



**BERGENBIO ASA**

(A public limited company incorporated under the laws of Norway)

**Listing of up to 2,860,012 new shares**

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This prospectus (the "**Prospectus**") has been prepared in connection with the issue of up to 2,860,012 new shares (the "**New Shares**"), each with a nominal value of NOK 0.10, of BerGenBio ASA ("**BerGenBio**" or the "**Company**"), a public limited company incorporated under the laws of Norway (together with its subsidiary, the "**Group**"), and the related listing of the New Shares on Oslo Børs, a stock exchange operated by Oslo Børs ASA (the "**Oslo Stock Exchange**").

New Shares will be issued by the Company if and when holders of option rights (the "**Option Holders**") under the Share Option Programmes (as defined and further detailed under Section 11.5.2) exercises their respective option rights.

This Prospectus is personal to each Option Holder and does not constitute or form a part of any public offer or solicitation to purchase or subscribe for securities in the Company. The New Shares may only be subscribed by Option Holders pursuant to the terms of the Share Option Programmes of the Group.

The Company's existing shares are, and the New Shares will be, listed on the Oslo Stock Exchange under the ticker code "BGBIO". Except where the context requires otherwise, references in this Prospectus to "**Shares**" will be deemed to include the existing shares in the Company and the New Shares. All of the existing shares in the Company are, and the New Shares will be, registered in the Norwegian Central Securities Depository (the "**VPS**") in book-entry form. All of the issued Shares rank pari passu with one another and each carries one vote.

The New Shares may only be subscribed by Option Holders in those jurisdictions in which, and only to those Option Holders to whom, subscription of the New Shares may lawfully be made and, for jurisdictions other than Norway, would not require any filing, registration or similar action.

**Investing in the Shares involves a high degree of risk. Prospective investors should read the entire document and, in particular, consider Section 2 "Risk factors" beginning on page 11 when considering an investment in the Company.**

**The Shares have not been, and will not be, registered under the United States Securities Act of 1933, as amended (the "U.S. Securities Act") or with any securities regulatory authority of any state or other jurisdiction in the United States of America (the "U.S." or the "United States"). The distribution of this Prospectus and the subscription of New Shares in certain jurisdictions may be restricted by law.**

**For more information regarding restrictions in relation to the New Shares, see Section 16 "Selling and transfer restrictions".**

**The date of this Prospectus is 29 August 2018**

## IMPORTANT INFORMATION

This Prospectus has been prepared in connection with the issuing and listing of the New Shares on the Oslo Stock Exchange. As the Group falls within the definition of small and medium-sized enterprises, as set out in Article 2(f) of the EU Prospectus Directive (as defined below), the level of disclosure in this Prospectus is proportionate to this type of company, cf. Article 26b of the Commission Regulation (EC) no. 809/2004.

This Prospectus has been prepared to comply with the Norwegian Securities Trading Act of 29 June 2007 no. 75 (the “**Norwegian Securities Trading Act**”) and related secondary legislation, including the Commission Regulation (EC) no. 809/2004 implementing Directive 2003/71/EC of the European Parliament and of the Council of 4 November 2003 regarding information contained in prospectuses, as amended, and as implemented in Norway (the “**EU Prospectus Directive**”). This Prospectus has been prepared solely in the English language. The Financial Supervisory Authority of Norway (*Nw.: Finanstilsynet*) (the “**Norwegian FSA**”) has reviewed and on 29 August 2018 approved this Prospectus in accordance with Sections 7-7 and 7-8 of the Norwegian Securities Trading Act. The Prospectus will be valid for up until 12 months from 29 August 2018. The Norwegian FSA has not controlled or approved the accuracy or completeness of the information included in this Prospectus. The approval by the Norwegian FSA only relates to the information included in accordance with pre-defined disclosure requirements. The Norwegian FSA has not made any form of control or approval relating to corporate matters described in or referred to in this Prospectus.

For definitions of certain other terms used throughout this Prospectus, see Section 18 “Definitions and glossary”.

The information contained herein is current as at the date hereof and subject to change, completion and amendment without notice. In accordance with Section 7-15 of the Norwegian Securities Trading Act, significant new factors, material mistakes or inaccuracies relating to the information included in this Prospectus, which are capable of affecting the assessment by Option Holders of the New Shares between the time of approval of this Prospectus by the Norwegian FSA and the listing of the New Shares on the Oslo Stock Exchange, will be included in a supplement to this Prospectus. Neither the publication nor distribution of this Prospectus, nor the subscription of any New Share, shall under any circumstances imply that there has been no change in the Group’s affairs or that the information herein is correct as at any date subsequent to the date of this Prospectus.

No person is authorised to give information or to make any representation concerning the Group or the New Shares other than as contained in this Prospectus. If any such information is given or made, it must not be relied upon as having been authorised by the Company or by any of the affiliates, representatives, advisors or agents of any of the Group.

**This Prospectus is personal to each Option Holder and does not constitute or form a part of any public offer or solicitation to purchase or subscribe for securities in the Company. The New Shares may only be subscribed by Option Holders pursuant to the terms of the Share Option Programmes of the Group.**

**No action to approve, register or file the Prospectus has been made outside Norway. The distribution of this Prospectus and the subscription of New Shares in certain jurisdictions may be restricted by law. This Prospectus does not constitute an offer of, or an invitation to purchase, any of the New Shares in any jurisdiction in which such offer or sale would be unlawful. Neither this Prospectus nor any advertisement or any other offering material may be distributed or published in any jurisdiction except under circumstances that will result in compliance with applicable laws and regulations. Persons in possession of this Prospectus are required to inform themselves about, and to observe, any such restrictions. In addition, the New Shares are subject to restrictions on transferability and resale and may not be transferred or resold except as permitted under applicable securities laws and regulations. Investors should be aware that they may be required to bear the financial risks of this investment for an indefinite period of time. Any failure to comply with these restrictions may constitute a violation of applicable securities laws. See Section 16 “Selling and transfer restrictions”.**

This Prospectus shall be governed by and construed in accordance with Norwegian law. The courts of Norway, with Bergen District Court as legal venue, shall have exclusive jurisdiction to settle any dispute which may arise out of or in connection with this Prospectus.

**In making an investment decision, prospective investors must rely on their own examination, and analysis of, and enquiry into the Group, including the merits and risks involved. Neither the Company, nor any of their respective representatives or advisers, is making any representation to any offeree or purchaser of the New Shares regarding the legality of an investment in the New Shares by such offeree or purchaser under the laws applicable to such offeree or purchaser. Each prospective investor should consult with his or her own advisors as to the legal, tax, business, financial and related aspects of a purchase of the New Shares.**

All Sections of the Prospectus should be read in context with the information included in Section 4 “General information”.

The Company has furnished the information in this Prospectus in order to provide a presentation of the Group and to inform the existing shareholders, potential subscribers of New Shares and the market about the issuance and listing of New Shares. Unless otherwise indicated, the source of information included in this Prospectus is the Company.

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**APPENDICES**

APPENDIX A ARTICLES OF ASSOCIATION AS OF 13 APRIL 2018 A1

**1 SUMMARY**

Summaries are made up of disclosure requirements known as "Elements". These Elements are numbered in Sections A–E (A.1 – E.7) below. This summary contains all the Elements required to be included in a summary for this type of securities and issuer. Because some Elements are not required to be addressed, there may be gaps in the numbering sequence of the Elements. Even though an Element may be required to be inserted in the summary because of the type of securities and issuer, it is possible that no relevant information can be given regarding the Element. In this case a short description of the Element is included in the summary with the mention of "not applicable".

**Section A – Introduction and Warnings**

<b>A.1 Warning</b>	<p>This summary should be read as an introduction to the Prospectus; any decision to invest in the securities should be based on consideration of the Prospectus as a whole by the investor;</p> <p>where a claim relating to the information contained in the Prospectus is brought before a court, the plaintiff investor might, under the national legislation of the member states, have to bear the costs of translating the Prospectus before the legal proceedings are initiated; and</p> <p>civil liability attaches only to those persons who have tabled the summary including any translation thereof, but only if the summary is misleading, inaccurate or inconsistent when read together with the other parts of the Prospectus or it does not provide, when read together with the other parts of the Prospectus, key information in order to aid investors when considering whether to invest in such securities.</p>
<b>A.2 Warning</b>	<p>Not applicable. No consent is granted by the Company for the use of the Prospectus for subsequent resale or final placement of the Shares.</p>

**Section B - Issuer**

<b>B.1 Legal and commercial name</b>	BerGenBio ASA
<b>B.2 Domicile and legal form, legislation and country of incorporation</b>	<p>The Company's registered name is BerGenBio ASA. The Company is organised as a public limited company under Norwegian law, in accordance with the Norwegian Public Limited Companies Act of 13 June 1997 no. 45 (the "<b>Norwegian Public Limited Companies Act</b>"), and is registered with the Norwegian Register of Business Enterprises with registration number 992 219 688.</p> <p>10 January 2017, the Company incorporated a wholly-owned subsidiary, BerGenBio Limited, incorporated in the UK with company number 10555293, which together with the Company is referred to as the Group.</p>
<b>B.3 Current operations, principal activities and markets</b>	<p>BerGenBio ASA is a clinical-stage biopharmaceutical company focused on developing a pipeline of first-in-class AXL kinase inhibitors, including the lead product bemcentinib, a selective AXL inhibitor in phase II clinical development, as a potential cornerstone of combination cancer therapy. The Company has an in-depth understanding of the role and function of AXL kinase (a receptor tyrosine kinase) in mediating cancer spread, immune evasion and drug resistance in multiple aggressive solid and haematological cancers. The Company's primary aim, either alone or in collaboration with a partner, is to develop and commercialise bemcentinib through to marketing approval by the regulatory agencies and subsequent commercialisation.</p> <p>AXL is generally accepted as a driver of many of the hallmarks of aggressive cancer and is also an essential mediator of cellular plasticity through the pathway known as EMT.</p> <p>Bemcentinib (formerly BGB324), is a potentially first-in-class, highly selective, orally bio-available small molecule AXL inhibitor, and the only</p>

	<p>selective AXL inhibitor in phase II clinical trials. The Company is currently sponsoring four Phase II clinical trials with bemcentinib as a single agent and in combination with standard-of-care drugs in patients with leukaemia (AML, MDS) and solid tumours (NSCLC, TNBC).</p> <p>BerGenBio is simultaneously developing a companion diagnostic test to identify patient subpopulations most likely to benefit from treatment with bemcentinib. This is anticipated to facilitate more efficient registration trials and support a precision medicine-based commercialisation strategy.</p> <p>In addition to bemcentinib, BerGenBio has developed a humanised monoclonal antibody, which shows high affinity and selectivity for AXL, and inhibits the activation of AXL. A clinical candidate, BGB149, has been nominated and the first human studies are planned to begin in 2018.</p> <p>Early stage research at BerGenBio is further expanding the understanding of the role of novel targets that regulate the transition of cancers into aggressive forms that acquire resistance to therapeutic intervention, while driving immunosuppression within the tumour microenvironment (processes collectively known as cellular plasticity). These findings have been translated into a pipeline of proprietary small molecule drug candidates targeting critical nodes in cellular plasticity and which are being evaluated as new strategies for therapeutic intervention.</p> <p>Furthermore, encouraging preclinical data has emerged pointing to an important role of AXL and AXL inhibition via bemcentinib in several fibrotic indications including the rare disease idiopathic pulmonary fibrosis (IPF) and the aggressive liver disease nonalcoholic steatohepatitis (NASH). BerGenBio continues to follow AXL biology and the potential of AXL inhibition by supporting such promising research carried out by leading researchers in the field.</p> <p>BerGenBio’s founding research was undertaken at the University of Bergen, and in 2007 the Company was established by Bergen Teknologioverføring AS (the technology transfer office of the UiB, UniResearch AS (the investment holding company of UiB), Prof. James Lorens and Dr. David Micklem. An initial public offering (IPO) of BerGenBio shares took place at the Oslo Stock Exchange on 18 April 2017 raising 400mn NOK and a private placement directed towards specialist investors was completed on 13 April 2018 raising a further 187.5mn NOK. The Company maintains its administrative and research offices in Bergen whilst its clinical development functions are the main responsibility of its fully owned UK subsidiary, BerGenBio Ltd, with offices in Oxford, UK.</p>
<p><b>B.4a Significant recent trends</b></p>	<p>The Group has not experienced any changes or trends that are significant to the Group between 30 June 2018 and the date of this Prospectus, nor is the Group aware of such changes or trends that may or are expected to be significant to the Group for the current financial year.</p>
<p><b>B.5 Description of the Company</b></p>	<p>The operations of the Company is carried out through the Company, and through its UK subsidiary incorporated in the UK 10 January 2017 as a wholly-owned subsidiary.</p>

<b>B.6 Interests in the Company and voting rights</b>	As of 23 August 2018, the Company had 3,076 shareholders. The table below shows the Company's 20 largest shareholders as of 23 August 2018.	
<b>Shareholders</b>	<b>Number of Shares</b>	<b>Per cent</b>
Meteva AS	14,923,000	27.28
Investinor AS	6,609,800	12.08
Sarsia Seed AS	2,117,900	3.87
Verdipapirfondet Alfred Berg Gamba	1,757,942	3.21
Euroclear Bank S.A./N.V. (NOM)	1,493,893	2.73
Datum Invest AS	1,485,467	2.72
Sarsia Development AS	1,175,000	2.15
VPF Nordea Avkastning	1,125,902	2.06
MP Pensjon PK	1,117,455	2.04
Bera AS	1,084,800	1.98
KLP Aksjenorge	1,029,279	1.88
VPF Nordea Kapital	913,187	1.67
Norsk Innovasjonskapital II AS	856,170	1.56
Verdipapirfondet Alfred Berg Norge	801,556	1.47
JPMorgan Chase Bank, N.A., London (UK) (NOM)	775,236	1.42
Jpmorgan Chase Bank, N.A., London (Sweden) (NOM)	733,752	1.34
Kommunal Landspensjonskasse	719,520	1.32
Clearstream Banking S.A. (Nom)	625,867	1.14
Verdipapirfondet Alfred Berg Aktiv	574,391	1.05
Norda ASA	536,281	0.98
<b>Others<sup>1</sup> .....</b>	<b>14,255,048</b>	<b>26.05</b>
<b>Total .....</b>	<b>54,711,446</b>	<b>100.00</b>
1	Remaining 3,056 shareholders.	
	<p>Shareholders owning 5% or more of the Shares have an interest in the Company's share capital which is notifiable pursuant to the Norwegian Securities Trading Act.</p> <p>There are no differences in voting rights between the Shares.</p> <p>The Company is not directly or indirectly owned or controlled, nor is the Company aware of any arrangements the operation of which may at a subsequent date result in a change of control of the Company.</p>	
<b>B.7 Selected historical key financial information</b>	<p>The following selected financial information has been extracted from the Group's unaudited interim consolidated financial information as of, and for the six month periods ended, 30 June 2018 and 2017 (the Interim Financial Statements) and the Group's audited consolidated financial statements as of, and for the years ended, 31 December 2017 and 2016 (the Financial Statements). The Financial Statements have been prepared in accordance with IFRS, while the Interim Financial Statements have been prepared in accordance with IAS 34.</p> <p>The selected financial information included herein should be read in connection with, and is qualified in its entirety by reference to, the Financial Information incorporated by reference hereto, see Section 17.3 "Incorporation by reference".</p>	

<b>Statement of profit and loss and other comprehensive income</b>				
<i>In NOK thousands</i>	<b>Six months ended 30 June</b>		<b>Year ended 31 December</b>	
	<b>2018</b>	<b>2017</b>	<b>2017</b>	<b>2016</b>
	(IAS 34) <i>(unaudited)</i>	(IAS 34) <i>(unaudited)</i>	(IFRS)	(IFRS)
Operating revenue .....	0	0	0	0
Operating profit (EBIT) .....	(105,513)	(99,635)	(183,708)	(131,570)
Profit/(loss) for the period .....	(103,017)	(99,148)	(182,208)	(129,799)
<b>Statement of financial position</b>				
<i>In NOK thousands</i>	<b>Six months ended 30 June</b>		<b>Year ended 31 December</b>	
	<b>2018</b>	<b>2017</b>	<b>2017</b>	<b>2016</b>
	(IAS 34) <i>(unaudited)</i>	(IAS 34) <i>(unaudited)</i>	(IFRS)	(IFRS)
Total non-current assets .....	518	467	557	410
Total current assets .....	455,398	456,852	383,780	174,126
Total assets .....	455,917	457,319	384,336	174,536
Total equity .....	424,678	430,245	350,350	153,270
Total non-current liabilities .....	0	0	0	0
Total current liabilities .....	31,238	27,074	33,986	21,266
Total liabilities .....	31,238	27,074	33,986	21,266
Total equity and liabilities .....	455,917	457,319	384,336	174,536
<b>Statement of cash flow</b>				
<i>In NOK thousands</i>	<b>Six months ended 30 June</b>		<b>Year ended 31 December</b>	
	<b>2018</b>	<b>2017</b>	<b>2017</b>	<b>2016</b>
	(IAS 34) <i>(unaudited)</i>	(IAS 34) <i>(unaudited)</i>	(IFRS)	(IFRS)
Cash flows from operating activities .....	(106,015)	(96,545)	(168,109)	(124,314)
Cash flows from investing activities .....	(70)	(159)	(340)	(255)
Cash flows from financing activities .....	176,997	375,179	376,974	212,402
Change in cash and cash equivalents .....	70,913	278,475	208,525	87,832
Cash and cash equivalents at period end ...	441,263	440,300	370,350	161,825
<b>B.8</b>	<b>Selected key pro forma financial information</b>	Not applicable. There is no pro forma financial information.		
<b>B.9</b>	<b>Profit forecast or estimate</b>	Not applicable. No profit forecast or estimates are made.		
<b>B.10</b>	<b>Audit report qualifications</b>	Not applicable. There are no qualifications in the audit reports.		
<b>B.11</b>	<b>Insufficient working capital</b>	Not applicable. The Company is of the opinion that the working capital available to the Company is sufficient for the Company's present requirements for the period covering at least 12 months from the date of this Prospectus.		

**Section C - Securities**

<b>C.1</b>	<b>Type and class of securities admitted to trading and identification number</b>	The Company has one class of Shares in issue and all Shares in that class provide equal rights in the Company. Each of the Shares carries one vote. The Shares have been created under the Norwegian Public Limited Companies Act and are registered in book-entry form with the VPS under ISIN NO 001 0650013.
<b>C.2</b>	<b>Currency of issue</b>	The Shares are issued in NOK.
<b>C.3</b>	<b>Number of shares in issue and par value</b>	As of the date of this Prospectus, the Company's share capital is NOK 5,471,144.60 divided into 54,711,446 Shares, with each Share having a nominal value of NOK 0.10.

