasure the lease liability upon the occurrence of certain events (e.g., a change in the lease term, a change in future lease payments resulting from a change in an index or rate used to determine those payments). The lessee will generally recognise the amount of the remeasurement of the lease liability as an adjustment to the right-of-use asset.

Lessor accounting under IFRS 16 is substantially unchanged from today's accounting under IAS 17. Lessors continue to classify all leases using the same classification principle as in IAS 17 and distinguish between two types of leases: operating and finance leases.

IFRS 16 also requires lessees and lessors to make more extensive disclosures than under IAS 17.

IFRS 16 is effective for annual periods beginning on or after 1 January 2019. A lessee can choose to apply the standard using either a full retrospective or a modified retrospective approach. The standard's transition provisions permit certain reliefs. The Group will use the modified retrospective approach when implementing IFRS 16 from 1 January 2019.

The Group/company will measure the right of use asset at an amount equal to the lease liability immediately before the date of initial application. The implementing effect on lease asset and financial liabilities is calculated to an increasement of mNOK 1.1 at 1 January 2019. There will not be any significant effect on profit and loss.

Other standards, interpretations and amendments that are issued, but not yet effective are either not applicable for the Group or is not expected to have a material impact of the financial statements.

#### Note 3 – Significant accounting judgements, estimates and assumptions

The preparation of the Group's financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of assets or liabilities affected in future periods.

#### **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.

#### **Share-based payments**

The Group initially measures the cost of cash-settled transactions with employees using the Black-Scholes model to determine the fair value of the liability incurred. Estimating fair value for share-based payment transactions requires determination of the most appropriate valuation model, which is dependent on the terms and conditions of the grant. This estimate also requires determination of the most appropriate inputs to the valuation model including the expected life of the share option, volatility and dividend yield and making assumptions about them. The assumptions and models used for estimating fair value for share-based payment transactions are disclosed in Note 6.

#### Note 4 – Segments and revenue

For management purposes the Group is organised as one business unit and the internal reporting is structured in accordance with this.

The Group has entered into a out licence agreement where development, regulatory and sales-based milestones are due upon the occurrence of certain specific events. In Q4 2018 a pre-clinical development milestone triggered a milestone payment and revenue to BerGenBio ASA at NOK 2.3 million.

#### Note 5 – Payroll and related expenses

Parent 2017	Parent 2018		Group 2018	Group 2017
17,211	13,232	Salaries	24,941	22,860
2,723	3,012	Social security tax	4,465	3,296
1,328	1,275	Pension expense	2,066	1,770
1,347	2,199	Bonus	2,199	2,170
2,314	1,678	Share option expense employees	1,678	2,314
(1,823)	1,712	Accrued social security tax on share options	1,712	(1 823)
749	2,320	Other remuneration	2 ,27	749
(2,508)	(1,376)	Government grants	(1,376)	(2 508)
21,341	24,054	Total payroll and related expenses	38,012	28,827
18	15	Average number of full time equivalent employees	24	24

#### Management remuneration

Total remuneration to management during the year ended 31 December 2018

			Salary	Bonus	Pension expense	Other remuneration
Richard Godfrey (CEO)		A)	2,802	920	182	11
Rune Skeie (CFO)	2)	B)	955		146	6
James B Lorens (CSO)	1)	C)	496	175	37	6
Anthony Brown (Director of Research)		D)	1,354	183	95	
Tone Bjaaland (Director of Clinical Operations)	3)	E)	651		46	
Petter Nielsen (former CFO)	4)		721		98	4
Viki Wills (former Director of Clinical Operations)	5)		839	210	59	
Murray Yule (Clinical Development Officer)	6)		2,150	318	150	
Total remuneration			9,967	1,806	813	27

- 1) Employed part-time in a 20% position.
- 2) Employed March 2018
- 3) Employed July 2018
- 4) Resigned May 2018
- 5) Resigned July 2018
- 6) Resigned November 2018

For management participating in the option program, the expense charged to the profit or loss for 2018 is as follows:

- A) Richard Godfrey, 583.5
- B) Rune Skeie 125 1
- C) James Lorens, 53.7
- D) Anthony Brown, 125.4 E) Tone Bjaaland, 45.6

In the event of termination of the CEO's employment contract by the company without cause, he is entitled to 12 months notice or severance payment in lieu of equivalent salary, bonus and benefits. In the event of a change of control the CEO is entitled to compensation of 18 months' salary and at the CEO's sole discretion buy back of his shares to fair market value, both in the event that the employment agreement is terminated within 18 months of a change of control of the company.

#### Total remuneration to management during the year ended 31 December 2017

			Salary	Bonus	Pension expense	Other remuneration
Richard Godfrey (CEO)		A)	2,270	289	179	11
Petter Nielsen (CFO)		B)	1,398	521	174	11
James B Lorens (CSO)	1)	C)	463	143	36	6
Murray Yule (Clinical Development Officer)		D)	2,217	0	155	0
Anthony Brown (Director of Research)		E)	1,277	124	89	0
Viki Wills (Director of Clinical Operations)			1,299	0	91	0
Total remuneration			8,924	1,078	724	28

1) Employed part-time in a 20% position.

For management participating in the option program, the expense charged to the profit or loss for 2017 is as follows:

- A) Richard Godfrev, 1,896.6
- B) Petter Nielsen, 310,6
- C) James Lorens, 1,401.6
- D) Murray Yule, 242.6 E) Anthony Brown, 535.6

In the event of termination of the CEO's employment contract by the Group without cause, he is entitled to 12 months notice or severance payment in lieu of equivalent salary, bonus and benefits. In the event of a change of control the CEO is entitled to compensation of 18 months' salary and at the CEO's sole discretion buy back of his shares to fair market value, both in the event that the employment agreement is terminated within 18 months of a change of control of the Group.

