



# Highlights – Q2 and first half year

- IPO completed, raising NOK 400 million from new and existing investors to fund further clinical development of BGB324 and pipeline programmes
  - BerGenBio shares began trading on OSE on 7 April 2017 under the ticker BGBIO
- Clinical collaboration agreement signed with Merck & Co (MSD) to evaluate combination of BGB324 with KEYTRUDA® (pembrolizumab)
- BGB324 four Phase II clinical trials ongoing
  - Following compelling Phase Ib data reported December 2016, recruitment continues with BGB324 as a single agent therapy in acute myeloid leukaemia (AML) / myelodysplastic syndrome (MDS)
  - Following compelling Phase Ib data reported in November 2016, Phase II clinical trial continues with BGB324 plus TARCEVA® (erlotinib) in advanced EGFR-positive lung cancer patients
  - Protocol accepted and site activation underway for combination studies of BGB324 plus KEYTRUDA® (pembrolizumab) in advanced lung cancer patients
  - Sites active and patient recruitment ongoing for combination studies of BGB324 plus KEYTRUDA® (pembrolizumab) in triple negative breast cancer patients

#### Two Phase II investigator-sponsored studies initiated

- First patients dosed in Phase Ib/II trial of BGB324 in combination with docetaxel chemotherapy in advanced lung cancer
- First patients dosed in randomised Phase II trial of BGB324 in combination with targeted or immune-oncology drugs in melanoma

#### Clinical and scientific presentations at global cancer conferences

- Phase II melanoma study design and preclinical evidence supporting BGB324 potential to resensitise lung and breast tumours to checkpoint inhibitors presented at American Association for Cancer Research (AACR) Annual Meeting in April
- Anti-tumour activity of BGB324 demonstrated *in vitro* and in patients with high-risk MDS presented at the American Society for Clinical Oncology (ASCO) Annual Meeting in May

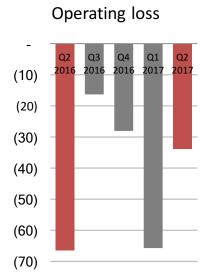
#### • Non-dilutive grants to support clinical trials of BGB324

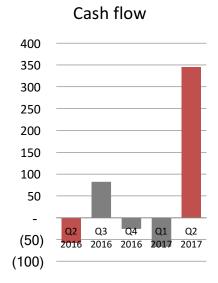
- NOK 24 million IFU grant from Innovasjon Norge
- Awarded a grant from the Research Council of Norway under the programme for user-driven Research based Innovation (BIA)

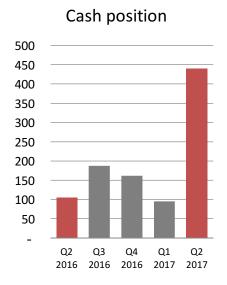


# **Key figures**

(NOK million)	Q2 2017	Q2 2016	YTD2017	YTD2016	FY 2016
Operating revenues	-	-	-	-	-
Operating expenses	33,8	66,5	99,6	87,2	131,6
Operating profit (loss)	-33,8	-66,5	-99,6	-87,2	-131,6
Profit (loss) after tax	-34,1	-66,2	-99,1	-86,5	-129,8
Basic and diluted earnings (loss) per share (NOK)	-0,70	-225,83	-2,41	-307,27	-419,68
Cash position end of period	440,3	105,2	440,3	105,2	161,8









# **Strategy**

BerGenBio is developing first-in-class drugs to treat aggressive, immune evasive, drug resistant and metastatic cancers. Its lead candidate, BGB324, is the only selective oral Axl inhibitor in clinical development. Axl is an essential mediator of the mechanisms that drive these aggressive properties of cancer cells: therefore effective Axl inhibitors present multiple opportunities to address significant unmet medical needs and high value market opportunities. The clinical program of the Company is designed to evaluate BGB324 in several solid and liquid tumours as a single agent and in combination with chemotherapy, targeted and the new immune checkpoint inhibitor drugs.

Strategic imperatives of the Company include:

- Complete four sponsored Phase II clinical trials with BGB324 in AML/MDS, NSCLC and TNBC.
- Advance BGB149, an anti-Axl antibody, through Phase I clinical trials.
- Parallel development of an Axl companion diagnostic to enrich future clinical trials with Axl-positive patients who are more likely to respond to BGB324, and adopt a precision medicine approach for commercialisation.
- Retain strategic flexibility for commercialisation: it is anticipated that the high novelty plus supportive therapeutic profile of drug portfolio will make them attractive targets for partnering; a Go-to market strategy will also be considered in an enriched patient population in discrete geographic regions.

# **Outlook**

The Company's pipeline of Axl inhibitors, strategic plan and flexibility in conjunction with new funds raised from its IPO provides a strong foundation to create and deliver significant value for shareholders.

The Board considers progress of the development programmes to date to be satisfactory in order to reach important value-inflection points in the second half of 2018.

Positive results from the ongoing Phase II studies should inform future clinical trials, support accelerated approval status and subsequent applications for regulatory approval, marketing authorisation and commercialisation.



# **Operational review**

BerGenBio made important progress during the second quarter and first half of 2017: the Company advanced its lead cancer drug candidate, BGB324, into multiple Phase II clinical trials, announced a clinical collaboration with global pharma company Merck & Co. (MSD outside the US) and completed an IPO and listing on the Oslo Stock Exchange. BerGenBio uses the ticker BGBIO.

The IPO was completed on 7 April with the Company raising NOK 400 million to fund the next stage of its development. The net proceeds and existing cash resources are anticipated to fund the Company into 2019, during which the following milestones are expected to be delivered:

- Complete four Phase II clinical trials with BGB324
- Complete a Phase I clinical trial of BGB149, an anti-Axl antibody
- Complete the development of an Axl companion diagnostic

In addition, the funds will be used to:

- Continue research & development to advance the pre-clinical pipeline
- · And for general corporate activities

#### **About BGB324**

BGB324 is a first-in-class, selective, potent and orally bioavailable small molecule Axl kinase inhibitor, currently in clinical development as a novel treatment as a single agent and in combination with established chemo- and immunotherapies for several haematological and solid cancers. Upregulation of Axl kinase is a key driver of cancer spread, immune evasion and drug resistance – the cause of approximately 90 percent of cancer deaths.