<b>C.4</b>	<b>Rights attaching to the securities</b>	The Company has one class of Shares in issue, and all Shares provide equal rights in the Company. Each of the Shares carries one vote.
<b>C.5</b>	<b>Restrictions on transfer</b>	The Articles of Association do not provide for any restrictions on the transfer of Shares, or a right of first refusal for the shareholders of the Company. Share transfers are not subject to approval by the Board of Directors.
<b>C.6</b>	<b>Admission to trading</b>	The Shares are, and the New Shares will be, admitted to trading on the Oslo Stock Exchange.
<b>C.7</b>	<b>Dividend policy</b>	The Company has not paid any dividends for the years ended 31 December 2017 and 2016 or any previous year. The Company is focusing on the development of novel pharmaceutical products and does not anticipate paying any cash dividend until sustainable profitability is achieved.

#### Section D - Risks

<b>D.1</b>	<b>Key risks specific to the Company or its industry</b>	<p><i>Risks related to the Company and the industry in which the Company operates</i></p> <ul style="list-style-type: none"> <li>• The Company has incurred significant operating losses since its inception and the Company expects to incur losses over the next several years and may never achieve or maintain profitability</li> <li>• Clinical development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results. The Company is in an early stage of development and its clinical trials may fail to demonstrate adequately the safety and efficacy of its product candidates, which would prevent or delay regulatory approval and commercialisation</li> <li>• The Company's business is highly dependent on the success of its lead product candidate, bemcentinib, which together with the Company's other product candidates will require significant additional clinical testing before the Company can seek regulatory approval and potentially commercialise products</li> <li>• Any significant delay or failure in the conduct of clinical studies may adversely impact the Company's ability to obtain regulatory approval for and commercialise its current and future drug candidates</li> <li>• The Company's product candidates may cause undesirable side effects that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, if approved, and result in other significant negative consequences</li> <li>• The Company has obtained orphan drug designations for bemcentinib in treatment of AML, but the Company may be unable to maintain the benefits associated with orphan drug designation</li> <li>• The financial success of the Company requires obtaining acceptable price and reimbursement for its products</li> <li>• The Company faces an inherent business risk of liability claims in the event that the use or misuse of the compounds results in personal injury or death</li> <li>• The Company's success, competitive position and future revenues will depend in part on the Company's ability to protect intellectual property and know-how</li> <li>• Patent applications filed by others could limit the Company's freedom to operate</li> <li>• The Company may not be able to maintain sufficient insurance to cover all risks related to its operations</li> </ul>
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	<ul style="list-style-type: none"> <li>• The Company faces significant competition from other biotechnology and pharmaceutical companies</li> <li>• The Company may lose market exclusivity and face competition from low-cost generic products</li> <li>• The Company relies, and will continue to rely, upon third-parties for clinical trials and manufacturing</li> <li>• The Company relies, and will continue to rely, upon third-parties for development and commercialisation of its products</li> <li>• The Company may not be able to develop new drug candidates</li> <li>• The Company may not be able to enter into partnership agreements</li> <li>• The Company is reliant on key personnel and the ability to attract new, qualified personnel</li> <li>• The Company is exposed to commercial risk</li> </ul> <p><i>Risks related to laws, regulations and litigation</i></p> <ul style="list-style-type: none"> <li>• The Company may be subject to litigation and disputes that could have a material and adverse effect on the Company’s business, financial condition, results of operations, cash flows, time to market and prospects</li> <li>• The Company is exposed to risks related to regulatory processes and changes in regulatory environment</li> <li>• Even if the Company obtains regulatory approval for a drug candidate, the Company’s products will remain subject to regulatory scrutiny</li> </ul> <p><i>Risks related to financing and market risk</i></p> <ul style="list-style-type: none"> <li>• The Company will require additional financing to achieve its goals, and a failure to obtain this necessary capital when needed could force the Company to delay, limit, reduce or terminate its product development or commercialisation efforts</li> <li>• Future debt levels could limit the Company’s flexibility to obtain additional financing and pursue other business opportunities</li> <li>• Interest rate fluctuations could in the future affect the Company’s cash flow and financial condition in addition to the price of the Shares</li> <li>• The Company’s results will be exposed to exchange rate risks</li> <li>• The Company may encounter financial reporting risk</li> </ul>
<p><b>D.3 Key risks specific to the securities</b></p>	<p><i>Risks related to the Shares</i></p> <ul style="list-style-type: none"> <li>• The market value of the Shares may fluctuate significantly, which could cause investors to lose a significant part of their investment</li> <li>• Future sales, or the possibility for future sales, of substantial numbers of Shares may affect the Shares’ market price</li> <li>• Future issuances of Shares or other securities may dilute the holdings of shareholders and could materially affect the price of the Shares</li> <li>• Pre-emptive rights to secure and pay for Shares in additional issuance could be unavailable to U.S. or other shareholders</li> <li>• Investors could be unable to exercise their voting rights for Shares registered in a nominee account</li> <li>• The transfer of Shares is subject to restrictions under the securities laws of the United States and other jurisdictions</li> <li>• The Company’s ability to pay dividends is dependent on the availability of distributable reserves and the Company may be unable or unwilling to pay any dividends in the future</li> <li>• Investors could be unable to recover losses in civil proceedings in jurisdictions other than Norway</li> </ul>

	<ul style="list-style-type: none"> <li>• Norwegian law could limit shareholders' ability to bring an action against the Company</li> <li>• Exchange rate fluctuations could adversely affect the value of the Shares and any dividends paid on the Shares for an investor whose principal currency is not NOK</li> <li>• Market interest rates could influence the price of the Shares</li> </ul>
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### Section E – Offer

<b>E.1</b>	<b>Net proceeds and estimated expenses</b>	The gross proceeds to the Company will be up to approximately NOK 44 million and the Company's total costs and expenses of, and incidental to, this Prospectus are estimated to amount to NOK 0.5 million (excluding VAT).
<b>E.2a</b>	<b>Reasons for the Offering and use of proceeds</b>	<p>Not applicable. There is no public offer made.</p> <p>New Shares are issued under the Group's Share Option Programmes which are intended 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 Share Option Programmes, in addition to some Board Members. The Share Option Programmes also serves to retain and attract senior management.</p> <p>The net proceeds from New Shares issued to Option Holders would be modest and will be used towards administrative activities including general corporate purposes.</p>
<b>E.3</b>	<b>Terms and conditions of the Offering</b>	Not applicable. There is no public offer made.
<b>E.4</b>	<b>Material and conflicting interests</b>	Not applicable. There is no public offer made.
<b>E.5</b>	<b>Selling shareholders and lock-up agreements</b>	Not applicable. There are no selling shareholders, and no lock-up agreements.
<b>E.6</b>	<b>Dilution resulting from the Scheme</b>	If all New Shares are issued and subscribed by the Option Holders, the resulting dilution is estimated to be approximately 5 %, based on the assumption that the Company issues 2,860,012 New Shares.
<b>E.7</b>	<b>Estimated expenses charged to investor</b>	Not applicable. No expenses or taxes will be charged by the Company.



## 2 RISK FACTORS

*An investment in the New Shares involves inherent risk. Before making an investment decision with respect to the New Shares, investors should carefully consider the risk factors and all information contained in this Prospectus, including the Financial Statements and related notes. The risks and uncertainties described in this Section 2 are the principal known risks and uncertainties faced by the Company as of the date hereof that the Company believes are the material risks relevant to an investment in the New Shares. An investment in the New Shares is suitable only for investors who understand the risks associated with this type of investment and who can afford to lose all or part of their investment. The absence of negative past experience associated with a given risk factor does not mean that the risks and uncertainties described herein should not be considered prior to making an investment decision in respect of the New Shares. If any of the following risks were to materialise, individually or together with other circumstances, they could have a material and adverse effect on the Company and/or its business, results of operations, cash flows, financial condition and/or prospects, which may cause a decline in the value and trading price of the New Shares, resulting in the loss of all or part of an investment in the same.*

*The order in which the risks are presented does not reflect the likelihood of their occurrence or the magnitude of their potential impact on the Company's business, results of operations, cash flows, financial condition and/or prospects. The risks mentioned herein could materialise individually or cumulatively. The information in this Section 2 is as of the date of this Prospectus.*

### 2.1 Risks related to the Company and the industry in which the Company operates

**The Company has incurred significant operating losses since its inception and the Company expects to incur losses over the next several years and may never achieve or maintain profitability**

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable.

Since inception, the Company has incurred significant losses. In 2017, the Company's operating loss was NOK 183.7 million and in 2016 the Company's operating loss was NOK 131.6 million. To date, the Company has financed its operations mainly through private equity and grants. The Company has devoted substantially all of the Company's financial resources and efforts to research and development, including preclinical studies and, since 2013, clinical trials. The Company expects to continue to incur significant expenses and losses over the next several years. The Company's net losses may fluctuate from quarter to quarter. The size of the Company's future losses will depend, in part, on the Company's future expenses and its ability to generate revenue, if any. The Company has no products approved for commercial sale and has not generated any revenue from product sales to date, and it continues to incur significant research and development and other expenses related to its ongoing operations. As a result, the Company is not profitable and has incurred losses in each period since inception.

To become and remain profitable, the Company must succeed in developing and eventually commercialising products that generate revenue or succeed in out-licensing assets or other types of partnering arrangements either on a global basis or for selected geographies. This will require the Company or its partners to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of the Company's products, discovering additional drug candidates, obtaining regulatory approval for these drug candidates and manufacturing, marketing and selling any products for which the Company may obtain regulatory approval. The Company is in the early stages of these activities. The Company may never succeed in these activities and, even if it does, may never generate revenue that is significant enough to achieve profitability. Should any of these risks materialize, it could have a material and adverse effect on the Company's business, financial condition, results of operations, cash flows, time to market and prospects.

**Clinical development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results. The Company is in an early stage of development and its clinical trials may fail to demonstrate adequately the safety and efficacy of its product candidates, which would prevent or delay regulatory approval and commercialisation**

Before obtaining regulatory approvals for the commercial sale of the Company's product candidates, the Company must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that its product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Drug development involves moving drug candidates through research and extensive testing of activity and side effects in preclinical models before authorisation is given for further testing in humans in the clinical stage. The clinical stage is divided into three consecutive Phases (I, II and III) with the aim to

elucidate the safety and efficacy of a drug candidate before an application for marketing authorisation can be filed with the health authorities. Each individual development step is associated with the risk of failure, hence an early stage drug candidate carries a considerable higher risk of failure than a later stage candidate. Moreover, the commencement and completion of clinical trials may be delayed by several factors, including, but not limited to, unforeseen safety issues, issues related to determination of dose, lack of effectiveness during clinical trials, slower than expected patient enrolment in clinical studies, unforeseen requirements from the regulatory agencies about the conduct clinical studies, inability or unwillingness of medical investigators to follow the proposed clinical protocols and termination of licence agreements necessary to complete trials. On average, five out of 5,000 drugs make it through the preclinical phase, and historically only one out of these five is approved by the U.S. Food and Drug Administration (the "FDA") for marketing<sup>1</sup>. Moreover, only 2 of 10 marketed drugs return revenues that match or exceed R&D costs<sup>2</sup>. It takes on average 12 years to develop a drug.

The results of preclinical studies and early clinical trials of the Company's product candidates may not be predictive of the results of later-stage clinical trials. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. The Company cannot be certain that it will not face similar setbacks. Most product candidates that commence clinical trials are never approved as commercial products. Should the Company's clinical studies fail to demonstrate adequately the safety and efficacy of one or more of its product candidates it could have a material and adverse effect on the Company's business, financial condition, results of operations, cash flows, time to market and prospects.

**The Company's business is highly dependent on the success of its lead product candidate, bemcentinib which together with the Company's other product candidates will require significant additional clinical testing before the Company can seek regulatory approval and potentially commercialise products**

The Company does not have any products that have gained regulatory approval. Its business and future success depend on its ability to obtain regulatory approval of, and then successfully commercialise, its lead product candidate, bemcentinib. bemcentinib, as well as the Company's other product candidates, is in the early stages of development. The Company's ability to develop, obtain regulatory approval for, and successfully commercialise bemcentinib effectively will depend on several factors, including, but not limited to, the following:

- successful completion of the clinical trials;
- receipt of marketing approvals;
- establishing commercial manufacturing and supply arrangements;
- establishing a commercial infrastructure;
- acceptance of the product by patients, the medical community and third-party payers;
- successfully establishing an adequate market share in competition with other therapies;
- successfully executing the Company's pricing and reimbursement strategy;
- a continued acceptable safety and adverse event profile of the product following regulatory approval; and
- identifying, registering, maintaining, enforcing and defending intellectual property rights ("IPR") and claims covering the product.

All of the Company's product candidates, including bemcentinib, will require additional clinical and nonclinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before the Company can generate any revenue

<sup>1</sup> <http://www.medicinenet.com/script/main/art.asp?articlekey=9877> (accessed 4 July 2018)

<sup>2</sup> Vernon JA, Golec JH, DiMasi JA. Drug development costs when financial risk is measured using the fama-french three-factor model. Health Econ. 2010;19(8):1002-1005

from product sales. The Company is not permitted to market or promote any of its product candidates before it receives regulatory approvals from the FDA to market in the U.S. and from the European Medicines Agency (“**EMA**”) to market in Europe, as well as equivalent regulatory authorities in other jurisdictions to commercialise in those regions. It cannot be assured that the Company will receive such regulatory approvals necessary to commercialise the final products. Regulatory approvals may be denied, delayed or limited for a number of reasons, as different regulatory authorities around the world have different requirements for approving pharmaceuticals. The authorities have wide discretion in their drug approval process and may request further testing before approval or post marketing. Delays in obtaining regulatory approvals may delay commercialisation and the ability to generate revenues from drug candidates, impose extra cost on the Company, diminish competitive advantages and, after product approval, safety or efficacy issues may emerge during post-marketing surveillance which may result in withdrawal or restriction of the product approval.

The Company’s future earnings are likely to be largely dependent on the timely approval of its lead drug candidate, bemcentinib, for various diseases and treatments. No assurances can be given with respect to obtaining such approvals or the timing thereof.

**Any significant delay or failure in the conduct of clinical studies may adversely impact the Company’s ability to obtain regulatory approval for and commercialise its current and future drug candidates**

The Company depends on collaboration with partners, medical institutions and laboratories to conduct clinical testing in compliance requirements from appropriate regulatory authority in the country of use. The Company’s ability to complete clinical studies in timely fashion or at all depends on several factors, including, but not limited to, the following:

- delays in the planning of future clinical studies;
- delays in the "**CMC**" (chemistry, manufacturing, control) and/or "**QA**" (quality assurance) work related to drug substance and drug product in present or future clinical studies;
- delays in, or inability of, attracting and retaining highly qualified managerial, scientific and medical personnel to assist in the clinical studies;
- delays in obtaining or failures to obtain regulatory approval to commence clinical studies because of safety concerns of regulators relating to the Company’s drug candidate or failure to follow regulatory guidelines or general safety issues;
- actions by regulators to place a proposed study on clinical hold or to temporarily or permanently stop a trial for a variety of reasons, principally for safety concerns;
- delays in recruiting patients to participate in a clinical study, and the rate of patients enrolment, which is itself a function of many factors, including size of the patients population, the proximity of patients to the clinical trial sites, the eligibility criteria for the study and the nature of the protocol;
- the inability to fully control experimental conditions;
- compliance of patients and investigators with the protocol and applicable regulations; failure of clinical studies and clinical investigators to be in compliance with relevant clinical protocol, or similar requirements in other countries;
- failure of third party clinical managers to satisfy their contractual duties, comply with regulations or meet expected deadlines;
- delays or failures in reaching agreement on acceptable terms with prospective study sites;
- the Company’s partners in clinical studies, the performance of which the Company cannot control;
- determination by regulators that the clinical design is not adequate; and
- delays or failures on obtaining clinical materials and manufacturing sufficient quantities of bemcentinib, BGB101 and BGB002 for use in trials.

Any significant delay or failure in the conduct of clinical studies may adversely impact the Company's ability to obtain regulatory approval for and commercialise its current and future product candidates, which again could have a material and adverse effect on the Company's business, financial condition, results of operations, cash flows, time to market and prospects.

**The Company's product candidates may cause undesirable side effects that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, if approved, and result in other significant negative consequences**

Undesirable side effects caused by the Company's product candidates could cause the Company or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA or comparable foreign regulatory authorities. Results of the Company's clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

If unacceptable side effects arise in the development of the Company's product candidates, the Company could suspend or terminate its clinical trials or the FDA, EMA or comparable foreign regulatory authorities could order the Company to cease clinical trials or deny approval of the Company's product candidates for any or all targeted indications. Treatment related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, side effects may not be appropriately recognized or managed by the treating medical staff.

Additionally, if one or more of the Company's product candidates receives marketing approval, and the Company or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- the Company may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- health care professionals or patients may not accept the product and prefer competing alternatives;
- the Company could be sued and held liable for harm caused to patients;
- the regulators may require additional data from studies; and
- the Company's reputation may suffer.

Any of these events could prevent the Company from achieving or maintaining market acceptance of the particular product candidate, if approved, and could have a material and adverse effect on the Company's business, financial condition, results of operations, cash flows, time to market and prospects.

**The Company has obtained orphan drug designations for bemcentinib in treatment of AML, but the Company may be unable to maintain the benefits associated with orphan drug designation**

Under the U.S. Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biopharmaceutical intended to treat a rare disease or condition in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, to market the same product for the same indication for 7 years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. In Europe, the EMA offers similar support and advantages

to products which have an orphan drug designation. It is granted to rare diseases defined as occurring 5<10,000 and provide marketing exclusivity for 10 years.

Even though the Company has received orphan drug designation for bemcentinib in treatment of AML, the Company may not be the first to obtain marketing approval of its product candidate for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products.

### **The financial success of the Company requires obtaining acceptable price and reimbursement**

In most markets, drug prices and reimbursement levels are regulated or influenced by authorities, other healthcare providers, insurance companies or health maintenance organisations. Furthermore, the overall healthcare costs to society have increased considerably over the last decades and governments all over the world are striving to control them. There can be no guarantee that the Company's drugs (if/when released to the market) will obtain the selling prices or reimbursement levels foreseen by the Company. If actual prices and reimbursement levels granted to the Company's products happen to be lower than anticipated, it may have a negative impact on its products' profitability and/or marketability, which again could have a material and adverse effect on the Company's business, financial condition, results of operations, cash flows, time to market and prospects.

