



Annual  
Report &  
Accounts  
2019





(OSE:BGBIO) is a clinical stage biopharmaceutical company developing innovative drugs against aggressive diseases, including immune evasive, drug resistant and metastatic cancers. BerGenBio is based in Bergen, Norway with a subsidiary in Oxford, UK





# Oxford Museum of Natural History



The Oxford University Museum of Natural History was established in 1860 to draw together scientific studies from across the University of Oxford. Highlights in the collections are the first scientifically described dinosaur *Megalosaurus Bucklandii* and the world-famous Oxford Dodo, the only remains of the extinct species.

The building is a spectacular example of Victorian neo-Gothic architecture with a striking glass and iron roof and over 126 columns, each made from a different British decorative rock, labelled with the name of the stone and its source.

Standing thoughtfully against the pillars around the court are 19 statues of great men of science, including Aristotle, Galileo, Isaac Newton, Charles Darwin and Linnaeus.

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For more information  
[www.bergenbio.com](http://www.bergenbio.com)



A portrait of a middle-aged man with a receding hairline, wearing black-rimmed glasses, a dark blue suit jacket, a white shirt, and a blue and gold patterned tie. He is smiling slightly and looking towards the camera. The background is a light grey gradient. On the far left, there is a vertical orange bar.

A cornerstone  
in future  
cancer  
treatment

## CHAIRMAN'S STATEMENT



## Dear Shareholders

2019 was a year of significant progress for BerGenBio. The main focus of the Company this year, has been the continued delivery of compelling clinical data demonstrating the potential of our lead product candidate, bemcentinib, as a monotherapy and in combination with existing standard of care medicines.

The potential of bemcentinib as a first- and second-line cancer treatment is being explored, with specific focus on non-small cell lung cancer (NSCLC), the largest cancer killer worldwide, and leukemia (AML and MDS). Whilst the standard of care for these diseases has improved markedly with the advent of new chemotherapies and immunotherapies like checkpoint-inhibitors, there remains a high unmet need with long term survival rates still very low, particularly amongst patients who do not respond to or relapse after treatment with these newer therapies.

Results generated from trials using a combination of bemcentinib and pembrolizumab, the market-leading checkpoint inhibitor, in relapsed NSCLC patients have generated meaningful results. Whilst in elderly AML patients, many of whom are too weak to receive intensive chemotherapy, bemcentinib in combination with low-dose chemotherapy was shown to provide a clinical benefit.

In parallel, the Company is also looking to find ways to quickly identify the patients who are most likely to benefit from treatment with bemcentinib, and this year the company has continued to work on a companion diagnostic platform to accompany the treatment.

As the pharmaceutical industry moves towards more personalized approaches to medicine, this will undoubtedly be an important tool.

In May I was proud to be appointed as Chair of the Board, having previously served as a non-executive board member. We were very pleased to make some key appointments to the executive team and to prepare the organization for next phase in its development. Professor Hani Gabra joined the organization as Chief Medical Officer and we were pleased to welcome Grunde Eriksen, Debra Barker and Pamela Trail as new board members.

Looking forward to 2020, the Company's aim is to further refine the clinical position and prepare for later stage clinical trials in NSCLC and AML. The Company is well funded to achieve its stated goals, having recently raised a further NOK 220m.

I would like to thank the staff and management of BerGenBio, on behalf of the Board, for their continued dedication and hard work, and our shareholders for their continued support as we continue our progress. The Board and Management have a clear strategy and goals laid out for the year ahead and we look forward to delivering these during an exciting 2020.



**Sveinung Hole**  
Chairman of the Board



# HIGHLIGHTS 2019

## **Our Vision**

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



# Our year in review

The year 2019 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

Non Small Cell Lung Cancer and Acute Myeloid Leukemia, 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 chemo therapy or immuno-therapy

## January

**09 January** – Commenced Phase I trial evaluating BGB149 in healthy volunteers

## March

**01 April** – Results from phase II trial of bemcentinib in combination with low-dose chemotherapy (LDAC) in AML patients achieves efficacy endpoint

**02 April** – BerGenBio extends phase II trial with bemcentinib and pembrolizumab® in NSCLC to include 2L IO relapsed patients

## May

**08 May** – BerGenBio completes recruitment into second stage of phase II trial with bemcentinib in combination with pembrolizumab® in advanced NSCLC patients

## June

**02 June** – BerGenBio presents preliminary clinical and biomarker data showing durable response & improved survival rates in phase II bemcentinib and pembrolizumab trial in advanced NSCLC patients at ASCO 2019

**03 June** – BerGenBio presents phase II clinical data AML trial at ASCO & EHA, showing bemcentinib & LDAC combo improves efficacy and duration of survival in elderly patients

**14 June** – Private placement completed, raising gross proceeds of NOK74.2m

## September

**27 September** – BerGenBio presents Phase Ib/II safety data at ESMO showing bemcentinib is well tolerated in combo with both dabrafenib/trametinib and pembrolizumab in patients with metastatic melanoma

New Phase II clinical data from bemcentinib/pembrolizumab NSCLC trial presented at WCLC, ESMO

## October

**23 October** – FDA approved Fast Track Designation for bemcentinib in relapsed AML

## November

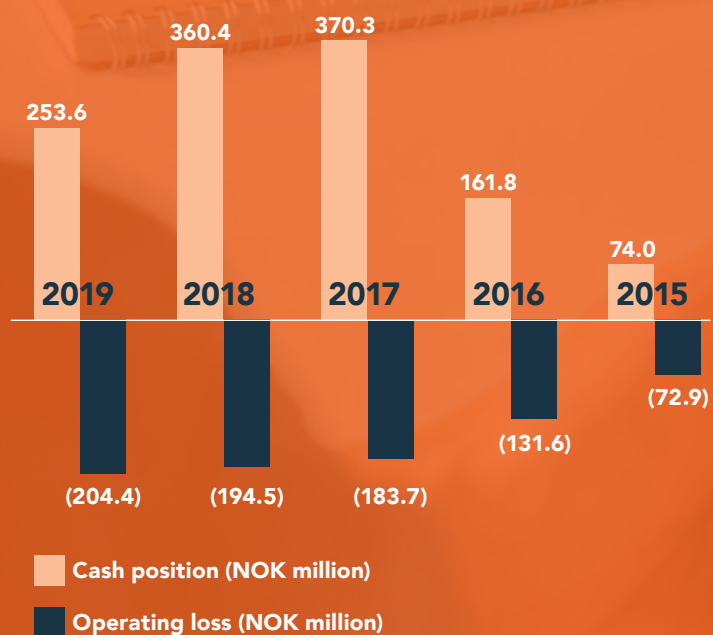
**08 November** – Proprietary composite AXL tumor-immune (cAXL) score biomarker, is under development to identify & diagnose patients that show durable benefit

## December

**09 December** – BerGenBio presents clinical data from phase II combo trial of bemcentinib and LDAC in elderly AML patients at ASH, showing it is well tolerated with promising efficacy

# KEY ACHIEVEMENTS

## Key financial figures



BerGenBio began 2019 with the objective to expand its phase II proof of concept trials with bemcentinib in NSCLC and AML.

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 tilvestamab as well as growth of the organisation to support the expansion of the pipeline.



## Priority

## Milestones

<b>BEMCENTINIB CLINICAL PROGRESS</b>	Clinical updates were presented at many major cancer congresses and indicate that NSCLC and AML are the right target indications	✓
	Clinical and translational data presented:	✓
	<ul style="list-style-type: none"> <li>• AML bemcentinib + LDAC: readouts at ASCO &amp; EHA</li> <li>• NSCLC bemcentinib + pembrolizumab: readouts at ASCO, WCLC, ESMO, SITC</li> </ul>	✓
<b>COMPANION DIAGNOSTICS DEVELOPMENT</b>	Proprietary composite AXL tumor-immune (cAXL) biomarker score is under development to identify & diagnose patients that show durable benefit	✓
<b>TILVESTAMAB (BGB 149) CLINICAL PROGRESS</b>	Commenced Phase I trial Tilvestamab (BGB 149) in healthy volunteers	✓
<b>ORGANISATIONAL DEVELOPMENT</b>	BGB has continued to build out the organisation with strategic medical, clinical, operational and regulatory hires	✓
<b>FINANCIAL MANAGEMENT</b>	Private placement completed in June, raising NOK74.2m	✓
	Disciplined management with cash runway to deliver key clinical data	✓

A portrait of a middle-aged man with a short beard and balding head, wearing a dark suit, white shirt, and dark tie. He is looking directly at the camera with a neutral expression. The background is a light grey gradient.

# Looking back on 2019

I am pleased to report on another successful year for BerGenBio, during which we sharpened the focus on investigating our lead drug candidate bemcentinib in combination with standard-of-care cancer drugs, in acute myeloid leukaemia (AML) and non-small cell lung cancer (NSCLC) patients that have relapsed on their first-line treatment. Bemcentinib is a novel once-a-day, orally administered, potent and highly selective AXL inhibitor. It is currently progressing through a broad Phase II clinical development programme as a monotherapy and in combination with existing standard of care medicines, including immuno-, targeted and chemotherapies, to patients with several different cancers.

AXL is a cell surface receptor protein that is 'hijacked' by cancers and renders them highly aggressive, immune evasive, resistant to therapy with conventional drugs and metastatic. Therefore, we strongly believe that drugs that effectively inhibit AXL signalling could serve as a cornerstone of therapy for aggressive diseases, including immune-evasive and therapy resistant cancers.

During the year we reported encouraging clinical trial results, and expanded our proof of concept trials in acute myeloid leukaemia (AML) and non-small cell lung cancer (NSCLC), to target patients whose cancers have not responded to, or have relapsed following first-line chemo therapy or immunotherapies. Both these indications represent a significant unmet medical need for effective, well-tolerated treatments. Our continuing goal is to confirm that the addition of bemcentinib can substantially improve patient outcomes in both these indications.

## CHIEF EXECUTIVE'S STATEMENT



As our clinical trial experience develops and matures with bemcentinib, I am increasingly reassured to note that it continues to be very well tolerated by cancer patients when taken as a monotherapy, and also when administered in combination with existing therapies.

Data reported this year in NSCLC has been particularly encouraging. In June at the annual meeting of the American Society of Clinical Oncology (ASCO) we presented preliminary data from our Phase II clinical trial combining bemcentinib with Merck's anti-PD-1 therapy pembrolizumab in patients with advanced NSCLC. In November, we were nominated to present at the 'High Impact Clinical Trials Oral Session' at the Society for Immunotherapy of Cancer (SITC) Annual Meeting. Here, we announced that bemcentinib had met the primary and secondary endpoints in the first of three cohorts of the NSCLC trial.

Data from the trial suggests that bemcentinib has the potential to enhance patient responses and overall survival when treated in combination with a checkpoint inhibitor. We were particularly pleased to see responses in patients with no or limited expression of PD-L1 (the biomarker for checkpoint inhibitor drugs), who would not be expected to respond to checkpoint inhibitor drugs alone. Indeed, post-period initial data from the Cohort B of the NSCLC trial showed initial benefit in patients who have relapsed on immunotherapy alone, which represents a very significant and encouraging development which is currently being further investigated.

We are delighted, not only by the continued significant patient benefit from bemcentinib in combination with pembrolizumab, but also by our improved ability to identify patients with durable clinical benefit with a refined

composite AXL tumour immune score, an important development for our AXL targeting clinical programs. To date, we have assessed data from the first of three cohorts where we are evaluating this combination in previously treated lung cancer patients and I look forward to reporting data from these additional cohorts in the coming months.

We remain committed to progressing bemcentinib through to regulatory approval. Towards the end of the year we were delighted that the US Food and Drug Administration (FDA) approved Fast Track Designation for bemcentinib for the treatment of elderly patients with AML whose disease has relapsed. There are currently no marketed drugs specifically approved for relapsed AML patients, representing a significant unmet medical need. BerGenBio has ongoing Phase II trials in this indication and plans to seek regulatory advice from the FDA and European Medicines Agency (EMA) to determine the optimal regulatory path for bemcentinib in relapsed AML.

Following on from the continuing trend of encouraging data we look forward to commencing our late-stage clinical trial programme for bemcentinib and to the continued growth of the company so that we are well-positioned to maximise and capture value for our shareholders, as well as offer improved prognoses for cancer patients. I am grateful to the individuals, families, and healthcare providers who are participating in our clinical trials. I would also 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**  
CEO

# WHY INVEST IN BERGENBIO?

BerGenBio is a world leader in understanding AXL biology and its role in mediating aggressive disease. We have two first-in-class potent and highly selective inhibitors of AXL in clinical development and a third out licensed for development.

AXL is a cell surface protein that renders cancers highly aggressive, immune-evasive and resistant to therapy with conventional drugs.



## World leaders in understanding AXL biology

- AXL tyrosine kinase is a novel drug target that mediates immune evasion, therapy resistance & spread
- AXL upregulates PD-L1 on dendritic cells and blocks T-cell activity
- AXL inhibitors may be a potential cornerstone of cancer therapy
- Pipeline opportunities in multiple cancers and fibrosis



## 3 selective AXL inhibitors in clinical development

- Bemcentinib (oral once a day pill)
- Tilvestamab Monoclonal antibody (MAb)
- ADCT601\* antibody drug conjugate (licensed to ADC SA)
- Phase II: Monotherapy and combinations with checkpoint-inhibitors, targeted and chemotherapies
- Biomarker correlation, parallel CDx development
- Bemcentinib clinical development focus AML (monotherapy), AML (chemo-combo), NSCLC (pembrolizumab combo)



## Resourced to deliver significant milestones

- Listed on Oslo Børs: BGBIO
- Clinical trial collaborations with Merck and leading academic centres in EU & USA
- 38 staff at two locations:
- HQ & R&D in Bergen, Norway;
- Clinical Development in Oxford, UK

Bemcentinib's clinical development is focussed on lung cancer and leukaemia. Internal clinical development is supported by a broad Investigator-Initiated-Trial (IIT) programme.

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



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

A highly experienced clinical development team is located in Oxford, UK, together with support functions.





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# 230,000

## NEW CASES

In the US alone, it is expected that 230,000 new cases of lung cancer will be diagnosed this year, of which around 85% will be NSCLC

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# Strategic report

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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

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) tilvestamab

Bemcentinib is in Phase II clinical testing with a focus on lung cancer and leukaemia, whereas tilvestamab, formerly known as BGB149, a wholly owned therapeutic anti-AXL antibody, is currently in 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 second half of 2020.

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 collaboration such as Merck & Co. with whom BerGenBio have multiple clinical trial collaboration agreements as well as a multitude of leading academic research institutions globally.

Tilvestamab, a therapeutic anti-AXL antibody discovered, developed and wholly owned by BerGenBio, is planned to enter Phase Ib First-in-Patient trials in 2020 pending results from Phase I testing. At that point, the further clinical strategy for this first-in-class anti-AXL antibody will be disclosed.

BerGenBio has previously also outlicensed an AXL antibody for antibody-drug-conjugate (ADC) development to ADC Therapeutics SA. The ADC is currently in Phase I.

#### RELAPSED/REFRACTORY AML/MDS:

**43%** monotherapy response rate in AXL positive patients

#### PREVIOUSLY TREATED NSCLC:

**33%** response rate to bemcentinib with pembrolizumab in cAXL positive patients

#### PROGRESSION FREE SURVIVAL:

**8.4 months** in cAXL positive NSCLC patients treated with bemcentinib + pembrolizumab

## Our business model

BerGenBio intends to develop its drug candidates itself and through strategic partnerships in multiple indications, and retains all strategic 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.