#### Note 5 – Payroll and related expenses continued

#### **Board of Directors remuneration**

**BerGenBio** 

The remuneration to the Board of Directors for the year ended 31 December

		Served since	Served until	2018	2017
Stein Holst Annexstad	A)	February 2016		369	365
Susan Foden 1)	B)	· ·	31 December 2018	169	160
Jon Øyvind Eriksen		January 2012		209	190
Sveinung Hole	C)	September 2010		209	190
Stener Kvinnsland	D)	September 2015		169	160
Hilde Furberg	E)	June 2015		189	175
Kari Grønås	F)	February 2016		189	175
Total remuneration				1,502	1,415

For members of the Board of Directors participating in the option program, the expense charged to the profit or loss for 2018 (2017) is as follows:

- A) Stein H. Annexstad, 0 (2017: 0)
- B) Susan Foden, 8.8 (2017: 121.4)
- C) Sveinung Hole, 0 (2017: 0)
- D) Stener Kvinnsland, 0 (2017: 0)
- E) Hilde Furberg, 5.9 (2017: 78.7)
- F) Kari Grønås, 3.5 (2017: 47.2)
- 1) Susan Foden resigned from BoD 1 January 2019.

#### Members of management and Board of Directors participating in the option program at year end

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	23-May-18	23-May-26	46.70
	50,000	31-Oct-18	31-Oct-26	28.50
James B Lorens	50,000	10-Sep-10	31-Dec-19	5.65
	25,000	27-May-11	31-Dec-19	7.56
	75,000	21-Jun-12	31-Dec-19	10.62
	55,000	3-Sep-13	3-Sep-21	10.62
	100,000	13-Jun-13	13-Jun-21	10.62
	70,000	11-Jun-14	11-Jun-22	11.15
	275,000	22-May-15	22-May-23	16.01
	50,000	1-Jan-16	1-Jan-24	24.00
	10,707	23-May-18	23-May-26	46.70
	7,000	31-Oct-18	31-Oct-26	28.50
Rune Skeie	24,090	23-May-18	23-May-26	46.70
	20,000	31-Oct-18	31-Oct-26	28.50
Anthony Brown	100,000	2-Sep-15	2-Sep-23	16.01
	50,000	1-Jan-16	1-Jan-24	24.00
	26,499	23-May-18	23-May-26	46.70
	10,000	31-Oct-18	31-Oct-26	28.50
Tone Bjaaland	45,000	31-Oct-18	31-Oct-16	28.50
Susan Foden 1)	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
Total	2,418,280			

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

<sup>1)</sup> Susan Foden resigned from BoD from 1 January 2019.

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### Notes to the financial statements continued

#### Note 6 – Employee share option program

The Group has a share option scheme for employees. Each option gives the right to acquire one share of 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.

Options vest 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 (NOK)
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 2023	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 2018	May 2026	46.70
Granted in October 2018	277,000	Oct 2018	Oct 2026	28.50
Forfeited in 2015 1)	(7,500)			10.62
Forfeited in 2016 1)	(50,000)			16.01
Exercised in 2017 1)	(230,000)			9.98
Forfeited and cancelled in 2017 1)	(220,000)			12.33
Exercised in 2018 1)	(160,000)			19,01
Forfeited in 2018 1)	(245,513)			26.27
Total	3,181,514	<u> </u>		

In the annual general meeting on the 22 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 average weighted expected remaining lifetime of options is 3.9 years at year end.

	2018		2017	
Total options	Number of options	Weighted average exercise price (NOK)	Number of options	Weighted average exercise price (NOK)
Balance at 1 January	2,925,000	14.20	3,325,000	13.66
Granted during the year	662,027	39.08	50,000	22.00
Exercised during the year	(245,513)	26.27	(230,000)	9.98
Forfeited and cancelled	(160,000)	19,01	(220,000)	12.33
Balance at 31 December	3,181,514	18.20	2,925,000	14.20

In the annual general meeting on the 22 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 table above takes into account the share split.

50,000 options were granted in 2017 with an exercise price of NOK 22. The weighted average fair value of the options granted in 2016 was NOK 1,012, totalling NOK 1.2 million.

Vested options	2018	2017
Options vested at 1 January	2,891,667	2,211,900
Exercised and forfeited in the period	(310,000)	(280 000)
Vested in the period	16,667	959,767
Options vested at 31 December	2,598,334	2891,667
Total outstanding number of options	3,181,514	2,925,000

In the annual general meeting on the 22 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. For figures in 2017 the overview above takes into account the share split.

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 43% expected future volatility has been applied. As BerGenBio 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 twelve month period ending 31 December 2018 the value of the share options expensed through the profit or loss amounts to NOK 1.7 million (for the same period in 2017: NOK 2.3 million). In addition a provision for social security contributions on share options of NOK 1.7 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.

<sup>\*1)</sup> The exercise price is calculated as the weighted average exercise price of the forfeited, cancelled and exercised options.

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**BerGenBio** 

# INANCIAL STATEMENTS

## Notes to the financial statements continued

#### Note 7 – Government grants

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

Parent 2017	Parent 2018		Group 2018	Group 2017
2,508		Payroll and related expenses	1,376	2,508
19,971		Other operating expenses	18,847	19,971
22,479	20,223	Total	20,223	22,479

Grants receivable as at 31 December are detailed as follows:

Parent 2017	Parent 2018		Group 2018	Group 2017
4,840		Grants from Research Council, BIA	2,297	4,840
		Grants from Innovasjon Norge	5,400	
6,958		Grants from SkatteFunn	7,933	6,958
11,798	15,630	Total	15,630	11,798

#### **BIA grants from the Research Council:**

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 2015 to April 2019. The Group has recognised NOK 2.9 million in Q4 2018 (Q4 2017: NOK 2.5 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 4.0 million in Q4 2018 (Q4 2017: NOK 4.0 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:

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 2018 (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 7.9 million in Q4 2018 (Q4 2017: NOK 7.0 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses.

#### Innovasjon Norge:

BerGenBio has been awarded a NOK 24 million (USD2.85m) grant from Innovasjon Norge to support the clinical development of bemcentinib in combination with Merck & Co.'s KEYTRUDA® (pembrolizumab) in patients with advanced lung cancer.

The grant from Innovasjon Norge is an Industrial Development Award (IFU). The IFU program is directed to Norwegian companies developing new products or services in collaboration with foreign companies. BerGenBio received NOK 7.2 million in Q4 2017 of this grant. The grant may be withdrawn under certain circumstances related to the organisation. The Group has recognised NOK 5.4 million in Q4 2018 (Q4 2017: NOK 7.2 million) classified as cost reduction of other operating expenses.