### **The Company faces an inherent business risk of liability claims in the event that the use or misuse of the compounds results in personal injury or death**

The Company faces an inherent risk of product liability as a result of the clinical testing of its product candidates and will face an even greater risk if it commercialises any products. For example, the Company may be sued if its product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. If the Company cannot successfully defend itself against product liability claims, it may incur substantial liabilities or be required to limit commercialisation of its product candidates. Even successful defence would require significant financial and management resources.

The Company has not experienced any clinical trial liability claims to date, but it may experience such claims in the future. The Company currently maintains clinical trial liability insurance for each trial. The insurance policy may not be sufficient to cover claims that may be made against the Company. Clinical trial liability insurance may not be available in the future on acceptable terms, or at all. Any claims against the Company, regardless of their merit, could have a material and adverse effect on the Company's business, financial condition, results of operations, cash flows, time to market and prospects.

### **The success, competitive position and future revenues will depend in part on the Company's ability to protect intellectual property and know-how**

The success of the Company will depend on the Company's ability to obtain and maintain patent protection for its products, methods, processes and other technologies, to preserve trade secrets, to prevent third parties from infringing proprietary rights of the Company and to operate without infringing the proprietary rights of third parties. To date, the Company holds certain exclusive patent rights in major markets, however, the Company cannot predict the degree and range of protection any patents will afford against competitors and competing technologies, including whether third parties will find ways to invalidate or otherwise circumvent the patents, if and when additional patents will be issued, whether or not others will obtain patents claiming aspects similar to those covered by the Company's patents and patents applications, whether the Company will need to initiate litigation or administrative proceedings, or whether such litigation or proceedings are initiated by third parties against the Company which may be costly or whether third parties will claim that the Company's technology infringes upon their rights. Should the Company not be able to protect its intellectual property and know-how, it could have a material and adverse effect on the Company's business, financial condition, results of operations, cash flows, time to market and prospects.

### **Patent applications filed by others could limit the Company's freedom to operate**

Competitors may claim that one or more of the Company's drug candidates infringes their patents or other intellectual property. Resolving a patent or other intellectual property infringement claim can be costly and time consuming and may require the Company to enter into royalty or licence agreements. If this should be necessary, the Company cannot guarantee that it would be possible to obtain royalty or licence agreements on commercially advantageous terms. A

successful claim of patent or other intellectual property infringement could subject the Company to significant damages or an injunction preventing the manufacture, sale or use of the Company's affected products or otherwise limit the freedom to operate. Any of these events could have a material adverse effect on the business, financial position, results of operations, cash flows, time to market and prospects.

**The Company may not be able to maintain sufficient insurance to cover all risks related to its operations**

The Company's business is subject to a number of risks and hazards, including, but not limited to industrial accidents, labour disputes and changes in the regulatory environment. Such occurrences could result in damage to properties, personal injury, monetary losses and possible legal liability. Although the Company seeks to maintain insurance or contractual coverage to protect against certain risks in such amounts as it considers reasonable, its insurances may not cover all the potential risks associated with the Company's operations. Any risks in respect of which the Company does not have sufficient insurance coverage may result in a material adverse effect on the Company's financial condition, operating results, cash flows, time to market and prospects.

**The Company faces significant competition from other biotechnology and pharmaceutical companies**

The biopharmaceutical industry is highly competitive with many large players and subject to rapid and substantial technological change. The Company's competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Many major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions continue to invest time and resources in developing novel approaches to cancer treatment. Many of the Company's competitors and potential competitors have substantially greater capital resources, research and development resources, regulatory and operational experience, manufacturing and marketing experience and production facilities. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in the Company's competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. The Company's competitors may succeed in developing, acquiring or licensing on an exclusive basis drugs or biological products that are more effective, safer, more easily commercialised or less costly than the Company's product candidates or may develop proprietary technologies or secure patent protection that the Company may need for the development of its technologies and products.

Even if the Company obtains regulatory approval of its product candidates, the availability and price of its competitors' products could limit the demand and the price the Company is able to charge for its product candidates. The Company may not be able to implement its business plan if the acceptance of its product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to the Company's product candidates, or if physicians switch to other new drug or biological products or choose to reserve the Company's product candidates for use in limited circumstances. For additional information regarding the Company's competition, see Section 7.5 "Key indications for BerGenBio".

**The Company may lose market exclusivity and face competition from low-cost generic products**

In the long-term the Company expects to face competition from lower-cost generic products. The Company's drug candidates are or are expected to be protected by patent rights that are expected to provide the Company with exclusive marketing rights in various countries. However, patent rights are of varying strengths and durations. Loss of market exclusivity and the introduction of a generic version of the same or a similar drug typically results in a significant and sharp reduction in net sales revenues for the relevant product, given that generic manufacturers typically offer their versions of the same drug at sharply lower prices. The Company's results may be affected by changes in public sentiment.

The pharmaceutical industry is under close scrutiny from the public, governments and the media. In addition, there is significant pressure on the industry from certain nations to make the products available to their population at drastically lower costs. Any increase in such negative public sentiment or increase in public scrutiny or pressure from such nations could lead, among other things, to changes in legislation, to changes in the demand for the products, additional pricing pressures with respect to the products, or increased efforts to undercut intellectual property protections. Such changes could adversely affect the Company's business, financial condition, results of operations, cash flows, time to market and prospects.

**The Company relies, and will continue to rely, upon third-parties for clinical trials and manufacturing**

The Company cannot be certain that it will be able to enter into or maintain satisfactory agreements with third-party suppliers, like contract research organisations (“CRO’s”) for the conduct of clinical studies or manufacturers. The Company’s need to amend or change providers for the conduct of clinical studies might impact the timelines of the conduct of such studies. The Company’s failure to enter into agreements with such suppliers or manufacturers on reasonable terms, if at all, could have a material and adverse effect on the business, financial condition, results of operations, cash flows, time to market and prospects. The Company needs to ensure that the manufacturing process complies with applicable regulations and manufacturing practices as well as the Company’s own high quality standards. Any drug/drug candidate, however, will require technically complex manufacturing processes or require a supply of highly specialized raw materials. As a result of these factors, the production of any drug/drug candidate may be disrupted from time to time.

The Company may also not be able to rapidly alter production volumes to respond to changes in future commercial sale or demand of a product. Poor manufacturing performance of third party manufacturers, a disruption in the supply or the Company’s failure to accurately predict the demand for any future commercial sale of a product could have a significant adverse effect on the Company’s business, financial condition, results of operations, cash flows, time to market and prospects. In addition, because the Company’s products are intended to promote the health of patients, any supply disruption could lead to allegations that the public health has been endangered and could subject the Company to lawsuits.

**The Company relies, and will continue to rely, upon third-parties for development and commercialisation of its products**

The Company cannot be certain that it will be able to enter into or maintain satisfactory agreements with third-party suppliers for the development and commercialisation of its products. The Company is in particular dependent on maintaining its exclusive worldwide royalty-bearing licence to the certain patents and know-how of Rigel Pharmaceuticals Inc (“Rigel”) which constitute important components for the development and commercialisation of the Company’s lead drug candidate, bemcentinib, the out-license to ADCT which may give rise to development and regulatory milestones payments and royalty payments to BerGenBio, as well as the collaboration agreements with MSD for further clinical trials for bemcentinib. Any event of breach of agreement by either party or other full or partial discharge of the relevant agreements and/or any of the rights thereunder could have a material adverse effect on the business, financial position, results of operations, cash flows, time to market and prospects. For more information about material contracts, see Section 8.8 “Dependency on contracts, suppliers and assets necessary for production”.

**The Company may not be able to develop new drug candidates**

The Company’s future success will depend to a large extent upon the Company’s ability to develop its lead drug candidate, bemcentinib. The Company may not have the ability to invent, explore and develop drug candidates that are of value to the medical market. Furthermore, the Company depends upon independent investigators and collaborators, such as universities and medical institutions, to do parts of the practical part of the chemical, pharmaceutical, analytical, preclinical and clinical research and development. These collaborators are not employees of the Company and the amount or timing of the resources they devote to the programmes cannot be fully controlled by the Company.

**The Company may not be able to enter into partnership agreements**

The Company’s business strategy is to retain marketing rights and actively participate in the commercialisation of bemcentinib, while exploring potential partnering opportunities in selected geographies partly through collaborative agreements with pharmaceutical or biotechnology companies. The Company cannot give any assurance that such agreements will be obtained on acceptable terms, nor that the Company will be able to enter into any such agreements at all. Furthermore, should such agreements be executed, there can be no assurance that the agreements are not terminated by the other party.

**The Company is reliant on key personnel and the ability to attract new, qualified personnel**

The Company is highly dependent upon having a highly qualified senior management and scientific team. The loss of a key employee might impede the achievement of the scientific development and commercial objectives. Competition for key personnel with the experience that is required is intense and is expected to continue to increase. There is no assurance that the Company will be able to retain key personnel, nor can assurances be given that the Company will be

able to recruit new key personnel in the future. Any failure to attract or retain such personnel could result in the Company not being able to successfully implement its business plan and could impact the compliance of the Company's quality system and thereby the compliance of the Company's development work, which again could have a material and adverse effect on the Company's business, financial condition, results of operations, cash flows, time to market and prospects.

In addition, the Company relies on its Board Members and consultants to assist in formulating the research and development strategy. The majority of the Board Members and all of the consultants are otherwise employed and each such member or consultant may have commitments to other entities that may limit their availability to the Company.

### **The Company is exposed to commercial risk**

The market for cancer products has to date shown itself to be relatively price insensitive to therapy costs. Healthcare budgets worldwide are however under severe stress. There is a risk that pricing of the kind experienced to date will become difficult to achieve. Once approval is obtained for a product there is no certainty that the Company or its licensees will achieve commercial success since several factors will determine this, including clinical performance of the product, approved indication, competitive environment, pricing and reimbursement. There is no guarantee that after regulatory approval reimbursement authorities will agree to cover the cost of the product. Delays in reimbursement or its denial will in turn delay or slow down adoption of the product in the market.

## **2.2 Risks related to laws, regulations and litigation**

### **The Company may be subject to litigation and disputes that could have a material and adverse effect on the Company's business, financial condition, results of operations, cash flows, time to market and prospects**

The Company may in the future be involved from time to time in litigation and disputes. The operating hazards inherent in the Company's business may expose the Company to, amongst other things, litigation, including personal injury litigation, intellectual property litigation, contractual litigation, environmental litigation, tax or securities litigation, as well as other litigation that arises in the ordinary course of business.

There can be no guarantee that the Company's construction and interpretation of the agreements to which it is a party are agreed by the counter-party. As is the general rule, in the event of a dispute over the construction and interpretation of provisions of an agreement to which the Company is a party, the agreement must be construed and interpreted according to the governing law specified in that agreement. In the event the dispute cannot be settled by mutual agreement, it will be referred to the courts or to arbitration for resolution as specified in the particular agreement. It cannot be guaranteed that the Company's viewpoint will prevail in any such court or arbitration proceedings.

The Company is currently not involved in any litigation. However, it may in the future be involved in litigation matters from time to time. The Company cannot predict with certainty the outcome or effect of any claim or other litigation matter. The ultimate outcome of any litigation matter and the potential costs associated with prosecuting or defending such lawsuits, including the diversion of the Management's attention to these matters, could have a material and adverse effect on the Company's business, financial condition, results of operations, cash flows, time to market and prospects.

### **The Company is exposed to risks related to regulatory processes and changes in regulatory environment**

Cancer therapies are sometimes characterized as first line, second line or third line, and the FDA and EMA often approve new therapies initially only for third line use. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, surgery, radiotherapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. The Company expects to seek approval of its product candidates in both previously treated and newly diagnosed patients.

Further, the Company's operations could be affected by changes in legal protections and remedies pertaining to intellectual property, trade regulations and procedures and actions affecting approval, production, pricing, reimbursement and marketing of products, as well as by unstable governments and legal systems and inter-governmental disputes. Any of these changes could adversely affect the Company's business, financial condition, results of operations, cash flows, time to market and prospects.



**Even if the Company obtains regulatory approval for a drug candidate, the Company's products will remain subject to regulatory scrutiny**

Any drug candidate for which the Company obtains marketing approval, along with the manufacturing processes, qualification testing, post-approval clinical data, labelling and promotional activities for such product, will be subject to continuous and additional requirements of the different national and regional regulatory authorities. These requirements include submissions of safety and other post-marketing information, reports, registration and listing requirements, good manufacturing practices, or good manufacturing processes ("GMP")<sup>3</sup> requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and recordkeeping. Even if marketing approval of a drug candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. The different regulatory authorities closely regulate the post-approval marketing and promotion of pharmaceutical and biological products to ensure such products are marketed only for the approved indications and in accordance with the provisions of the approved labelling.

In addition, late discovery of previously unknown problems with the Company's products, manufacturing processes, or failure to comply with regulatory requirements, may lead to various adverse results, including, but not limited to, restrictions on such products, manufacturers or manufacturing processes, requirements to conduct post-marketing clinical trials, withdrawal of the products from the market, refusal to approve pending applications or supplements to approve applications that the Company submits and refusals to permit the import or export of the Company's products.

The regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of the Company's drug candidates. If the Company is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if the Company is not able to maintain regulatory compliance, it may lose any marketing approval that it may have obtained, which would adversely affect the Company's business, prospects and ability to achieve or sustain profitability.

**2.3 Risks related to financing and market risk**

**The Company will require additional financing to achieve its goals, and a failure to obtain this necessary capital when needed could force the Company to delay, limit, reduce or terminate its product development or commercialisation efforts**

The Company's operations have consumed substantial amounts of cash since inception. The Company expects to continue to spend substantial amounts to continue the clinical development of its product candidates. The exact amounts needed are unknown. If the Company is able to gain regulatory approval for any of its product candidates, it will require significant additional amounts of cash in order to launch and commercialise any such product candidates. In addition, other unanticipated costs may arise. Because the design and outcome of the Company's planned and anticipated clinical trials is highly uncertain, the Company cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialisation of its product candidates. Significantly additional amounts of cash must be raised to enable the Company to complete such development and commercialisation.

The Company's future capital requirements depend on many factors, including but not limited to:

- the scope, progress, results and costs of researching and developing the Company's product candidates, and conducting preclinical studies and clinical trials;
- the size of the organization needed to take product candidates through clinical trials and potentially commercialisation;
- the timing of, and the costs involved in, obtaining regulatory approvals for the Company's product candidates if clinical trials are successful;

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<sup>3</sup> "Good Manufacturing Practices" is defined as practices that are required in order to conform to guidelines recommended by agencies that control authorization and licensing for manufacture and sale of food, drug products, and active pharmaceutical products. These guidelines provide minimum requirements that a pharmaceutical or a food product manufacturer must meet to assure that the products are of high quality and do not pose any risk to the consumer or public. Good manufacturing practices, along with good laboratory practices and good clinical practices, are overseen by regulatory agencies in the United States, Canada, Europe, China, in addition to other countries.

- the cost of commercialisation activities for the Company’s product candidates, if any of its product candidates is approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing the Company’s product candidates for clinical trials in preparation for regulatory approval and in preparation for commercialisation;
- the Company’s ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt and amount of sales of, or royalties on, the Company’s future products, if any; and
- the emergence of competing cancer therapies and other adverse market developments.

Adequate sources of capital funding may not be available when needed or may not be available on favourable terms. The Company’s ability to obtain such additional capital or financing will depend in part upon prevailing market conditions as well as conditions of its business and its operating results, and those factors may affect its efforts to arrange additional financing on satisfactory terms. If the Company raises additional funds by issuing additional Shares or other equity or equity-linked securities, it may result in a dilution of the holdings of existing shareholders. If funding is insufficient at any time in the future, the Company may have to delay, reduce the scope of or suspend one or more of its clinical trials or research and development programs or its commercialisation efforts, which could have a material adverse effect on the Company’s business, financial condition, results of operations, cash flows, time to market and prospects.

**Future debt levels could limit the Company’s flexibility to obtain additional financing and pursue other business opportunities**

The Company currently has no long term debt, but the Company may incur indebtedness in the future. This level of future debt could have important consequences to the Company, including the following:

- the Company’s ability to obtain additional financing for working capital, capital expenditures, acquisitions or other purposes may be impaired or such financing may be unavailable on favourable terms;
- the Company’s costs of borrowing could increase as it becomes more leveraged;
- the Company may need to use a substantial portion of its cash from operations to make principal and interest payments on its debt, reducing the funds that would otherwise be available for operations, future business opportunities and dividends to its shareholders;
- the Company’s future debt level could make it more vulnerable than its competitors with less debt to competitive pressures, a downturn in its business or the economy generally; and
- the Company’s debt level may limit its flexibility in responding to changing business and economic conditions.

The Company’s ability to service its future debt will depend upon, among other things, its future financial and operating performance, which will be affected by prevailing economic conditions as well as financial, business, regulatory and other factors, some of which are beyond its control. If the Company’s operating income is not sufficient to service its current or future indebtedness, the Company will be forced to take action such as reducing or delaying its business activities, acquisitions, investments or capital expenditures, selling assets, restructuring or refinancing its debt or seeking additional equity capital. The Company may not be able to affect any of these remedies on satisfactory terms, or at all.

**Interest rate fluctuations could in the future affect the Company’s cash flow and financial condition in addition to the price of the Shares**

Currently, the Company has no long-term debt. However, the Company may in the future be exposed to interest rate risk primarily in relation to any future interest bearing debt issued at floating interest rates and to variations in interest rates on bank deposits. Consequently, movements in interest rates could in such event have material adverse effects on the Company’s business, financial condition, results of operations, cash flows, time to market and prospects. The

Company would for future interest bearing debt try to minimize such interest rate risk by depositing funds in a number of financial institutions, and by using fixed interest rate deposits.

### **The Company's results will be exposed to exchange rate risks**

The value of non-Norwegian currency denominated revenues and costs will be affected by changes in currency exchange rates or exchange control regulations. The Company undertakes various transactions in foreign currencies and is consequently exposed to fluctuations in exchange rates. The exposure arises largely from research and clinical expenses. The Company is mainly exposed to fluctuations in euro ("EUR"), pounds sterling ("GBP") and U.S. Dollar ("USD").