#### Clinical Update on BGB324

BGB324 is currently being evaluated or being prepared for evaluation in four Company sponsored Phase II clinical studies with associated biomarker studies, with read-outs expected in 2018. Two of these studies are a clinical collaboration between BerGenBio and Merck & Co. to evaluate BGB324 in combination with the anti-PD1 immune checkpoint inhibitor KEYTRUDA® (pembrolizumab).

# 1. Acute myeloid leukaemia (AML) and myelodysplastic syndrome (MDS)

This study (BGBC003) is a Phase Ib/II dose-escalation study of BGB324 in patients with relapsed or refractory AML and MDS to determine the maximum tolerated dose (MTD) and/or recommended dose for Phase II (RP2D); followed by a cohort expansion study of BGB324 either as a single agent in patients with AML or MDS, or in combination with cytarabine or decitabine in patients with AML.

The study is underway at sites in Germany, Norway and the US and aims to enrol up to approximately 75 patients.

The Phase Ib part of the trial is complete with BGB324 as a single agent showing promising efficacy (32% clinical benefit rate\* in 25 heavily pretreated AML/MDS patients) and a good safety profile. The R2PD was also established and enrolment is well underway in the Phase II dose-expansion trial with interim results expected Q4 2017.

\*Clinical benefit rate includes complete response (CR), partial response (PR) and stable disease (SD)

# 2. EGFR-positive non-small cell lung cancer (NSCLC)

BerGenBio is conducting a multi-centre open-label Phase Ib/II study (BGBC004) of BGB324 in combination with TARCEVA® (erlotinib) in patients with advanced NSCLC (Stage IIIb or Stage IV) driven by a mutation in the EGFR gene. Patients with EGFR mutations tend to respond well to erlotinib initially, but drug resistance mediated by an Axl-driven mechanism often emerges in many of these patients.

The trial, which is being conducted at cancer centres in the US, is evaluating the combination of BGB324 and erlotinib in up to 66 NSCLC patients in both first and second line settings (to prevent and reverse erlotinib-resistance, respectively). The Phase Ib part of the trial is complete, with encouraging efficacy being observed: clinical benefit observed in 50% of patients; one-year progression free survival demonstrated in 25% of patients, with one patient reporting good disease control after 20 months on treatment. Patient enrolment into the Phase II part is



on schedule and interim results are expected Q4 2017.

## 3. Triple negative breast cancer (TNBC)

BerGenBio in collaboration with Merck & Co. is conducting an international open label, single arm, multi-centre Phase II study (BGBC007) to assess the anti-tumour activity and safety of BGB324 in combination with pembrolizumab in up to 56 patients with previously treated, locally advanced and unresectable or metastatic TNBC. The trial protocol has been approved in the US and UK (protocol under review in other countries) and patient recruitment is underway, with the first patient expected imminently.

#### 4. NSCLC adenocarcinoma of the lung

The Company also in collaboration with Merck & Co. has initiated a second Phase II clinical trial of BGB324 in combination with pembrolizumab: the trial (BGBC008) is an open label, single arm, multi-centre Phase II study to assess the anti-tumour activity and safety of BGB324 in combination with pembrolizumab in up to 48 patients with previously treated, advanced adenocarcinoma of the lung.

The trial protocol has been approved in the US and UK (protocol under review in other countries) and site activation is underway with first patients expected to be dosed in the coming months.

## Biomarker development

To date, the Company has seen encouraging clinical responses with BGB324 observed in difficult-to-treat leukaemia and lung cancer patients, as well as a compelling correlation between Axl expression levels and clinical outcomes. Based on this correlation, BerGenBio is developing biomarkers and companion diagnostics to enrich the patient population in ongoing and future clinical trials and ultimately to direct treatment choices once BGB324 is an approved medicine.

# Collaboration with Merck & Co.

BerGenBio and Merck & Co. announced in March 2017 that they were entering a clinical development collaboration to investigate the combination of BGB324 with KEYTRUDA pembrolizumab, Merck & Co.'s anti-PD1 antibody approved for the treatment of multiple cancers including NSCLC and with sales in 2016 of USD 1.4 billion. Pembrolizumab is a novel cancer therapy, known as an immune checkpoint inhibitor (CPI), which acts to block a survival

mechanism that makes tumour cells invisible to the immune system.

Preparations to start the collaborative studies of BGB324 with pembrolizumab are well underway as described above with results anticipated in the second half of 2018.

The clinical trials will be sponsored by BerGenBio, Merck & Co. will provide pembrolizumab for both studies, the rights to the study results will be shared and there are provisions for further combination studies to be undertaken by either or both companies.

The collaboration also covers biomarker studies to assess Axl and PD-L1 expression, which will be conducted by both parties in parallel to the clinical trials, with the objective of developing companion diagnostics to identify patients who would be most suitable for treatment with the BGB324/pembrolizumab combination.

# Rationale for combination with checkpoint inhibitors

The rationale for combining BGB324 and CPIs is based on compelling preclinical and genomics data proposing that Axl plays a crucial role in the ability of tumour cells to evade the immune system and develop resistance to CPIs.

At the American Association for Cancer Research (AACR) Annual Meeting in April, BerGenBio reported data that further confirms the role of Axl kinase in tumour resistance to immune CPIs. These results provide further strong evidence supporting Axl inhibition as a mechanism that can be targeted through combination therapy with BGB324.

Furthermore, the data showed that BGB324, in preclinical models of lung and breast cancer, led to enhanced activation of the anti-tumour immune response.

## Investigator-led clinical studies of BGB324

Two investigator-led studies are underway, including a Phase II trial (BGBIL005) of BGB324 in previously treated NSCLC patients in combination with docetaxel chemotherapy. This study was opened in Q1 2017 at the University of Texas Southwestern Medical Center, and has enrolled its first patients.

A second randomised Phase II clinical trial, with BGB324 in combination with dabrafenib/trametinib or



pembrolizumab in advanced melanoma (BGBIL006), is being conducted at Haukeland University Hospital in Bergen, Norway, with grant funding from the Norwegian Health Authorities. This is a 'real-world' study where BGB324 is used in combination with all existing treatments that melanoma patients could be prescribed. This study opened in 2017 and has enrolled the first patients.