#### Note 8 - Property, plant and equipment

Year ended 31 December 2018 Parent/Group	Furnitures	Equipment / fittings	Total
Cost at 1 January 2018	0	1,474	1,474
Additions in the year	70	159	228
Disposals in the year	0	0	0
Cost at 31 December 2018	70	1,632	1,702
Accumulated depreciation at 1 January 2018	0	(917)	(917)
Depreciation in the year	(8)	(196)	(204)
Accumulated depreciation at 31 December 2018	(8)	(1,113)	(1,121)
Net carrying amount at 31 December 2018	61	520	581
Estimated useful life	5 years	5 years	
Depreciation method	Straight-line	Straight-line	

Year ended 31 December 2017 Parent/Group	Furnitures	Equipment / fittings	Total
Cost at 1 January 2017	16	1,134	1,150
Additions in the year	0	340	340
Disposals in the year	0	0	0
Cost at 31 December 2017	16	1,474	1,490
Accumulated depreciation at 1 January 2017	(15)	(725)	(740)
Depreciation in the year	(1)	(192)	(193)
Accumulated depreciation at 31 December 2017	(16)	(917)	(933)
Net carrying amount at 31 December 2017	0	557	557
Estimated useful life	5 years	5 years	
Depreciation method	Straight-line	Straight-line	

#### Research & Development

Expenses for research and development for the financial year 2018 for Parent/Group was gross NOK 150.4 million (net NOK 130.2 million reduced of grants NOK 20.2 million) of which gross NOK 146.6 million (net NOK 127.8 million) was classified as other operating expenses and gross NOK 3.8 million (net NOK 2.4 million) was classified as payroll.

For 2017 gross NOK 160.0 million (net NOK 137.5 million) was expensed for research and development, of which gross NOK 152.0 million (net NOK 132.0 million reduced of grants NOK 22.5 million) was classified as other operating expenses and gross NOK 8.0 million (net NOK 5.5 million) was classified as payroll.

The figures are net of government grants that have been recognised in the profit or loss as a reduction of related expense.

The group has not entered any arrangements that are classified as finance leases.

#### Note 9 – Leases

The Group has not entered into any arrangements that are classified as finance leases. The following arrangements are classified as operating leases:

The Group rents premises in Bergen for office and laboratory purposes under two rental agreements. In addition to the rent the Group is charged for a proportionate share of common variable expenses.

The rented premises are in total 245 square metres. Both rental agreements expire on 1 December 2020, with an option of extension for an additional five plus five years. The rental agreements can be terminated by either party with a 12 months notice period.

The annual rental amount, including the share of common variable expense, for the premises is NOK 386,506 (2017: NOK 386,506).

The rent is subject to a yearly adjustment in accordance with the Norwegian consumer price index.

Under the same rental agreement the Group has access to the use of defined scientific equipment at a cost of NOK 43,253 (2017: NOK 41,993) per employee per year. The price is subject to a yearly adjustment of 3.5%.

From September 2015 the Group rents an office in Magdalen Centre, The Oxford Science Park, UK. The rental agreements can be terminated by either party with a 1 months notice period. The monthly rental amount is GBP 7,025.

Parent 2017	Parent 2018	Future minimum rental payable for premises	Group 2018	Group 2017
398		Within 1 year	787	466
0		Within 1–5 years	311	0
0	_	Over 5 years	0	0
398	1,019	Total	1,098	466

#### Note 10 – Pensions

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.

#### Note 11 – Financial income and expense

Parent 2017	Parent 2018		Group 2018	Group 2017
		Financial income		
18	17	Interest income on tax repaid	17	18
2,796	3,499	Interest income on bank deposits	3,499	2,796
1,278	1,279	Other finance income	1,342	1,355
4,092	4,794	Total financial income	4,857	4,168
Parent 2017	Parent 2018		Group 2018	Group 2017
Parent 2017	Parent 2018	Financial expense	Group 2018	Group 2017
<b>Parent 2017</b> 31		Financial expense Other interest expense	<b>Group 2018</b> 47	<b>Group 2017</b>
	47			
31	47 1,842	Other interest expense	47	31

#### Note 12 – Income tax

Parent 2017	Parent 2018		Group 2018	Group 2017
(178,104)		Profit before tax	(191 747)	(182,208)
(42,745)		Income taxes calculated at 23% (2017: 24%)	(44 102)	(43,730)
(1,119)	(1,442)	Non deductible expenses	(1,555)	(1,119)
5,464		Effect of change in tax rate	7,450	5,464
38,399		Change in deferred tax asset not recognised	38,207	39,385
0	0	Tax expense	0	0

#### Deferred tax and deferred tax assets

Parent 2017	Parent 2018		Group 2018	Group 2017
		Deferred tax assets (22% of temporary differences (2017: 23%))		
(124,994)	, , ,	Tax losses carried forward	(162,842)	(124,994)
5		Property, plant and equipment	(6)	5
(695)	( 1 - )	Other	(1,041)	(695)
(125,683)		Deferred tax asset not recognised	(163,889)	(125,683)
0	0	Deferred tax assets – gross	0	0

The Group has a tax loss of NOK 197 million in 2018, and in total a tax loss carried forward as of 31 December 2018 og NOK 744 million. There are no timing restrictions on carrying forward the tax loss, and it can be carried forward indefinitely.

The deferred tax asset has not been recognised in the statement of financial position, as the company does not consider that taxable income in the short-term will sufficiently support the use of a deferred tax asset.

#### Note 13 – Other operating expenses

Parent 2017	Parent 2018		Group 2018	Group 2017
106,468		Program expenses, clinical trials and research	133,699	106,468
27,921	0	Milestone and license payments to Rigel Pharmaceuticals	0	27,921
1,553		Office rent and expenses	1,950	1,553
12,519		Consultants R&D projects	10,290	12,519
4,424		Patent and license expenses	3,289	4,424
25,148	28,625	Other operating expenses	28,277	21,774
(19,971)		Government grants	(18,847)	(19 971)
158,062	173,217	Total	158,657	154,687

#### Specification auditor's fee

Parent 2017	Parent 2018		Group 2018	Group 2017
211		Statutory audit	264	211
152		Other assurance services	227	152
121		Tax consultant services	32	121
484	523	Total	523	484

Amounts are excluding VAT.

#### Note 14 – Earnings per share

Parent 2017	Parent 2018		Group 2018	Group 2017
(178,104)	(192,234)	Profit after tax	(191,747)	(182,208)
45,494,721	53,284,520	Average number of outstanding shares during the year	53,284,520	45,494,721
(3.91)	(3.61)	Earnings (loss) per share – basic and diluted (NOK)	(3.60)	(4.01)

Share options issued have a potential dilutive effect on earnings per share. No dilutive effect has been recognised 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.