### **The Company may encounter financial reporting risk**

As part of its responsibility to prevent and detect errors and fraud affecting its financial statements, the Company's management has set up specific accounting and reporting procedures in relation to, amongst other things, revenue recognition process, taxation and other complex accounting issues. Any failure to prevent and detect errors and fraud within the implementation of such procedures may affect its reputation, business, financial results as well as its ability to meet its objectives.

## **2.4 Risks related to the Shares**

### **The market value of the Shares may fluctuate significantly, which could cause investors to lose a significant part of their investment**

An investment in the Shares may decrease in market value as well as increase. The market volume of the Shares could fluctuate significantly in response to a number of factors beyond the Company's control, including, changes in financial estimates and investment recommendations or ratings by securities analysts, announcements by the Company or its competitors of new product and service offerings, significant contracts, acquisitions or strategic relationships, publicity about the Company, its products and services or its competitors, lawsuits against the Company, unforeseen liabilities, changes in management, changes to the regulatory environment in which it operates or general market conditions.

### **Future sales, or the possibility for future sales, of substantial numbers of Shares may affect the Shares' market price**

The Company cannot predict what effect, if any, future sales of the Shares, or the availability of Shares for future sales, will have on the market price of the Shares. Sales of substantial amounts of the Shares in the public market, or the perception that such sales could occur, may adversely affect the market price of the Shares, making it more difficult for holders to sell their Shares or the Company to sell equity securities in the future at a time and price that they deem appropriate.

### **Future issuances of Shares or other securities may dilute the holdings of shareholders and could materially affect the price of the Shares**

The Company may in the future decide to offer additional Shares or other securities in order to finance new capital-intensive projects, in connection with unanticipated liabilities or expenses or for any other purposes. There can be no assurance the Company will not decide to conduct further offerings of securities in the future. Depending on the structure of any future offering, certain existing shareholders may not be able to purchase additional equity securities. If the Company raises additional funds by issuing additional equity securities, holdings and voting interests of existing shareholders may be diluted.

### **Pre-emptive rights to secure and pay for Shares in additional issuance could be unavailable to U.S. or other shareholders**

Under Norwegian law, unless otherwise resolved at the Company's general meeting of shareholders (the "General Meeting"), existing shareholders have pre-emptive rights to participate on the basis of their existing ownership of Shares in the issuance of any new Shares for cash consideration. Shareholders in the United States, however, could be unable to exercise any such rights to subscribe for new Shares unless a registration statement under the U.S. Securities Act is in effect in respect of such rights and Shares or an exemption from the registration requirements under the U.S. Securities Act is available. Shareholders in other jurisdictions outside Norway could be similarly affected if the rights and the new Shares being offered have not been registered with, or approved by, the relevant authorities in such jurisdiction. The Company is under no obligation to file a registration statement under the U.S. Securities Act or seek similar approvals

under the laws of any other jurisdiction outside Norway in respect of any such rights and Shares, and doing so in the future could be impractical and costly. Accordingly, there is no assurance that shareholders residing or domiciled in the United States will be able to participate in future capital increases or rights offerings. To the extent that the Company's shareholders are not able to exercise their rights to subscribe for new Shares, their proportional interests in the Company will be diluted.

**Investors could be unable to exercise their voting rights for Shares registered in a nominee account**

Beneficial owners of Shares that are registered in a nominee account (such as through brokers, dealers or other third parties) could be unable to vote such Shares unless their ownership is re-registered in their names with the VPS prior to any General Meeting. There is no assurance that beneficial owners of the Shares will receive notice of any General Meeting in time to instruct their nominees to either effect a re-registration of their Shares or otherwise vote their Shares in the manner desired by such beneficial owners.

**The transfer of Shares is subject to restrictions under the securities laws of the United States and other jurisdictions**

The Shares have not been registered under the U.S. Securities Act or any U.S. state securities laws or any other jurisdiction outside Norway and are not expected to be registered in the future. As such, the Shares may not be offered or sold except pursuant to an exemption from, or in transactions not subject to, the registration requirements of the U.S. Securities Act and other applicable securities laws. See Section 16 "Selling and transfer restrictions". In addition, there is no assurance that shareholders residing or domiciled in the United States will be able to participate in future capital increases or rights offerings.

**The Company's ability to pay dividends is dependent on the availability of distributable reserves and the Company may be unable or unwilling to pay any dividends in the future**

Norwegian law provides that any declaration of dividends must be adopted by the shareholders at the General Meeting. Dividends may only be declared to the extent that the Company has distributable funds and the Company's Board of Directors finds such a declaration to be prudent in consideration of the size, nature, scope and risks associated with the Company's operations and the need to strengthen its liquidity and financial position. As the Company's ability to pay dividends is dependent on the availability of distributable reserves, the Company may, among other things, be dependent upon receipt of dividends and other distributions of value from its subsidiaries and companies in which the Company may invest, if any. As a general rule, the General Meeting may not declare higher dividends than the Board of Directors has proposed or approved. If, for any reason, the General Meeting does not declare dividends in accordance with the above, a shareholder will, as a general rule, have no claim in respect of such non-payment, and the Company will, as a general rule, have no obligation to pay any dividend in respect of the relevant period.

The Company is focusing on the development of pharmaceutical products and does not anticipate paying any dividend until sustainable profitability is achieved. In addition, the Company may choose not, or may be unable, to pay dividends in future years. The amount of dividends paid by the Company, if any, for a given financial period, will depend on, among other things, the Company's future operating results, cash flows, financial position, capital requirements, the sufficiency of its distributable reserves, credit terms, general economic conditions, legal restrictions (as set out in Section 6.2 "Legal constraints on the distribution of dividends") and other factors that the Company may deem to be significant from time to time.

**Investors could be unable to recover losses in civil proceedings in jurisdictions other than Norway**

The Company is a public limited company organised under the laws of Norway. Some of the Board Members and the members of the Management reside outside of Norway, specifically Hilde Furberg (Board member), Susan Foden (Board member), Anthony Brown (Director of Research) and Murray Yule (Clinical Development Officer). As a result, it may not be possible for investors to effect service of process in other jurisdictions upon such persons or the Company, to enforce against such persons or the Company judgments obtained in courts outside the relevant Board Members' jurisdiction of domicile including any judgments obtained in non-Norwegian courts, or to enforce judgments on such persons or the Company in other jurisdictions.

**Norwegian law could limit shareholders' ability to bring an action against the Company**

The rights of holders of the Shares are governed by Norwegian law and by the Articles of Association. These rights may

differ from the rights of shareholders in other jurisdictions. In particular, Norwegian law limits the circumstances under which shareholders of Norwegian companies may bring derivative actions. For instance, under Norwegian law, any action brought by the Company in respect of wrongful acts committed against the Company will be prioritized over actions brought by shareholders claiming compensation in respect of such acts. In addition, it could be difficult to prevail in a claim against the Company under, or to enforce liabilities predicated upon, securities laws in other jurisdictions.

**Exchange rate fluctuations could adversely affect the value of the Shares and any dividends paid on the Shares for an investor whose principal currency is not NOK.**

The Shares are priced and traded in NOK on the Oslo Stock Exchange and any future payments of dividends on the Shares will be denominated in NOK. Investors registered in the VPS whose address is outside Norway and who have not supplied the VPS with details of any NOK account or linked a local cash account and swift address to their local bank, will, however, receive dividends by cheque in their local currency, as exchanged from the NOK amount distributed through the VPS. If it is not practical in the sole opinion of DNB Bank ASA, being the Company's VPS registrar, to issue a cheque in a local currency, a cheque will be issued in USD. The issuing and mailing of cheques will be executed in accordance with the standard procedures of DNB Bank ASA. The current policy of DNB Bank ASA is to apply the exchange rate(s) on the date of issuance, and there is no guarantee that DNB Bank ASA will not adopt an alternative policy in the future. Exchange rate movements of NOK will therefore affect the value of these dividends and distributions for investors whose principal currency is not NOK. Further, the market value of the Shares as expressed in foreign currencies will fluctuate in part as a result of foreign exchange fluctuations. This could affect the value of the Shares and of any dividends paid on the Shares for an investor whose principal currency is not NOK.

**Market interest rates could influence the price of the Shares.**

One of the factors that could influence the price of the Shares is its annual dividend yield as compared to yields on other financial instruments. Thus, an increase in market interest rates will result in higher yields on other financial instruments, which could adversely affect the price of the Shares.

### **3 RESPONSIBILITY FOR THE PROSPECTUS**

This Prospectus has been prepared in connection with the listing of the New Shares on the Oslo Stock Exchange.

The Board of Directors of BerGenBio ASA accepts responsibility for the information contained in this Prospectus. The members of the Board of Directors confirm that, after having taken all reasonable care to ensure that such is the case, the information contained in this Prospectus is, to the best of their knowledge, in accordance with the facts and contains no omission likely to affect its import.

29 August 2018

#### **The Board of Directors of BerGenBio ASA**

Stein Holst Annexstad  
*Chairman*

Hilde Furberg  
*Board Member*

Stener Kvinnsland  
*Board Member*

Jon Øyvind Eriksen  
*Board Member*

Susan Foden  
*Board Member*

Sveinung Hole  
*Board Member*

Kari Grønås  
*Board member*

## **4 GENERAL INFORMATION**

### **4.1 Other important investor information**

The Company has furnished the information in this Prospectus.

This Prospectus is personal to each Option Holder and does not constitute or form a part of any public offer or solicitation to purchase or subscribe for securities in the Company. The New Shares may only be subscribed by Option Holders pursuant to the terms of the Share Option Programmes of the Group.

Neither the Company, nor any of their respective representatives or advisers, is making any representation to any offeree or purchaser of the New Shares regarding the legality of an investment in the New Shares by such offeree or purchaser under the laws applicable to such offeree or purchaser. Each prospective investor should consult with his or her own advisors as to the legal, tax, business, financial and related aspects of a purchase of the New Shares.

**Investing in the New Shares involves a high degree of risk. See Section 2 "Risk factors" beginning on page 11.**

### **4.2 Presentation of financial and other information**

#### *4.2.1 Financial information*

The financial information contained in this Prospectus related to the Group has been derived from the Group's audited consolidated financial statements as of, and for the years ended, 31 December 2017 and 2016 (the "**Financial Statements**") and the Group's unaudited interim consolidated financial statements as of, and for the six months' periods ended, 30 June 2018 and 2017 (the "**Interim Financial Statements**").

The Financial Statements have been prepared in accordance with International Financial Reporting Standards as adopted by the EU ("**IFRS**"), while the Interim Financial Statements have been prepared in accordance with International Accounting Standard 34 "Interim Financial Reporting" as adopted by the EU ("**IAS 34**"). The Financial Statements have been audited by Ernst & Young AS ("**EY**"), as set forth in their reports thereon included herein. The Interim Financial Statements have not been audited.

The Financial Statements and the Interim Financial Statements are together referred to as the "Financial Information". The Financial Information is incorporated by reference hereto, see Section 17.3 "Incorporation by reference".

#### *4.2.2 Industry and market data*

This Prospectus contains statistics, data, statements and other information relating to markets, market sizes, market shares, market positions and other industry data pertaining to the Group's business and the industries and markets in which the Group operates. Unless otherwise indicated, such information reflects the Group's estimates based on analysis of multiple sources, including data compiled by professional organisations, consultants and analysts and information otherwise obtained from other third party sources, such as annual and interim financial statements and other presentations published by listed companies operating within the same industry as the Group, as well as the Group's internal data and its own experience, or on a combination of the foregoing. Unless otherwise indicated in the Prospectus, the basis for any statements regarding the Group's competitive position is based on the Company's own assessment and knowledge of the market in which it operates.

The Company confirms that where information has been sourced from a third party, such information has been accurately reproduced and that as far as the Company is aware and is able to ascertain from information published by that third party, no facts have been omitted that would render the reproduced information inaccurate or misleading. Where information sourced from third parties has been presented, the source of such information has been identified. The Company does not intend, and does not assume any obligations to update industry or market data set forth in this Prospectus.

Industry publications or reports generally state that the information they contain has been obtained from sources believed to be reliable, but the accuracy and completeness of such information is not guaranteed. The Company has not independently verified and cannot give any assurances as to the accuracy of market data contained in this Prospectus that was extracted from these industry publications or reports and reproduced herein. Market data and statistics are inherently predictive and subject to uncertainty and not necessarily reflective of actual market conditions. Such statistics are based on market research, which itself is based on sampling and subjective judgments by both the researchers and the respondents, including judgments about what types of products and transactions should be included in the relevant market.

As a result, prospective investors should be aware that statistics, data, statements and other information relating to markets, market sizes, market shares, market positions and other industry data in this Prospectus and projections, assumptions and estimates based on such information may not be reliable indicators of the Group's future performance and the future performance of the industry in which it operates. Such indicators are necessarily subject to a high degree of uncertainty and risk due to the limitations described above and to a variety of other factors, including those described in Section 2 "Risk factors" and elsewhere in this Prospectus.

#### 4.2.3 Other information

In this Prospectus, all references to "**NOK**" are to the lawful currency of Norway, all references to "**GBP**" are to the lawful currency of the United Kingdom, all references to "**CHF**" are to the lawful currency of Switzerland, all references to "**USD**" are to the lawful currency of the United States and all references to "**EUR**" are to the lawful common currency of the member states of the European Union (the "**EU**") who have adopted the Euro as their sole national currency.

#### 4.2.4 Rounding

Certain figures included in this Prospectus have been subject to rounding adjustments (by rounding to the nearest whole number or decimal or fraction, as the case may be). Accordingly, figures shown for the same category presented in different tables may vary slightly. As a result of rounding adjustments, the figures presented may not add up to the total amount presented.

### 4.3 Cautionary note regarding forward-looking statements

This Prospectus includes forward-looking statements that reflect the Company's current views with respect to future events and financial and operational performance. These forward-looking statements may be identified by the use of forward-looking terminology, such as the terms "anticipates", "assumes", "believes", "can", "could", "estimates", "expects", "forecasts", "intends", "may", "might", "plans", "projects", "should", "will", "would" or, in each case, their negative, or other variations or comparable terminology. These forward-looking statements are not historic facts. They appear in the following Sections in this Prospectus, Section 7 "Industry and market overview", Section 8 "Business of the Company" and Section 10 "Selected Financial and Other Information", and include statements regarding the Company's and Group's intentions, beliefs or current expectations concerning, among other things, financial strength and position of the Group, operating results, liquidity, prospects, growth, the implementation of strategic initiatives, as well as other statements relating to the Group's future business development and financial performance, and the industry in which the Group operates.

Prospective investors in the Shares are cautioned that forward-looking statements are not guarantees of future performance and that the Group's actual financial position, operating results and liquidity, and the development of the industry in which the Group operates, may differ materially from those made in, or suggested by, the forward-looking statements contained in this Prospectus. The Company cannot guarantee that the intentions, beliefs or current expectations upon which its forward-looking statements are based will occur.

These forward-looking statements speak only as at the date on which they are made. The Company undertakes no obligation to publicly update or publicly revise any forward-looking statement, whether as a result of new information, future events or otherwise. All subsequent written and oral forward-looking statements attributable to the Company or to persons acting on the Company's behalf are expressly qualified in their entirety by the cautionary statements referred to above and contained elsewhere in this Prospectus.



## **5 REASONS FOR THE LISTING OF THE NEW SHARES**

The New Shares may only be subscribed by Option Holders pursuant to the terms of the Share Option Programmes of the Group. This Prospectus will be valid for up until 12 months from 29 August 2018, and would thus apply to the 2,715,000 options which are vested as of the date of this Prospectus, and the additional 145,012 options which will be vested during the 12 months from 29 August 2018, in total 2,860,012 options under the Share Option Programmes.

The Group's Share Option Programmes are intended 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 Share Option Programmes, in addition to some Board Members. The Share Option Programmes also serves to retain and attract senior management.

The net proceeds from New Shares issued to Option Holders would be modest and will be used towards administrative activities including general corporate purposes.

See Section 11.5.2 "Share Option Programmes" for more information regarding the Share Option Programmes.

## **6 DIVIDENDS AND DIVIDEND POLICY**

### **6.1 Dividend policy**

In deciding whether to propose a dividend and in determining the dividend amount, the Board of Directors will take into account legal restrictions, as set out in the Norwegian Public Limited Companies Act (see Section 6.2 “Legal constraints on the distribution of dividends”), the Company’s capital requirements, including capital expenditure requirements, its financial condition, general business conditions and any restrictions that its contractual arrangements in place at the time of the dividend may place on its ability to pay dividends and the maintaining of appropriate financial flexibility. Except in certain specific and limited circumstances set out in the Norwegian Public Limited Companies Act, the amount of dividends paid may not exceed the amount recommended by the Board of Directors.

The Company has not paid any dividends during its lifetime. The Company is focusing on the development of novel pharmaceutical products and does not anticipate paying any dividend until sustainable profitability is achieved.

There can be no assurance that a dividend will be proposed or declared in any given year.

### **6.2 Legal constraints on the distribution of dividends**

Dividends may be paid in cash, or in some instances, in kind. The Norwegian Public Limited Companies Act provides the following constraints on the distribution of dividends applicable to the Company:

- Section 8-1 of the Norwegian Public Limited Companies Act provides that the Company may distribute dividends to the extent that the Company’s net assets following the distribution cover (i) the share capital, (ii) the reserve for valuation variances and (iii) the reserve for unrealised gains. The amount of any receivable held by the Company which is secured by a pledge over Shares in the Company, as well as the aggregate amount of credit and security which, pursuant to Section 8-7 to Section 8-10 of the Norwegian Public Limited Companies Act fall within the limits of distributable equity, shall be deducted from the distributable amount.

The calculation of the distributable equity shall be made on the basis of the balance sheet included in the approved annual accounts for the last financial year, provided, however, that the registered share capital as of the date of the resolution to distribute dividends, shall be applied. Following the approval of the annual accounts for the last financial year, the General Meeting may also authorise the Board of Directors to declare dividends on the basis of the Company’s annual accounts. Dividends may also be resolved by the General Meeting based on an interim balance sheet which has been prepared and audited in accordance with the provisions applying to the annual accounts and with a balance sheet date not further into the past than six months before the date of the General Meeting’s resolution.

- Dividends can only be distributed to the extent that the Company’s equity and liquidity following the distribution is considered sound.

The Norwegian Public Limited Companies Act does not provide for any time limit after which entitlement to dividends lapses. Subject to various exceptions, Norwegian law provides a limitation period of three years from the date on which an obligation is due. There are no dividend restrictions or specific procedures for non-Norwegian resident shareholders to claim dividends. For a description of withholding tax on dividends applicable to non-Norwegian residents, see Section 14 “Taxation”.