In parallel to this study, an extensive biomarker discovery and validation programme is underway under a collaboration between leading Norwegian melanoma experts together with collaborators at Massachusetts Institute of Technology and Harvard Medical School (Boston, USA).

## **Non-dilutive Grants to support**

In January, BerGenBio was awarded a grant from the Research Council of Norway under the programme for user-driven Research based Innovation (BIA). The grant application was named "Leveraging Investigator-Initiated Trials to develop novel treatment options for Axl driven cancers with high unmet clinical need".

In June, BerGenBio was awarded a NOK 24 million IFU grant from Innovasjon Norge to support the Phase II clinical development of BGB324 in combination with pembrolizumab in patients with advanced lung cancer.

# **BGB149 Axl monoclonal antibody**

In addition to BGB324, which is a small molecule Axl inhibitor, BerGenBio has developed a humanised anti-Axl monoclonal antibody, which shows high affinity and selectivity for Axl. The antibody prevents the activation of Axl by blocking the binding site for its natural ligand (Gas6).

A clinical candidate, BGB149, has been nominated and cell line development and manufacturing of the antibody is underway with a leading biologics manufacturer and expected to enter clinical trials in 2018.

#### Preclinical pipeline

BerGenBio maintains an active research team focused on further expanding the understanding of the role of novel targets that regulate the transition of cancers into aggressive forms and resistance to therapeutic intervention (a process known as the epithelial-mesenchymal transition, EMT). BerGenBio has a pipeline of small molecule and antibody

inhibitors targeting critical nodes in EMT signalling pathways. These novel first-in-class proprietary drug candidates are being evaluated as new strategies for therapeutic intervention in oncology and other indications for which EMT has been shown to be a key driver of the disease pathology.

#### **New Chair of the Board**

Mr. Stein Annexstad, the former CEO of Nycomed AS (subsequently merged with Amersham Plc and thereafter merged with GE) and former Chairman of Algeta ASA (acquired by Bayer), was elected new Chair of the board at an extraordinary general meeting on 16 January 2017. He replaces Hilde Furberg who stepped down from the role and remains a Non-Executive Director of the Company.

#### Risks and uncertainties

The Company operates in a highly competitive industry sector with many large players and may be subject to rapid and substantial technological change. BerGenBio is currently in a development phase involving activities that entail exposure to various risks. BerGenBio's lead product candidate BGB324 is currently in Phase II clinical trials. This is regarded as an early stage of development and the clinical studies may not prove to be successful. Timelines for completion of clinical studies are to some extent depending on external factors outside the control of the Company, including resource capacity at clinical trial sites, competition for patients, etc.

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

BerGenBio and / or its commercial partners will need approvals from the US Food 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 future earnings are likely to be largely dependent on the timely marketing authorisation of BGB324 for various indications.

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



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

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

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

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



# Financial review

(Figures in brackets = same period 2016 unless stated otherwise)

#### Financial results

Total operating expenses for the second quarter and the six months ended June 2017 respectively amounted to NOK 33.8 million (NOK 66.5 million) and NOK 99.6 million (NOK 87.2 million). Employee costs were NOK 5.9 million (NOK 5.4 million) for the quarter and NOK 12.2 million (NOK 13.0 million) for the six months ending June 2017.

Other operating costs amounted to NOK 27.9 million (NOK 61.0 million) for the quarter. For the first six months other operating costs amounted to NOK 87.3 million (74.1 million). A significant element of the operating cost in the first quarter of 2017 related to a Phase II milestone payment to Rigel Pharmaceuticals Inc., amounting to NOK 27.8 million. Similarily, in the second quarter of 2016 the Company had an option payment to Rigel Pharmaceuticals Inc., influencing the expenses in that period. Furthermore, the increase in operating costs is driven by expansion of clinical trials and preparations for new clinical trials.

The operating loss for the quarter came to NOK 33.8 million (NOK 66.5million) and NOK 99.6 million (NOK 87.1 million) for the first six months of the year, reflecting the increased level of research and development activities described above and the milestone payments.

Net financial items were NOK -0.2 million (NOK 0.3 million) for the second quarter and NOK 0.5 million (0.7 million) for the first six months of the year.

Losses after tax for the second quarter were NOK 34.1 million (NOK 66.2 million) and NOK 99.1 million (NOK 86.5 million) for the first six months of the year.

# **Financial position**

Total assets at 30 June 2017 increased to NOK 457.3 million (NOK 174.5 million at year-end 2016), mainly due to the capital raise completed in April 2017 as part of the IPO of the Company.

Total liabilities were NOK 27.1 million (NOK 21.3 million at year-end 2016).

Total equity as of 30 June 2017 was NOK 430.2 million (NOK 153.3 million at year-end 2016), corresponding to an equity ratio of 94.1% (87.8%).

In April 2017 BerGenBio raised NOK 400 million through a capital raise in conjunction with its IPO, strengthening its equity.

#### Cash flow

Net cash flow from operating activities was negative by NOK 96.5 million for the first six months of the year (NOK 80.8 million), mainly driven by the the ongoing development and research activities as well as milestone payment.

Net cash flow used in investing activities during the first six months of the year was NOK 0.2 million (NOK 0.0 million).

Net cash flow from financing activities was NOK 375.2 million (NOK 112.2 million), reflecting the share issue in April 2017 in relation to the successful completion of the IPO. The Company carried out a targeted capital raise in the first half of 2016.

Cash and cash equivalents increased to NOK 440.3 million (NOK 161.8 million at year-end 2016).

# **Declaration by the Board of Directors and CEO**

The board today considered and approved the condensed, consolidated financial statements for the six months ending June 30, 2017 for BerGenBio.

The half year report has been prepared in accordance with IAS 34 Interim Financial Reporting as endorsed by the EU and additional Norwegian regulations.