## Near term goals

H1 2020	H2 2020
Bemcentinib – selective AXL inhibitor	
NSCLC: Expand 2L Phase 2 IO refractory in combination with pembrolizumab (BGBC008/B2)	Preliminary data from expanded 2L relapse AML trial in combination with LDAC
NSCLC: Initiate 2L Phase 2 IO + CHEMO refractory in combination with pembrolizumab (BGBC008/C1)	Preliminary data from 2L phase II in IO refractory patients in combination with pembrolizumab
	Preliminary data from 2L phase II in IO+chemo refractory patients in combination with pembrolizumab
Tilvestamab – therapeutic AXL function blocking antibody	
	Phase 1b patient study





# Two AXL targeting drug candidates in clinical development



## Bemcentinib (BGB324)

- Orally bioavailable small molecule TKI
- Highly selective for AXL
- Potent
- Once a day administration
- Favourable safety profile
- Combines with other cancer drugs



## Tilvestamab (BGB149)

- Wholly owned anti-AXL antibody
- Highly selective to human AXL
- Robust, scalable manufacturing process

## AXL

Extracellular

Intracellular

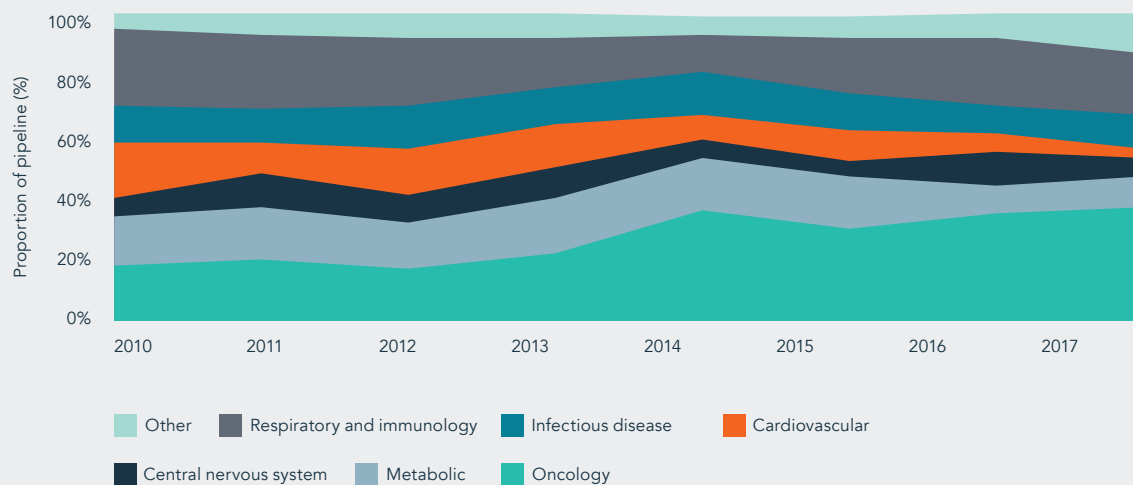
AXL signalling

# INDUSTRY CONTEXT

## Oncology – a large healthcare burden attracting significant pharmacological innovation and advances

Cancer remains one of the most pressing healthcare challenges accounting for the second most common cause of death globally. The oncology vertical attracts the most interest within the pharmaceutical industry and enjoys the highest rate of innovation. Among 48 novel medicines that the FDA approved in 2019, 9 – almost 20% – 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

### Pharma R&D investment in oncology has steadily risen illustrating the sector's attractiveness



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. It has only been in the last five to six years that these two completely new treatment paradigms have been introduced: CAR-T therapy (a gene- and cell therapy in one) and immune checkpoint inhibitors.

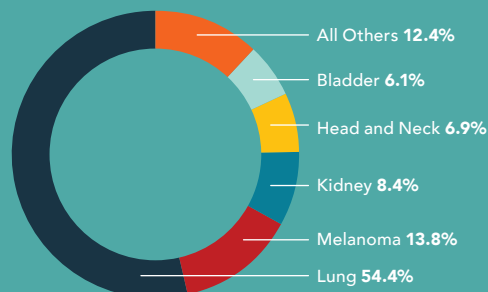
Among these novel immuno-oncology drugs, it is particularly the checkpoint inhibitors that have seen broad uptake across many tumour types. Agents inhibiting the PD-1 checkpoint (by blocking PD-1 or its ligand PD-L1) for example, are now approved in over 20 different cancer indications and are progressively being adopted earlier in treatment.





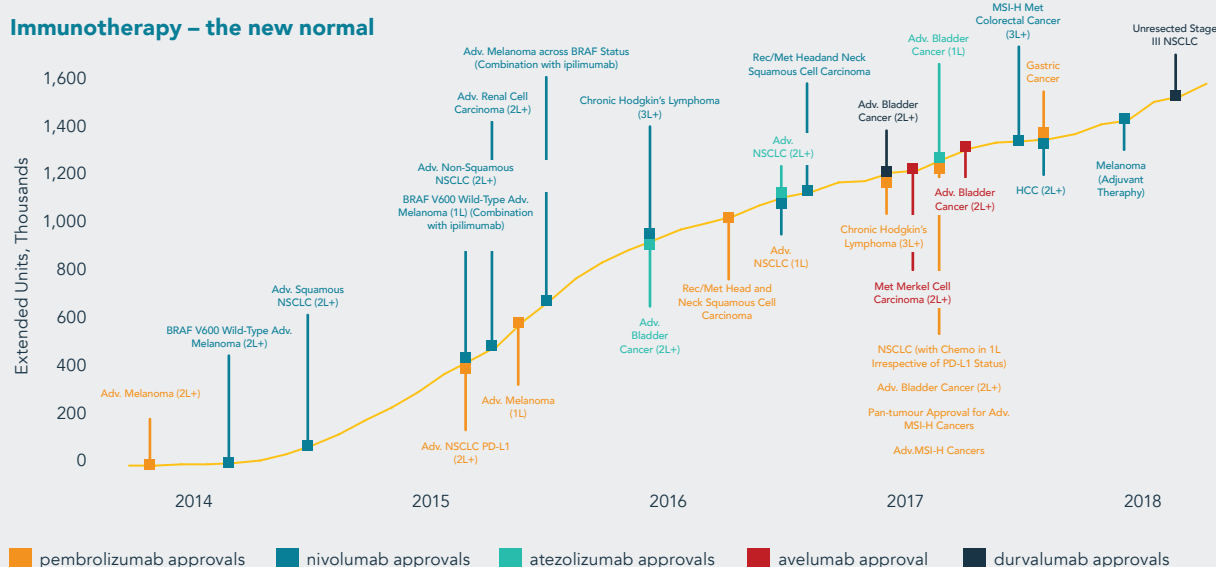
### PD-1 and PD-L1 inhibitor treated patients by tumour type in the United States

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

### Immunotherapy – the new normal



Novel therapies tend to be introduced later down the line, however checkpoint inhibitors are now already rapidly moving into first line treatment paradigms for a multitude of indications. However, many patients do not benefit from these novel therapies and those that do frequently progress, this creates a need for novel and effective follow-on second line (2L) treatments as well as combination therapies that further increase initial responses in the first line setting.

The first indications for checkpoint inhibitors were lung cancer and melanoma. In NSCLC treatment, data at the end of 2018 showed that PD-1/PD-L1 drugs constituted 55% of first-line treatments for newly diagnosed patients and 59% of later lines of therapy.

Among immunotherapy mechanisms of action, blockade of the PD-1/PD-L1 pathway is the predominant class of therapy in use with approvals across

many tumour types. Prominent PD-1 inhibitors in use are pembrolizumab (pembrolizumab) marketed by Merck and Co. (known as MSD outside the US) and OPDIVO (nivolumab) marketed by BMS.

In their third quarter 2019 report, Merck and Co announced that pembrolizumab brought in sales of USD 3.1 billion in the quarter thus rendering pembrolizumab the market leader.



### **Immunotherapies harness the body's immune system to target and kill cancer cells, they are generally well tolerated and can be very effective in some patients**

In January 2019, an estimated 16.9 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.

Indeed, it is with thanks to novel immunotherapies that scientists are beginning to suggest cancer is turning into a chronic disease, rather than death sentence

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 both novel medicines and an overall trend of populations that are aging more healthily.

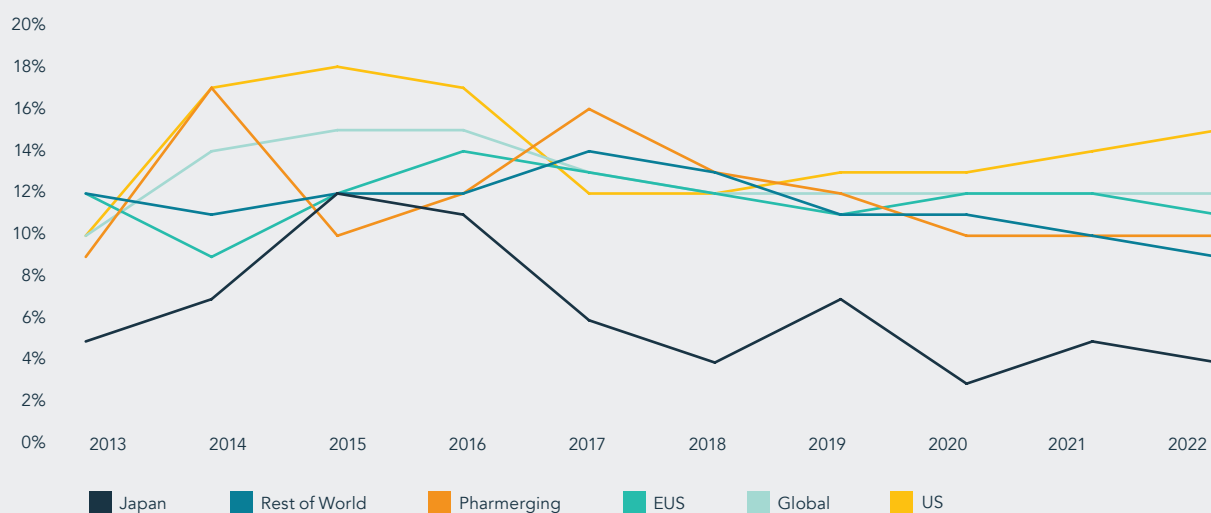
List prices of innovative cancer drugs have steadily risen over the past decade, starting with novel targeted therapies and now immunotherapies. New cancer drugs launched in 2017 had a median annual price of over USD 150,000, compared to USD 79,000 in 2013. The total cost of oncology medicines rose by USD 29.4 billion to USD 56.7 billion in the United States between 2013 and 2018.

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 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.



Double digit growth rates forecast for global cancer market: Constant US\$, 2013–2022<sup>3</sup>

The ability to predict which patients will respond to a certain therapy spares patients 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.

Although immunotherapies can lead to dramatic and long-lasting patient benefits, only a small subset of patients are likely to see such benefit. The effectiveness of these novel medicines has been shown to depend on an individual cancer's pre-existing immune contexture – in other words, it is more likely that checkpoint 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 cases there will be no response to checkpoint inhibitor 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 by a market for biomarkers and 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.

Comparing oncology drugs developed in the absence of a biomarker vs those with a biomarker showed an almost seven-fold improvement. 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.



BB-Building, University of Bergen, Bergen

### Personalised medicine and rational combination approaches to improve outcomes continued

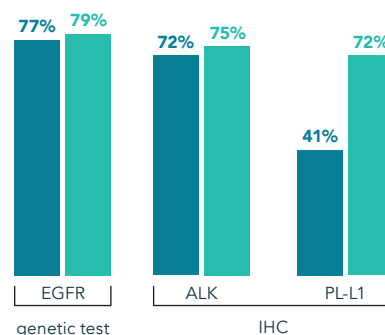
BerGenBio's development strategy for bemcentinib encompasses both combining with immunotherapy for which AXL expression is a known resistance mechanism as well as aiming at identifying patients most likely to respond to therapy by testing for AXL biomarkers.

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.

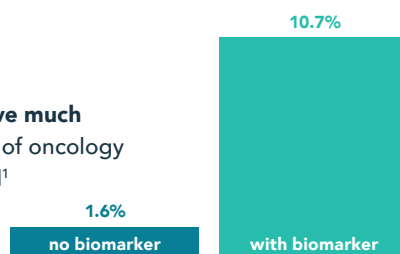
**The vast majority of NSCLC patients are now tested for biomarkers to determine the right treatment approach:** Immunohistochemistry (IHC) is a standard method for testing

Source: IQVIA BrandImpact, IQVIA Institute, Apr 2018

■ 2016 ■ 2017



**Biomarker supported clinical trials have much higher chances of success:** Percentage of oncology trials reaching from Phase 1 to Approval<sup>1</sup>



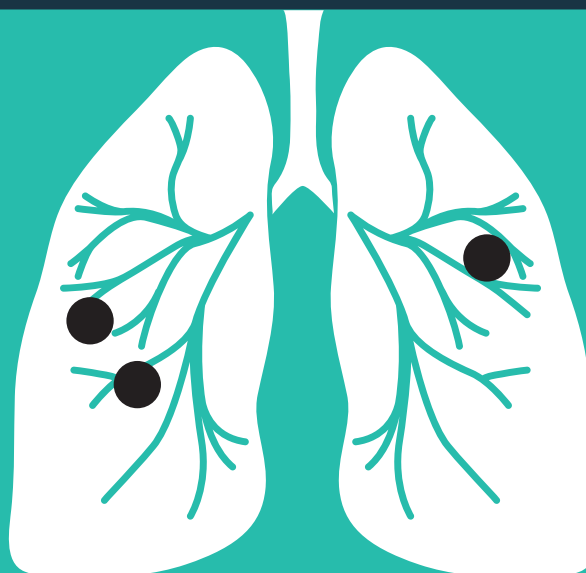
## Lung cancer remains one of the most common cancers and thus a large healthcare burden

<sup>1</sup> Wong et al: Estimation of clinical trial success rates and related parameters, Biostatistics (2018) <https://doi.org/10.1093/biostatistics/kxx069>



# 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

## 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 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, so treatment options thus are limited.

85% of lung cancer is of so-called 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. For example, 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 was 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 cancers with actionable genetic drivers.

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

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

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) recently commented that “we now have a strong argument that every patient with advanced NSCLC should receive immunotherapy<sup>2</sup>”.

2 [https://www.eurekalert.org/pub\\_releases/2018-04/esfm-ipl040518.php](https://www.eurekalert.org/pub_releases/2018-04/esfm-ipl040518.php), accessed Feb 15 2019

85%

## OF LUNG CANCER

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

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

>USD 8<sup>bn</sup>

## 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<sup>3</sup>, 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 pembrolizumab (marketed by Merck & Co<sup>4</sup>), or TECENTRIQ (marketed by Roche<sup>5</sup>) with chemotherapy are novel approaches that have gained recent approval due to their superior effectiveness compared to just chemo- or immunotherapy alone.

Indeed, combination therapies are the current focus for pushing the frontier further in improving outcomes for many lung cancer patients, while reducing side effects and enhancing quality of life.