### **6.3 Manner of dividend payments**

Any future payments of dividends on the Shares will be denominated in NOK, and will be paid to the shareholders through the VPS. Investors registered in the VPS whose address is outside Norway and who have not supplied the VPS with details of any NOK account or linked a local cash account and swift address to their local bank, will however receive dividends by cheque in their local currency, as exchanged from the NOK amount distributed through the VPS. If it is not practical in the sole opinion of DNB Bank ASA, DNB Markets, being the Company’s VPS registrar, to issue a cheque in a local currency, a cheque will be issued in USD. The issuing and mailing of cheques will be executed in accordance with the standard procedures of DNB Bank ASA. The exchange rate(s) that currently is applied is DNB Bank ASA’s rate on the date of issuance. Dividends will be credited automatically to the VPS registered shareholders’ NOK accounts, or in lieu of such registered NOK account, by cheque, without the need for shareholders to present documentation proving their ownership of the Shares.

## 7 INDUSTRY AND MARKET OVERVIEW

This section seeks to describe relevant industry dynamics and the potential market for BerGenBio’s products. However, as mentioned in chapter 2 “Risk Factors”, BerGenBio does not yet have any commercial, marketable products. In order to introduce the Company’s lead compound bemcentinib and/or other product candidates to the oncology market they will require, amongst others, additional clinical testing. Upon successful clinical trials, the Company is also dependent on regulatory approval for the relevant markets before they are eligible for sale to patients. In summary, the Company’s ability to develop, obtain regulatory approval for, and successfully commercialise bemcentinib effectively will depend on several factors, including, but not limited to, the following:

- successful completion of the clinical trials;
- receipt of marketing approvals;
- establishing commercial manufacturing and supply arrangements;
- establishing a commercial infrastructure;
- acceptance of the product by patients, the medical community and third-party payers;
- successfully establishing an adequate market share in competition with other therapies;
- successfully executing the Company’s pricing and reimbursement strategy;
- a continued acceptable safety and adverse event profile of the product following regulatory approval; and
- identifying, registering, maintaining, enforcing and defending IPR and claims covering the product.

Importantly, the Company is not permitted to market or promote any of its product candidates before it receives regulatory approvals from the FDA to market in the U.S. and from the EMA to market in Europe, as well as equivalent regulatory authorities in other jurisdictions to commercialise in those regions. Although BerGenBio expects to obtain such regulatory approvals necessary to commercialise the final products, this cannot be assured.

### 7.1 The oncology market

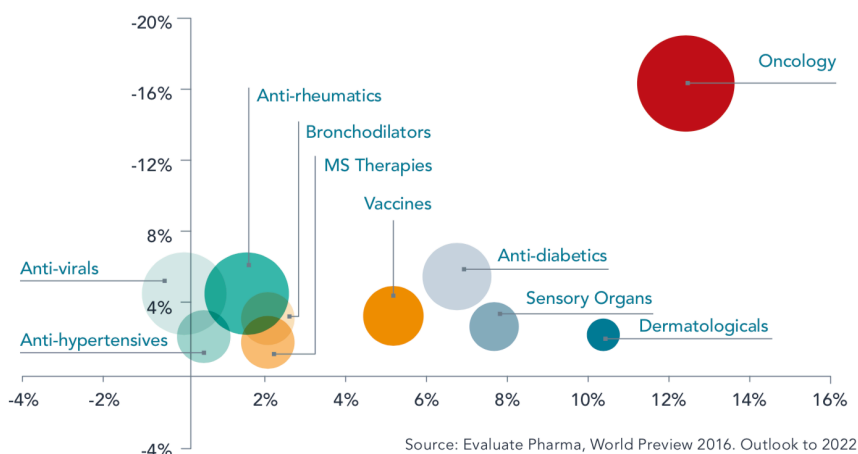
#### 7.1.1 The oncology market size and growth

Measured in sales, oncology is the world’s largest therapeutic area<sup>4</sup>. According to estimates from QuantilesIMS (formerly IMS Institute), the global oncology market reached USD 107 billion in 2015 and is expected to grow with a compound aggregate growth rate (“CAGR”) of between 7.5-10.5 % to reach USD 148-178 billion by 2020<sup>5</sup>.

The chart below illustrates Evaluate Pharma’s expected top 10 therapeutic areas in 2022. The size of the bubble represents 2015 worldwide sales, whilst worldwide market share and 2015-2022 revenue growth is measured on the vertical and horizontal axis respectively. As illustrated, oncology is expected to remain a significant medical field, maintaining a relatively high market share through revenue growth.

Figure 1: Expected top 10 therapeutic areas in 2022

### Expected top 10 therapeutic areas in 2022

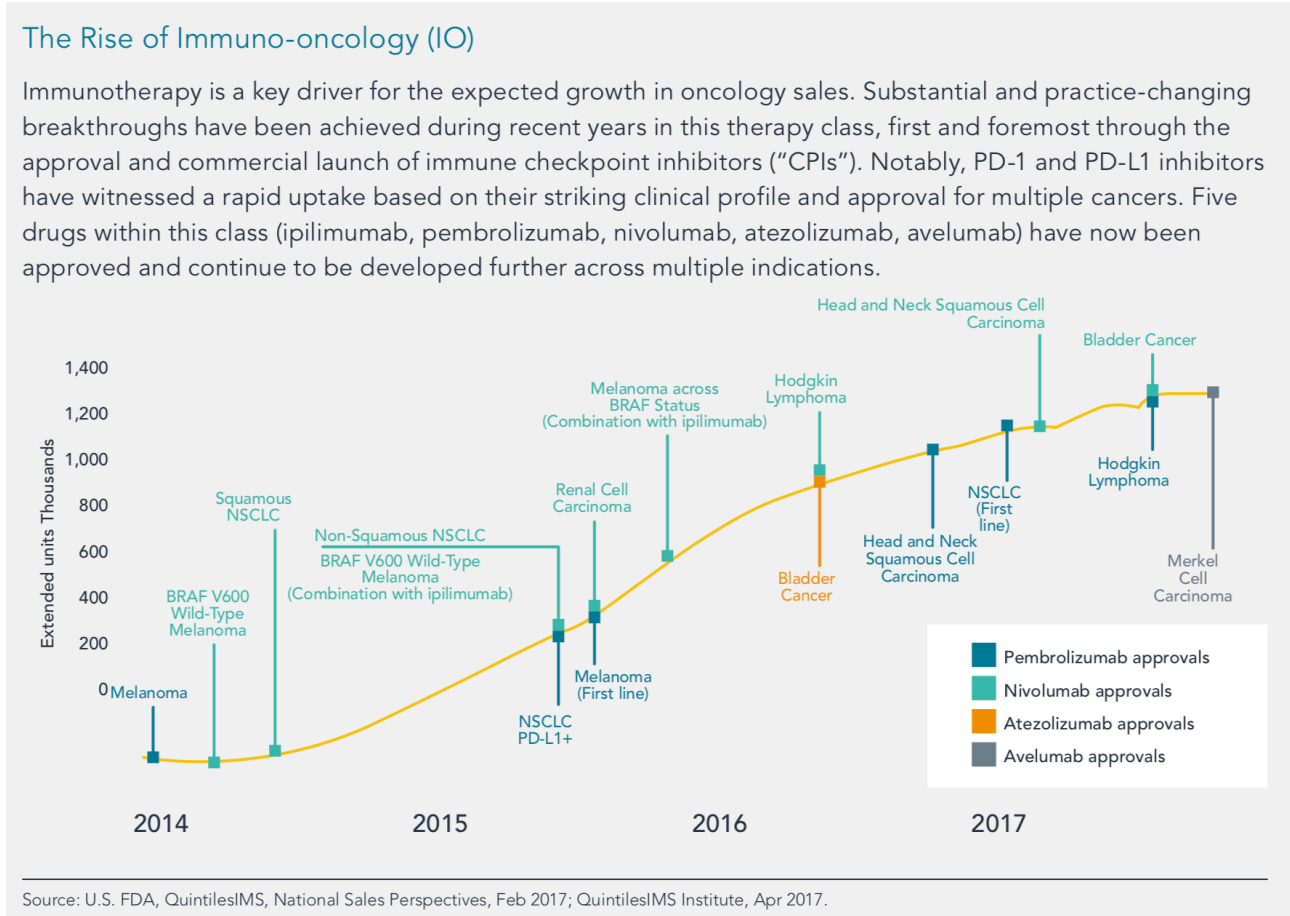


<sup>4</sup> IMS Health, Top 20 Global Therapy Areas 2015, Nov 2015

<sup>5</sup> IMS Institute For Healthcare and Informatics, Global Oncology Trend Report – A Review of 2015 and Outlook to 2020 (June 2016)

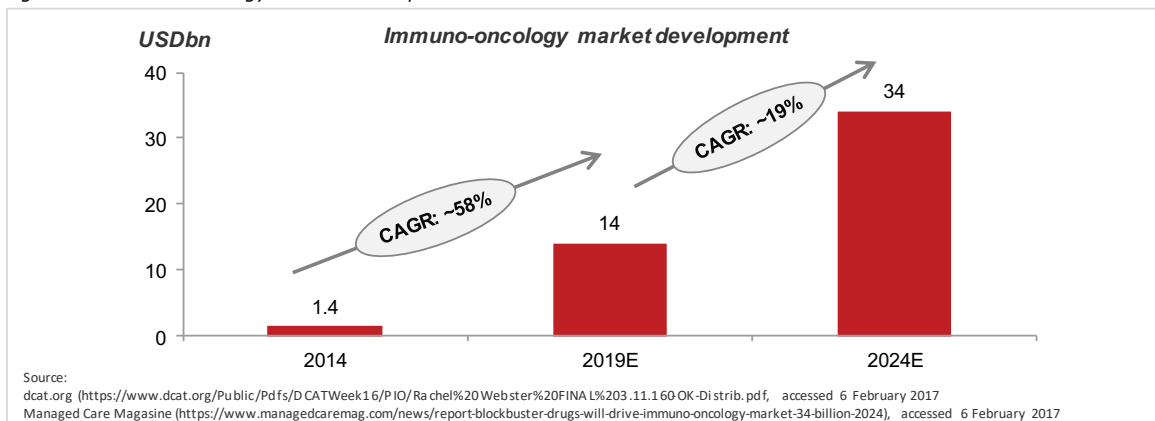
Several publications point to the area of immunotherapy as one of the key drivers for the expected growth in oncology sales<sup>6</sup>. This is an area in which substantial breakthroughs have been achieved during the last recent years, first and foremost through the approval and commercial launch of immune checkpoint inhibitors (“**CPIs**”):

Figure 2: The Rise of Immuno-oncology (IO)



As depicted in the graph below, sales within this drug category are forecasted to increase significantly over the 10 year period from 2014 to 2024 (aggregated figures for the seven major markets U.S., France, Germany, Italy, Spain, the UK and Japan):

Figure 3: Immuno-oncology market development

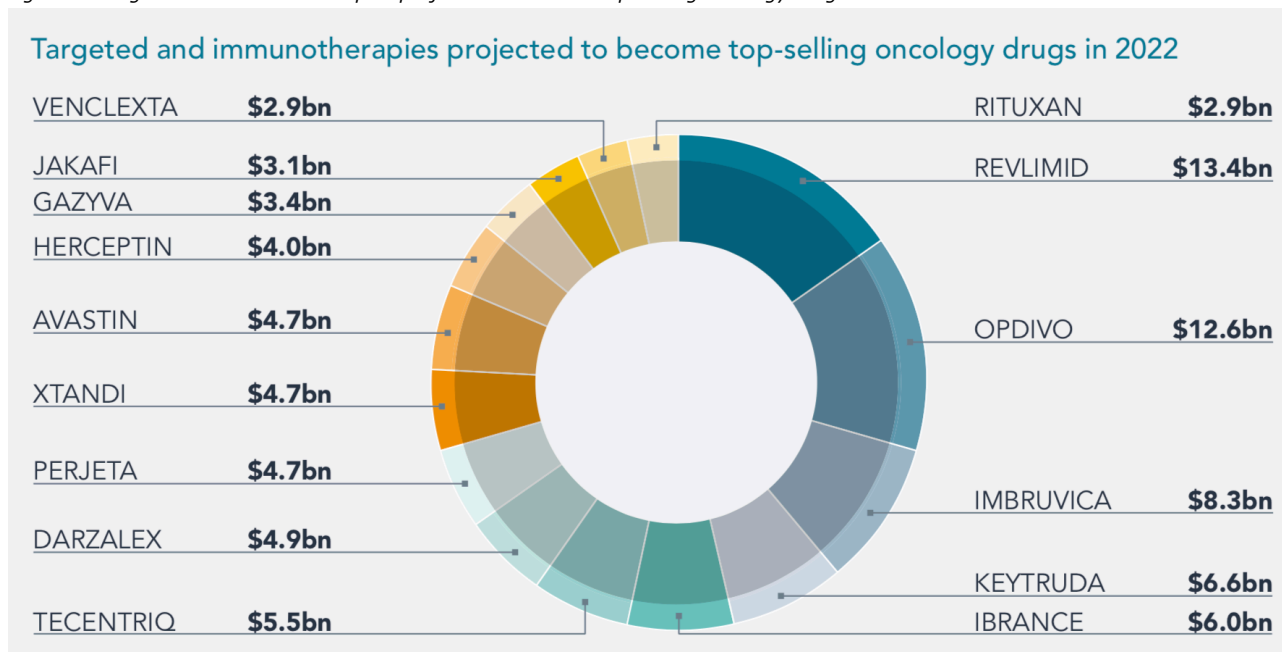


This fact is also prevalent when looking at which products currently on the market that are expected to dominate over the coming 5 year horizon. In the following forecasts for 2022, sales of several immunomodulatory and

<sup>6</sup> Including e.g. Radiant Insights (<http://www.radiantinsights.com/research/global-cancer-immunotherapies-market-to-2022>) and Research and Markets (<http://www.prnewswire.com/news-releases/global--usa-cancer-immunotherapy-market-analysis-2015---forecasts-to-2020-300157219.html>), both accessed 26 June 2018

immunotherapy drugs are expected to have multibillion sales (USD), including e.g. REVLIMID, OPDIVO and Keytruda™:

Figure 4: Targeted and immunotherapies projected to become top-selling oncology drugs in 2022



Source: BerGenBio ASA Annual Report 2017 page 22

### 7.1.2 Different types of cancer

According to the World Health Organisation (“WHO”), an estimated 8.2 million cancer deaths occurred in 2012, making cancer a leading cause of death worldwide<sup>7</sup>. WHO estimates that there were approximately 14 million new cases of cancer in 2012, and this number is expected to rise by about 70% over the next two decades<sup>8</sup>. By 2030, the American Cancer Society expects the number of global annual deaths by cancer to increase to 13.0 million<sup>9</sup>.

There are more than 100 different types of cancer<sup>10</sup>, and they are often named after the organs or tissues where they start to grow from, or by the type of cell that formed them. According to the National Cancer Institute, cancers can be categorised according to the specific cell type it develops from: **Carcinomas** are the most common type of cancer which begins in the skin or in tissues that line or cover internal organs. **Sarcoma** is another type of cancer that form in the bone and soft tissue of the body like muscle, fat, and blood vessels. Cancers that form in the blood-forming tissue of the bone marrow are called **leukaemia**. These cancers do not form solid tumours, but rather form large numbers of abnormal white blood cells that crowd out normal blood cells, which reduces the body’s ability to get oxygen to tissue, control bleeding and fight infections. Another type of cancer is **lymphoma**. Lymphoma begins in the lymphocytes, which are disease fighting white blood cells (that are part of the immune system), building up abnormal lymphocytes in the lymph nodes and lymph vessels. **Multiple myeloma** is a cancer that begins in plasma cells, a type of white blood cell which is part of the immune system that produces large amounts of a specific antibody<sup>11</sup>. The abnormal plasma cells build up in the bone marrow and form tumours all through the body. **Melanoma** is a skin cancer and begins in the cells that become melanocytes, which are the cells that make melanin, the pigment that gives skin its colour. **Brain and spinal cord tumours** can be divided into several different types depending on the type of cell in which they were formed and where the tumour first appeared in the nervous system<sup>12,13</sup>.

<sup>7</sup> <http://www.who.int/mediacentre/factsheets/fs297/en/>, accessed 26 June 2018

<sup>8</sup> WHO, World Cancer Report 2014, 26 June 2018

<sup>9</sup> Cancer facts and figures 2017, American Cancer Society, 26 June 2018

<sup>10</sup> <http://www.cancer.org/cancer/cancer-basics/what-is-cancer.html>, accessed 26 June 2018

<sup>11</sup> <https://www.cancer.gov/publications/dictionaries/cancer-terms?cdrid=46230>, accessed 26 June 2018

<sup>12</sup> <https://www.cancer.gov/about-cancer/understanding/what-is-cancer>, accessed 26 June 2018

<sup>13</sup> <http://www.cancerresearchuk.org/about-cancer/what-is-cancer/how-cancer-starts/types-of-cancer>, accessed 26 June 2018

## 7.2 Development of cancer treatments

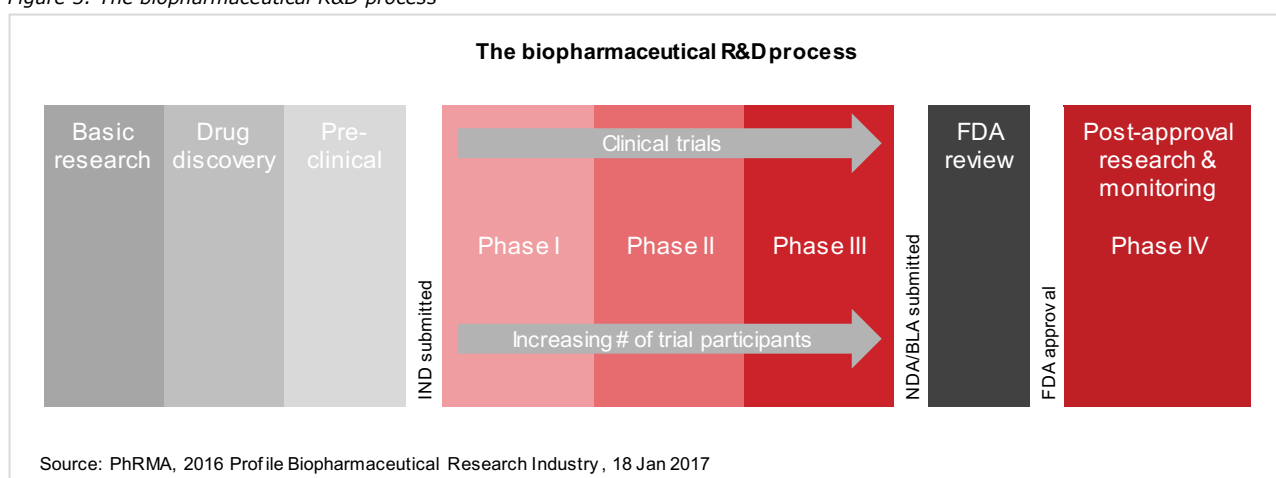
The development of a biopharmaceutical product can be a risk-filled, time consuming and expensive process, which, provided the drug is approved for marketing, has the potential for high returns on investment. On average, five out of 5,000 drugs make it through the preclinical phase, and historically only one out of these five is approved by the FDA for marketing<sup>14</sup>. Pharmaceutical Research and Manufacturers of America (“PhRMA”) estimates that it takes on average 10 years to progress a medicine from drug discovery through FDA approval<sup>15</sup>.