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

#### Note 15 – Other current assets

Parent 2017	Parent 2018		Group 2018	Group 2017
11,798		Government grants	15,630	11,798
458	1,356	Refundable VAT	1,356	458
438	488	Prepayments	488	438
9,812		Other receivables	358	735
22,507	21,430	Total	17,831	13,430

#### Note 16 - Cash and cash equivalents

Parent 2017	Parent 2018		Group 2018	Group 2017
717		Employee withholding tax	798	717
21	21	Deposits	21	21
368,688		Short-term bank deposits	359,594	369,611
369,426	359,403	Total	360,413	370,350

Of the total balance in cash and cash equivalents, NOK 0.8 million (2017: NOK 0.7 million) relates to restricted funds for employee withholding taxes.

The Group's short-term bank deposits are on variable rate terms.

#### Note 17 – Share capital and shareholder information

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

As of 31 December	Number of shares	Nominal value (NOK)	Book value (NOK)
Ordinary shares 2018	54,711,446	0.10	5,471,145
Ordinary shares 2017	49,922,200	0.10	4,992,220

#### Changes in the outstanding number of shares

	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, after share split	4,789,246	16,180,000
Ordinary shares at 31 December	54,711,446	49,922,200

#### Ownership structure 31.12.2018

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		1,937,000	3.5%
DATUM INVEST AS		1,485,467	2.7%
KLP AKSJENORGE		1,331,867	2.4%
EUROCLEAR BANK S.A./N.V.	NOM	1,275,027	2.3%
SARSIA DEVELOPMENT AS		1,175,000	2.1%
VPF NORDEA KAPITAL	_	1,173,187	2.1%
VPF NORDEA AVKASTNING		1,125,902	2.1%
MP PENSJON PK		1,117,455	2.0%
BERA AS		1,084,800	2.0%
KOMMUNAL LANDSPENSJONSKASSE	_	892,886	1.6%
NORSK INNOVASJONSKAPITAL II AS		856,170	1.6%
VERDIPAPIRFONDET ALFRED BERG NORGE		801,556	1.5%
NORRON SICAV – TARGET		800,000	1.5%
J.P. MORGAN BANK LUXENBOURG S.A.	NOM	657,232	1.2%
VERDIPAPIRFONDET ALFRED BERG AKTIV		574,391	1.0%
NORDA ASA		536,281	1.0%
VERDIPAPIRFONDET DELPHI NORGE		475,714	0.9%
Top 20 shareholders		40,950,635	74.8%
Total other shareholders		13,760,811	25.2%
Total number of shares		54,711,446	100.0%

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 programme 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

#### Note 17 – Share capital and shareholder information continued

#### Ownership structure 31.12.2017

Shareholder		Number of shares	Percentage share of total shares
METEVA AS		14,923,000	29.9%
INVESTINOR AS		6,609,800	13.2%
SARSIA SEED AS		2,117,900	4.2%
VERDIPAPIRFONDET ALFRED BERG GAMBA		1,852,500	3.7%
MP PENSJON PK		1,830,300	3.7%
KLP AKSJENORGE		1,306,901	2.6%
JPMORGAN CHASE BANK, N.A., LONDON	NOM	1,272,000	2.5%
DATUM INVEST AS		1,209,200	2.4%
SARSIA DEVELOPMENT AS		1,195,000	2.4%
BERA AS		1,084,800	2.2%
NORSK INNOVASJONSKAPITAL II AS		973,100	1.9%
VPF NORDEA AVKASTNING		972,354	1.9%
KOMMUNAL LANDSPENSJONSKASSE		946,919	1.9%
VERDIPAPIRFONDET ALFRED BERG NORGE		845,000	1.7%
JPMORGAN CHASE BANK, N.A., LONDON	NOM	720,000	1.4%
VPF NORDEA KAPITAL		700,000	1.4%
VERDIPAPIRFONDET ALFRED BERG AKTIV		552,500	1.1%
BIRK VENTURE AS		500,000	1.0%
STATOIL PENSJON		440,000	0.9%
FLU AS		360,000	0.7%
Top 20 shareholders		40,411,274	80.9%
Total other shareholders		9,510,926	19.1%
Total number of shares		49,922,200	100.0%

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

	Current position within the company	Employed since	2018	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
Total shares held by management			410,408	410,408

<sup>1)</sup> Richard Godfrey holds 160,408 shares in the Group through Gnist Holding AS.

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

	Position	Served since	Served until	2018	2017
Stein H. Annexstad 1)		February 2016		7,539	7,539
Susan Elizabeth Foden 4)			31 December 2018	6,700	6,700
Hilde Furberg 2)	Board Member	June 2015		3,769	3,769
Kari Grønås 3)	Board Member	February 2016		4,522	4,522
Total shares held by members of	the Board of Directors			22,530	22,530

- 1) Stein H. Annexstad holds 7,539 shares in the Group through Holstein AS, a closely associated company of Stein H. Annexstad.
- 2) Hilde Furberg holds 3,769 shares in the Group through J&J Future Invest AS, a closely associated company of Hilde Furberg.
- 3) Kari Grønås holds 4,522 shares in the Group through K og K AS, a closely associated company of Kari Grønås.
- 4) Susan Foden resigned from BoD 1 January 2019.

In the annual general meeting on the 22 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 18 – Other current liabilities

Parent 2017	Parent 2018		Group 2018	Group 2017
1,649		Unpaid duties and charges	2,893	1,896
1,290		Unpaid vacation pay	1,342	1,290
6,107		Other accrued costs	8,640	6,205
9,046	12,094	Total	12,875	9,391

#### Note 19 – Provisions

	Social security contributions on share options	Total
Balance at 1 January 2018	3,020	3,020
Additional provisions recognised	1,712	1,712
Balance at 31 December 2018	4,732	4,732
Current	4,732	4,732
Non-current	0	0

The provision for social security contributions on share options is calculated based on the number of options outstanding at the reporting date that are expected to be exercised. The provision is based on the difference between market price and strike price. Market price of the shares at the reporting date is the best estimate of market price at the date of exercise.