To the best of our knowledge:

- the condensed, consolidated financial statements for the six months ending June 30, 2017 for the Company have been prepared in accordance with all applicable accounting standards
- the information provided in the condensed, consolidated financial statements gives a true and fair view of the Company's assets, liabilities, financial position and results taken as a whole as of June 30, 2017

- BerGenBio's report and condensed, consolidated financial statements for the six months ending June 30, 2017 provide a true and fair overview of:
  - the Company's assets, liabilities, financial position and result for the period of BerGenBio
  - important events that have occurred during the accounting period and a description of the most significant risks and uncertainties facing the Comapny for the remaining six months of the financial year

Bergen, August 17, 2017

Board of Directors and CEO of BerGenBio ASA

Stein M. Annexstad, Chairman

Eriksen

Susan Foden

rberg

Stoner Kvinneland

Richard Godfrey (CEO



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

(NOK 1000) Unaudited

	Note	Q2 2017	Q2 2016	YTD 2017	YTD 2016	Full year 2016
Revenue		-	-	-	-	-
Employee benefit expenses	3	5 895	5 407	12 189	13 003	20 561
Depreciation		51	45	101	89	207
Other operating expenses	6	27 899	61 012	87 345	74 103	110 802
Total operating expenses		33 846	66 464	99 635	87 195	131 570
Operating profit		-33 846	-66 464	-99 635	-87 195	-131 570
Finance income		541	535	1 660	1 127	3 031
Finance expense		778	280	1 173	454	1 260
Financial items, net		- 236	255	487	673	1 771
Profit before tax		-34 082	-66 208	-99 148	-86 522	-129 799
Income tax expense			-	-	-	-
Profit after tax		-34 082	-66 208	-99 148	-86 522	-129 799
Other comprehensive income Items which will not be reclassified over profit and loss Actuarial gains and losses on defined benefit pension plans		-	-	-	-	-1 089
Total comprehensive income for the period		-34 082	-66 208	-99 148	-86 522	-130 888
Earnings per share:		0.70	005.00	0.44	007.57	440.63
- Basic and diluted per share	7	-0,70	-225,83	-2,41	-307,27	-419,68



# **Condensed consolidated statement of financial position**

# (NOK 1000)

Unaudited

Total non-current assets   467	Officialities	Note	30 Jun 2017	31 Dec 2016
Property, plant and equipment         467         410           Total non-current assets         467         410           Current assets         8         16 552         12 302           Cash and cash equivalents         440 300         161 825           Total current assets         456 852         174 126           TOTAL ASSETS         457 319         174 536           EQUITY AND LIABILITIES         Equity         Feature         Paid in capital           Share capital         9         4 974         3 369           Share premium         9         406 142         131 875           Other paid in capital         4, 9         18 969         18 026           Paid in, not registered capital raise         9         159            Total paid in capital         430 245         153 270           Non-current liabilities         9         159            Pension liability         10         -            Non-current liabilities         0         0           Current liabilities         0         0           Accounts payable         10 826         10 703           Other current liabilities         12 605         5 721	ASSETS			
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Paid in, not registered capital raise         9         159         -           Total paid in capital         430 245         153 270           Total equity         430 245         153 270           Non-current liabilities         10         -         -           Pension liability         10         -         -         -           Total non-current liabilities         0         0         0           Current liabilities         10 826         10 703           Other current liabilities         12 605         5 721           Provisions         3 643         4 843	•			
Total paid in capital         430 245         153 270           Total equity         430 245         153 270           Non-current liabilities         10         -         -           Pension liability         10         -         -           Total non-current liabilities         0         0           Current liabilities         10 826         10 703           Other current liabilities         12 605         5 721           Provisions         3 643         4 843	·			18 026
Total equity         430 245         153 270           Non-current liabilities         10         -         -           Pension liability         10         -         -           Total non-current liabilities         0         0           Current liabilities         10 826         10 703           Other current liabilities         12 605         5 721           Provisions         3 643         4 843	Paid in, not registered capital raise	9		
Non-current liabilities           Pension liability         10         -         -         -           Total non-current liabilities         0         0         0           Current liabilities         10 826         10 703           Other current liabilities         12 605         5 721           Provisions         3 643         4 843	Total paid in capital			
Pension liability         10         -	Total equity		430 245	153 270
Total non-current liabilities  Current liabilities  Accounts payable Other current liabilities  Provisions  0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Non-current liabilities			
Current liabilities           Accounts payable         10 826         10 703           Other current liabilities         12 605         5 721           Provisions         3 643         4 843	Pension liability	10	-	-
Accounts payable       10 826       10 703         Other current liabilities       12 605       5 721         Provisions       3 643       4 843	Total non-current liabilities		0	0
Other current liabilities         12 605         5 721           Provisions         3 643         4 843	Current liabilities			
Provisions 3 643 4 843	Accounts payable		10 826	10 703
1.0.000.00	Other current liabilities		12 605	5 721
	Provisions		3 643	4 843
Total current liabilities 27 074 21 266	Total current liabilities		27 074	21 266
Total liabilities 27 074 21 266	Total liabilities		27 074	21 266
TOTAL EQUITY AND LIABILITIES 457 319 174 536	TOTAL EQUITY AND LIABILITIES		457 319	174 536



# Condensed consolidated statement of changes in equity

# (NOK 1000)

# Unaudited

	Note	Share capital	Share premium	Other paid in capital	Paid in, not registered	Total equity
Balance at 1 January 2017		3 369	131 875	18 026	-	153 270
Loss for the period		-	-99 148	-	-	-99 148
Other comprehensive income (loss) for the net of income tax	ne period,	-	-	-	-	-
Total comprehensive income for the period		-	-99 148	-	-	-99 148
Recognition of share-based payments	3, 4	_	_	944	-	944
Issue of ordinary shares	9	1 605	398 926	-	-	400 531
Paid in, not registed capital raise	9	-	-	-	159	159
Share issue costs		-	-25 511	-	-	-25 511
Balance at 30 June 2017		4 974	406 142	18 969	159	430 245