### 7.2.1 The biopharmaceutical R&D process

The process of developing a drug product candidate is divided into several phases. The illustration below gives a basic overview of the biopharmaceutical R&D process. Whilst this is a general description of how drugs progress through the different phases in drug development, it is also applicable for the development of cancer drugs. However, developing cancer drugs can be a shorter process than developing drugs for other uses. For example, a fast track review approach can be applied for, if the drug shows superior efficacy or spares serious side effects compared to treatments that are currently available<sup>16</sup>.

The figure below shows the biopharmaceutical R&D and approval process in the U.S.:

Figure 5: The biopharmaceutical R&D process



The first step is to identify potential biological targets (a specific biomolecule within the cell) which when modulated by a therapeutic intervention may improve the outcome for specific illnesses. Understanding how a disease functions allows scientists to zoom in on specific targets and then look for a compound that could influence the target and potentially become a medicine<sup>17</sup>.

After having discovered a compound, it needs to be determined whether the compound is suitable for further development. The most promising candidates are selected to undergo preclinical testing. To determine the safety profile of the drug, researchers in this phase conduct a series of laboratory and animal studies. At the end of the process, which may take several years, only a few compounds move to testing in humans<sup>18</sup>.

The clinical phase of drug development involves extensive testing of the drug's effect on humans, and is divided into three sub-phases.

### Phase I

In Phase I 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<sup>19</sup>. In Phase I, different doses are given to a small group which is closely supervised. The dose is typically low to start with and then gradually increased, while continuously monitoring how the side effects change.

<sup>14</sup> Medicine Net, Drug Approvals – From Invention to Market... A 12- Year Trip, 18 January 2017

<sup>15</sup> PhRMA, 2015 Profile Biopharmaceutical Research Industry, 18 January 2017

<sup>16</sup> FDA, Accelerated Approval Program, 26 June 2018

<sup>17</sup> <http://www.fda.gov/ForPatients/Approvals/Drugs/ucm405382.htm>, accessed 26 June 2018

<sup>18</sup> <http://www.fda.gov/ForPatients/Approvals/Drugs/ucm405658.htm>, accessed 26 June 2018

<sup>19</sup> <http://www.cancer.net/navigating-cancer-care/how-cancer-treated/clinical-trials/phases-clinical-trials>, accessed 26 June 2018

Data are collected on the dose, timing, and safety of the treatment. It is common to include approximately 10-30 individuals in this phase of clinical testing<sup>20</sup>.

### **Phase Ib**

Phase Ib studies are usually conducted in patients diagnosed with the disease, or condition for which the study drug is intended, who demonstrate some biomarker, surrogate, or possibly clinical outcome that could be considered for "proof of concept". These studies are also used to demonstrate safety when the investigational drug is combined with another drug.

### **Phase II**

In Phase II clinical trials, the goal is to provide more detailed information about the effect of a drug candidate for a specific disease, as well as further granularity regarding the safety of the treatment. The trials are performed on larger groups than in Phase I, and whilst the groups can still be relatively small, they should be large enough to provide satisfactory statistical significance to assess efficacy (typically between 30-120 patients)<sup>21</sup>. Within oncology, Phase II studies are conducted with patients suffering from the cancer the new drug candidate is intended to treat. The results need to show that it is likely to yield clinical benefit and that it is safe when compared to the standard treatment for a drug candidate to be progressed to Phase III<sup>22</sup>. The latter part of Phase II studies – Phase IIb – are well controlled trials to evaluate efficacy and safety in patients with the disease or condition to be treated, diagnosed, or prevented. These clinical trials usually represent the most rigorous demonstration of a medicine's efficacy and are sometimes referred to as pivotal trials or registration-directed clinical trials (the latter term is used in this Prospectus).

### **Phase III**

In Phase III, companies carry out one or several studies with the ambition to generate data that is convincing enough to obtain commercial licensing from the FDA/EMA. A Phase III drug candidate is typically compared to the clinical results of what is currently the standard treatment for the same disease (Standard of Care). The focus is on confirming previous efficacy and safety findings in a larger patient population. A Phase III clinical trial typically involves more than 300 patients, and may take many years to complete<sup>23</sup>.

In the event of a successful Phase III trial, a company can submit a new drug application ("**NDA**") to the FDA requesting approval to market the drug (relevant for the U.S.). The application process is relatively similar in Europe, where the company submits a marketing authorisation application ("**MAA**") to the EMA.

#### *7.2.2 Orphan drug designation*

Health authorities in the U.S., the EU and in Japan can also grant certain drugs an orphan drug designation. This could be the case if the drug treats a disease that only affects a small number of people. This is a way to stimulate R&D on drugs for less common diseases. If a company were to get an orphan drug designation, it can result in a series of advantages for the company, including premium pricing, lower registration fees and extended market exclusivity<sup>24</sup>. The market exclusivity in the U.S. is 7 years from approval, and in the EU 10 years from approval<sup>25</sup>.

#### *7.2.3 Accelerated approval*

If a drug candidate shows extraordinarily promising results, it might receive marketing approval as early as in Phase II. This is often referred to as an accelerated approval ("**AA**"). The AA programme is developed to allow for earlier approval of drugs that treat serious conditions and fill an unmet medical need. If a drug gets an AA, the company is still required to perform further studies to confirm that the drug is delivering the expected clinical benefit. These studies are known as Phase IV confirmatory trials and have to be completed in order to achieve the traditional market approval. If the Phase IV trial does not show that the drug provides clinical benefit, the drug could be removed from the market<sup>26</sup>.

<sup>20</sup> <http://www.cancer.net/navigating-cancer-care/how-cancer-treated/clinical-trials/phases-clinical-trials>, accessed 26 June 2018

<sup>21</sup> <http://www.cancer.net/navigating-cancer-care/how-cancer-treated/clinical-trials/phases-clinical-trials>, accessed 26 June 2018

<sup>22</sup> <http://www.cancer.net/navigating-cancer-care/how-cancer-treated/clinical-trials/phases-clinical-trials>, accessed 26 June 2018

<sup>23</sup> <http://www.cancer.net/navigating-cancer-care/how-cancer-treated/clinical-trials/phases-clinical-trials>, accessed 26 June 2018

<sup>24</sup> FDA, Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review, 26 June 2018

<sup>25</sup> EvaluatePharma, Orphan Drug Report 2015, 26 June 2018

<sup>26</sup> FDA, Accelerated Approval Program, 26 June 2018

### 7.3 Treatment types and their evolution

Due to the high number and diversity of cancer types, the market for cancer therapies is highly diversified. A recommended treatment would depend on the type and stage of the cancer, as well as personal traits of the individual patient. For some patients the overall goal of treatment may be to cure the disease, whilst for others it may be to relieve suffering only. Traditionally the most common treatments have been, amongst others, surgery, chemotherapy, radiation therapy and hormone therapy. In recent years however, approaches such as targeted therapies and immunotherapy have become increasingly relevant<sup>27</sup>. With respect to the last two-year period, the regulatory approval, commercial launch and increased acceptance among physicians of various immunotherapies may be considered as the most significant change in the market relevant for BerGenBio. As described under Section 7.1.1 "The oncology market size and growth", it is also this treatment type which is expected to be the largest contributor to market growth in the short and medium term.

Below follows an overview over systemic therapies which form major classes of treatment in many cancers.

#### Radiation therapy

Radiation therapy is a common treatment of cancer, and involves using high-energy particles or waves to destroy or damage cancer cells. It is a local treatment, meaning that it only affects the part of the body being treated. Radiation can be given alone or used with other therapies, such as surgery or chemotherapy. Often, radiation is used together with certain drugs which make cancer cells more sensitive to radiation, thus improving its effectiveness. As radiation can also damage surrounding healthy cells and tissue, it is associated with certain side effects<sup>28</sup>.

#### Hormone therapy

Hormones are substances produced naturally in the body, acting as chemical messengers that influence the growth and activity of cells. By altering the production or activity of particular hormones, such therapies aim to stop or slow down the growth of cancer cells affected by fluctuating hormone levels. The type of therapy given will vary dependent of the type of cancer being treated<sup>29</sup>.

#### Chemotherapy

More than 100 chemotherapy drugs are used to treat cancer – either alone or in combination with other drugs and treatments. Chemotherapy is often used in combination with surgery or radiation therapy in order to kill remaining cancer cells or control the tumour<sup>30</sup>. Chemotherapy drugs are cytotoxic, meaning its toxic to cells, both normal cells and tumour cells, and the different types can vary greatly in chemical composition. Patients may experience severe side effects from some types of chemotherapy. The side effects of chemotherapy are primarily driven by the fact that these drugs lack good specificity for tumour cells and cannot distinguish between healthy cells and cancer cells, and thus kill both<sup>31</sup>. Recently, chemotherapy has been very successfully used in combination with immunotherapy, for example immune checkpoint inhibitors. This is exemplified by the recent FDA approval for use of Keytruda™ in combination with chemotherapy in first line lung cancer patients irrespective of their PD-L1 biomarker status<sup>32</sup>. This approval is thought to render this combination a major route for the treatment of lung cancer.

#### Targeted therapies

Since the more traditional cancer treatment types were discovered and developed, scientists have gained further insight into the molecular mechanisms driving cancer cell growth. This enables scientists to design new medicines which specifically target a particular aspect of the tumour cell's "broken machinery". In other words, targeted therapies are able to zoom in on some of the characteristics that make cancer cells different from healthy cells, and target specific areas of the cancer cell that allow the cell to grow faster and abnormally<sup>33</sup>.

<sup>27</sup> <http://www.cancer.org/latest-news/immunotherapy-disrupting-the-cancer-treatment-world.html>, accessed 26 June 2018

<sup>28</sup> <http://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/radiation/radiation-therapy-guide/benefits-risks-and-questions-to-ask.html>, accessed 26 June 2018

<sup>29</sup> <http://www.macmillan.org.uk/information-and-support/treating/hormonal-therapies/hormonal-therapies-explained/what-are-hormonal-therapies.html>, accessed 26 June 2018

<sup>30</sup> <http://www.macmillan.org.uk/information-and-support/treating/chemotherapy/chemotherapy-explained/what-is-chemotherapy.html>, accessed 26 June 2018

<sup>31</sup> <http://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/chemotherapy/how-chemotherapy-drugs-work.html>, accessed 26 June 2018

<sup>32</sup> <https://www.cancer.gov/news-events/cancer-currents-blog/2017/fda-pembrolizumab-lung-expanded> - accessed 26 June 2018

<sup>33</sup> <http://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/targeted-therapy/what-is.html>, accessed 26 June 2018



One of the first successful examples of such a targeted therapy was imatinib, which is marketed by Novartis and in 2015 generated sales of USD 4.65 billion<sup>34</sup>. The target for imatinib is a protein (BCR-Abl) that only exists in cancer cells and not healthy cells, and the protein can lead to uncontrolled cell growth and tumour development.

Another example of a relatively new, targeted therapy is erlotinib, which is used to treat non-small cell lung cancer (NSCLC) and pancreatic cancer<sup>35</sup>. It targets a molecule called epithelial growth factor receptor (“**EGFR**”) which is found at high levels in various forms of cancer.

On the back of the successes of imatinib, erlotinib and other similar targeted therapies, the academic and commercial focus on targeted therapies has risen markedly<sup>36</sup>. Generally, the focus of global cancer research has shifted away from drugs that work by indiscriminately killing all cells that are rapidly dividing, and the industry has applied itself to designing and developing new medicines that specifically hit tumour cells while leaving normal cells relatively unscathed.

### **Immunotherapies**

There has been long-running interest in how the immune system and tumours interact, with researchers able to demonstrate tumour control by the immune system in model animal systems. Translating that effect into the human setting however, has been much more challenging. In the recent period, scientific insight into how the human immune system interacts with cancer cells has increased, and with it, the focus on immunotherapy. In contrast to the previously mentioned cancer treatments, immunotherapy aims to harness the power of the body’s own immune system to fight cancer. This can be done in different ways, but the most common is to either “boost” the immune system or stimulate it to recognise the cancer cells as something that should be removed.

These scientific advances have enabled immunotherapy to grow into an important treatment for some types of cancer<sup>37</sup>. Therapies mediated by T-cells (immune cells that the body ordinarily activates to seek and destroy cancer cells) have been and are currently being developed by different biopharmaceutical companies in multiple forms, including CPIs, therapeutic vaccines, bispecific antibody-based approaches, small molecules and cell based therapies. Of these different forms, CPIs have gained special attention<sup>38</sup>. Unlike other immunotherapies that work by strengthening the immune system or training it to attack tumour cells, CPIs work to defeat the cancer cells’ immune resistance mechanism. Enabling the immune system to “see the cancer cells for what they are”, the T-cells of the immune system can then respond appropriately.

According to a report published by Citi Research, immunotherapy is one of the fastest growing areas within oncology R&D, forecasted to make up 60% of all cancer management regimes in the developed world by 2023. This is estimated to represent a potential revenue opportunity for the biopharmaceutical industry in excess of USD 35 billion<sup>39</sup>.

### **Combination Treatments**

The cancer treatments described in this Section 7.3 have largely been presented as monotherapies. However, different types of therapies are often combined to treat cancer. Studies have shown that drug combination within oncology has the potential to improve treatment response, minimize development of resistance or minimize adverse events<sup>40</sup>. One of the reasons for combining different therapies is to use drugs that work by different mechanisms, and thereby decreasing the likelihood for resistant cancer to develop. For some cancers, a good approach is a combination of surgery, radiation therapy and chemotherapy<sup>41</sup>. Combination approaches of particular current focus within immune-oncology are to combine CPIs with existing cancer therapies, or combinations of CPIs with other active immunotherapies<sup>42</sup>.

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<sup>34</sup> <http://www.pharmaceutical-technology.com/features/featurethe-worlds-most-sold-cancer-drugs-in-2015-4852126/>, accessed 26 June 2018

<sup>35</sup> Chemocare.com, Erlotinib, 26 June 2018

<sup>36</sup> <http://edcan.org.au/edcan-learning-resources/supporting-resources/targeted-therapies/overview-of-targeted-therapies>, accessed 26 June 2018

<sup>37</sup> <http://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/immunotherapy/what-is-immunotherapy.html>, accessed 26 June 2018

<sup>38</sup> <https://www.citivelocity.com/citigps/OpArticleDetail.action?recordId=209>, accessed 26 June 2018

<sup>39</sup> <https://www.citivelocity.com/citigps/OpArticleDetail.action?recordId=209>, accessed 26 June 2018

<sup>40</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4361221/>, accessed 26 June 2018

<sup>41</sup> <http://www.merckmanuals.com/home/cancer/prevention-and-treatment-of-cancer/combination-cancer-therapy>, accessed 26 June 2018

<sup>42</sup> <https://www.citivelocity.com/citigps/OpArticleDetail.action?recordId=209>, accessed 26 June 2018

## 7.4 Tumour cell plasticity and the role of AXL

Epithelial-Mesenchymal-Transition (EMT) is a natural cellular mechanism where cells transition from an epithelial to a mesenchymal (fibroblast-like) state. EMT is important during embryonic vertebrate development where it gives rise to different structures and organs. EMT is seldom activated in healthy adults. It is however induced in response to inflammation following injury or disease and plays a role in wound healing and tissue repair, and occurs during organ degenerative disease<sup>43</sup>.

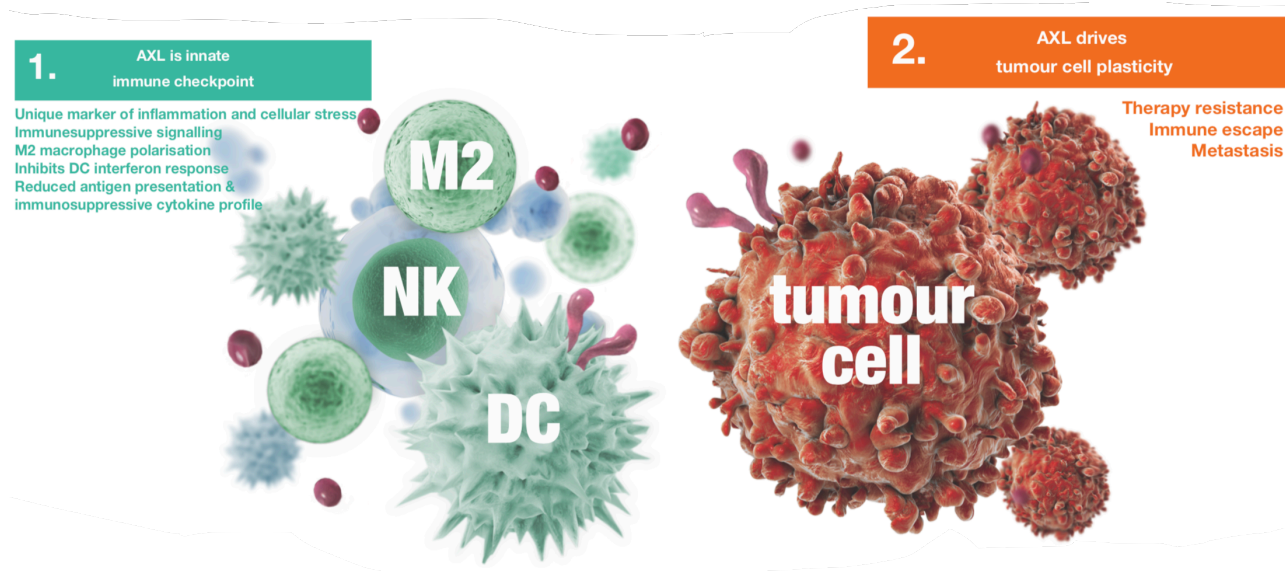
When this process occurs inappropriately in cancer cells, EMT – or tumour cell plasticity as it is called in this context – can mediate aggressive properties. Accumulating evidence points to an important role of tumour cell plasticity during tumour progression to greater malignancy<sup>44</sup>. Studies show that tumour cells undergoing the tumour cell plasticity survival programme acquire the capacity to disarm the body's anti-tumour defences, evade the immune system, become resistant to anti-cancer drugs, and to escape from the primary tumour and spread throughout the body<sup>45</sup>.