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#### **Notes to the financial statements** continued

#### Note 20 – Financial instruments and risk management objectives and policies

The Group's activities are exposed to certain financial risks including foreign exchange risk, credit risk and liquidity risk. The risk is however of such character that the Group has chosen not to put in place any measures to mitigate the potential unpredictability of the financial markets. The Group has NOK 360.41 million in cash and cash equivalents at year end. The main purpose of this is to finance the Group's activities and ongoing clinical trials. The Group has various assets and liabilities such as receivables and trade payables, which originate directly from its operations. All financial assets and liabilities are carried at amortised cost. All financial assets and liabilities are short-term in nature and their carrying value approximates fair value.

The Group does currently not use financial derivatives.

#### Foreign currency risk

**BerGenBio** 

The value of non-Norwegian currency denominated revenues and 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 research expenses. The Group is mainly exposed to fluctuations in euro (EUR), pounds sterling (GBP) and US dollar (USD).

The Group has chosen not to hedge its operational performance as the Group's cash flow is denominated in several currencies that changes depending on where clinical trials are run. 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 necessary.

#### Interest rate risk

The Group holds NOK 360.4 million in 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 affects the financial income and the return on cash. The Group had NOK 3.5 million in interest income in 2018 (NOK 2.8 million 2017).

#### **Credit risk**

Credit risk is the risk of a 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 company only 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 2018 and the Group considers its credit risk as low.

#### Liquidity risk

Liquidity is monitored on a continual basis by Group management. Management considers the Group's liquidity situation to be satisfactory. The Group raised NOK 187.5 million in a private placements in 2018 securing funding into 2020 at current burn rate. The cash position of the Group at year end 2018 was NOK 360.4 million, compared to NOK 370.4 million in 2017.

#### Capital management

The Board of Directors' goal is to maintain a strong capital base in order to preserve the confidence of investors, creditors and to develop business activities.

#### Note 21 – Subsidiary

The Group's subsidiary at 31 December 2018 are set out below. The share capital consist solely of ordinary shares that are held directly by the Group, and the proportion of ownership interests held equals the voting rights held by the Group.

Name of entity BerGenBio Limited

Place of business Oxford, U.K.

Ownership interest held by the Group 100%

Principal activities Management of clinical studies

#### Note 22 – Intercompany

BerGenBio ASA have entered into an intercompany management agreement with BerGenBio Limited. Services are delivered from BerGenBio Limited to BerGenBio ASA.

	Parent 2018	Parent 2017
Purchase from BerGenBio Limited (included in other operation expenses)	16,998	4,663
Receivables BerGenBio Limited (included in other current assets)	3,599	4,490

## Auditor's report



Statsautoriserte revisorer Ernst & Young AS

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#### INDEPENDENT AUDITOR'S REPORT

To the Annual Shareholders' Meeting of BerGenBio ASA

#### Report on the audit of the financial statements

#### Opinion

We have audited the financial statements of BerGenBio ASA, which comprise the financial statements for the parent company and the Group. The financial statements for the parent company and the Group comprise the statement of financial position as at 31 December 2018, the statements of income and other comprehensive income, the statements of cash flows and changes in equity for the year then ended and notes to the financial statements, including a summary of significant accounting policies.

In our opinion, the financial statements have been prepared in accordance with laws and regulations and present fairly, in all material respects, the financial position of the Company and the Group as at 31 December 2018 and their financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards as adopted by the EU.

#### Basis for opinion

We conducted our audit in accordance with laws, regulations, and auditing standards and practices generally accepted in Norway, including International Standards on Auditing (ISAs). Our responsibilities under those standards are further described in the Auditor's responsibilities for the audit of the financial statements section of our report. We are independent of the Company and the Group in accordance with the ethical requirements that are relevant to our audit of the financial statements in Norway, and we have fulfilled our ethical responsibilities as required by law and regulations. We have also complied with our other ethical obligations in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Key audit matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements for 2018. We have determined that there are no key audit matters to communicate in our report.

#### Other information

Other information consists of the information included in the Company's annual report other than the financial statements and our auditor's report thereon. The Board and Chief Executive Officer (management) are responsible for the other information. Our opinion on the financial statements does not cover the other information, and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information, and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

#### Responsibilities of management for the financial statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with International Financial Reporting Standards as adopted by the EU, and for such internal control as management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.



In preparing the financial statements, management is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting, unless management either intends to liquidate the Company or to cease operations, or has no realistic alternative but to do so.

#### Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with law, regulations and generally accepted auditing principles in Norway, including ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control;
- obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control:
- evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management;
- conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Company to cease to continue as a going concern;
- evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.
- obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide those charged with governance with a statement that we have complied with relevant ethical requirements regarding independence, and communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

## Auditor's report continued



#### Report on other legal and regulatory requirements

# Opinion on the Board of Directors' report and on the statements on corporate governance and corporate social responsibility

Based on our audit of the financial statements as described above, it is our opinion that the information presented in the Board of Directors' report and in the statements on corporate governance and corporate social responsibility concerning the financial statements and the going concern assumption, and proposal for the allocation of the result is consistent with the financial statements and complies with the law and regulations.

#### Opinion on registration and documentation

Based on our audit of the financial statements as described above, and control procedures we have considered necessary in accordance with the International Standard on Assurance Engagements (ISAE) 3000, Assurance Engagements Other than Audits or Reviews of Historical Financial Information, it is our opinion that management has fulfilled its duty to ensure that the Company's accounting information is properly recorded and documented as required by law and bookkeeping standards and practices accepted in Norway.

Bergen, 20 February 2019

for Enubren

ERNST & YOUNG AS

Jørn Knutsen

State Authorised Public Accountant (Norway)

## Glossary

OSE	Oslo Exchange
BGBio	BerGenBio ticker symbol on Oslo Stock Exchange
BGB	BerGenBio
UK	United Kingdom
NSCLC	Non-Small Cell Lung Cancer
AML	Acute Myeloid Leukaemia
MDS	Myelodysplastic Syndrome
WHO	World Health Organisation
ASCO-SITC	American Society of Clinical Oncology – Society for Immunotherapy of Cancer
AACR	American Association for Cancer Research
ASCO	American Society of Clinical Oncology
WCLC	World Conference on Lung Cancer
ESMO	European Society for Medical Oncology
PFS	progression free survival
SITC	Society for Immunotherapy of Cancer
MD	medical doctor
R/R	relapsed/refractory
ASH	American Society of Hematology
PoC	proof-of-concept
EHA	European Hematology Association
TNBC	Triple Negative Breast Cancer
IIT	investigator initiated trial
IHC	Immunohistochemistry
sAXL	soluble AXL
МоА	mechanism of action
СТА	clinical trial authorisation
R&D	research & development
PD-L1	programmed death-ligand 1
PD-1	programmed death 1
NASH	Non-Alcoholic Steato-Hepatitis
IPF	Idiopathic Pulmonary Fibrosis
CDx	companion diagnostics
ADC	antibody-drug conjugate
HQ	head quarter
PhD	Doctor of philosophy
CRO	contract research organisation
TKI	Tyrosine Kinase Inhibitor
СМС	chemistry, manufacturing and control