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)<sup>6</sup> and dendritic cells<sup>7</sup>, which are important for the detection and destruction of metastasising tumours 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>6</sup>.

- 3 KN001; Garon et al NEJM 2015; KN-010 Herbst et al, Lancet 2016
- 4 KN189; Gandhi et al NEJM May 2018
- 5 IMPower150; Reck et al The Lancet March 2019
- 6 Davidsen et, AACR 2018
- 7 Kurowska-Stolarska et al Nature Communications: 8 (2017)



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

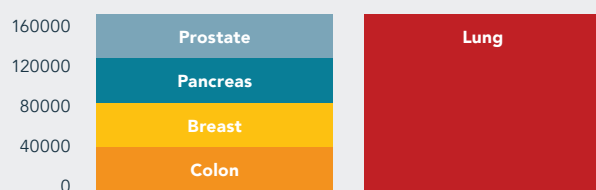
Checkpoint inhibitors alone or in combination are now approved for first-line treatment of all advanced NSCLC (adeno- and squamous cell carcinoma) apart from the comparably small fraction of adenocarcinoma patients harbouring a driver mutation who still derive most benefit from targeted therapy as a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

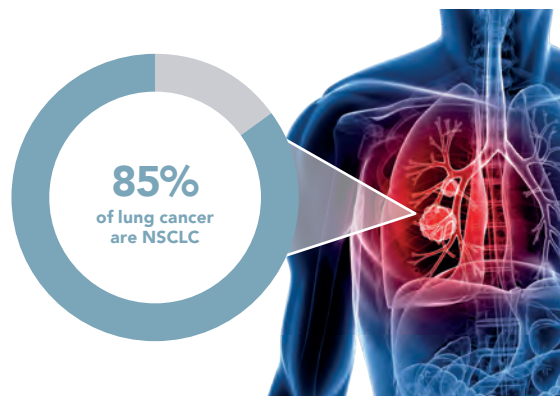
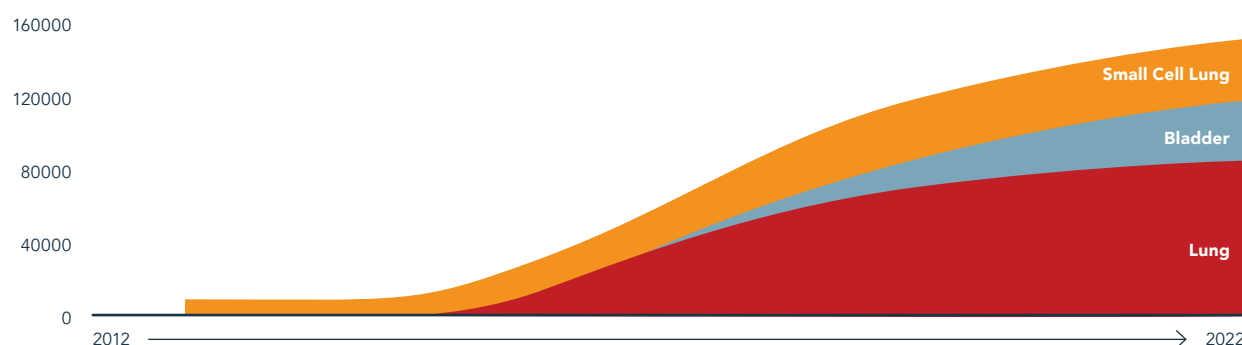
The global lung cancer market is estimated to grow at a CAGR of c. 13% and already in 2018, it is estimated that approved PD-(L)1 inhibitors have brought in over USD 8 billion in lung cancer alone.

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.

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



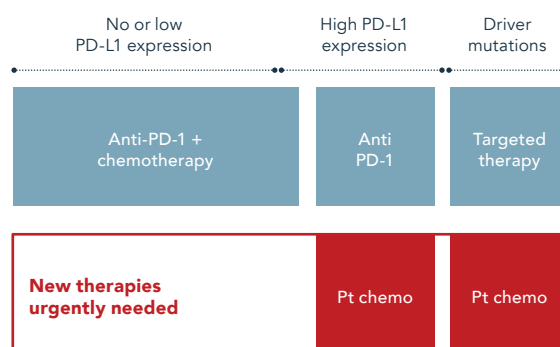
### Lung cancer is a driver for anti-PD-1 therapies sales forecast



The largest cancer killer, most patients depend on drug therapy

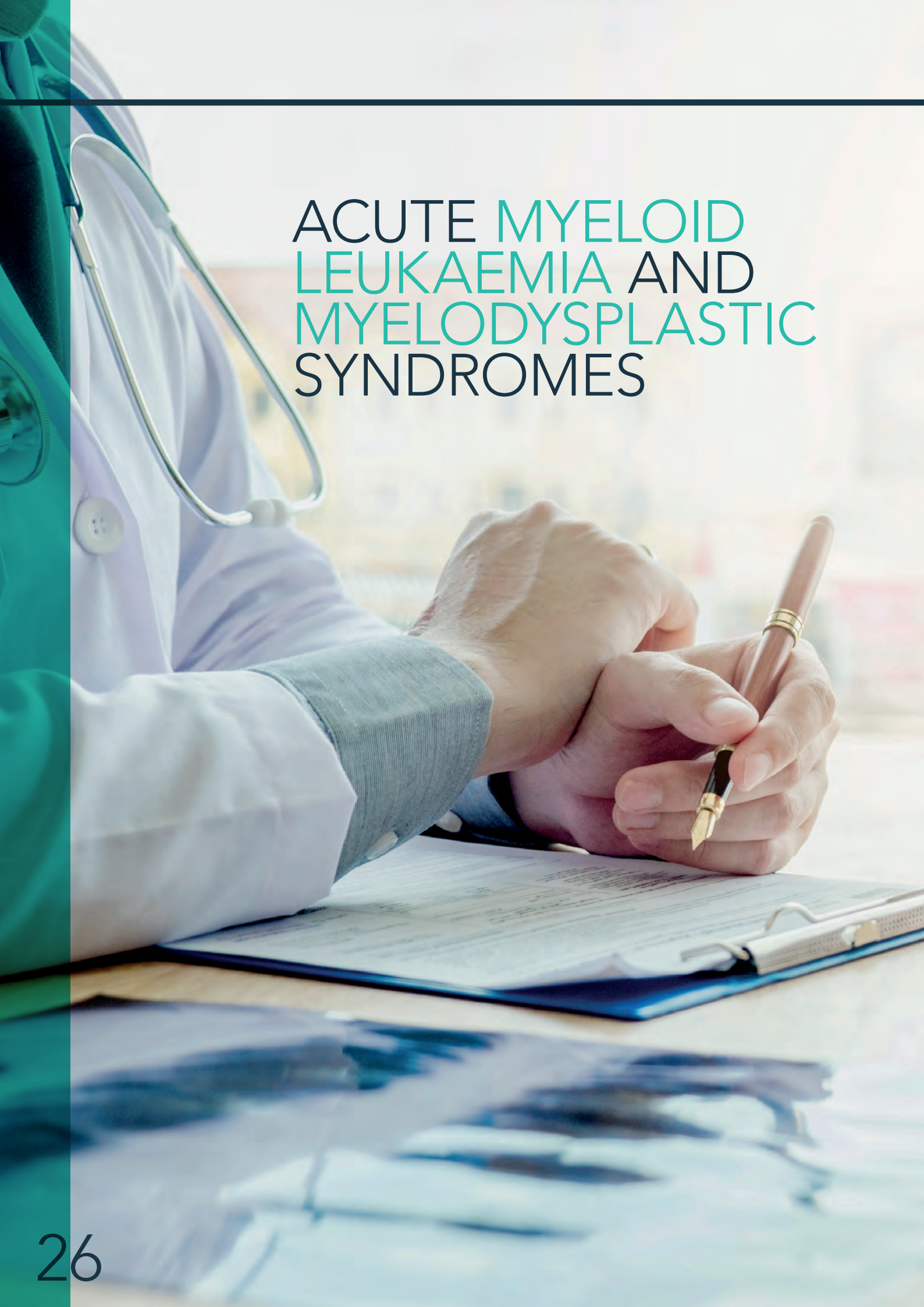
More than 1.76 million lung cancer deaths/yr worldwide

### NSCLC evolving standard of care (SoC)



Rapidly emerging SoC creates opportunities for effective, chemo free combinations

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



# ACUTE MYELOID LEUKAEMIA AND MYELODYSPLASTIC SYNDROMES



# Acute Myeloid Leukaemia

## is the most common acute leukaemia in adults

# >5%

### AML PATIENTS

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

# 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

### 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>8</sup>.

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).

# 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

### Treatment options beyond chemotherapy still limited continued

For newly diagnosed patients, the focus has been on improving the effectiveness of lower intensity treatment regimens 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

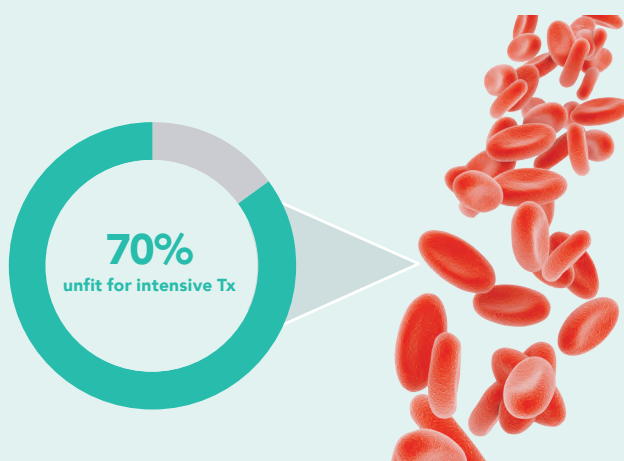
Despite recent progress, there still aren't any approved standard treatment options for a large proportion of older, less fit patients in the relapsed/refractory setting and treatment in the first line depends on chemotherapies which are encumbered by severe side effects.

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 chronic nature 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>9</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 33 billion in 2018 and is projected to grow with an CAGR of 11% on the years leading up to 2025<sup>10</sup>.



### AML evolving standard of care (SoC)

Younger fit patients

Induction chemotherapy  
+/- FLT3 inhibitor

>75 yo / unfit for intensive therapy

low dose chemo /  
hypomethylating agents / best  
supportive care

New therapies needed for patients w/o actionable mutations

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

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

### Treatment options beyond chemotherapy still limited

Urgent need particularly in older and R/R patients

\* SEER

9 Ben-Batalla et al. Blood (2013)

10 Polaris Market research: Global Blood Cancer Drugs Market: Market Size & Forecast, 2017 – 2025; April 2018





# 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

The company has successfully translated its world-leading research of AXL's biological role and function into two first-in-class clinical stage assets: the highly selective, oral small molecule AXL kinase inhibitor bemcentinib and the novel functionally blocking anti-AXL therapeutic monoclonal antibody (mAb) tilvestamab and an AXL antibody has been outlicensed for targeting ADC development (ADCT-601).

During 2019, BerGenBio's 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.

BerGenBio's sponsored clinical development is focused on NSCLC and AML. Phase II data was particularly strong in combination with pembrolizumab in NSCLC patients, and in combination with low-dose cytarabine (LDAC) and as a monotherapy in AML. Further development in these indications is on going.



Tilvestamab, a proprietary, therapeutic anti-AXL antibody, is BerGenBio's second clinical asset and is currently in Phase I testing in healthy volunteers. Phase 1b First-in-Patient trials are expected to start in 2020.

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.

## BerGenBio pipeline - 3 selective AXL inhibitors in clinical development

Multiple attractive opportunities in AML and NSCLC

Candidate	Targeted Indication
Bemcentinib	>2L AML
Bemcentinib (combination with LDAC)	2L AML
 Bemcentinib (combination with pembrolizumab)	2L NSCLC (chemo refractory)
	2L NSCLC (CPI refractory)
	2L NSCLC (CPI+chemo refractory)
Tilvestamab (BGB149)	TBA
BGB601 	Various solid tumors

CPI – checkpoint inhibitor

 Completed studies

 Ongoing studies



SITES ACROSS  
EUROPE & USA:

50

PATIENTS:

350

Discovery	Preclinical	Phase I	Phase II	Phase III
Ph II safety and POC efficacy demonstrated in 39 patient trial				
Ph Ib Safety demonstrated, efficacy POC expansion study – 28 pts				
Ph II safety and POC efficacy demonstrated in 50 patient trial, end points met				
Ph II POC study on going 29 pts – stage 1 met end point				
Ph II POC study on going 29 pts				
Ph I Healthy volunteer study ongoing				
Ph I safety study ongoing				

# PRODUCT PIPELINE



## 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<sup>11</sup> and destruction by therapy<sup>12</sup> 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 shown as a 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>13, 14, 15, 16</sup>.

AXL has also been reported to be implicated in life-threatening fibrotic conditions.

- 11 Terry et al., (2019 Cancer Immunology Research)
- 12 Quinn et al., (Mol Cancer Ther.2019)
- 13 Hugo et al. Cell (2016)
- 14 Davidsen et al. AACR (2018)
- 15 Kurowska-Stolarska et al. Nature Communications (2017)
- 16 Paolino et al. Nature (2014)
- 17 Ludvig et al Can Res, 2018; Davidsen et al., submitted
- 18 Kurowska-Stolarska et al Nature Comm 2017; Rothlin et al Cell 2007
- 19 Ludvig et al Can Res, 2018; Davidsen et al., submitted

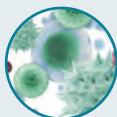


## AXL receptor tyrosine kinase drives aggressive disease including therapy resistant, immune-evasive tumours

### Key suppressor of innate immune response

AXL is an innate immune checkpoint:

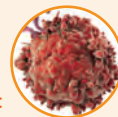
- M1 to M2 macrophage polarisation<sup>17</sup>
- Decreased antigen presentation by DCs<sup>18</sup>
- Immunosuppressive cytokine profile<sup>19</sup>



### 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**



## 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 2L NSCLC as a monotherapy and in combination



### 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 has focused its clinical development with bemcentinib on second line NSCLC and AML/MDS patients, in several company sponsored trials.

In 2019, these trials delivered important and highly promising interim 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 pembrolizumab (33% overall response rate and 8.4 months median PFS in cAXL positive patients).

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.





### AXL IHC identified NSCLC pts with improved outcomes to bemcentinib + pembrolizumab

Approximately half of previously treated NSCLC patients had AXL positive disease

Biomarker at screen	cAXL pos	cAXL neg
ORR	33%	7%
CBR	73%	40%
mPFS	8.4 months	2.9 months

(cohort A, n = 44 pts evaluable patients ref. SITC 8th November 2019)



### Soluble AXL levels identified 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 = 25 pts evaluable for sAXL status ASH 2018)

Additional predictive soluble and tissue markers identified and under investigation

## 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 development programme. The objective is to clinically validate relevant biomarkers and seek regulatory approval for their use in future clinical trials and pursue a personalised medicine approach to reimbursement.

### Key results to date:

#### AXL IHC

- Proprietary cAXL IHC method has been developed
- Half of the cAXL evaluable advanced NSCLC patients in BerGenBio's BGBC008 Phase II clinical study of bemcentinib in combination with pembrolizumab (NCT03184571) were found to stain positive for tumour cAXL
- cAXL positive patients reported superior response (33% vs 7%) and median progression free survival (PFS, c. 8.4 months vs 2.9 months) compared to cAXL 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 of 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

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 2019 in conjunction with biomarker findings, the company was able to confirm its focus for late stage clinical trials in NSCLC and AML.