Tumour cell plasticity is driven and maintained by AXL.

AXL and in turn the tumour survival programme is triggered by a hostile microenvironment caused for example by the body's inflammatory or immune response, or cancer treatments such as chemotherapeutics or modern targeted cancer therapies. In such a hostile microenvironment, many cancer cells will die, but some will activate the tumour cell plasticity survival mechanism and transition from an epithelial to a mesenchymal state. This transition involves reprogramming many features of the cancer cell resulting in changes in the structure and shape of the cell, the cell membrane and metabolism. It can further enable mesenchymal tumour cells to tolerate the hostile environment and avoid the body's anti-tumour immune response and become resistant to different types of drugs. Furthermore, these mesenchymal tumour cells can spread (metastasise) to other organs in the body where they either remain dormant or develop into secondary tumours.

In parallel, AXL has a suppressive effect on cells of the innate immune system. AXL acts as an innate immune checkpoint – meaning it is switched on in response to an immune reaction to avoid over-reaction. In the context of tumours this is not desirable as a sustained immune reaction is thought to help clear the tumour and lead to long lasting responses. The ability to both trigger and sustain an immune reaction is also a key pre-requisite for immune checkpoint inhibitors to work.

Figure 6: AXL



### 7.4.1 AXL is a recognised target in aggressive disease

A growing body of data in the scientific literature confirms that AXL drives tumour cell survival, drug resistance to a multitude of cancer drug classes, immune suppression and evasion as well as metastasis.

<sup>43</sup> Nieto, M. et al, EMT:2016, Cell, 2016: 166 (1): 21-45


<sup>44</sup> <http://www.nature.com/onc/journal/v24/n50/full/1209091a.html>, accessed 26 June 2018

<sup>45</sup> <http://www.nature.com/nrd/journal/v15/n5/full/nrd.2015.13.html>, accessed 26 June 2018

Research by BerGenBio and others clearly shows that targeting AXL is able to reverse these processes in animal models of aggressive tumours. The result is reduction of tumour progression, reduced tumour initiation, increased susceptibility to anti-cancer drugs, increased anti-tumour immune activity and reduced metastasis.

Emerging clinical data from BerGenBio clinical trials with bemcentinib, the selective, oral inhibitor of AXL, has thus far confirmed that this effect can also be observed in a subset of patients taking the AXL inhibitor either as a monotherapy or in combination with other drugs (see Section 8.5 “Overview of the Company’s business areas”).

Figure 7: AXL is a receptor tyrosine kinase



**AXL is a receptor tyrosine kinase**

**Gas6, single high affinity ligand**

**Low expression in normal tissues; upregulated by inflammation and cellular stress**

**Unique signal transduction drives**

- Survival
- Drug resistance
- Immune suppression / evasion
- Metastasis

**Interest in AXL as a key target for aggressive disease is increasing rapidly**

AXL is a protein expressed on the surface of cells, it is a member of class of proteins called receptor tyrosine kinase (“RTK”). RTKs have proven to be valuable cancer drug targets, with several important drugs acting through RTK modulation. One example is erlotinib (marketed by Roche, 2014 sales CHF 1,292m<sup>46</sup>), mentioned above, which targets EGFR, a type of RTK. RTKs play an important role in mediating cancer cell signalling, which can be a key driver of uncontrolled cell proliferation and enhanced cell survival<sup>47</sup>.

Emerging pre-clinical evidence generated by BerGenBio collaborators and others also points to an important role for AXL in driving aggressive fibrotic diseases such as idiopathic pulmonary fibrosis (IPF) or the liver disease non-alcoholic steatohepatitis (NASH) that is characterised by liver fibrosis<sup>48</sup>.

<sup>46</sup> <http://www.roche.com/dam/jcr:c374fdd5-798a-4bcc-b367-3299a5ebd7ef/en/med-cor-2015-01-28-e.pdf>, accessed 26 June 2018

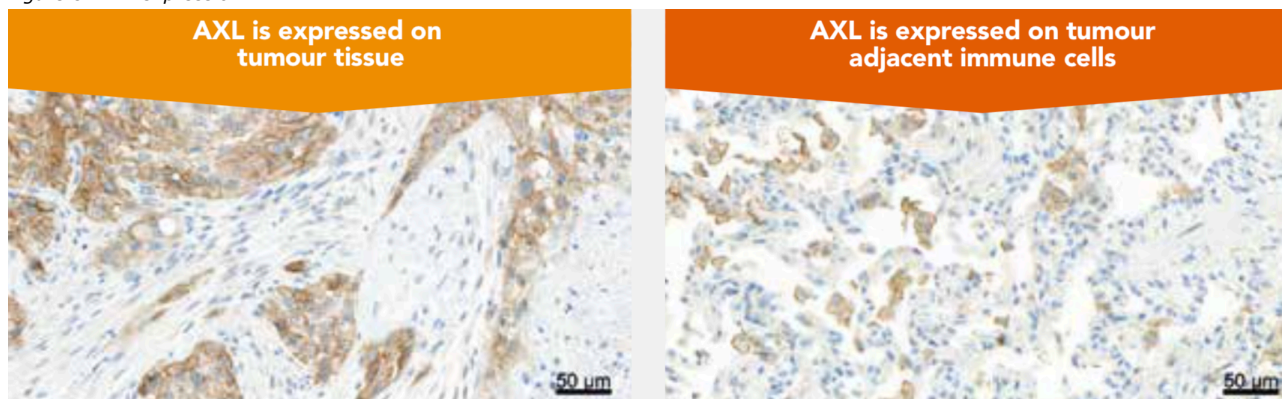
<sup>47</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4586793/>, accessed 26 June 2018

<sup>48</sup> Hogaboam and Barcena

### 7.4.2 AXL expression in cancer

AXL is expressed both on tumour and immune cells, as seen in the pictures below where brown staining indicates AXL expression and blue staining indicates cell nuclei:

Figure 8: AXL expression



Based on published scientific literature it is estimated that most cancer indications comprise a sizable subset of AXL expressing tumours (between 20 and 80%)<sup>49</sup>.

BerGenBio has developed a suite of tools to test patient samples for the presence of AXL to confirm these findings, see Section 8.5.1 "Companion Diagnostics".

As further described in Section 8 "Business of the Company", BerGenBio's asset portfolio comprise, amongst others, the AXL kinase inhibitor bemcentinib, the anti-AXL monoclonal antibody BGB149 and the antibody drug conjugate BGB601 (licensed to ADCT). While certain other companies are developing inhibitors with some degree of AXL activity, bemcentinib is the only selective AXL inhibitor currently in clinical development. Similarly, BGB149 is the furthest progressed cold monoclonal antibody targeting AXL, potentially entering clinical development in 2018. With regards to BGB601, the competitive situation is also favourable, with relatively few similar compounds and only one competitor potentially being able to enter clinical development on or about the same time as BerGenBio's candidate licensed to ADCT (which is indicatively expected in Q1 2019)<sup>50</sup>.

## 7.5 Key indications for BerGenBio

As previously mentioned, AXL is expressed across a wide range of cancers. In their current clinical development programme, the studies controlled by BerGenBio will be run in acute myeloid leukaemia (AML) and myelodysplastic syndrome (MDS), non-small cell lung cancer (NSCLC) and triple negative breast cancer (TNBC). Therefore, these cancer types will be the focus of this sub-section.

### 7.5.1 AML and MDS

AML is a type of cancer that affects the bone marrow and blood. According to the Cleveland Clinic, AML is the most common acute leukaemia type in adults. It is named "acute", rather than "chronic", as this type of cancer progresses relatively rapidly<sup>51</sup>. AML affects the myeloid stem cells, which come from blood stem cells (immature cells) in the bone marrow. Normal myeloid stem cells turn into one of three types of mature cells; red blood cells that carry oxygen and other substances to all tissues of the body; white blood cells that fight infection and disease; or platelets that form blood clots to stop bleeding. In AML the myeloid stem cell becomes a type of immature and abnormal white or red blood cell or platelet. The abnormal cells build up in the bone marrow and blood so there is less room for healthy cells. This in turn can cause infection, anaemia and easy bleeding. The leukaemia cells can spread outside the blood to other parts of the body like the central nervous system, skin and gums<sup>52</sup>.

<sup>49</sup> SEER Program – National Cancer Institute (National Institute of Health), Cancer Biology & Therapy, 2010; 10 (10) (Head and neck cancer), Thyroid, 1999; 9 (6): 563-567 (Thyroid cancer), Oncogene, 2013; 32: 3420-3431 (Lung cancer), Annals of Oncology, 2001; 12: 819-824 (Breast cancer), Cancer Biology & Therapy, 2009; 8 (7): 618-626 (Pancreatic cancer), Neoplasia, 2012; 14: 535-546 (Renal cancer), Cancer Res, 2010: 70-7570 (Ovarian cancer), Oncogene, 2013; 32(6): 689-698 (Prostate cancer), Clin Cancer Res, 2014: 20-164 (Colon cancer), Blood, 1994; 84 (6): 1931-1941 (CML), Leukaemia. 1999 Impact Factor: 9.38 (AML)

<sup>50</sup> Competitive analysis done by the Company's management

<sup>51</sup> <http://www.healthline.com/health/acute-myeloid-leukemia-survival-rates-outlook#Overview1>, accessed 26 June 2018

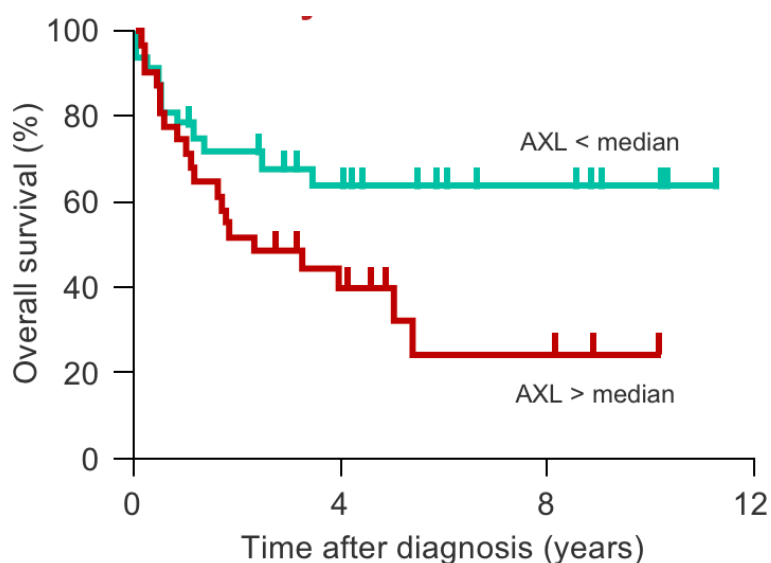
<sup>52</sup> <https://www.cancer.gov/types/leukemia/patient/adult-aml-treatment-pdq>, accessed 26 June 2018

The probability of getting AML increases with age, and the disease is most frequently diagnosed among people aged 65 to 84. The median age for being diagnosed with AML is 67 years old. National Cancer Institute estimates that in the U.S. in 2017 there will be an estimated 21,380 cases of AML and that 10,590 will die of this disease<sup>53</sup>. In the EU, more than 15,000 patients die of AML each year<sup>54</sup>. By 2035, the number of new cases is forecasted to reach 48,910 per year combined for the U.S., Japan, and the five major EU markets (France, Germany, Italy, Spain and the UK, defined as the "EU5"), emphasizing the high need for new treatments within this indication<sup>55</sup>.

The outcome of treatment for patients with AML has changed little during the last decade, with the majority of affected adults succumbing to their disease despite the use of intensive chemotherapy regimens and the availability of haematopoietic stem cell transplantation. Population based studies have reported 3-year survival rates of only 9-10% and 5-year survival rate of 3-8% in patients aged 60 years and older, compared with 5-year survival rates of up to 50% for younger patients<sup>56,57,58</sup>.

AXL expression on AML cells is associated with more rapid progression of the disease and poor overall survival in AML patients<sup>59</sup>. This phenomenon is depicted in the figure below:

Figure 9: AXL expression AML, overall probability of survival



In the graph above, the percentage survival in the patient population (measured on the vertical axis) is depicted as a function of time (indicated on the horizontal axis). The green line represents patients with AXL levels that are below the median, and the red line shows patients whose tumours have AXL levels above the median. As can be seen from the chart, higher than median AXL expression patients are typically associated with lower overall survival rates than cases of lower than median AXL expression. This is because AXL dysfunction is essentially involved in the root cause of the mechanism that causes AML, therefore the more AXL expression the worse the disease and the weaker the treatment results (leading to a lower overall survival rate). In AML, AXL is the molecular driver of the disease in approximately 45% of patients<sup>60</sup>, as such the Company sees an opportunity to treat AML patients with its AXL inhibitor as a single agent

MDS on the other hand refers to a range of conditions that can occur when the blood-forming cells in the bone marrow are damaged, leading to problems when making new blood cells. Many of the blood cells formed by the damaged bone

<sup>53</sup> American Cancer Society, Cancer Facts and Figures 2017, available at <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2017.html>, accessed 26 June 2018

<sup>54</sup> World Health Organisation, Globocan 2012, available at <http://globocan.iarc.fr/Default.aspx>, accessed 26 June 2018

<sup>55</sup> Datamonitor Healthcare. Data available at the Company, sourced through its advisor Alacrita Consulting

<sup>56</sup> Juliusson, G. et al, Age and acute myeloid leukemia: real world data on decision to treat and outcomes from the Swedish Acute Leukemia Registry, *Blood*, 2009; 113 (18): 4179-87

<sup>57</sup> Lerch, E. et al, Prognosis of acute myeloid leukemia in the general population: data from southern Switzerland, *Tumori*, 2009; 95 (3): 303-10

<sup>58</sup> Alibhai, et al., Outcomes and quality of care in acute myeloid leukemia over 40 years, *Cancer*, 2009; 115 (13): 2903-11

<sup>59</sup> Ben-Batalla, I. et al, AXL, a prognostic and therapeutic target in acute myeloid leukemia mediates paracrine crosstalk of leukemia cells with bone marrow stroma, *Blood*, 2013; 122 (14): 2443-2452

<sup>60</sup> Ben-Batalla, I. et al, AXL, a prognostic and therapeutic target in acute myeloid leukemia mediates paracrine crosstalk of leukemia cells with bone marrow stroma, *Blood*, 2013:122:2443-2452

marrow cells are defective and die, leaving the patient with a too low number of one or more types of blood cells. In about one-third of patients, MDS can progress into AML. Because the majority of patients do not get AML, MDS was previously classified as a disease of low malignant potential. However, as the medical field has learned more about the severity of the disease, MDS is considered to be a form of cancer<sup>61</sup>.

MDS patients are often categorised by their risk level, broken into i) Low risk, ii) Intermediate risk (two levels) and iii) High risk. The “risk” technically refers to the relative probability of the illness either becoming fatal or changing to AML, which is influenced by a range of factors<sup>62</sup>.

#### 7.5.1.1 Competitive landscape within AML/MDS

Over the last 20 years there has been little change to the standard treatment for AML, which is typically based on cytarabine chemotherapy with an anthracycline (a class of chemotherapy drugs). Some older patients may not be able to tolerate the standard of care due to its toxicity. For these patients, drugs such as decitabine and azacitidine and may be used instead<sup>63</sup>. Although some patients may achieve remission (a leukaemia-free state) following treatment the disease recurs in the majority of patients and there is a clear need for new therapies<sup>64</sup>. BerGenBio will pursue marketing approval to treat patients whose disease has recurred following treatment with either azacitidine or decitabine. Thus, neither of these drugs represents competitive therapies.

There are currently no targeted therapies approved for treatment of AML in the absence of a known driver mutation.

Among targeted inhibitors that have been developed for subsets of previously treated AML, the most notable ones are inhibitors against mutated IDH or FLT3.

In July 2017, the FDA approved IDHFA (enasidenib; Celgene & Agios) for relapsed / refractory (R/R) AML patients with an IDH2 mutation<sup>65</sup>. It is important to note that only 8-19% of R/R AML patients are expected to exhibit this mutation, i.e. a large proportion of R/R patients will not be eligible for this treatment.

In April 2018, Astellas Pharma submitted a new drug application for gilteritinib in R/R AML patients who display a specific FLT3 mutation.<sup>66</sup> Should this application lead to approval this would constitute another targeted drug in the indication, however again the subset of eligible patients is restricted to those who exhibit a specific mutation which is true for less than 25% of patients<sup>67</sup>.

Several other targeted treatments for R/R AML are currently under development, however there are a number of obstacles standing in the way of widespread adoption of targeted therapy into daily practice, such as high cost, the impracticality of such treatments and restriction to relatively small sub-sets of patients<sup>68</sup>.

As current treatments are inadequate, there is a need for new therapies which extend survival. Within AML, BerGenBio targets to achieve this within a specified subset of patients, characterised by the following traits:

- Previously treated with a hypomethylating agent
- 65 years of age or older
- evidence of AXL pathway activation

With regards to the last criteria, BerGenBio will carefully select patients with the appropriate AXL expression in order to achieve best possible results. For this purpose, the Company will utilise its proprietary biomarker diagnostic tool (please refer to Section 8 "Business of the Company" for further details). As such, the three main criteria for screening the competitive landscape are as follows:

- Does the drug selectively target AXL?

<sup>61</sup> <https://www.cancer.org/cancer/myelodysplastic-syndrome/about/what-is-mds.html>, accessed 26 June 2018

<sup>62</sup> Mesa, R. (MD, Professor of Medicine, Chair Division of Hematology & Medical Oncology), Treating higher risk MDS (presentation available at [http://assets.aamds.org/aplastic/files/dms/phoenix\\_mesa\\_higherrisk.pdf](http://assets.aamds.org/aplastic/files/dms/phoenix_mesa_higherrisk.pdf))

<sup>63</sup> <http://www.cancer.net/cancer-types/leukemia-acute-myeloid-aml/treatment-options>, accessed 26 June 2018

<sup>64</sup> <https://academic.oup.com/annonc/article/27/5/770/2769776/New-drugs-in-acute-myeloid-leukemia>

<sup>65</sup> <http://investor.agios.com/news-releases/news-release-details/fda-grants-approval-idhifar-first-oral-targeted-therapy-adult>

<sup>66</sup> <http://www.targetedonc.com/news/gilteritinib-submitted-for-fda-approval-in-flt3-aml>











<sup>67</sup> <http://www.bloodjournal.org/content/129/5/565?sso-checked=true>

<sup>68</sup> <http://www.hematologyandoncology.net/index.php/archives/november-2015-3/moving-toward-targeted-therapies-in-acute-myeloid-leukemia/>, accessed 26 June 2018



- Does the targeted population comprise previously treated patients?
- Is the patient selection biomarker-based?