# **Glossary** continued

NHS National Health Service FDA Food and Drug Administration Vc venture capital MSD Merck & Co., Inc., d.b.a. Merck Sharp & Dohme outside the United States and Canada BMS Bristol-Myers Squibb US United States NCI US National Cancer Institute MIT Massachusetts Institute of Technology EGGR epidermal growth factor receptor ALK anaplastic lymphoma kinase NK cells natural killer cells Soc standard of care CAGR complete response GAGR overall response rate CR complete response with incomplete recovery of peripheral counts PR partial response with incomplete recovery of peripheral counts PR partial response with incomplete recovery of peripheral counts PR partial response with incomplete recovery of peripheral counts PR partial response with incomplete recovery of peripheral counts PR partial response with incomplete recovery of peripheral counts PR partial response of the CTP long term incentive scheme LTP long term incentive scheme LTP long term incentive plan IND Investigational New Drug NCGB/NUES The Norwegian Corporate Governance Board IFRS International Financial Reporting Standards AGM Annual General Meeting IPO initial public offering CSR corporate social responsibility GDPR General Data Protection Regulation KPI Key Performance Indicator IR investor relations EY Erst and Young AS EMA European Medicines Agency EU European Medicines Agency EU European Information OCI other comprehensive income EIR effective Interest rate BIA The Norwegian Research council's User-driven Research based Innovation programme EMT Epithelial-mesenchymal transition IFU Innovesjon Norges industrial development award		
VC  Wenture capital  Macrol. & Co., Inc., d.b.a. Merck Sharp & Dohme outside the United States and Canada  BMS  Bristol-Myers Squibb  US  United States  NCI  US National Cancer Institute  MIT  Massachusettis Institute of Technology  EGFR  epidermal growth factor receptor  ALK  anaplastic Jymphoma kinase  NK cells  natural killer cells  Soc  standard of care  CAGR  compound annual growth rate  MaB  monoclonal antibody  ORR  overall response rate  CR  complete response  CRI  complete response with incomplete recovery of peripheral counts  PR  partial response  IO  immune encology  CPI  immune checkpoint inhibitor  STI-scheme  short term incentive scheme  LTP  long term incentive plan  IND  Investigational New Drug  NCGB/NUES  The Norwegian Corporate Governance Board  IFRS  International Financial Reporting Standards  AGM  Annual General Meeting  IPO  initial public offoring  CSR  corporate social responsibility  GDPR  General Data Protection Regulation  KPI  Kay Performance Indicator  IR  investor relations  EY  Ernst and Young AS  EMA  European Union  OCI  other comprehensive income  EIR  effective interest rate  BIA  The Norwegian Research council's User-driven Research based Innovation programme  EMT  Epithelial-mesenchymal transition	NHS	National Health Service
MSD Merck & Co., Inc., d.b.a. Merck Sharp & Dohme outside the United States and Canada BMS Bristol-Myers Squibb  US United States NCI US National Cancer Institute MIIT Massachusetts Institute of Technology EGFR epidermal growth factor receptor ALK anaplastic lymphoma kinase NK cells natural killer cells SoC standard of care CAGR compound annual growth rate MAB monoclonal antibody ORR overall response rate CR complete response with incomplete recovery of peripheral counts PR partial response IO immune oncology CPI immune checkpoint inhibitor STI-scheme short term incentive scheme LTP long term incentive scheme LTP long term incentive blan IND Investigational New Drug NCGB/NUES The Norwegian Corporate Governance Board IFRS International Financial Reporting Standards AGM Annual General Meeting IPO initial public offering CSR corporate social responsibility GDPR General Data Protection Regulation KPI Key Performance Indicator IR investor relations EY Ernst and Young AS EMA European Medicines Agency EU European Union OCI other comprehensive income EIR effective interest rate BIA The Norwegian Research council's User-driven Research based Innovation programme EMT Epithelial-mesenchymal transition	FDA	Food and Drug Administration
BMS Bristol-Myers Squibb  US United States  NCI US National Cancer Institute  MIT Massachusetts Institute of Technology  EGFR epidermal growth factor receptor  ALK anaplastic lymphoma kinase  NK cells natural killer cells  SoC standard of care  CAGR compound annual growth rate  MaB monoclonal antibody  ORR overall response rate  CR complete response  CRI complete response  IO immune encelogy  CPI immune checkpoint inhibitor  STI-scheme short term incentive scheme  LTP long term incentive plan  IND Investigational New Drug  NCGB/NUES The Norwegian Corporate Governance Board  IFRS International Financial Reporting Standards  AGM Annual General Meeting  IPO initial public offering  CSR corporate social responsibility  GDPR General Data Protection Regulation  KPI Key Performance Indicator  IR investor relations  EY Ernst and Young AS  EMA European Medicines Agency  EU European Melicines Agency  EU European International  ENT eithelial-mesenchymal transition	VC	venture capital
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EGFR epidermal growth factor receptor  ALK anaplastic lymphoma kinase  NK cells natural killer cells  SoC standard of care  CAGR compound annual growth rate  MaB monoclonal antibody  ORR overall response rate  CR complete response  CRI complete response  CRI complete response  IO immune oncology  CPI immune checkpoint inhibitor  STI-scheme short term incentive scheme  LTP long term incentive scheme  LTP long term incentive plan  IND Investigational New Drug  NCGB/NUES The Norwegian Corporate Governance Board  IERS International Financial Reporting Standards  AGM Annual General Meeting  IPO initial public offering  CSR corporate social responsibility  GDPR General Data Protection Regulation  KPI Key Performance Indicator  IR investor relations  EY Ernst and Young AS  EMA European Medicines Agency  EU European Medicines Agency  EU European Inloin  OCI other comprehensive income  EIR effective interest rate  BIA The Norwegian Research council's User-driven Research based Innovation programme  EMT Epithelial-mesenchymal transition	NCI	US National Cancer Institute