# (NOK 1000)

# Unaudited

	Note	Share capital	Share premium	Other paid in capital	Paid in, not registered	Total equity
Balance at 1 January 2016		2 479	49 944	12 324	-	64 747
Loss for the period		_	-86 522	-	-	-86 522
Other comprehensive income (loss) for the net of income tax	ne period,	-	-	-	-	-
Total comprehensive income for the period		-	-86 522	-	-	-86 522
Recognition of share-based payments	3, 4	_	-	1 389	-	1 389
Issue of ordinary shares	9	452	108 005	-	-	108 458
Paid in, not registed capital raise	9	-	-	-	4 999	4 999
Share issue costs		-	-	-	-	-
Balance at 30 June 2016		2 932	71 428	13 713	4 999	93 072



# Condensed consolidated statement on cash flow

# (NOK 1000)

Unaudited

	Note	YTD 2017	YTD 2016
Cash flow from operating activities			
Loss before tax		-99 148	-86 522
Non-cash adjustments to reconcile loss before tax to net cash flows			
Depreciation of property, plant and equipment		101	89
Calculated interest element on convertible loan		-	19
Share-based payment expense	3, 4	944	1 389
Movement in provisions and pensions		-1 200	2 584
Working capital adjustments:			
Decrease in trade and other receivables and prepayments		-4 250	673
Increase in trade and other payables		7 008	975
Net cash flow from operating activities		-96 545	-80 793
Cash flows from investing activities			
Purchase of property, plant and equipment		- 159	- 199
Net cash flow used in investing activities		- 159	- 199
Cash flows from financing activities			_
Proceeds from issue of share capital	9	375 020	107 220
Paid in, not registered capital increase	9	159	4 999
Proceeds from borrowings, convertible loan		-	-1 307
Conversion of loan by issue of share capital		-	1 238
Net cash flow from financing activities		375 179	112 150
Net increase/(decrease) in cash and cash equvivalents		278 475	31 158
Cash and cash equivalents at beginning of period		161 825	73 993
Cash and cash equivalents at end of period		440 300	105 150



# Selected notes to the interim financial statements

# Note 1 – Corporate information

BerGenBio ASA ("the Company") and its subsidiary (together "the Group") is a clinical stage biopharmaceutical company focused on developing innovative drugs for aggressive, drug resistant cancers.

BerGenBio ASA is a limited public liability company incorporated and domiciled in Norway. The address of the registered office is Jonas Lies vei 91, 5009 Bergen, Norway.

The Company is a world leader in understanding epithelial-mesenchymal transition (EMT) biology, which is widely recognised as a key pathway in immune evasion and acquired cancer drug-resistance and metastasis. Building on this original biological insight BerGenBio is developing a promising pipeline of novel EMT inhibitors.

BerGenBio intends to develop its product candidates to proof of concept stage; further clinical development and subsequently commercialisation will be through strategic alliances and partnerships with experienced global biopharma oncology businesses.

The condensed interim financial information is unaudited. These interim financial statements cover the three-months period ended 30 June 2017 and were approved for issue by the Board of Directors on 17 August, 2017.

# Note 2 – Basis for preparation and significant accounting policies

# **Basis for preparation**

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

The interim condensed consolidated financial statements do not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with BerGenBio's annual financial statements as at 31 December 2016.

The accounting policies adopted in the preparation of the interim condensed consolidated financial statements are consistent with those followed in the preparation of the Group's annual financial statements for the year ended 31 December 2016, except for the adoption of new standards and interpretations effective as of 1 January 2017.

#### Summary of significant accounting policies

The new and amended standards and interpretations from IFRS that were adopted by the EU with effect from 2017 did not have any significant impact on the reporting for 2017.

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

#### Basis for consolidation

The consolidated financial statements comprise the financial statements of the Company and its subsidiary as at 30 June 2017. The subsidiary is BerGenBio Limited, located in Oxford in the United Kingdom and is 100% owned and controlled by the parent company BerGenBio ASA.



# **Estimates and assumptions**

Preparation of the accounts in accordance with IFRS requires the use of judgment, estimates and assumptions that have consequences for recognition in the balance sheet of assets and liabilities and recorded revenues and expenses. The use of estimates and assumptions is based on the best discretionary judgment of the Group's management.

The Group works continuously to ensure financial flexibility in the short and long term to achieve its strategic and operational objectives. Capital markets are used as a source of liquidity when this is appropriate and when conditions in these markets are acceptable. An IPO and capital increase of NOK 400 million was successfully completed on the 7<sup>th</sup> of April 2017, and thus the Board of Directors has reasonable expectation that the Group will maintain adequate resources to continue in operational existence for the foreseeable future. The interim financial statements are prepared under the going concern assumption.

# Note 3 - Payroll and related expenses

	For the six months end	ded 30 June
	2017	2016
Salaries	12 134	7 966
Social security tax	1 076	1 189
Pension expense	905	560
Share option expense employees	944	1 389
Accrued social security tax on share options	-1 200	2 969
Other remuneration	253	363
Government grants 1)	-1 923	-1 434
Total payroll and related expenses	12 189	13 003
Average number of full time equivalent employees	24	19

1) See also note 5 for government grants



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

Option holder	Number of options outstanding	Grant date	Expiry date	Exercise price (NOK)
Richard Godfrey	50 000	10-Sep-10	31-Dec-19	5,65
	100 000	27-May-11	31-Dec-19	7,56
	75 000	21-Jun-12	31-Dec-19	10,62
	150 000	3-Sep-13	3-Sep-21	10,62
	75 000	13-Jun-13	13-Jun-21	10,62
	120 000	11-Jun-14	11-Jun-22	11,15
	275 000	22-May-15	22-May-23	16,01
	100 000	1-Jan-16	1-Jan-24	24,00
James B Lorens	50 000	10-Sep-10	31-Dec-19	5,65
	25 000	27-May-11	31-Dec-19	7,56
	75 000	21-Jun-12	31-Dec-19	10,62
	55 000	3-Sep-13	3-Sep-21	10,62
	100 000	13-Jun-13	13-Jun-21	10,62
	70 000	11-Jun-14	11-Jun-22	11,15
	275 000	22-May-15	22-May-23	16,01
	50 000	1-Jan-16	1-Jan-24	24,00
Petter Nielsen	100 000	22-May-15	22-May-23	16,01
	50 000	1-Jan-16	1-Jan-24	24,00
Anthony Brown	100 000	2-Sep-15	2-Sep-23	16,01
	50 000	1-Jan-16	1-Jan-24	24,00
Murray Yule	100 000	3-Sep-13	3-Sep-21	10,62
	50 000	1-Jan-16	1-Jan-24	24,00
Susan Foden	100 000	18-Jun-12	18-Jun-20	10,62
	55 000	3-Sep-13	3-Sep-21	10,62
	25 000	20-Jun-13	20-Jun-21	10,62
	50 000	19-Jun-14	19-Jun-22	11,15
	37 500	1-Feb-16	1-Feb-24	24,00
Hilde Furberg	25 000	1-Feb-16	1-Feb-24	24,00
Kari Grønås	15 000	1-Feb-16	1-Feb-24	24,00
	2 402 500			