\* US only, <https://seer.cancer.gov>, accessed Feb 15 2019  
20 Garon et al: KEYNOTE-001 study. NEJM (2015)





## Monotherapy / Chemo combo 1L & 2L AML

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

**21,000 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 reported 19% ORR in r/r AML as a monotherapy, and is now approved in combination with chemo in first line setting

**Clinical Trial Identifier:** NCT02488408

## Pembrolizumab combo 2L NSCLC

Increase response rate - including in  
PD-L1 negative

**200,000 new cases annually\***

**Results** in advanced previously treated patients

- Cohort A stage 1 and 2 complete: Predominantly PD-L1 negative / low patient population
  - 33% ORR in AXL positive patients
  - Median PFS 8,4 months in AXL positive patients

The trial have been expanded into:

- Cohort B – Patients previously treated with a checkpoint inhibitor (PD-L1 or PD-1 inhibitor)
- Cohort C – Patients previously treated 1st line with a checkpoint inhibitor- containing regimen in combination with a platinum-containing chemotherapy

### Context

- Pembrolizumab 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>20</sup>

**Clinical Trial Identifier:** NCT03184571

# Exploring additional pipeline opportunities through investigator initiated trials (IITs)

## Investigator Initiated Trials

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 ultimately 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.

## Potential label expansion with additional phase II studies with bemcentinib

		Clinical Proof-of-concept
Monotherapy Selected, biomarker directed patients	Glioblastoma	Ongoing
	Ovarian (EMT signature selected)	Potential
Chemotherapy Combinations Improve responses in hard to treat settings	Pancreatic	Ongoing
	NSCLC	Ongoing
Immunotherapy Combinations Target resistance, enlarge addressable patient population	Melanoma	Ongoing
	Mesothelioma	In set-up
	Bladder ++, CAR-T combos	Under consideration
Targeted Therapy Combinations Target resistance, enlarge addressable patient population	Melanoma	Ongoing
	PARPi combos ++	Under consideration
Earlier Line Opportunities Radiotherapy and maintenance opportunities	Multitude of maintenance opportunities given very favourable safety profile	



## Tilvestamab, 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, Phase 1b First-in-Patient trials planned in 2020

Tilvestamab 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 2020.

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 bodies.

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 activate or antagonise a cell surface 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.

Tilvestamab is an antibody that binds the extracellular portion of the AXL receptor and blocks its signal. Tilvestamab 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 antibodies like tilvestamab are most commonly administered intravenously (bemcentinib on the other hand, a small molecule, is taken orally).

A Phase I placebo controlled healthy volunteer trial with tilvestamab (NCT03795142) was initiated in the end of 2018 and the company reported dosing of the first human in January 2019. Enrollment is complete and final readout is expected in the coming months. Pending readout of this First-in-Human trial, the company will commence Phase 1b First-in-Patient trials in 2020.

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







# Governance

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# BOARD OF DIRECTORS



## **Sveinung Hole**

### **Chair**

Sveinung Hole is the CEO of Trond Mohn Foundation and Stiftelsen Kristian Gerhard Jebsen. He also works for Meteva AS. Hole holds a number of Board positions amongst others at Tromsø Research Foundation, Sarsia investment funds, Nordic and Europe Health Invest AS, PE Helse AS and Prophylx Pharma AS. Formerly he was the CEO of 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 in the Nordic and US. Hole holds a Master of International Management from BI Norwegian Business School.

*Mr Hole joined the Board of Directors on 1 September 2010 and as Chairman 13 March 2019. He is an Norwegian citizen and resides in Norway. He attended 13 Board meeting in 2019.*



## **Dr. Stener Kvinnsland**

### **Non-Executive Director**

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 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 in Milan.

*Mr Kvinnsland joined the Board of Directors on 22 February 2015. He is a Norwegian citizen and resides in Norway. He attended 10 Board meetings in 2019.*





### Dr. Pamela A. Trail

#### Non-Executive Director

Pamela A. Trail most recently served as CSO of Molecular Partners AG. Previously she held key strategic oncology leadership roles at Regeneron, MedImmune, Bayer Healthcare and BMS and served as CSO at Seattle Genetics. Dr. Trail received her Ph.D. from the University of Connecticut, Storrs, CT and was a postdoctoral Research Fellow at the Memorial Sloan-Kettering Institute for Cancer Research, NY. She is a US citizen.

*Mrs Trail joined the Board of Directors on 13 March 2019. She is a American citizen and resides in USA. She attended 9 Board meetings in 2019.*



### Grunde Eriksen

#### Non-Executive Director

Grunde Eriksen is the founder and CEO of Altitude Capital AS, a private investment company established in 2016. Grunde is an experienced capital markets advisor and investor. He began his career in 1998 in SEB Enskilda's corporate finance division in Stockholm before moving to the equity capital markets team in London. After 6 years there, he spent another two years at SEB in Norway before joining Arctic Securities in 2007 as a partner working in equity sales. He is a Norwegian citizen.

*Mr Eriksen joined the Board of Directors on 13 March 2019. He is a Norwegian citizen and resides in Norway. He attended 10 Board meetings in 2019.*



### Dr. Debra Barker

#### Non-Executive Director

Debra Barker is a seasoned clinical development executive with experience from Novartis, Roche, Smithkline Beecham and Knoll and served until recently as the Chief Medical and Development Officer at Polyphor Ltd. Dr Barker has a Diploma in Pharmaceutical Medicine and received a MSc in immunology from the King's College in London and a Medical Degree from the Queens College, Cambridge, UK. She is a UK-Swiss citizen.

*Mrs Barker joined the Board of Directors on 13 March 2019. She is a UK citizen and resides in Switzerland. She attended 7 Board meetings in 2019.*

# MANAGEMENT TEAM



**Richard Godfrey** MPharmS, MBA

**Chief Executive Officer**

Mr Godfrey joined BerGenBio as Chief Executive Officer in 2008. Mr Godfrey has more than 30 years' experience leading and developing international biopharmaceutical organisations. From 2003-2007 Mr Godfrey 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 held positions of increasing responsibility in research, development and commercial roles at Catalant, Eli Lilly and Reckitt Benckiser. Mr Godfrey is a qualified Pharmacist, holds a degree in Pharmaceutical Chemistry from Liverpool University and received an M.B.A. from Bath University. Mr Godfrey is a British citizen and resides in Norway.



**Professor Hani Gabra**

MD, PhD, FRCPE, FRCP

**Chief Medical Officer**

Professor Hani Gabra joined BerGenBio in September 2019 as Chief Medical Officer, based in Oxford UK. He has extensive experience of preclinical cancer biology and clinical drug development, having previously been Vice President in Early Clinical Development at AstraZeneca in Cambridge, UK, concurrently holding the positions of Professor of Medical Oncology at Imperial College London and Honorary Consultant in Medical Oncology at Imperial College Healthcare NHS Trust (since 2003) and Adjunct Professor at the Centre for Cancer Biomarkers at University of Bergen (since 2016). Prof Gabra is an internationally recognised leader in translational research and gynaecological oncology. His research interests include tumour suppressor genes that regulate receptor tyrosine kinase networks (including AXL), the molecular basis of clinical platinum resistance, and all phases of ovarian cancer clinical research.



**Rune Skeie**

**Chief Financial Officer**

Rune Skeie joined BerGenBio in 2018 as CFO. He has over 20 years of financial management, corporate development, corporate governance and advisory experience with public and private companies across multiple industry sectors. The majority of his career was spent at EY (formerly Ernst & Young), where he held the role of Executive Director, before joining REMA Franchise Norge AS, the multinational supermarket business. Mr Skeie is a Registered Accountant and a State Authorized Public Accountant.



**Prof James Lorens**

**Chief Scientific Officer**

Professor James Lorens is the co-founder of BerGenBio, serves as the company's Senior Scientific Advisor and is also a Professor at the Department of Biomedicine at the University of Bergen. On completing his postdoctoral research studies at Stanford University he joined Rigel Inc., a San Francisco based biotechnology company, as a founding scientist and research director. Prof. Lorens has managed several large scientific collaborations in cancer research and development with major pharmaceutical and biotechnology companies. He leads a large internationally active academic research laboratory comprising 22 researchers. His group is active in EMT, angiogenesis and cancer research. Prof. Lorens is an author of more than 70 peer-reviewed articles and patents.





### **James Barnes** PhD

#### **Director of Operations**

Dr James Barnes joined BerGenBio in March 2019 as Director of Regulatory Affairs and Programme Management, based in Oxford, UK. He has 14 years' experience in the fields of regulatory strategy, regulatory policy and project management across a wide range of therapeutic areas, including oncology. His early and late stage development experience, recently focused on innovative breakthrough products for rare diseases, has been gained from both pharmaceutical and consultancy roles. He has a Cellular & Molecular Biology PhD from the University of Bristol in the field of colorectal cancer and held a Postdoctoral Research position in Human Embryonic Stem Cells at the University of Sheffield.



### **Gro Gausdal** PhD

#### **Director of Research & Bergen Site Leader**

Dr Gro Gausdal joined BerGenBio in 2013 and holds the position of Director of Research and Bergen Site Leader. Prior to joining BerGenBio, she obtained her PhD degree investigating mechanisms of drug induced cell death and resistance in leukaemia. Dr Gausdal carried out her Post Doc training at the MD Andersen Cancer Center in Houston and at the University of Bergen, and has over 15 years' experience in academic research and supervision.



### **Endre Kjærland** PhD

#### **Associate Director of IP and Contracts**

Dr Endre Kjærland joined BerGenBio AS 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.



### **Debbie Molyneux**

#### **Interim HR Director**

Debbie Molyneux joined the Company in 2019 as Consultant for Human Resources. She has 20 years experience of HR in multi-national organisations and SME's in a variety of Industry sectors, including medical devices. Debbie has experience of leading multi-national HR teams with strategic leadership and her consultancy has seen her support businesses undergoing change, advising management teams and providing a wide range of HR services including organisation design and learning and development. Debbie is a graduate of the University of Birmingham, a member of the Russell Group of Universities, holds a post graduate qualification in Human Resource Management from Oxford Brookes University, and is a Chartered Member of the CIPD (Chartered Institute of Personnel and Development).



### **Alison Messom** PhD

#### **Director of Clinical Operations**

Dr Alison Messom joined BerGenBio in June 2019 based in Oxford, UK. She brings over 20 years' clinical research experience having held a wide variety of leadership roles, within Pharma Companies & CROs. She has detailed experience of directing global clinical trials across phases I-IV and has worked in a wide variety of leadership roles, within Pharma Companies & CROs. Alison has been awarded a PhD in molecular genetics by The University of Leeds and a postgraduate certificate in international business management by University College Dublin.

# REMUNERATION REPORT 2019

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 and instructions from the Board of Directors, these are summarised in this statement to the Annual General Meeting.

BerGenBio is a growing company with several drug candidates in clinical development. The business operates in a competitive international market. As such, employees of the Company gain valuable experience and become visible to a external community of potential employers. It is therefore crucial to be able to both attract and retain highly qualified staff to the organisation with competitive compensation.

The Committee has updated 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 attract, incentivise, retain and align employees with shareholders.

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  
21 February 2020

## 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 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, which is communicated to the shareholders through the annual report. The Board of Directors also has final approval of the remuneration of the senior management, based on recommendation from the Remuneration Committee.

In 2019, the Committee has not taken paid advice in association with the assignment. The Board of Directors appoints the Remuneration Committee which consists of members of the Board of Directors. The members in 2019 were:

- Debra Barker
- Grunde Eriksen
- Sveinung Hole, Chairman

The Committee met six times in 2019. The CEO and CFO have given input to levels of remuneration and performance, and have not participated in final conversations regarding their own levels of remuneration.



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

- Updated 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.
- 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 2019.
- Reviewed CEO performance according to the 2019 Bonus Plan.
- Participated in recruitment of key personnel, interviews and agreeing remuneration packages.
- Reviewed ongoing organizational development process and plan.

## Section 3 – Overview of the Remuneration Policy

### The Remuneration Policy

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

Principle	Summary
<b>Market competitive remuneration</b>	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.
<b>Pay for performance</b>	An appropriate proportion of the compensation 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.
<b>Transparency</b>	Remuneration programmes are designed and communicated in a manner that reinforces the linkage between business objectives, vision and culture.
<b>Business alignment and consistency</b>	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.
<b>Shareholder alignment</b>	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 2019 update, the BerGenBio Comparator Peer Group consists of 20 companies from the Nordic countries (15) and the UK (5) 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

The chart below shows, as a proportion of the 2019 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.

#### CEO

Base salary	40%
Short-term incentive	20%
Share options	40%



#### All other executives

Base salary	58%
Short-term incentive	12%
Share options	29%





## Section 4 – Remuneration Policy for each element

### Base salary

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 refers 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 for all personnel costs, which will have retroactive effect from 1 January.

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 members of the executive team. The Board sets the individual objectives of the CEO and the overall objective for the executive team. 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 gives his recommendation to the Committee and based on the recommendation from the Committee the Board finally approves any STI award to the CEO.

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	Maximum bonus in % of salary, inc. stretch
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.

### Share options

BerGenBio operates with a share option plan (Long-term Incentive Plan – LTIP). The purpose of the LTIP 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. The Company's use of share options reflects practice in the sector. Relevant surveys confirm more than 70% of LTIPs deployed in the sector use a share option schemes. 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 critical.

Share options may in extraordinary cases be granted to selected consultants and Board members to attract and retain the individuals with the experience, knowledge, and international industry network and acumen that will benefit the company. 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). The Nomination Committee may recommend the award of share options to Board members, this will be the exception, and based on a case by case recommendation. No such cases have occurred in 2019.

## Section 4 – Remuneration Policy for each element continued

### Share options continued

The Board of Directors has been authorised by the General Meeting of BerGenBio ASA on 13th March 2019 to award up to 5,485,140 shares as part of the share option plan, constituting a maximum 10% of outstanding shares. In 2019 the total number of outstanding share options decreased by 1.61%, from 5.82% to 4.21%. At Year End 2019, just 2,569,347 share options were outstanding, of which 1,701,781 were vested and exercisable. Senior management held 2,053,515 share options, the remaining 515,832 share options are held by other employees. See Note 5 and 6 of the consolidated financial statements for 2019 for an overview of options granted per 31 December 2019. This is below common market practise, and well below most of BerGenBio's peer companies.

The Board of Directors determines if share options are to be granted and makes the 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 sector share option schemes, without performance conditions and is compliant with IFRS2.

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

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. 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.

Individual Share Option awards are determined by considering the overall performance, potential, competitiveness of the employment terms, position responsibility, need for retention, and the overall long-term organisation need.

Vested share options can be exercised partly or fully at four specified points per year. In addition, the Board may allow exercise at other suitable times during the year.

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. All deviations must be decided by the Board of Directors.

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.

### 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, life and accident insurance, etc. on customary terms. The type of benefit provision, the level of cover and the coverage will be reviewed when deemed relevant.

### 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 at fair market value at his sole discretion.



**Board of Directors**

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. For international Board Directors there are individual agreements with some compensation for travel and hours dedicated to meetings. The Annual General Meeting sets the fees after recommendation from the Nominations Committee.

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 2018 and 2019**

See Notes 5 and 6 to the group financial statements.