ALK anaplastic lymphoma kinase  NK cells natural killer cells  SoC standard of care  CAGR compound annual growth rate  MaB monoclonal antibody  ORR overall response rate  CR complete response with incomplete recovery of peripheral counts  PR partial response  IO immune oncology  CPI immune checkpoint inhibitor  STI-scheme short term incentive scheme  LTP long term incentive plan  IND Investigational New Drug  NCGB/NUES The Norwegian Corporate Governance Board  IFRS International Financial Reporting Standards  AGM Annual General Meeting  IPO initial public offering  CSR corporate social responsibility  GDPR General Dat Protection Regulation  KPI Key Performance Indicator  IR investor relations  EY Erst and Young AS  EMA European Medicines Agency  EU European Union  OCI other comprehensive income  EIR effective interest rate  BIA The Norwegian Research council's User-driven Research based Innovation programme  EMT Epithelial-mesenchymal transition	MIT	Massachusetts Institute of Technology
NK cells  natural killer cells  SoC  standard of care  CAGR  compound annual growth rate  MaB  monoclonal antibody  ORR  overall response rate  CR  complete response  CRI  complete response with incomplete recovery of peripheral counts  PR  partial response  IO  immune oncology  CPI  immune checkpoint inhibitor  STI-scheme  short term incentive scheme  LTP  long term incentive plan  IND  Investigational New Drug  NCGB/NUES  The Norwegian Corporate Governance Board  IFRS  International Financial Reporting Standards  AGM  Annual General Meeting  IPO  initial public offering  CSR  corporate social responsibility  GDPR  General Data Protection Regulation  KPI  Key Performance Indicator  IR  investor relations  EY  Ernst and Young AS  EMA  European Medicines Agency  EU  European Union  OCI  other comprehensive income  EIR  effective interest rate  BIA  The Norwegian Research council's User-driven Research based Innovation programme  EMT  Epithelial-mesenchymal transition	EGFR	epidermal growth factor receptor
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CAGR compound annual growth rate  MaB monoclonal antibody ORR overall response rate CR complete response CRi complete response CRi complete response with incomplete recovery of peripheral counts PR partial response IO immune oncology CPI immune checkpoint inhibitor STI-scheme short term incentive scheme LTP long term incentive plan IND Investigational New Drug NCGB/NUES The Norwegian Corporate Governance Board IFRS International Financial Reporting Standards AGM Annual General Meeting IPO initial public offering CSR corporate social responsibility GDPR General Data Protection Regulation KPI Key Performance Indicator IR investor relations EY Ernst and Young AS EMA European Medicines Agency EU European Union OCI other comprehensive income EIR effective interest rate BIA The Norwegian Research council's User-driven Research based Innovation programme EMT Epithelial-mesenchymal transition	NK cells	natural killer cells
MaB overall response rate CR complete response CRI complete response IO immune oncology CPI immune checkpoint inhibitor STI-scheme short term incentive scheme LTP long term incentive plan IND Investigational New Drug NCGB/NUES The Norwegian Corporate Governance Board IFRS International Financial Reporting Standards AGM Annual General Meeting IPO initial public offering CSR corporate social responsibility GDPR General Data Protection Regulation KPI Key Performance Indicator IR investor relations EY Ernst and Young AS EMA European Medicines Agency EU European Union OCI other comprehensive income EIR effective interest rate BIA The Norwegian Research council's User-driven Research based Innovation programme EMT Epithelial-mesenchymal transition	SoC	standard of care
ORR overall response rate CR complete response CRi complete response CRi complete response with incomplete recovery of peripheral counts PR partial response IO immune oncology CPI immune checkpoint inhibitor STI-scheme short term incentive scheme LTP long term incentive plan IND Investigational New Drug NCGB/NUES The Norwegian Corporate Governance Board IERS International Financial Reporting Standards AGM Annual General Meeting IPO initial public offering CSR corporate social responsibility GDPR General Data Protection Regulation KPI Key Performance Indicator IIR investor relations EY Ernst and Young AS EMA European Medicines Agency EU European Union OCI other comprehensive income EIR effective interest rate BIA The Norwegian Research council's User-driven Research based Innovation programme EMT Epithelial-mesenchymal transition	CAGR	compound annual growth rate
CR complete response CRi complete response with incomplete recovery of peripheral counts PR partial response IO immune oncology CPI immune checkpoint inhibitor STI-scheme short term incentive scheme LTP long term incentive plan IND Investigational New Drug NCGB/NUES The Norwegian Corporate Governance Board IFRS International Financial Reporting Standards AGM Annual General Meeting IPO initial public offering CSR corporate social responsibility GDPR General Data Protection Regulation KPI Key Performance Indicator IR investor relations EY Ernst and Young AS EMA European Medicines Agency EU European Union OCI other comprehensive income EIR effective interest rate BIA The Norwegian Research council's User-driven Research based Innovation programme EMT Epithelial-mesenchymal transition	MaB	monoclonal antibody
CRI complete response with incomplete recovery of peripheral counts  PR partial response  IO immune oncology  CPI immune checkpoint inhibitor  STI-scheme short term incentive scheme  LTP long term incentive plan  IND Investigational New Drug  NCGB/NUES The Norwegian Corporate Governance Board  IFRS International Financial Reporting Standards  AGM Annual General Meeting  IPO initial public offering  CSR corporate social responsibility  GDPR General Data Protection Regulation  KPI Key Performance Indicator  IR investor relations  EY Ernst and Young AS  EMA European Union  OCI other comprehensive income  EIR effective interest rate  BIA The Norwegian Research council's User-driven Research based Innovation programme  EMT Epithelial-mesenchymal transition	ORR	overall response rate
PR partial response  IO immune oncology  CPI immune checkpoint inhibitor  STI-scheme short term incentive scheme  LTP long term incentive plan  IND Investigational New Drug  NCGB/NUES The Norwegian Corporate Governance Board  IFRS International Financial Reporting Standards  AGM Annual General Meeting  IPO initial public offering  CSR corporate social responsibility  GDPR General Data Protection Regulation  KPI Key Performance Indicator  IR investor relations  EY Ernst and Young AS  EMA European Medicines Agency  EU European Union  OCI other comprehensive income  EIR effective interest rate  BIA The Norwegian Research council's User-driven Research based Innovation programme  EMT Epithelial-mesenchymal transition	CR	complete response