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



# Note 4 – Employee share option program

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

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

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

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

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

	Number of			
	options	Grant date	Expiry date	Exercise price
Granted in September 2010	225 000	Sep 2010	Dec 2017/2019	5,65
Granted in May 2011	175 000	May 2011	Dec 2017/2019	7,56
Granted in June 2012	285 000	Jun 2012	Dec 2017/2019	10,62
Granted in June 2012	225 000	Jun 2012	Jun 2020	10,62
Granted in June 2013	360 000	Jun 2013	Jun 2021	10,62
Granted in September 2013	400 000	Sep 2013	Sep 2021	10,62
Granted in June 2014	280 000	Jun 2014	Jun 2022	11,15
Granted in May 2015	650 000	May 2015	May 2023	16,01
Granted in September 2015	260 000	Sep 2015	Sep 2023	16,01
Granted in January 2016	400 000	Jan 2016	Jan 2024	24,00
Granted in February 2016	122 500	Feb 2016	Feb 2024	24,00
Forfeited in 2015	-7 500			10,62
Forfeited in 2016	-50 000			16,01
Exercised in 2017	-65 000			10,62
Forfeited and cancelled in 2017 *	-170 000			14,29
Total	3 090 000			

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

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



	For the six months ended 30 June						
	2	2017	2	016			
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price			
Balance at 1 January	3 325 000	13,66	28 525	1 181,05			
Granted during the period	-	<del>-</del>	1 225	2 400			
Exercised during the period	-65 000	10,62	-	-			
Forfeited and cancelled	-170 000	14,29	- 500	1 601			
Balance at 30 June	3 090 000	13,69	29 250	1 224,93			

There were no options granted in the period in 2017. The weighted average fair value of the options granted in the period in 2016 was NOK 1,012, totalling to NOK 1.2 million.

	For the six months er	nded 30 June
	2017	2016
Options vested at 1 January	2 211 900	11 426
Vested in the period	839 300	-
Options vested at 30 June	3 051 200	11 426
Total outstanding number of options	3 090 000	29 250

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

The options are valued using the Black & Scholes model.

The risk free interest rates are based on rates from Norges Bank and Oslo Børs on the Grant Date (bonds and certificates) equal to the expected term of the option being valued. Where there is no exact match between the term of the interest rates and the term of the options, interpolation is used to estimate a comparable term.

The vesting period is the period during which the conditions to obtain the right to exercise must be satisfied. Most of the options vest dependent on meeting milestones and is thus dependent on a performance condition. The Company has estimated an expected vesting date and this date is used as basis for the expected lifetime. The Company 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 Company and experience from other companies in combination with the relatively long lifetime of these options (up to 8 years). For Options granted in 2014 or later, it has been assumed that the holders will exercise their options earlier as the shares have been assumed to be tradable, hence an assumption has been made that these options will be exercised on average 1 year following vesting as most of these have vesting contingent on IPO.

For valuation purposes 70% expected future volatility has been applied. As the Company recently went public it has limited history of volatility in its share price, therefore the historical volatility of similar listed companies has been used as a benchmark for expected volatility.

For the six month period ending 30 June 2017 the value of the share options expensed through the profit or loss amounts to NOK 0.9 million (for the same period in 2016: NOK 1.4 million). In addition a provision for social security contributions on share options of NOK -1.2 million (for the same period in 2016: NOK 2.9 million) is



recognised based on the difference between the share price and exercise price on exercisable option as at the end of the period.

# Note 5 – Government grants

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

	For the six months end	ed 30 June
	2017	2016
Payroll and related expenses	1 923	1 434
Other operating expenses	4 794	3 489
Total	6 717	4 923

	For the six months ended 30 June		
	2017	2016	
Grants from Research Council, BIA	1 709	1 547	
Grants from Research Council, PhD	392	159	
Grants from SkatteFunn	11 268	4 145	
Total	13 370	5 851	

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

The Company currently has two grants from the Research Council, programmes for user-driven Research based Innovation (BIA).

The first BIA grant ("Novel therapeutics targeting the EMT/Axl pathway in aggressive cancers") totals to NOK 13.2 million and covers the period from May 2014 to April 2017. The Company has recognised NOK 1.4 million (2016: NOK 1.9 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses.

The second BIA grant ("AxI targeting therapeutics to treat fibrotic diseases") totals to NOK 12.0 million and covers the period from April 2015 to March 2018. The Company has recognised NOK 1.2 million (2016: NOK 2.7 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses.

In January 2017 BerGenBio was awarded another BIA grant. The grant application was named "Leveraging Investigator-Initiated Trials to develop novel treatment options for Axl driven cancers with high unmet clinical need". The final terms and conditions are being negotiated, and as such in 2017 the Company has not yet recognised anything from this grant.

#### PhD grants from the Research Council

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

The Company has recognised NOK 0.6 million (2016: NOK 0.4 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses.



#### SkatteFunn

R&D projects have been approved for SkatteFunn (a Norwegian government R&D tax incentive programme designed to stimulate R&D in Norwegian trade and industry) for the period from 2016 until the end of 2017. The Company has recognised NOK 3.5 million in 2017 (2016: NOK 0.0 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses. The Company recognised in total NOK 7.7 million in 2016 (Q4).