# CORPORATE GOVERNANCE REPORT 2019

## 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

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/engagements.

## 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 2019.

## 3. Equity and Dividends

### Capital adequacy

BerGenBio's total equity at 31 December 2019 was NOK 219.8 million, corresponding to an equity ratio of 81.3%. 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 requirements.

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, on 13 March 2019, the Board of Directors was granted the following authorisation:

- Authorisation to increase the company's share capital by up to NOK 548,514 in connection with its existing share option scheme. The authorisation is effective until the earlier of the AGM in 2020 and 30 June 2020.

For supplementary information on the authorisations, reference is made to the minutes of the annual general meeting held on 13 March 2019, available from the company's website and [www.newsweb.no](http://www.newsweb.no).

At the company's annual general meeting, held on 13 March 2019, 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 1,097,028 by subscription of up to new shares, which constitute 20% 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 14 June 2019 the Board of Directors issued 5,495,144 shares under this authorisation. In addition, on 29 January 2020, the Board of Directors issued the remaining 5,475,136 shares under this authorisation. For supplementary information on the authorisations, reference is made to the minutes of the annual general meeting held on 13 March 2019, available from the company's website and [www.newsweb.no](http://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.

#### 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 2019.

#### 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 third-party 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 2019.

### 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.

## 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 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 2019, BerGenBio held its annual general meeting on 13 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 13 March 2019, and consists of:

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

The members were elected with a term until the annual general meeting in 2021. 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 2019, the Board of Directors consisted of five members, whereof two women:

- Sveinung Hole (Chair)
- Stener Kvinnsland
- Grunde Eriksen
- Debra Barker
- Pamela Trail

All members are elected for a term of two years and may be re-elected.



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 four to five members, then each gender shall be represented by at least two members.

Except for Sveinung Hole and Stener Kvinnsland, 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. The following shares are held by the board as of 31 December 2019:

Name	Position	Considered independent	Served since	Term expires	Board Meeting Attendance 2019	Shares	Share options
Sveinung Hole	Chair	No	01.09.2010	AGM 2020	13	107,394 1)	0
Stener Kvinnsland	Board member	No	22.02.2015	AGM 2020	10	104,444	0
Grunde Eriksen	Board member	Yes	13.03.2019	AGM 2021	10	0 2)	0
Debra Barker	Board member	Yes	13.03.2019	AGM 2021	7	0	0
Pamela Trail	Board member	Yes	13.03.2019	AGM 2021	9	0	0

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

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

## 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 2019, the Board of Directors held 13 meetings.

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 2019, and met with the Auditor, EY, separately without the executive management present.

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

### Audit Committee continued

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:

- Grunde Eriksen (Chair)
- Sveinung Hole
- Pamela Trail

### 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 four to six 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)
- Grunde Eriksen
- Debra Barker

## 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 undergone 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 2019 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. 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 2019.

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 2019.

## 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](http://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.

#### 15. Auditor

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 2019

## 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 treatment-resistant cancers. The company has a portfolio of multiple clinical assets targeting the receptor tyrosine kinase AXL and is focused on developing a pipeline of first-in-class 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 tilvestamab (former BGB149), a first-in-class 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 and NSCLC
- Develop companion diagnostics to enrich future clinical trials and improve chances of regulatory success
- Advance the clinical development of tilvestamab
- Secure additional pipeline opportunities for the company's AXL inhibitors in oncology and non-oncology indications

## Operational review

**Important progress in 2019: encouraging clinical data support potential of bemcentinib and confirm focus for next stages of development.**

During 2019, BerGenBio continued to provide updates from ongoing Phase II clinical trials investigating bemcentinib in combination and as a monotherapy. 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 pembrolizumab in lung cancer and with low-dose chemotherapy (LDAC) in AML/MDS as particularly promising.

Encouraging data generated so far has enabled the Company to commit to progressing bemcentinib through to regulatory approval. The US Food and Drug Administration (FDA) approved Fast Track Designation for bemcentinib for the treatment of elderly patients with AML whose disease has relapsed. Late stage studies in NSCLC and in AML/MDS are planned to start during 2020. Accelerated routes to approval will be pursued where appropriate.

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 tilvestamab (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.

**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 2019 with a cash position of NOK 253 million and completed a private placement in January 2020 raising NOK 220 million and is positioned to execute its strategy for bemcentinib and tilvestamab (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 2019:

- BGBC003 – bemcentinib in combination with low dose chemotherapy (LDAC) in AML and MDS
- BGBC008 – combination therapy with pembrolizumab in NSCLC

Results from the BGBC003 phase II trial of bemcentinib in combination with low-dose chemotherapy (LDAC) in AML patients showed that the trial achieved its efficacy endpoint and showed encouraging efficacy and favourable safety in the very frail population of relapsed/refractory AML and MDS patients. An extensive translational programme continues to explore potential biomarkers for bemcentinib combination therapy. Further details will be presented at upcoming medical conferences. Furthermore, the Company is proceeding with preparations for a late-stage bemcentinib monotherapy trial in AML.

Data from the BGBC008 study of bemcentinib in combination with pembrolizumab in NSCLC was presented at the 2019 annual meeting of the American Society of Clinical Oncology (ASCO). Encouraging activity was reported for the combination particularly in AXL positive patients. In November 2019 the Company reported that the trial had met primary and secondary endpoints in the first of three cohorts enrolled at the Society for Immunotherapy of Cancer (SITC) Annual Meeting.

Data from the trial suggests that bemcentinib has the potential to enhance patient responses and overall survival when treated in combination with a PD-1 inhibitor. We were particularly pleased to see responses in patients

with no or limited expression of PDL1, who would not be expected to respond to anti-PDL1 drugs alone. Indeed, post-period initial data from the Cohort B of the NSCLC trial showed promising data in patients who have relapsed on immunotherapy alone, which represents a very significant and encouraging development which warrants further investigation.

**Progress: tilvestamab (BGB149)**

Tilvestamab (BGB149) is the first functional blocking anti-AXL monoclonal antibody to enter clinical development and is BerGenBio's second clinical stage drug development programme targeting AXL. In January 2019 the Company initiated first-in-human clinical trial testing tilvestamab in healthy volunteers.

**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.

**Other progress**

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 2019, increasing the knowledge of selective AXL inhibition as a promising drug target and contributing positively to BerGenBio newsflow.



## 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.

### Financial risks

#### Interest rate risk

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

#### Exchange rate risk

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

on where clinical trials are run, but holds a significant part of the working capital in foreign currency. The foreign currency exposure is also mostly linked to trade payables with short payment terms. The Group might consider changing its current risk management of foreign exchange rate if it deems it appropriate.

### Credit risk

Credit risk is the risk of counterparty's default in a financial asset, liability or customer contract, giving a financial loss. The Group's receivables are generally limited to receivables from public authorities by way of government grants. The credit risk generated from financial assets in the Group is limited since it is cash deposits. The Group places its cash in bank deposits in recognised financial institutions to limit its credit risk exposure.

The Group has not suffered any loss on receivables during 2019 and the Group considers its credit risk as low.

### Liquidity risk

Liquidity is monitored on a continued basis by Group management.

The Group works continuously to ensure financial flexibility in the short and long term to achieve its strategic and operational objectives. Management considers the Group's liquidity situation to be satisfactory. The Group secured equity funding of NOK 74 million gross in June 2019 and additional gross NOK 219.9 million in January 2020.

### 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 2018 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 2019. Figures is for the Group and for the parent company BerGenBio ASA labelled ASA below).

#### Financial results

##### Operating revenues

Revenue for the full year 2019 amounted to NOK 8.9 million (2.3 million) for the Group and NOK 9.0 million (NOK 2.3 million) for ASA. The revenue represents a preclinical milestone from an out-license agreement with ADCT.

##### Operating expenses

Total operating expenses for 2019 for the Group amounted to NOK 213.3 million (NOK 196.9 million), and NOK 214.7 million (NOK 197.5 million) for ASA. Employee costs in the Group were NOK 35.7 million (NOK 38.0 million), and NOK 21.3 million (NOK 24.1 million) for ASA for the full year 2019.

For the full year 2019 other operating costs for the Group amounted to NOK 176.8 million (NOK 158.7 million), and 192.6 million (173.2 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 has recognised government grants for a total of NOK 26.0 million (NOK 20.2 million) for the full year 2019.

Payroll expenses has been reduced by NOK 5.3 million (NOK 1.4 million) and operating expenses by NOK 20.7 million (NOK 18.9 million) as a result of these government grants. ASA has recognised government grants for a total of NOK 22.9 million (NOK 20.2 million) for the full year 2019. Payroll expenses has been reduced by NOK 2.1 million (NOK 1.4 million) and operating expenses by NOK 20.7 million (NOK 18.9 million) as a result of these government grants.

The operating loss for the Group in 2019 was NOK 204.4 million (NOK 194.5 million) and NOK 205.7 million (NOK 195.1 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 5.1 million (NOK 2.8 million) and NOK 5.0 million (NOK 2.9 million) for ASA for the full year 2019.

Losses after tax for the Group was NOK 199.3 million (NOK 191.7 million) and NOK 200.7 million (NOK 192.2 million) for the full year 2019.

#### Financial position

Total assets at 31 December 2019 for the group decreased to NOK 270.4 million (378.8 million at year-end 2018) for the Group and to NOK 270.6 (NOK 381.4 million at year-end 2018) for ASA, mainly due to the cash spent on operating activities adjusted for the capital raise completed in June 2019.

Total liabilities were NOK 50.6 million (NOK 41.5 million at year-end 2018) for the Group and NOK 48.6 million (NOK 40.5 million at year-end 2018) for ASA.

Total equity as of 31 December 2019 was NOK 219.8 million (NOK 337.3 million at year-end 2018) for the Group and NOK 222.0 million (NOK 340.9 million at year-end 2018) for ASA, corresponding to an equity ratio of 81.3% (89.0%) for the Group and 82.0% (89.4%) for ASA.

#### Cash flow

Net cash flow from operating activities was negative by NOK 184.1 million (NOK 186.7 million) for the Group and negative by NOK 184.1 million (NOK 186.8 million) for ASA for the full year 2019, mainly driven by the 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 2019 was negative by NOK 0.0 million (NOK -0.2 million) for the Group and NOK 0.0 million (NOK -0.2 million) for ASA.

Net cash flow from financing activities was NOK 77.3 million (NOK 177.0 million) for the Group and NOK 77.3 million (NOK 177.0 million) for ASA for the full year 2019, reflecting the share issue in June 2019 in relation to the completion of the private placement.

Cash and cash equivalents decreased to NOK 253.6 million (NOK 360.4 million) for the Group and NOK 252.7 million (NOK 359.4 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.

### 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 pre-commercial 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 26 people (26 people), of which 15 in Bergen and 11 in Oxford. The working environment in the Group is regarded as good.

Absence due to illness for the year for BerGenBio ASA totalled 38 working days (247 working days), which corresponds to 1.07 per cent (6.68 per cent) of total working days. No work-related incidents or accidents were registered in 2019 (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, three out of nine executives in the management team were women. Among the Board of Directors, two out of five 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 2019 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 2019.

### 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 comparable companies in the industry. All production and distribution are outsourced to carefully selected qualified vendors.

### Share information

As of 31 December 2019, there were 61,076,590 ordinary shares outstanding, up from 54,711,446 shares at year end 2018, following the private placement in June 2019 and shares issued under the employee share option program.

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

The company had more than 4,000 shareholders at 31 December 2019.

The result for 2019 show a loss of tNOK 200,696. 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 late stage Phase II trials with bemcentinib in NSCLC and AML during 2020. 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 "go-to market" strategy may also be considered in select indications in discrete territories, where greater value for shareholders could be created.

### Bergen

The Board of Directors, BerGenBio ASA  
21 February 2020



**Sveinung Hole**  
Chairman



**Dr. Stener Kvinnsland**  
Non-Executive Director



**Dr. Pamela A. Trail**  
Non-Executive Director



**Grunde Eriksen**  
Non-Executive Director



**Dr. Debra Barker**  
Non-Executive Director



**Richard Godfrey**  
CEO



## 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 2019 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

The Board of Directors, BerGenBio ASA  
21 February 2020



**Sveinung Hole**  
Chairman



**Dr. Stener Kvinnsland**  
Non-Executive Director



**Dr. Pamela A. Trail**  
Non-Executive Director



**Grunde Eriksen**  
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**Dr. Debra Barker**  
Non-Executive Director



**Richard Godfrey**  
CEO



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# INCOME STATEMENT AND OTHER COMPREHENSIVE INCOME

1 January – 31 December (NOK 1000)

Parent 2018	Parent 2019		Note	Group 2019	Group 2018
<b>2,335</b>	<b>9,000</b>	<b>Revenue</b>	4	<b>8,900</b>	<b>2,335</b>
24,054	21,350	Employee benefit expenses	5, 7, 10	35,717	38,012
204	785	Depreciation	8	785	204
173,217	192,589	Other operating expenses	7, 9, 13, 22	176,773	158,658
<b>197,475</b>	<b>214,724</b>	<b>Total operating expenses</b>		<b>213,274</b>	<b>196,874</b>
<b>(195,140)</b>	<b>(205,723)</b>	<b>Operating profit</b>		<b>(204,374)</b>	<b>(194,539 )</b>
4,794	11,288	Finance income	11	11,530	4,857
1,888	6,261	Finance expense	9, 11	6,434	2,065
<b>2,906</b>	<b>5,027</b>	<b>Financial items, net</b>		<b>5,096</b>	<b>2,792</b>
<b>(192,234)</b>	<b>(200,696)</b>	<b>Profit before tax</b>		<b>(199,278)</b>	<b>(191,747)</b>
0	0	Income tax expense	12	0	0
<b>(192,234)</b>	<b>(200,696)</b>	<b>Profit after tax</b>		<b>(199,278 )</b>	<b>(191,747)</b>
		<b>Other comprehensive income</b>			
		<i>Items which will not be reclassified over profit and loss</i>			
<b>(192,234)</b>	<b>(200,696)</b>	<b>Total comprehensive income for the year</b>		<b>(199,278)</b>	<b>(191,747)</b>
		<b>Earnings per share:</b>			
(3.61)	(3.46)	– Basic and diluted per share	14	(3.43)	(3.60)



# STATEMENT OF FINANCIAL POSITION

31 December (NOK 1000)

Parent 2018	Parent 2019		Note	Group 2019	Group 2018
		<b>ASSETS</b>			
		<b>Non-current assets</b>			
581	974	Property, plant and equipment and right-of-use assets	8	974	581
<b>581</b>	<b>974</b>	<b>Total non-current assets</b>		<b>974</b>	<b>581</b>
		<b>Current assets</b>			
21,430	16,923	Other current assets	7, 15, 22	15,818	17,831
359,403	252,653	Cash and cash equivalents	16, 20	253,586	360,413
<b>380,833</b>	<b>269,575</b>	<b>Total current assets</b>		<b>269,404</b>	<b>378,245</b>
<b>381,414</b>	<b>270,550</b>	<b>TOTAL ASSETS</b>		<b>270,378</b>	<b>378,826</b>
		<b>EQUITY AND LIABILITIES</b>			
		<b>Equity</b>			
		<b>Paid in capital</b>			
5,471	6,108	Share capital	17	6,108	5,471
313,408	189,985	Share premium	17	187,786	309,791
22,018	25,860	Other paid in capital	6, 17	25,860	22,018
<b>340,897</b>	<b>221,953</b>	<b>Total paid in capital</b>		<b>219,754</b>	<b>337,280</b>
<b>340,897</b>	<b>221,953</b>	<b>Total equity</b>		<b>219,754</b>	<b>337,280</b>
		<b>Current liabilities</b>			
23,692	25,620	Accounts payable		26,746	23,939
12,094	20,902	Other current liabilities	18, 9	21,803	12,875
4,732	2,074	Provisions	19	2,074	4,732
<b>40,517</b>	<b>48,596</b>	<b>Total current liabilities</b>		<b>50,624</b>	<b>41,546</b>
<b>40,517</b>	<b>48,596</b>	<b>Total liabilities</b>		<b>50,624</b>	<b>41,546</b>
<b>381,414</b>	<b>270,550</b>	<b>TOTAL EQUITY AND LIABILITIES</b>		<b>270,378</b>	<b>378,826</b>