IO immune oncology CPI immune checkpoint inhibitor STI-scheme short term incentive scheme LTP long term incentive plan IND Investigational New Drug NCGB/NUES The Norwegian Corporate Governance Board IFRS International Financial Reporting Standards AGM Annual General Meeting IPO initial public offering CSR corporate social responsibility GDPR General Data Protection Regulation KPI Key Performance Indicator IR investor relations EY Ernst and Young AS EMA European Medicines Agency EU European Union OCI other comprehensive income EIR effective interest rate BIA The Norwegian Research council's User-driven Research based Innovation programme EMT Epithelial-mesenchymal transition	CRi	complete response with incomplete recovery of peripheral counts
CPI immune checkpoint inhibitor  STI-scheme short term incentive scheme  LTP long term incentive plan  IND Investigational New Drug  NCGB/NUES The Norwegian Corporate Governance Board  IFRS International Financial Reporting Standards  AGM Annual General Meeting  IPO initial public offering  CSR corporate social responsibility  GDPR General Data Protection Regulation  KPI Key Performance Indicator  IR investor relations  EY Ernst and Young AS  EMA European Medicines Agency  EU European Union  OCI other comprehensive income  EIR effective interest rate  BIA The Norwegian Research council's User-driven Research based Innovation programme  EMT Epithelial-mesenchymal transition	PR	partial response
STI-scheme short term incentive scheme  LTP long term incentive plan  IND Investigational New Drug  NCGB/NUES The Norwegian Corporate Governance Board  IFRS International Financial Reporting Standards  AGM Annual General Meeting  IPO initial public offering  CSR corporate social responsibility  GDPR General Data Protection Regulation  KPI Key Performance Indicator  IR investor relations  EY Ernst and Young AS  EMA European Medicines Agency  EU European Union  OCI other comprehensive income  EIR effective interest rate  BIA The Norwegian Research council's User-driven Research based Innovation programme  EMT Epithelial-mesenchymal transition	Ю	immune oncology
LTP long term incentive plan IND Investigational New Drug  NCGB/NUES The Norwegian Corporate Governance Board  IFRS International Financial Reporting Standards  AGM Annual General Meeting IPO initial public offering  CSR corporate social responsibility  GDPR General Data Protection Regulation  KPI Key Performance Indicator IR investor relations  EY Ernst and Young AS  EMA European Medicines Agency  EU European Union  OCI other comprehensive income  EIR effective interest rate  BIA The Norwegian Research council's User-driven Research based Innovation programme  EMT Epithelial-mesenchymal transition	СРІ	immune checkpoint inhibitor
IND Investigational New Drug  The Norwegian Corporate Governance Board  IFRS International Financial Reporting Standards  AGM Annual General Meeting  IPO initial public offering  CSR corporate social responsibility  GDPR General Data Protection Regulation  KPI Key Performance Indicator  IR investor relations  EY Ernst and Young AS  EMA European Medicines Agency  EU European Union  OCI other comprehensive income  EIR effective interest rate  BIA The Norwegian Research council's User-driven Research based Innovation programme  EMT Epithelial-mesenchymal transition	STI-scheme	short term incentive scheme
NCGB/NUES The Norwegian Corporate Governance Board IFRS International Financial Reporting Standards  AGM Annual General Meeting IPO initial public offering CSR corporate social responsibility GDPR General Data Protection Regulation KPI Key Performance Indicator IR investor relations EY Ernst and Young AS EMA European Medicines Agency EU European Union OCI other comprehensive income EIR BIA The Norwegian Research council's User-driven Research based Innovation programme EMT Epithelial-mesenchymal transition	LTP	long term incentive plan
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IPO initial public offering  CSR corporate social responsibility  GDPR General Data Protection Regulation  KPI Key Performance Indicator  IR investor relations  EY Ernst and Young AS  EMA European Medicines Agency  EU European Union  OCI other comprehensive income  EIR effective interest rate  BIA The Norwegian Research council's User-driven Research based Innovation programme  EMT Epithelial-mesenchymal transition	IFRS	International Financial Reporting Standards
CSR corporate social responsibility GDPR General Data Protection Regulation  KPI Key Performance Indicator  IR investor relations  EY Ernst and Young AS  EMA European Medicines Agency  EU European Union  OCI other comprehensive income  EIR effective interest rate  BIA The Norwegian Research council's User-driven Research based Innovation programme  EMT Epithelial-mesenchymal transition	AGM	Annual General Meeting
GDPR General Data Protection Regulation  KPI Key Performance Indicator  IR investor relations  EY Ernst and Young AS  EMA European Medicines Agency  EU European Union  OCI other comprehensive income  EIR effective interest rate  BIA The Norwegian Research council's User-driven Research based Innovation programme  EMT Epithelial-mesenchymal transition	IPO	initial public offering
KPI Key Performance Indicator IR investor relations EY Ernst and Young AS EMA European Medicines Agency EU European Union OCI other comprehensive income EIR effective interest rate BIA The Norwegian Research council's User-driven Research based Innovation programme EMT Epithelial-mesenchymal transition	CSR	corporate social responsibility
IR investor relations  EY Ernst and Young AS  EMA European Medicines Agency  EU European Union  OCI other comprehensive income  EIR effective interest rate  BIA The Norwegian Research council's User-driven Research based Innovation programme  EMT Epithelial-mesenchymal transition	GDPR	General Data Protection Regulation
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EU European Union  OCI other comprehensive income  EIR effective interest rate  BIA The Norwegian Research council's User-driven Research based Innovation programme  EMT Epithelial-mesenchymal transition	EY	Ernst and Young AS
other comprehensive income  EIR effective interest rate  BIA The Norwegian Research council's User-driven Research based Innovation programme  EMT Epithelial-mesenchymal transition	EMA	European Medicines Agency
EIR effective interest rate  BIA The Norwegian Research council's User-driven Research based Innovation programme  EMT Epithelial-mesenchymal transition	EU	European Union
BIA The Norwegian Research council's User-driven Research based Innovation programme  EMT Epithelial-mesenchymal transition	OCI	other comprehensive income
EMT Epithelial-mesenchymal transition	EIR	effective interest rate
	BIA	The Norwegian Research council's User-driven Research based Innovation programme
IFU Innovasjon Norges industrial development award	EMT	Epithelial-mesenchymal transition
	IFU	Innovasjon Norges industrial development award

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