# Note 6 – Other operating expenses

	For the six months ended 30 June	
	2017	2016
Program expenses, clinical trials and research	44 153	30 360
Milestone and license payments to Rigel Pharmaceuticals	27 921	31 148
Office rent and expenses	813	839
Consultants R&D projects	6 265	9 711
Patent and licence expenses	1 767	1 343
Other operating expenses	11 220	4 190
Government grants	-4 794	-3 489
Total	87 345	74 103

# Note 7 – Earnings per share

	For the six months ended 30 June		
	2017	2016	
Loss for the period	-99 148	-86 522	
Average number of outstanding shares during the year	41 147 172	281 585	
Earnings (loss) per share - basic and diluted (NOK)	-2,41	-307,27	

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 Company is currently loss-making an increase in the average number of shares would have anti-dilutive effects.

# Note 8 - Other current assets

	30 Jun 2017	30 Jun 2016
Government grants	13 370	5 851
Refundable VAT	1 519	566
Prepaid expenses	544	314
Other receivables	1 119	634
Total	16 552	7 365



# Note 9 – Share capital and shareholder information

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

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

As of 30 June	Number of shares	Nominal value (NOK)	Book value (NOK)
Ordinary shares 2017	49 742 200	0,10	4 974 220
Ordinary shares 2016	293 172	10	2 931 720

# Changes in the outstanding number of shares

	For the six months ended 30 June		
	2017	2016	
Ordinary shares at 1 January	336 922	247 924	
Issue of ordinary shares, prior to share split	500	44 675	
Issue of ordinary shares from conversion of loan	-	573	
Effect of share split (1 to 100) 22 March 2017	33 404 778	-	
Issue of ordinary shares, after share split	16 000 000	-	
Ordinary shares at 30 June	49 742 200	293 172	

# **Ownership structure**

		Percentage share
Shareholder	Number of shares	of total shares
METEVA AS	14 923 000	30,0%
INVESTINOR AS	6 609 800	13,3%
SARSIA SEED AS	2 117 900	4,3%
VERDIPAPIRFONDET ALFRED BERG GAMBA	1 852 500	3,7%
MP PENSJON PK	1 780 300	3,6%
JPMorgan Chase Bank, NORDEA TREATY ACCOUN	1 272 000	2,6%
DATUM INVEST AS	1 209 200	2,4%
SARSIA DEVELOPMENT AS	1 195 000	2,4%
NORSK INNOVASJONSKAP	1 173 100	2,4%
BERA AS	1 084 800	2,2%
KLP AKSJENORGE	1 041 837	2,1%
VPF NORDEA AVKASTNIN C/O JPMORGAN EUROPE	972 354	2,0%
VERDIPAPIRFONDET ALFRED BERG NORGE	845 000	1,7%
KOMMUNAL LANDSPENSJONSKASSE	738 330	1,5%
VERDIPAPIRFONDET HANDELSBANKEN NORGE	720 000	1,4%
VPF NORDEA KAPITAL C/O JPMORGAN EUROPE	700 000	1,4%
VERDIPAPIRFONDET ALFRED BERG AKTIV	552 500	1,1%
BIRK VENTURE AS	525 000	1,1%
STATOIL PENSJON C/O JP MORGAN CHASE	440 000	0,9%
VERDIPAPIRFONDET NORDEA NORGE PLUS	360 000	0,7%
Top 20 shareholders	40 112 621	80,6%
Total other shareholders	9 629 579	19,4%
Total number of shares	49 742 200	100,0%

The Board of Directors have been granted a mandate from the general meeting held on 22 March 2017 to increase the share capital with up to NOK 329,340 by subscription of new shares. The power of attorney was granted for the



purpose of issuance of new shares in accordance with the Company's share incentive programme and is valid until the earlier of the annual general meeting in 2018 and 30 June 2018.

An employee had exercised 15,000 options and paid the subscription price as of 30 June 2017. The shares were registered on 13 July 2017 and following the registration the number of shares in BerGenBio is 49,757,200.

# Shares in the Group held by the management group

	Current position within the Company	Employed since	30 Jun 2017	30 Jun 2016
Richard Godfrey 1)	Chief Executive Officer	January 2009	160 408	1 589
James Bradley Lorens	Chief Scientific Officer	January 2009	250 000	2 500
Petter Nielsen	Chief Financial Officer	February 2015	1 508	-
Total shares held by management			411 916	4 089

1) Richard Godfrey holds 160,408 shares in the Company through Gnist Holding AS.

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

	Position	Served since	30 Jun 2017	30 Jun 2016
Stein H. Annexstad 1)	Chairman	February 2016	7 539	-
Susan Elizabeth Foden	<b>Board Member</b>	September 2011	6 700	67
Hilde Furberg 2)	<b>Board Member</b>	June 2015	3 769	-
Kari Grønås 3)	<b>Board Member</b>	February 2016	4 522	-
Total shares held by members of the Board of Directors			22 530	67

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

# Note 10 - Pension

The Company is required to have an occupational pension scheme in accordance with the Norwegian law on required occupational pension ("lov om obligatorisk tjenestepensjon").

The Company has a pension scheme which complies with the Act on Mandatory company pensions.

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



# Medical and biological terms

Adenocarcinoma Cancerous tumour that can occur in several parts of the body and that forms in mucus-secreting

glands throughout the body. It can occur in many different places in the body and is most prevalent in the following cancer types; lung cancer, prostate cancer, pancreatic cancer, esophageal cancer

and colorectal cancer. Adenocarcinomas are part of the larger grouping of carcinomas.

AML Acute myeloid leukaemia.

Antibody Proteins produced by the B Lymphocytes of the immune system in response to foreign proteins

called antigens. Antibodies function as markers, biding to the antigen so that the antigen molecule

can be recognized and destroyed.

API Active pharmaceutical ingredient.

Axl Cell surface expressed receptor tyrosine kinase, being an essential mediator of the EMT

programme. Axl is up-regulated in a variety of malignancies and and associated with immune

evasion, acquired drug resistance and correlates with poor clinical prognosis.

Axl Mab Axl Monoclonal antibody. A monoclonal antibody that recognizes Axl and binds to the Axl receptor.

BGB324 BerGenBio's lead drug candidate; a highly selective inhibitor of Axl currently undergoing a Phase

Ib/II clinical trial showing promising clinical results.

BGB101 Two monoclonal antibody programs against Axl in late stage preclinical development.