## Bergen

The Board of Directors, BerGenBio ASA  
21 February 2020



**Sveinung Hole**  
Chairman



**Dr. Stener Kvinnsland**  
Non-Executive Director



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Non-Executive Director



**Dr. Debra Barker**  
Non-Executive Director



**Richard Godfrey**  
CEO



# STATEMENT OF CHANGES IN EQUITY

(NOK 1000)

Group 2019	Note	Share capital	Share premium	Other paid in capital	Total equity
<b>Balance at 1 January 2019</b>		<b>5,471</b>	<b>309,791</b>	<b>22,018</b>	<b>337,280</b>
Profit after tax		–	(199,278)	–	(199,278)
Other comprehensive income (loss) for the year, net of income tax		–	–	–	–
<b>Total comprehensive income for the year</b>		<b>–</b>	<b>(199,278)</b>	<b>–</b>	<b>(199,278)</b>
Recognition of share-based payments	5,6	–	–	3,842	3,842
Issue of ordinary shares	17	637	82,148	–	82,785
Share issue costs	17	–	(4,875)	–	(4,875)
Transactions with owners		637	77,273	3,842	81,752
<b>Balance at 31 December 2019</b>		<b>6,108</b>	<b>187,786</b>	<b>25,860</b>	<b>219,754</b>

Group 2018	Note	Share capital	Share premium	Other paid in capital	Total equity
<b>Balance at 1 January 2018</b>		<b>4,992</b>	<b>325,018</b>	<b>20,340</b>	<b>350,350</b>
Profit after tax		–	(191,747)	–	(191,747)
Other comprehensive income (loss) for the year, net of income tax		–	–	–	–
<b>Total comprehensive income for the year</b>		<b>–</b>	<b>(191,747)</b>	<b>–</b>	<b>(191,747)</b>
Recognition of share-based payments	5,6	–	–	1,678	1,678
Issue of ordinary shares	17	479	190,047	–	190,525
Share issue costs	17	–	(13,527)	–	(13,527)
Transactions with owners		479	176,519	1,678	178,677
<b>Balance at 31 December 2018</b>		<b>5,471</b>	<b>309,791</b>	<b>22,018</b>	<b>337,280</b>

Parent 2019	Note	Share capital	Share premium	Other paid in capital	Total equity
<b>Balance at 1 January 2019</b>		<b>5,471</b>	<b>313,408</b>	<b>22,018</b>	<b>340,897</b>
Loss for the year		–	(200,696)	–	(200,696)
Other comprehensive income (loss) for the year, net of income tax		–	–	–	–
<b>Total comprehensive income for the year</b>		<b>–</b>	<b>(200,696)</b>	<b>–</b>	<b>(200,696)</b>
Recognition of share-based payments	5,6			3,842	3,842
Issue of ordinary shares	17	637	82,148	–	82,785
Share issue costs	17	–	(4,875)	–	(4,875)
Transactions with owners		637	77,273	3,842	81,752
<b>Balance at 31 December 2019</b>		<b>6,108</b>	<b>189,985</b>	<b>25,861</b>	<b>221,953</b>

Parent 2018	Note	Share capital	Share premium	Other paid in capital	Total equity
<b>Balance at 1 January 2018</b>		<b>4,992</b>	<b>329,122</b>	<b>20,340</b>	<b>354,454</b>
Loss for the year		–	(192,234)	–	(192,234)
Other comprehensive income (loss) for the year, net of income tax		–	–	–	–
<b>Total comprehensive income for the year</b>		<b>–</b>	<b>(192,234)</b>	<b>–</b>	<b>(192,234)</b>
Recognition of share-based payments	5,6			1,678	1,678
Issue of ordinary shares	17	479	190,047	–	190,525
Share issue costs	17	–	(13,527)	–	(13,527)
Transactions with owners		479	176,519	1,678	178,677
<b>Balance at 31 December 2018</b>		<b>5,471</b>	<b>313,408</b>	<b>22,018</b>	<b>340,897</b>

# STATEMENT OF CASH FLOWS

1 January – 31 December (NOK 1000)

Parent 2018	Parent 2019		Note	Group 2019	Group 2018
		<b>Cash flow from operating activities</b>			
(192,234)	(200,696)	Profit before tax		(199,278)	(191,747)
		Non-cash adjustments to reconcile loss before tax to net cash flows			
204	785	Depreciation of property, plant and equipment	8	785	204
1,678	3,842	Share-based payment expense	5	3,842	1,678
1,712	(2,658)	Movement in provisions and pensions	10, 19	(2,658)	1,712
		Working capital adjustments:			
1,076	4,508	Decrease in trade and other receivables and prepayments		2,013	(4,401)
770	10,152	Increase in trade and other payables		11,151	5,847
<b>(186,793)</b>	<b>(184,067)</b>	<b>Net cash flow from operating activities</b>		<b>(184,145)</b>	<b>(186,706)</b>
		<b>Cash flows from investing activities</b>			
(228)	0	Purchase of property, plant and equipment	8	0	(228)
<b>(228)</b>	<b>0</b>	<b>Net cash flow used in investing activities</b>		<b>0</b>	<b>(228)</b>
		<b>Cash flows from financing activities</b>			
190,525	82,785	Proceeds from issue of share capital	17	82,785	190,525
(13,527)	(4,875)	Share issue cost		(4,875)	(13,527)
0	(593)	Cash payments for the principal portion of the lease liability	9	(593)	0
<b>176,998</b>	<b>77,317</b>	<b>Net cash flow from financing activities</b>		<b>77,317</b>	<b>176,998</b>
(10,023)	(106,750)	Net increase/(decrease) in cash and cash equivalents		(106,828)	(9,936)
369,426	359,403	Cash and cash equivalents at beginning of period	16	360,414	370,350
<b>359,403</b>	<b>252,653</b>	<b>Cash and cash equivalents at end of period</b>	16	<b>253,586</b>	<b>360,414</b>



# 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 metastatic 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 2020. 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 2019 and were approved for issue by the Board of Directors on 21 February 2020.

## 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. The consolidated financial and the company financial statements have been prepared on a historical cost basis.

### Basis for consolidation

The consolidated financial statements comprise the financial statements of the Company and its subsidiary as at 31 December 2019. The subsidiary is BerGenBio Limited, located in Oxford in the United Kingdom and is 100% owned and controlled by the parent company BerGenBio ASA. 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 was successfully completed on the 13 April 2018. Further a private placement raising gross NOK 74.2 million was completed 14 June 2019. After the balance date, in January 2020, a private placement raising gross NOK 219.9 million have been placed where NOK 98.6 million have been received and additional NOK 121.3 million was approved in an Extraordinary General Meeting held on 20 February 2020, 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.

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

### Summary of significant accounting policies

The new and amended standards and interpretations from IFRS that were adopted by the EU with effect from 2019 did not have any significant impact on the reporting for 2018 and 2019.

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

### Revenue recognition

Revenue from contracts with customers is recognised when control of the goods or services are transferred to the customer at an amount that reflects the consideration to which the Group and the Company expects to be entitled in exchange for those goods or services. The Group and the Company has generally concluded that it is the principal in its revenue arrangements, because it typically controls the goods or services before transferring them to the customer.

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

The Group (the Company) has entered into an out licence agreement where development, regulatory and sales-based milestones trigger revenue payment to the Group (the Company). Revenue from the out licence agreement is recognised in the period when the milestone event 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 transaction date.

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 of 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.

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.

**Investment in subsidiaries**

Subsidiaries are consolidated in the Group Financial statement. In the Company Financial Statement subsidiaries are consolidated in the Group Financial statement. In the Company Financial Statement subsidiaries are measured at cost.

**Leases**

The Group has applied IFRS 16 using the modified retrospective approach. The impact of changes in accounting policies and impact of the initial application is disclosed in note 9.

**Significant accounting policies****Identifying a lease**

At the inception of a contract, The Group assesses whether the contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

**The Group (the Company) as a lessee****Separating components in the lease contract**

For contracts that constitute, or contain a lease, the Group (the Company) separates lease components if it benefits from the use of each underlying asset either on its own or together with other resources that are readily available, and the underlying asset is neither highly dependent on, nor highly interrelated with, the other underlying assets in the contract. The Group (the Company) then accounts for each lease component within the contract as a lease separately from non-lease components of the contract.

**Recognition of leases and exemptions**

At the lease commencement date, the Group (the Company) recognises a lease liability and corresponding right-of-use asset for all lease agreements in which it is the lessee, except for the following exemptions applied:

- Short-term leases (defined as 12 months or less)
- Low value assets

For these leases, the Group (the Company) recognises the lease payments as other operating expenses in the statement of profit or loss when they incur.



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

### Lease liabilities

The lease liability is recognised at the commencement date of the lease. The Group (the Company) measures the lease liability at the present value of the lease payments for the right to use the underlying asset during the lease term that are not paid at the commencement date. The lease term represents the non-cancellable period of the lease, together with periods covered by an option either to extend or to terminate the lease when the Group (the Company) is reasonably certain to exercise this option.

The lease payments included in the measurement comprise of fixed lease payments (including in-substance fixed payments), less any lease incentives receivable.

The lease liability is subsequently measured by increasing the carrying amount to reflect interest on the lease liability, reducing the carrying amount to reflect the lease payments made and remeasuring the carrying amount to reflect any reassessment or lease modifications.

The Group (the Company) does not include variable lease payments in the lease liability. Instead, the Group (the Company) recognises these variable lease expenses in profit or loss when they occur.

### Right-of-use assets

The Group measures the right-of use asset at cost, less any accumulated depreciation and impairment losses, adjusted for any remeasurement of lease liabilities. The cost of the right-of-use asset comprise:

- The amount of the initial measurement of the lease liability recognised
- Any lease payments made at or before the commencement date, less any incentives received
- Any initial direct costs incurred by the Group.

The Group (the Company) applies the depreciation requirements in IAS 16 Property, Plant and Equipment in depreciating the right-of-use asset, except that the right-of-use asset is

depreciated from the commencement date to the earlier of the lease term and the remaining useful life of the right-of-use asset. The Group (the Company) applies IAS 36 Impairment of Assets to determine whether the right-of-use asset is impaired and to account for any impairment loss identified.

### 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 and fair value through other comprehensive income.

#### **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.

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

### 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 tax

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.

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.

#### 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 short-term 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 7-10% 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.

### Changes in accounting policies and disclosures

The accounting policies adopted are consistent with those of the previous financial year, except for the amendments to IFRS which have been implemented by the Group during the current financial year. Below we have listed the amendments in IFRS which have been applicable for the Group's 2019 financial statements, as well as the effect of the amendments.

The following new and amended standards and interpretations have been implemented for the first time in 2019:

#### IFRS 16 Leases

IFRS 16 was issued in January 2016 and it replaces IAS 17 Leases, IFRIC 4 Determining whether an Arrangement contains a Lease, SIC-15 Operating Leases-Incentives and SIC-27 Evaluating the Substance of Transactions Involving the Legal Form of a Lease.

#### The Group as a lessee

IFRS 16 sets out the principles for the recognition, measurement, presentation and disclosure of leases and requires lessees to account for most leases under a single on-balance sheet model. At the commencement date of a lease, a lessee will recognise a liability to make lease payments and an asset representing the right to use the underlying asset during the lease term ("right-of-use asset"). The standard includes a number of optional practical expedients related to recognition and initial application. Lessees will be required to separately recognise the interest expense on the lease liability and the depreciation expense on the right-of-use asset.

Effective 1 January 2019 the Group adopted IFRS 16 using the modified retrospective approach and accordingly comparative information has not been restated. The Group recognised the cumulative effect of initially applying this Standard as an adjustment to the opening balance of retained earnings.

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

### Determining whether a contract is or contains a lease

On the transition to IFRS 16, the Group elected to not reassess whether a contract is, or contains a lease, as a practical expedient. The Group applied IFRS 16 only to contracts that were previously identified as leases.

### Leases previously classified as operating leases under IAS 17

At the date of initial application of IFRS 16, the Group measured lease liabilities at the present value of the remaining lease payments, discounted using the Group's incremental borrowing rate at 1 January 2019. Further, the Group recognised right-of-use assets at an amount equal to the lease liability adjusted by the amount of any prepaid or accrued lease payments.

The Group has applied the following practical expedients to leases previously classified as operating leases at the date on initial application:

- Exemption for short-term leases (defined as 12 months or less)
- Exemption for low value assets
- Excluded any initial direct costs from the measurement of the right-of-use asset
- Applied hindsight when determining the lease term for contracts containing options.

The Group have not any leases previously classified as finance leases under IAS 17.

### IFRS 16 impact on the consolidated financial statements

On transition to IFRS 16, the Group recognised MNOK 1.2 in right-of-use assets and MNOK as lease liabilities.

	Group	Parent
Operational minimum lease as of 31.12.2018	1,098	1,019
Short term lease	(79)	0
Other	232	232
Discounting effect	(73)	(73)
<b>Lease liabilities at 1.1.2019</b>	<b>1,178</b>	<b>1,178</b>
Implementing effect recorded against equity 1.1.	0	0
Average weighted marginal borrowing rate	6%	6%

### Other standards

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 Q1 2019 a pre-clinical development milestone triggered a milestone payment and revenue to BerGenBio ASA at NOK 8.7 million.

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 2018	Parent 2019		Group 2019	Group 2018
13,232	14,845	Salaries	28,643	24,941
3,012	3,322	Social security tax	5,055	4,465
1,275	1,355	Pension expense	2,358	2,066
2,199	2,143	Bonus	3,033	2,199
1,678	3,842	Share option expense employees	3,842	1,678
1,712	(2,658)	Accrued social security tax on share options	(2,658)	1,712
2,320	629	Other remuneration	740	2,327
(1,376)	(2,128)	Government grants	(5,297)	(1,376)
<b>24,054</b>	<b>21,350</b>	<b>Total payroll and related expenses</b>	<b>35,717</b>	<b>38,012</b>
15	14	Average number of full time equivalent employees	26	24

#### Management remuneration

Total remuneration to management during the year ended 31 December 2019

		Salary	Bonus	Pension expense	Other remuneration
Richard Godfrey (CEO)	A)	2,949	1,073	193	11
Rune Skeie (CFO)	B)	1,275	195	188	11
James B Lorens (CSO)	1) C)	1,446	230	111	7
Anthony Brown (Director of Research)	2) D)	480	–	34	
Tone Bjaaland (Director of Clinical Operations)	3) E)	1,519		54	
James Barnes (Director of Operations)	4) F)	1,334	168	12	
Hani Gabra (CMO)	5)	723		19	56
<b>Total remuneration</b>		<b>9,727</b>	<b>1,666</b>	<b>611</b>	<b>86</b>

1) Employed part-time in a 20% position until July 2019. 100 % position rest of the year

2) Resigned March 2019

3) Resigned May 2019

4) Employed March 2019

5) Employed September 2019

For management participating in the option program, the expense charged to the profit or loss for 2019 is as follows:

A) Richard Godfrey, 1716.3

B) Rune Skeie, 412.9

C) James Lorens, 164.8

D) Anthony Brown, - 125.4

E) Tone Bjaaland, - 45.6

F) James Barnes, 214.4



**Note 5 – Payroll and related expenses continued****Management remuneration** continued

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 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	
<b>Total remuneration</b>			<b>9,967</b>	<b>1,806</b>	<b>813</b>	<b>27</b>

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.

**Board of Directors remuneration**

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

		Served since	Served until	2019	2018
Sveinung Hole		September 2010		446	209
Stener Kvinnsland		September 2015		215	169
Grunde Eriksen		March 2019		231	0
Pamela Trail		March 2019		197	0
Debra Barker		March 2019		216	0
Stein Holst Annexstad		February 2016	March 2019	113	369
Susan Foden <sup>1</sup>	A)	September 2011	31 December 2018	0	169
Jon Øyvind Eriksen		January 2012	March 2019	76	209
Hilde Furberg	B)	June 2015	March 2019	56	189
Kari Grønås	C)	February 2016	March 2019	56	189
<b>Total remuneration</b>				<b>1,606</b>	<b>1,502</b>

For members of the Board of Directors participating in the option program, the expense charged to the profit or loss for 2019 (2018) is as follows:

A) Susan Foden, 0 (2018: 8.8)

B) Hilde Furberg, 0 (2018: 5.9)

C) Kari Grønås, 0 (2018: 3.5)

1) Susan Foden resigned from BoD 1 January 2019.

## Note 5 – Payroll and related expenses continued

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

Option holder	Number of options outstanding	Grant date	Expiry date	Exercise price (NOK)
Richard Godfrey	150,000	3-Sep-13	3-Sep-21	10.62
	75,000	13-Jun-13	13-Jun-21	10.62
	120,000	11-Jun-14	11-Jun-22	11.15
	275,000	22-May-15	22-May-23	16.01
	100,000	1-Jan-16	1-Jan-24	24.00
	122,484	23-May-18	23-May-26	46.70
	50,000	31-Oct-18	31-Oct-26	28.50
	236,800	17-Apr-19	17-Apr-27	25.00
James B Lorens	55,000	3-Sep-13	3-Sep-21	10.62
	100,000	13-Jun-13	13-Jun-21	10.62
	70,000	11-Jun-14	11-Jun-22	11.15
	275,000	22-May-15	22-May-23	16.01
	50,000	1-Jan-16	1-Jan-24	24.00
	10,707	23-May-18	23-May-26	46.70
	7,000	31-Oct-18	31-Oct-26	28.50
	20,800	17-Apr-19	17-Apr-27	25.00
Rune Skeie	24,090	23-May-18	23-May-26	46.70
	20,000	31-Oct-18	31-Oct-26	28.50
	52,000	17-Apr-19	17-Apr-27	25.00
James Barnes	59,400	17-Apr-19	17-Apr-27	25.00
<b>Total</b>	<b>1,873,281</b>			

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.

## Note 6 – Employee share option program

The Group has a share option scheme for employees. Each option gives the right to acquire one share in BerGenBio on exercise.

The Group has a share option program to ensure focus and align the Group's long term performance with shareholder values and interest. Most of the employees in the Group take part in the option program. The program also serves to retain and attract senior management.

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

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) <sup>1)</sup>
Granted in September 2010	225,000	Sep 2010	Dec 2017/2019	5.65
Granted in May 2011	175,000	May 2011	Dec 2017/2019	7.56
Granted in June 2012	285,000	Jun 2012	Dec 2017/2019	10.62
Granted in June 2012	225,000	Jun 2012	Jun 2020	10.62
Granted in June 2013	360,000	Jun 2013	Jun 2021	10.62
Granted in September 2013	400,000	Sep 2013	Sep 2021	10.62
Granted in June 2014	280,000	Jun 2014	Jun 2022	11.15
Granted in May 2015	650,000	May 2015	May 2023	16.01
Granted in September 2015	260,000	Sep 2015	Sep 2021	16.01
Granted in January 2016	400,000	Jan 2016	Jan 2024	24.00
Granted in February 2016	122,500	Feb 2016	Feb 2024	24.00
Granted in December 2017	50,000	Dec 2017	Dec 2025	22.00
Granted in May	385,027	May 2018	May 2026	46.70
Granted in October 2018	277,000	Oct 2018	Oct 2026	28.50
Granted in April 2019	784,629	April 2019	April 2027	25.00
Forfeited in 2015	(7,500)			10.62
Forfeited in 2016	(50,000)			16.01
Forfeited and cancelled in 2017	(220,000)			12.33
Exercised in 2017	(230,000)			9.98
Exercised in 2018	(160,000)			19.01
Forfeited in 2018	(245,513)			26.27
Exercised in 2019	(870,000)			9.89
Forfeited in 2019	(511,596)			28.19
Cancelled in 2019	(15,000)			24.00
<b>Total</b>	<b>2,569,547</b>			

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 3.0 years at year end.

1) The exercise price is calculated as the weighted average exercise price of the forfeited, cancelled and exercised options.

## Note 6 – Employee share option program continued

Total options	2019		2018	
	Number of options	Weighted average exercise price (NOK)	Number of options	Weighted average exercise price (NOK)
Balance at 1 January	3,181,514	18.20	2,925,000	14.20
Granted during the year	784,629	25.00	662,027	39.08
Exercised during the year	(870,000)	9.89	(160,000)	19.01
Forfeited and cancelled	(526,596)	28.07	(245,513)	26.27
<b>Balance at 31 December</b>	<b>2,569,547</b>	<b>21.07</b>	<b>3,181,514</b>	<b>18.20</b>

Vested options	2019	2018
Options vested at 1 January	2,598,334	2,891,667
Exercised and forfeited in the period	(1,396,596)	(310,000)
Vested in the period	500,243	16,667
<b>Options vested at 31 December</b>	<b>1,701,981</b>	<b>2,598,334</b>
Total outstanding number of options	2,569,547	3,181,514

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. 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 52% 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 2019 the value of the share options expensed through the profit or loss amounts to NOK 3.8 million (2018: NOK 1.7 million). In addition a provision for social security contributions on share options of NOK - 2.7 million (2018: NOK 1.7 million) is recognised based on the difference between the share price and exercise price on exercisable option as at the end of the period.

### Note 7 – Government grants

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

Parent 2018	Parent 2019		Group 2019	Group 2018
1,376	2,128	Payroll and related expenses	5,297	1,376
18,847	20,727	Other operating expenses	20,727	18,847
<b>20,223</b>	<b>22,854</b>	<b>Total</b>	<b>26,024</b>	<b>20,223</b>

Grants **receivable** as at 31 December are detailed as follows:

Parent 2018	Parent 2019		Group 2019	Group 2018
2,297	2,531	Grants from Research Council, BIA	2,531	2,297
5,400	0	Grants from Innovasjon Norge	0	5,400
7,933	8,033	Grants from SkatteFunn	8,033	7,933
0	0	Grants R&D UK	2,637	0
<b>15,630</b>	<b>10,564</b>	<b>Total</b>	<b>13,202</b>	<b>15,630</b>

#### BIA grants from the Research Council:

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

The first BIA grant ("Axl targeting therapeutics to treat fibrotic diseases") totals to NOK 12.0 million and covers the period from April 2015 to April 2019. The Group have recognised NOK 0.9 million in 2019 (2018: NOK 2.9 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses.

The second BIA grant ("Investigator-Initiated Trials for AXL driven cancers with high unmet clinical need") totals to NOK 15.1 million and covers the period from February 2017 to January 2021. The Group has recognised NOK 4.0 million in 2019 (2018: NOK 4.0 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses.

The third BIA grant ("AXL as a therapeutic target in fibrosis; biology and biomarkers") has been awarded from 2019 and amount up to NOK 10.7 million. The Group has recognised NOK 3.6 million in 2019 (2018: NOK 0.0 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses.

#### SkatteFunn:

R&D projects have been approved for SkatteFunn (a Norwegian government R&D tax incentive program designed to stimulate R&D in Norwegian trade and industry) for the period from 2018 until the end of 2020. The Group has recognised NOK 8.0 million in 2019 (2018: NOK 7.9 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses.

#### Innovasjon Norge:

BerGenBio has been awarded a NOK 24 million (USD2.85m) grant from Innovasjon Norge to support the clinical development of BGB324 in combination with Merck & Co.'s 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 2017 of this grant and further NOK 12 million in 2019. The grant may be withdrawn under certain circumstances. The Group has recognised NOK 6.3 million in 2019 (2018: NOK 5.4 million) classified as cost reduction of other operating expenses.



## Note 7 – Government grants continued

### R&D tax grants UK:

BerGenBio Limited, a 100% subsidiary of BerGenBio ASA, has been granted R&D tax grants in UK for 2017 and 2018. R&D grants are approved retrospect by application. Grants for 2017 and 2018 have been approved and received in 2019. Application for R&D grants are expected to be approved for 2019. The Group has in 2019 recognised NOK 3.2 classified as reduction of payroll and related expenses for the years 2017, 2018 and 2019.

## Note 8 – Property, plant and equipment

Year ended 31 December 2019 Parent/Group	Furnitures	Equipment / fittings	Right to use property	Total
Cost at 1 January 2019	70	1,632	1,178	2,880
Additions in the year	0	0	0	0
Disposals in the year	0	0	0	0
<b>Cost at 31 December 2019</b>	<b>70</b>	<b>1,632</b>	<b>1,178</b>	<b>2,880</b>
Accumulated depreciation at 1 January 2019	(8)	(1,113)	0	(1,121)
Depreciation in the year	(14)	(151)	(620)	(785)
<b>Accumulated depreciation at 31 December 2019</b>	<b>(22)</b>	<b>(1,264)</b>	<b>(620)</b>	<b>(1,906)</b>
<b>Net carrying amount at 31 December 2019</b>	<b>48</b>	<b>369</b>	<b>558</b>	<b>974</b>
Estimated useful life	5 years	5 years	2 years	
Depreciation method	Straight-line	Straight-line	Over right of use time	

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

### Research & Development

Expenses for research and development for the financial year 2019 for Parent/Group was gross NOK 163.4 million (net NOK 140.6 million reduced of grants NOK 22.9 million) of which gross NOK 158.8 million (net NOK 139.1 million) was classified as other operating expenses and gross NOK 3.6 million (net NOK 1.5 million) was classified as payroll.

For 2018 gross NOK 150.4 million (net NOK 130.2 million reduced of grants NOK 20.2) was expensed for research and development, 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.

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

## Note 9 – Leases

### The Group (the Company) as a lessee

The Company rent premises in Bergen, Norway, for office and laboratory purposes under two rental agreements. The rental agreements expire on 1 December 2020, with an option to extend for an additional five plus five years. The rental agreements can be terminated by either party with a 12 month notice period. In addition, the Group rent office premises in UK. The rental agreement can be terminated by either party with a one month notice period. The two rental agreements in Bergen are recognised on the statement of financial position, while the rental agreement in UK is considered a short term lease recognised directly in profit or loss.

### Right-of-use assets

The Group (the Company) leases offices. The Group's (the Company's) right-of-use assets are categorised and presented in Note 8.

### Lease liabilities

Summary of the lease liabilities	Total
At initial application 01.01.2019	1,178
New lease liabilities recognised in the year	0
Cash payments for the principal portion of the lease liability	(593)
Cash payments for the interest portion of the lease liability	(55)
Interest expense on lease liabilities	55
Currency exchange differences	0
<b>Total lease liabilities at 31 December 2019</b>	<b>585</b>
<b>Current lease liabilities (note 18)</b>	<b>585</b>
<b>Non-current lease liabilities</b>	<b>0</b>
<b>Total cash outflows for leases</b>	<b>593</b>

The leases do not contain any restrictions on the Group's dividend policy or financing. The Group does not have significant residual value guarantees related to its leases to disclose.

Undiscounted lease liabilities and maturity of cash outflows	Total
Less than 1 year	604
<b>Total undiscounted lease liabilities at 31 December</b>	<b>604</b>

Summary of other lease expenses recognised in profit or loss	Total
Variable lease payments expensed in the period	0
Operating expenses in the period related to short-term leases (including short-term low value assets)	1,232
Operating expenses in the period related to low value assets (excluding short-term leases included above)	26
<b>Total lease expenses included in other operating expenses</b>	<b>1,258</b>

### Practical expedients applied

The Group have a lease agreement for offices in Oxford. The lease agreement is short term and is renewed at one months basis.

The Group also leases printers with contract terms of 5 years. The Group has elected to apply the practical expedient of low value assets for some of these leases and does not recognise lease liabilities or right-of-use assets. The leases are instead expensed when they incur. The Group has also applied the practical expedient to not recognise lease liabilities and right-of-use assets for short-term leases, presented in the table above.

**Note 9 – Leases** continued**Extension options**

The Group's lease of buildings expires in 2020 however the rental agreements include option to extend (five plus five years). The Group (the Company) has not recognised lease liability corresponding to the option period, as the Group (the Company) do not consider it reasonable certain that extension rights will be executed. The Group's potential future lease payments not included in the lease liabilities related to extension options is MNOK 5.2 (gross) at 31 December 2019.

**IAS 17 – Leases;**

As of 31 December 2018 the Group and the Company applied IAS 17 on its lease liabilities, while as of 1. January 2019 the Group and the Company has applied IFRS 16. As of 31 December 2018 the Company rented premises in Bergen, Norway, for office and laboratory purposes under two rental agreements. The rental agreements expire on 1 December 2020, with an option to extend for an additional five plus five years. The rental agreements can be terminated by either party with a 12 month notice period. In addition, the Group rent office premises in UK. The rental agreement can be terminated by either party with a one month notice period.