Biomarkers A measurable indicator of some biological state or condition. More specifically, a biomarker

indicates a change in expression or state of a protein that correlates with the risk or progression of

a disease, or with the susceptibility of the disease to a given treatment.

CellSelect™ A unique patented and powerful technology platform used to identify and validate novel drug

targets missed by other technologies.

Checkpoint inhibitors The immune system depends on multiple checkpoint to avoid overactivation of the immune system

on healthy cells. Tumour cells often take advantage of these checkpoints to escape detection by the immune system. Checkpoint inhibitors, inhibit these checkpoints by "releasing the brakes" on

the immune system to enhance an anti-tumour T-cell response.

Clinical Research The research phases involving human subjects.

Clinical Trials Clinical Trials are conducted with human subjects to allow safety and efficiency data to be collected

for health inventions (e.g., drugs, devices, therapy protocols). There trials can only take place once satisfactory information has been gathered on the quality of the non-clinical safety, and Health Authority/Ethics Committee approval is granted in the country where the trial is taking place.

CML Chronic myelogenous leukemia

CMO's Contract manufacturing organisations.

Comorbidity The presence of one or more additional disorders (or diseases) co-occurring with a primary disease

or disorder.

CRO Contract research organisation.

CTL Cytotoxic T-lymphocytes. Key effector cells of the body's immune response to cancer.

Cytarabine A chemotherapy agent used mainly in the treatment of cancers of white blood cells such as acute

myeloid leukemia (AML).

Decitabine A cancer treatment drug used for acute myeloid leukemia (AML).

Docetaxel A clinically well-established anti-mitotic chemotherapy medication that works by interfering with cell

division.

Epithelial state A state of the cell where the cells are stationary, typically forming layers and tightly connected and

well ordered. They lack mobility tending to serve their specific bodily function by being anchored in

place.

Epithelial tumour cell Tumour cells in an epithelial state.

EGFR inhibitors Epidermal growth factor receptor inhibitors. EGFRs play an important role in controlling normal cell

growth, apoptosis and other cellular functions, but mutations of EGFRs can lead to continual or abnormal activation of the receptors causing unregulated EGFR inhibitors are either tyrosine

kinase inhibitors or monoclonal antibodies that slow down or stop cell growth.

EMT Epithelial-mesenchymal transition, a cellular process that makes cancer cells evade the immune

system, escape the tumour and acquire drug resistant properties.

EMT inhibitors Compounds that inhibit Axl and other targets that in turn prevent the formation of aggressive



cancer cells with stem-cell like properties.

Erlotinib A drug used to treat non-small cell lung cancer (NSCLC), pancreatic cancer and several other

types of cancer. It is a reversible tyrosine kinase inhibitor, which acts on epidermal growth factor

receptor (EGFR).

In vivo Studies within the living.

In vitro Studies in a laboratory environment using test tubes, petri dishes etc.

MAb Monoclonal antibodies. Monospecific antibodies that are made by identical immune cells that are

all clones of a unique parent cell, in contrast to polyclonal antibodies which are antibodies obtained

from the blood of an immunized animal and thus made by several different immune cells.

Mesenchymal state A state of the cell where the cells have loose or no interactions, do not form layers and are less

well ordered. They are mobile, can have invasive properties and have the potential to differentiate

into more specialised cells with a specific function.

Mesenchymal cancer cells Cancer cells in a mesenchymal state, meaning that they are aggressive with stem-cell like

properties.

Metastatic cancers A cancer that has spread from the part of the body where it started (the primary site) to other parts

of the body.

Myeloid leukemia A type of leukemia affecting myeloid tissue. Includes acute myeloid leukemia (AML) and chronic

myelogenous leukemia.

NSCLC Non-small cell lung cancer.

Paclitaxel A medication used to treat a number of types of cancer including ovarian cancer, breast cancer,

lung cancer and pancreatic cancer among others.

Phase I The phase I clinical trials where the aim is to show that a new drug or treatment, which has proven

to be safe for use in animals, may also be given safely to people.

Phase Ib Phase Ib is a multiple ascending dose study to investigate the pharmacokinetics and

pharmacodynamics of multiple doses of the drug candidate, looking at safety and tolerability.

Phase II The phase II clinical trials where the goal is to provide more detailed information about the safety of

the treatment and its effect. Phase II trials are performed on larger groups than in Phase I.

Phase III In the phase III clinical trials data are gathered from large numbers of patients to find out whether

the drug candidate is better and possibly has fewer side effects than the current standard

treatment.

Receptor tyrosine kinase High-affinity cell surface receptors for many polypeptide growth factors, cytokines and hormones.

Receptor tyrosine kinases have been shown not only to be key regulators of normal cellular prosesses but also to have a critical role in the development and progression of many types of

cancer.

RTK Receptor tyrosine kinase.

Small molecule A small molecule is a low molecular weight (<900 dalthons) organic compound that may help

regulate a biological process, with a size on the order of 10<sup>-9</sup>m.

Squamous cell carcinoma Is an uncrontrolled growth of abnormal cells arising in the squamous cells, which compose most of

the skin's upper layers. Squamous cell carcinoma is the second most common form of skin cancer.

TNBC Triple negative breast cancer.



# **Disclaimer**

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



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#### **About BerGenBio**

BerGenBio is a clinical-stage biopharmaceutical company focused on developing a pipeline of first-in-class Axl kinase inhibitors to treat multiple cancer indications. The Company is a world leader in understanding the central role of Axl kinase in promoting cancer spread, immune evasion and drug resistance in multiple aggressive liquid and solid cancers.

BerGenBio's lead product, BGB324, is a selective, potent and orally available small molecule Axl inhibitor in Phase II clinical development in three major cancer indications. BGB324 is being developed by BerGenBio as a single agent therapy in acute myeloid leukaemia (AML) and in combination with Tarceva® erlotinib in advanced non-small-cell lung cancer (NSCLC); and in combination with a checkpoint inhibitor in advanced NSCLC and triple negative breast cancer (TNBC).

The Company's is also developing a diversified pre-clinical pipeline of also includes selective Axl inhibitors including BGB149, anti-Axl monoclonal antibody and an antibody drug conjugate (ADC).