Future minimum rental payable for premises under IAS 17 was as of 31 December 2018:

Parent 2018	Future minimum rental payable for premises	Group 2018
709	Within 1 year	787
311	Within 1-5 years	311
0	Over 5 years	0
<b>1,019</b>	<b>Total</b>	<b>1,098</b>

**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.

**Note 11 – Financial income and expense**

Parent 2018	Parent 2019		Group 2019	Group 2018
		<b>Financial income</b>		
17	28	Interest income on tax repaid	28	17
3,499	2,236	Interest income on bank deposits	2,236	3,499
1,279	9,023	Other finance income	9,265	1,342
<b>4,794</b>	<b>11,288</b>	<b>Total financial income</b>	<b>11,530</b>	<b>4,857</b>
		<b>Financial expense</b>		
47	90	Other interest expense	109	47
1,842	6,170	Other finance expense	6,325	2,018
<b>1,888</b>	<b>6,261</b>	<b>Total financial expense</b>	<b>6,434</b>	<b>2,065</b>
<b>2,906</b>	<b>5,027</b>	<b>Net financial income</b>	<b>5,096</b>	<b>2,792</b>



## Note 12 – Income tax

Parent 2018	Parent 2019		Group 2019	Group 2018
<b>(192 234)</b>	<b>(200 696)</b>	<b>Profit before tax</b>	<b>(199 278)</b>	<b>(191 747)</b>
(44,214)	(44,153)	Income taxes calculated at 22% (2018: 23%)	(43,841)	(44,102)
		Adjustment in respect of current income tax of previous years		
		Changes in unrecognised deferred tax asset		
(1,442)	(918)	Non deductible expenses	(918)	(1,555)
		Non-taxable income		
		Change in temporary differences		
7,450		Effect of change in tax rate	0	7,450
38,207	45,071	Change in deferred tax asset not recognized	44,759	38,207
<b>0</b>	<b>0</b>	<b>Tax expense</b>	<b>0</b>	<b>0</b>
		Income tax expense reported in income statement	–	–

## Deferred tax and deferred tax assets

Parent 2018	Parent 2019		Group 2019	Group 2018
		<b>Deferred tax assets (22% of temporary differences)</b>		
		Pensions	–	–
(162,806)	(208,462)	Tax losses carried forward	(208,150)	(162,842)
(42)	(42)	Property, plant and equipment	(42)	(6)
		Inventory		–
(1,041)	(456)	Other	(456)	(1,041)
163,889	208,961	Deferred tax asset not recognized	208,649	163,889
0	0	Deferred tax asset not recognized in other comprehensive income (OCI)	–	–
<b>0</b>	<b>0</b>	<b>Deferred tax assets - gross</b>	<b>0</b>	<b>0</b>

The Company has a tax loss of NOK 207.5 million in 2019, and in total a tax loss carried forward as of 31 December 2019 on NOK 947.6 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 2018	Parent 2019		Group 2019	Group 2018
133,699	141,630	Program expenses, clinical trials and research	141,630	133,699
1,145	855	Office rent and expenses	2,087	1,950
25,307	23,467	Consultants R&D projects	21,225	10,290
3,289	3,810	Patent and licence expenses	3,810	3,289
28,625	43,555	Other operating expenses	28,748	28,277
(18,847)	(20,727)	Government grants	(20,727)	(18,847)
<b>173,217</b>	<b>192,589</b>	<b>Total</b>	<b>176,773</b>	<b>158,657</b>

### Specification auditor's fee

Parent 2018	Parent 2019		Group 2019	Group 2018
264	284	Statutory audit	383	264
227	196	Other assurance services	196	227
		Other non-assurance services	60	
32	20	Tax consultant services	67	32
<b>523</b>	<b>500</b>	<b>Total</b>	<b>706</b>	<b>523</b>

Amounts are excluding VAT. Of the Group fee 2019 NOK 206 relates to non Group auditor.

### Note 14 – Earnings per share

Parent 2018	Parent 2019		Group 2019	Group 2018
(192,234)	(200,696)	Profit after tax	(199,278)	(191,747)
53,284,520	58,030,714	Weighted average number of outstanding shares during the year	58,030,714	53,284,520
<b>(3.61)</b>	<b>(3.46)</b>	<b>Earnings (loss) per share – basic and diluted (NOK)</b>	<b>(3.43)</b>	<b>(3.60)</b>

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.

## Note 15 – Other current assets

Parent 2018	Parent 2019		Group 2019	Group 2018
15,630	10,564	Government grants	13,202	15,630
1,356	1,996	Refundable VAT	1,996	1,356
488	371	Pepaid expenses	371	488
3,957	3,991	Other receivables	249	358
<b>21,430</b>	<b>16,923</b>	<b>Total</b>	<b>15,818</b>	<b>17,831</b>

## Note 16 – Cash and cash equivalents

Parent 2018	Parent 2019		Group 2019	Group 2018
798	861	Employee withholding tax	861	798
21	0	Deposits	0	21
358,584	251,792	Short-term bank deposits	252,725	359,594
<b>359,403</b>	<b>252,653</b>	<b>Total</b>	<b>253,586</b>	<b>360,413</b>

Of the total balance in cash and cash equivalents, NOK 0.9 million (2018: NOK 0.8 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 authorized shares	Nominal value (NOK)	Book value (NOK)
Ordinary shares 2019	61,076,590	0.10	6,107,659.00
Ordinary shares 2018	54,711,446	0.10	5,471,144.60

## Changes in the outstanding number of shares

	2019	2018
Ordinary shares at 1 January	54,711,446	49,922,200
Issue of ordinary shares	6,365,144	4,789,246
<b>Ordinary shares at 31 December</b>	<b>61,076,590</b>	<b>54,711,446</b>



## Note 17 – Share capital and shareholder information continued

## Ownership structure 31.12.2019

Shareholder		Number of shares	Percentage share of total shares
METEVA AS		16,458,750	26.9%
INVESTINOR AS		7,270,780	11.9%
VERDIPAPIRFONDET ALFRED BERG GAMBA		2,474,793	4.1%
SARSIA SEED AS		2,117,900	3.5%
VERDIPAPIRFONDET KLP AKSJENORGE		1,937,484	3.2%
KOMMUNAL LANDSPENSJONSKASSE		1,378,322	2.3%
VERDIPAPIRFONDET NORDEA KAPITAL		1,278,740	2.1%
VERDIPAPIRFONDET NORDEA AVKASTNING		1,228,174	2.0%
BERA AS		1,204,800	2.0%
SARSIA DEVELOPMENT AS		1,175,000	1.9%
MP PENSJON PK		1,045,555	1.7%
VERDIPAPIRFONDET NORDEA NORGE VERD		1,039,488	1.7%
VERDIPAPIRFONDET ALFRED BERG NORGE		921,160	1.5%
NORSK INNOVASJONSKAPITAL II AS		806,170	1.3%
ALTITUDE CAPITAL AS		715,000	1.2%
VERDIPAPIRFONDET ALFRED BERG AKTIV		639,296	1.0%
VERDIPAPIRFONDET NORDEA NORGE PLUS		623,060	1.0%
Morgan Stanley & Co. LLC	NOM	535,000	0.9%
Skandinaviska Enskilda Banken AB	NOM	500,000	0.8%
J.P. Morgan Bank Luxembourg S.A.	NOM	482,541	0.8%
<b>Top 20 shareholders</b>		<b>43,832,013</b>	<b>71.8%</b>
Total other shareholders		17,244,577	28.2%
<b>Total number of shares</b>		<b>61,076,590</b>	<b>100.0%</b>

The Board of Directors has been granted a mandate from the general meeting held on 13 March 2019 to increase the share capital with up to NOK 548,514 by subscription of new shares. The power of attorney was granted for the purpose of issuance of new shares in accordance with the Company's share incentive program and is valid until the earlier of the annual general meeting in 2020 and 30 June 2020. In Q1 2019 there was issued 140,000 new shares under this proxy at a nominal value of NOK 14,000 and in Q2 2019 there was issued 190,000 new shares under this proxy at a nominal value of NOK 19,000. In Q3 2019 there was issued 540,000 new shares under this proxy at a nominal value of NOK 54,000. See note 4 for more information about the share incentive program and number of option granted.

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

In January 2020 there was placed an private placement of 12,215,318 shares. Of this 5,475,136 shares at a nominal value of 547,513.60 have been issued under the proxy granted in the general meeting 13 March 2019 before date of this report. Additional 6,740,182 have been placed but issue of these shares is subject to approval of the General Meeting to be held on 20 February 2020.

### 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	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	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%
<b>Top 20 shareholders</b>			<b>40,950,635</b>	<b>74.8%</b>
Total other shareholders			13,760,811	25.2%
<b>Total number of shares</b>			<b>54,711,446</b>	<b>100.0%</b>

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

	Current position within the Company	Employed since	2019	2018
Richard Godfrey 1)	Chief Executive Officer	January 2009	215,449	160,408
James Bradley Lorens	Chief Scientific Officer	January 2009	280,039	250,000
<b>Total shares held by management</b>			<b>495,488</b>	<b>410,408</b>

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

**Note 17 – Share capital and shareholder information continued****Shares in the Group held by members of the Board of Directors**

	Position	Served since	2019	2018
Sveinung Hole <sup>1</sup>	Chairman	September 2010	107,394	0
Stener Kvinnsland	Board Member	February 2015	104,444	0
<b>Total shares held by members of the Board of Directors</b>			<b>211,838</b>	<b>0</b>

<sup>1</sup> Sveinung Hole holds 104,444 shares in the Company through Svev AS, a wholly owned company of Sveinung Hole, and 2,950 shares directly. Grunde Eirksen (board member) is CEO in Altitude Capital AS. Altitude Capital AS is holding 715,000 shares in BerGenBio ASA at 31 December 2019.

**Note 18 – Other current liabilities**

Parent 2018	Parent 2019		Group 2019	Group 2018
2,116	1,630	Unpaid duties and charges	653	2,893
1,342	1,390	Unpaid vacation pay	1,390	1,342
	585	Current lease liabilities	585	
8,636	17,296	Other accrued costs	19,175	8,640
<b>12,094</b>	<b>20,902</b>	<b>Total</b>	<b>21,803</b>	<b>12,875</b>

**Note 19 – Provisions**

	Social security contributions on share options	Total
Balance at 1 January 2019	4,732	4,732
Additional provisions recognised	(2,658)	(2,658)
<b>Balance at 31 December 2019</b>	<b>2,074</b>	<b>2,074</b>
<b>Current</b>	<b>2,074</b>	<b>2,074</b>
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.

**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 253.6 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 amortized cost. All financial assets and liabilities are short-term in nature and their carrying value approximates fair value. The cash and cash equivalent and account payable is in entire financial instruments measured at amortized cost.

The Group does currently not use financial derivatives.



**Foreign currency risk**

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, but holds a significant part of the working capital in foreign currency. 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 253.6 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 2.2 million in interest income in 2019 (NOK 3.5 million 2018).

**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 2019 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 74 million in a private placements in June 2019 and in January 2020 the Group placed a funding raising NOK 219.9 million securing funding into 2021 at current burn rate. The cash position of the Group at year end 2019 was NOK 253.6 million, compared to NOK 360.4 million in 2018.

**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 2019 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 has entered into an intercompany management agreement with BerGenBio Limited. Services are delivered from BerGenBio Limited to BerGenBio ASA.

	Parent 2019	Parent 2018
Purchase from BerGenBio Limited (included in other operation expenses)	33,860	16,998
Receivables BerGenBio Limited (included in other current assets)	3,742	3 599

**Note 23 – Subsequent events**

29 January 2020 there was a private placement of 12,215,318 shares. Of this 5,475,136 shares at a nominal value of 547,513.60 have been issued under the proxy granted in the general meeting 13 March 2019 before date of this report. An additional 6,740,182 shares have been placed but issuance of these shares is subject to approval by the Extraordinary General Meeting to be held on 20 February 2020. In addition a subsequent offering of up to 1,500,000 shares has been proposed for approval at the Extraordinary General Meeting, to be held 20 February 2020, furthermore an updated prospectus will be published shortly thereafter.



Statsautoriserte revisorer  
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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 2019, 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 2019 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 2019. 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 of Directors 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.



## 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, 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, 21 February 2020  
ERNST & YOUNG AS

Jørn Knutsen  
State Authorised Public Accountant (Norway)

# GLOSSARY

<b>AACR</b>	American Association for Cancer Research
<b>ADC</b>	Antibody-drug conjugate
<b>AGM</b>	Annual General Meeting
<b>ALK</b>	Anaplastic lymphoma kinase
<b>AML</b>	Acute Myeloid Leukaemia
<b>ASCO</b>	American Society of Clinical Oncology
<b>ASCO-SITC</b>	American Society of Clinical Oncology – Society for Immunotherapy of Cancer
<b>ASH</b>	American Society of Hematology
<b>BGB</b>	BerGenBio
<b>BGBio</b>	BerGenBio ticker symbol on Oslo Stock Exchange
<b>BIA</b>	The Norwegian Research council's User-driven Research based Innovation programme
<b>BMS</b>	Bristol-Myers Squibb
<b>CAGR</b>	Compound annual growth rate
<b>CAR-T</b>	Chimeric Antigen Receptor T Cells
<b>CDx</b>	Companion diagnostics
<b>CMC</b>	Chemistry, manufacturing and control
<b>CPI</b>	Immune checkpoint inhibitor
<b>CR</b>	Complete response
<b>CRi</b>	Complete response with incomplete recovery of peripheral counts
<b>CRO</b>	Contract research organisation
<b>CSR</b>	Corporate social responsibility
<b>CTA</b>	Clinical trial authorisation
<b>DCs</b>	Dendritic Cells
<b>EGFR</b>	Epidermal growth factor receptor
<b>EHA</b>	European Hematology Association
<b>EIR</b>	Effective interest rate
<b>EMA</b>	European Medicines Agency
<b>EMT</b>	Epithelial-mesenchymal transition
<b>ESMO</b>	European Society for Medical Oncology
<b>EU</b>	European Union
<b>EY</b>	Ernst and Young AS
<b>FDA</b>	Food and Drug Administration
<b>GDPR</b>	General Data Protection Regulation
<b>HQ</b>	Headquarters
<b>IFRS</b>	International Financial Reporting Standards
<b>IFU</b>	Innovasjon Norges industrial development award
<b>IHC</b>	Immunohistochemistry
<b>IIT</b>	Investigator initiated trial
<b>IND</b>	Investigational New Drug



<b>IO</b>	Immune oncology
<b>IPO</b>	Initial public offering
<b>IR</b>	Investor relations
<b>KPI</b>	Key Performance Indicator
<b>LDAC</b>	Low-dose chemotherapy
<b>LTP</b>	Long term incentive plan
<b>MaB</b>	Monoclonal antibody
<b>MD</b>	Medical doctor
<b>MDS</b>	Myelodysplastic Syndrome
<b>MIT</b>	Massachusetts Institute of Technology
<b>MoA</b>	Mechanism of action
<b>MSD</b>	Merck & Co., Inc., d.b.a. Merck Sharp & Dohme outside the United States and Canada
<b>NCGB/NUES</b>	The Norwegian Corporate Governance Board
<b>NCI</b>	US National Cancer Institute
<b>NHS</b>	National Health Service
<b>NK cells</b>	Natural killer cells
<b>NSCLC</b>	Non-Small Cell Lung Cancer
<b>OCI</b>	Other comprehensive income
<b>ORR</b>	Overall response rate
<b>OSE</b>	Oslo Exchange
<b>PD-1</b>	Programmed death 1
<b>PD-L1</b>	Programmed death-ligand 1
<b>PFS</b>	Progression free survival
<b>PhD</b>	Doctor of philosophy
<b>PoC</b>	Proof-of-concept
<b>PR</b>	Partial response
<b>R/R</b>	Relapsed/refractory
<b>R&amp;D</b>	Research & development
<b>sAXL</b>	Soluble AXL
<b>SITC</b>	Society for Immunotherapy of Cancer
<b>SoC</b>	Standard of care
<b>STI-scheme</b>	Short term incentive scheme
<b>TKI</b>	Tyrosine Kinase Inhibitor
<b>TNBC</b>	Triple Negative Breast Cancer
<b>UK</b>	United Kingdom
<b>US</b>	United States
<b>VC</b>	Venture capital
<b>WCLC</b>	World Conference on Lung Cancer
<b>WHO</b>	World Health Organisation

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**Link to reports from Trinity Delta:**

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