Based on these criteria, the following drugs comprise a selected late stage development landscape in AML. Importantly, there are clear opportunities for bemcentinib both as monotherapy and a combination therapy, as none of the listed drug candidates has the same profile<sup>69</sup>:

Selected late stage development landscape in AML				Competing population?		
Drug	Lead company	Drug type	Phase	Selectively target Axl?	R/R patients?	Biomarker-based patient selection?
gilteritinib		Small molecule	Ph III	No	Yes	Yes (But different kinase)
quizartinib		Small molecule	Ph III	No	Yes	Yes (But different kinase)
enasidenib		Small molecule	Ph III	No	Yes	Yes (But different gene)
idasanutlin		Small molecule	Ph III	No	Yes	
crenolanib		Small molecule	Ph III	No	Yes	Yes (But different kinase)
vadastuximab talirine		ADC <sup>1</sup>	Ph III	No	No	No
guadecitabine		Small molecule	Ph III	No	No	No
oral azacitidine		Small molecule	Ph III	No	No	No
Vyxeos		Small molecule	NDA	No	No	No
midostaurin		Small molecule	NDA	No	No	No

Note: 1) ADC = Antibody drug conjugate

In MDS, treatment typically includes supportive therapy, including transfusions, and may include bone marrow stimulation, hypomethylating agents and cytotoxic chemotherapy<sup>70</sup>. Existing therapies are particularly inadequate in patients with high risk MDS, who have a median survival of less than one year<sup>71</sup>.

Within MDS, BerGenBio is targeting patients classified as intermediate and high risk. Based on this criterion, the following drugs comprise a selected late stage development landscape in MDS. As none of the drug candidates in the landscape has the same profile as bemcentinib, there are clear market opportunities for BerGenBio's lead compound<sup>72</sup>:

Selected late stage development landscape in MDS				Competing population?	
Drug	Lead company	Drug type	Phase	Selectively target Axl?	High risk MDS?
Rigosertib		Small molecule	Phase III	No	Yes
Imetelstat		Oligo-nucleotide	Phase III	No	No
Galunisertib		Small molecule	Phase III	No	Yes

### 7.5.2 Non-small cell lung cancer (NSCLC)

NSCLC is one of the two main types of lung cancer, the other being small cell lung cancer. Cells from the cancer may break away from the original tumour and spread (metastasise) to other parts of the body. Lung cancer has typically already spread beyond the primary tumour prior to appearance of symptoms or before the tumour can be detected on

<sup>69</sup> Biomedtracker. Data available at the company, sourced through its advisor Alacrita Consulting

<sup>70</sup> <http://emedicine.medscape.com/article/207347-overview>, accessed 26 June 2018

<sup>71</sup> <https://www.cancer.org/cancer/myelodysplastic-syndrome/detection-diagnosis-staging/survival.html>, accessed 26 June 2018

<sup>72</sup> Biomedtracker. Data available at the company, sourced through its advisor Alacrita Consulting

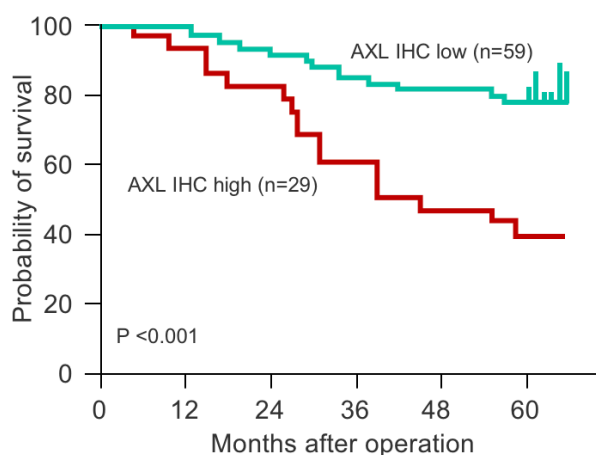
a chest x-ray. About 80% to 85% of lung cancers are NSCLC, and there are three main subtypes; squamous cell carcinoma, adenocarcinoma and large cell carcinoma<sup>73,74</sup>.

Lung cancer is the leading cause of global cancer death. About 1.8 million new cases occur worldwide each year, and in 2012 there were approximately 1.6 million deaths related to lung cancer<sup>75</sup>. The five-year survival rate for lung-cancer is 18.6%, and 25.3% of all cancer deaths are lung and bronchus cancer<sup>76</sup>. Looking to 2035, Datamonitor Healthcare estimates the combined number of new cases for the U.S., Japan, and the EU5 to be 684,750 per year, up 33% from 513,570 in 2015<sup>77</sup>.

Surgery is the preferred treatment approach for NSCLC patients with early-stage disease<sup>78</sup>. For patients with advanced NSCLC significant biological heterogeneity exists, with first line treatments including chemotherapy and targeted drug treatments, eg EGFR inhibitors, ALK inhibitors and PD-1 blockade (standard of care drugs for patients with these special diagnostic markers). Individual treatments are selected on an increasing understanding of individual tumour biology. For unresectable disease, the responses to such treatments have proven limited and patients inevitably become resistant. Patients with unresectable NSCLC typically die from their disease<sup>79</sup>. Specific targeted therapies have been developed for the treatment of advanced NSCLC through an increased understanding of tumour biology<sup>80</sup>.

AXL expression on NSCLC cells is associated with more rapid progression of the disease and poor overall survival in NSCLC patients<sup>81</sup>. This phenomenon is depicted in the figure below. "AXL IHC" (IHC meaning immunohistochemistry) refers to a score given to each patient in the study sample, grading them according to their level of AXL expression. The "n" in parenthesis refers to the number of study participants that fall within the relevant category.

Figure 10: AXL expression NSCLC, overall probability of survival



In the graph above, the percentage survival in the patient population (measured on the vertical axis) is depicted as a function of time (indicated on the horizontal axis). The green line represents the patients whose tumours express relatively low levels of AXL, and the red line represents patients with tumours expressing relatively higher levels of AXL. From the chart above, there is a trend that NSCLC patients with high of AXL expression experience lower percent survival than patients with lower levels of AXL.

<sup>73</sup> National cancer institute, Non-Small Cell Lung Cancer Treatment – for health professionals, 26 June 2018

<sup>74</sup> <http://www.cancer.org/cancer/non-small-cell-lung-cancer/about/what-is-non-small-cell-lung-cancer.html>, accessed 26 June 2018

<sup>75</sup> World Health Organisation, Globocan 2012, available at <http://globocan.iarc.fr/Default.aspx>, accessed 26 June 2018

<sup>76</sup> National cancer institute, SEER, 26 June 2018

<sup>77</sup> Datamonitor Healthcare. Data available at the Company, sourced through its advisor Alacrita Consulting

<sup>78</sup> <http://www.cancer.org/cancer/non-small-cell-lung-cancer/treating/by-stage.html>, accessed 26 June 2018

<sup>79</sup> <http://www.cancer.org/cancer/non-small-cell-lung-cancer/treating/by-stage.html>, accessed 26 June 2018

<sup>80</sup> <http://www.cancer.org/cancer/non-small-cell-lung-cancer/treating/targeted-therapies.html>, accessed 26 June 2018

<sup>81</sup> Lung adenocarcinoma (NSCLC): Ishikawa, M., *Annals of Surgical Oncology*, 2012; 20 (Suppl 3): 467-476



### 7.5.2.1 Competitive landscape within NSCLC

Traditionally treated with indiscriminate cytotoxic agents<sup>82</sup>, the treatment options for late stage NSCLC patients have increased dramatically as the biology of the disease has become better understood. Among tumours driven by specific mutations, two specific groups have been identified that appear most dominant: NSCLC arising as a consequence of an activating mutation of the EGFR (a receptor on the surface of the cell)<sup>83</sup> – the most common – and the second type being cancer occurring through abnormal signalling of a kinase called ALK<sup>84</sup>. There are therapies targeting EGFR which are approved in the major markets, one of which is erlotinib. BerGenBio is conducting trials in combination with erlotinib, and as such this drug is not a direct competitor to bemcentinib.

For advanced non-squamous NSCLC (a type of NSCLC targeted by BerGenBio), platinum-based chemotherapy is the most common first line therapy alone or in combination with immunotherapy, and when patients progress docetaxel provides an effective alternative<sup>85</sup>. Bemcentinib is being studied in an investigator-initiated clinical trial in combination with docetaxel.

Several CPIs have been approved to treat NSCLC and are rapidly gaining market share<sup>86</sup>. There is currently strong competition within this area among large pharma companies (MSD with pembrolizumab, Bristol-Myers Squibb with nivolumab, Roche with atezolizumab), with numerous late stage trials underway, which is expected to further influence the future standard of care in NSCLC. As previously mentioned, combination treatments involving CPIs together with other agents is an area currently receiving great attention. BerGenBio is conducting a clinical trial in collaboration with MSD, combining bemcentinib with pembrolizumab in second line advanced adenocarcinoma of the lung, in patients who have been previously treated with a platinum-based chemotherapy. As such, the CPIs do not necessarily represent direct competition for the Company, but conversely represent a significant opportunity.

Based on BerGenBio's targeted patient population in NSCLC, there are particularly three criteria which are important when screening the competitive landscape:

- Does the drug target AXL?
- Does the targeted population comprise patients with EGFR mutations (relevant for the combination study with erlotinib)?
- Is the drug being studied in a combination with a CPI targeting the PD-1 receptor (relevant for the combination study with pembrolizumab)?

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<sup>82</sup> Schiller, J., Current standards of care in small-cell and non-small cell lung cancer, *Oncology*, 2011: 61 (1): 3-13












<sup>83</sup> Riely, G. & Yu, H., EGFR: The Paradigm of an Oncogene-Driven Lung Cancer, *Clinical Cancer Research*, 2015: 21 (10): 2221-2226

<sup>84</sup> Morán, T. et al, Targeting EML4-ALK driven non-small cell lung cancer, *Translational Lung Cancer Research*, 2013: 2 (2): 128-141

<sup>85</sup> Fosella, F., Docetaxel for Previously Treated Non-Small Cell Lung Cancer, *Oncology*, 2002: 16 (6): 45-51

<sup>86</sup> <http://www.cancerresearch.org/cancer-immunotherapy/impacting-all-cancers/lung-cancer>, accessed 26 June 2018

Based on these criteria, the below table comprises a selected late stage development landscape in NSCLC. As can be seen, none of the listed drug candidates target AXL and none are directly competing on the two other criteria, indicating clear opportunities for bemcentinib<sup>87</sup>:

Selected late stage development landscape in NSCLC				Competing population?		
Drug	Lead company	Drug type	Ph	Selectively target Axl?	EGFR positive?	Phase III combination with CPI <sup>1</sup> targeting PD-1?
ASP8273		Small molecule	Ph III	No	Yes (Competing with erlotinib, not in combination trial)	No
dacomitinib		Small molecule	Ph III <sup>2</sup>	No	Yes (Competing with erlotinib, not in combination trial)	No
Tecentriq		MAB <sup>1</sup>	BLA	No	Not directly competitive <sup>2</sup>	No
avelumab		MAB <sup>1</sup>	Ph III	No	Not directly competitive <sup>2</sup>	Also developed by Merck. Not directly competitive
veliparib		Small molecule	Ph III	No	Not directly competitive	No
napabucasin		Small Molecule	Ph III	No	Not directly competitive	No
brigatinib		Small molecule	NDA	No	No	No
ensartinib		Small molecule	Ph III	No	No	No
abemaciclib		Small molecule	Ph III	No	No	No
durvalumab		MAB <sup>1</sup>	Ph III	No	No	No
Plinabulin		Small molecule	Ph III	No	No	No

Note: 1) MAB = Monoclonal antibody; 2) Immune checkpoint inhibitors

It should be noted that recently, Daiichi Sankyo has revealed an AXL selective inhibitor programme, DS-1205. The selective inhibitor is currently in phase I/II clinical development in second line NSCLC in combination with the EGFR inhibitor osimertinib (TAGRISSO). While this is a potential competitor, its development is lagging behind bemcentinib; additionally, the chosen development strategy follows BerGenBio's closely and as such may be viewed as important external validation for BerGenBio's work.

### 7.5.3 Triple Negative Breast Cancer (TNBC)

TNBC is considered the most aggressive type of breast cancer and associated with a shorter median time to relapse, including an increased risk of spread beyond the breast, and death. TNBC is generally diagnosed based upon the lack of three receptors known to fuel most breast cancers: estrogen receptors, progesterone receptors and human epidermal growth factor receptor 2 (HER2) overexpression. Unfortunately, the most successful treatments for breast cancer target these receptors, which are not found in women with TNBC<sup>88</sup>. On a positive note, this type of breast cancer is typically responsive to chemotherapies. Present treatments are restricted to cytotoxic chemotherapy and radiotherapy, although several targeted therapeutics are in clinical development<sup>89</sup>.

Currently, about 15-20% of breast cancers are found to be triple-negative<sup>90</sup>. The five-year survival rate for a Stage III TNBC patient is 72%, but drops sharply to 22% for patients with metastases<sup>91</sup>. Datamonitor Healthcare estimates the number of new cases across the U.S. and the EU5 in 2015 to a total of 63,550, and expects this figure to grow to 76,145 by 2035<sup>92</sup>.

<sup>87</sup> Datamonitor Healthcare, Biomedtracker, Medtrack. Data available at the Company, sourced through its advisor Alacrita Consulting

<sup>88</sup> <https://tnbcfoundation.org/understanding-triple-negative-breast-cancer/>, accessed 27 June 2018

<sup>89</sup> Breastcancer.org, Research on New Treatment for Triple Negative Breast Cancer, 27 June 2018

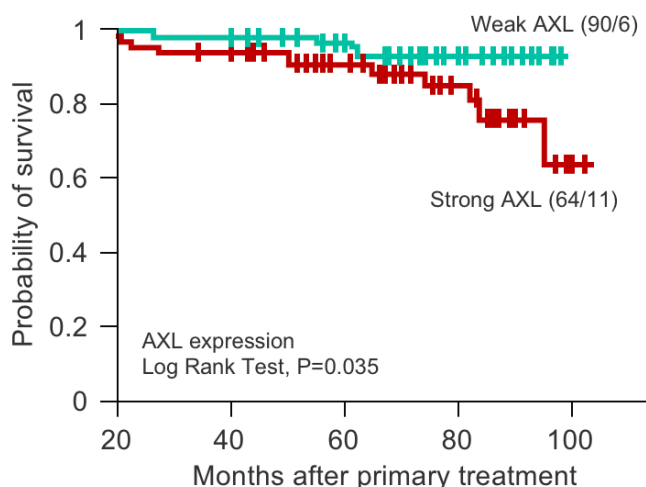
<sup>90</sup> <http://www.healthline.com/health/triple-negative-breast-cancer-outlook-survival-rates-stage#Overview1>, accessed 27 June 2018

<sup>91</sup> <https://www.cancer.org/cancer/breast-cancer/understanding-a-breast-cancer-diagnosis/breast-cancer-survival-rates.html>, accessed 27 June 2018

<sup>92</sup> Datamonitor Healthcare. Data available at the Company, sourced through its advisor Alacrita Consulting

Similarly to AML and NSCLC, AXL expression on breast cancer cells is associated with more rapid progression of the disease and poor overall survival. This has been shown in a study in a population of breast carcinoma patients<sup>93</sup>. This phenomenon is depicted in the figure below:

Figure 11: AXL expression TNBC, overall probability of survival



In the figure above, the percentage survival in the patient population (measured on the vertical axis) is depicted as a function of time (indicated on the horizontal axis). The line on top represents patients that have relatively weak AXL tumour expression, and the line below represents patients with relatively stronger AXL tumour expression. As can be seen, there is a trend that patients with relatively strong levels of AXL experience a lower percent survival than patients with relatively weaker levels of AXL.

The published literature indicates that a large number of TNBC patients, particularly those with worst prognosis, exhibit high AXL expression<sup>94</sup>. These findings were not replicated using BerGenBio's AXL test in a sample of second line metastatic TNBC patients that were enrolled in a phase II clinical trial combining bemcentinib with Keytruda™ (BGBC007, reference to clinical section 8.5.2.6). Thus, the use of an AXL inhibitor in this particular patient population may be of limited use.

#### 7.5.3.1 Competitive landscape within TNBC

Traditionally, chemotherapy together with surgery and radiotherapy has been the mainstay of systemic treatments of TNBC. Despite initial responses to chemotherapy, resistance frequently and rapidly develops, and metastatic TNBC patients have a poor prognosis<sup>95</sup>. Metastatic breast cancers in general have 5 year relative survival rates as low as 22%, and TNBC is proven to be among the most aggressive types of breast cancers<sup>96</sup>. New targeted approaches are, therefore, urgently needed.

Unlike certain other breast cancer subtypes, targeted agents specifically aimed at triple negative breast tumours are not yet available. This is because TNBC cells by definition test negatively for estrogen receptors, progesterone receptors and HER2 (making them triple-negative) which drive other forms of the disease. Because TNBC lacks these known primary drivers, medical professionals have lacked targets for new treatments, instead largely depending on decade-old techniques<sup>97</sup>.

More recently, scientific efforts aimed at dissecting the biology of TNBC have revealed certain promising targeted strategies for future treatments. These include inhibitors of EGFR, PARP (a gene active in the molecular events leading to cell recovery from DNA damage) and immune checkpoints<sup>98</sup>. Compared with other breast cancer subtypes, TNBC has

<sup>93</sup> Gjerdum, C. et al, AXL is an essential epithelial-to-mesenchymal transition-induced regulator of breast cancer metastasis and patient survival, PNAS, 2010; 107 (3), 1124-1129

<sup>94</sup> <https://www.nature.com/articles/njbcancer201633>

<sup>95</sup> Marmé, F. & Schneeweiss, A., Targeted Therapies in Triple-Negative Breast Cancer, Breast Care, 2015: 10 (3): 159-166

<sup>96</sup> <https://www.cancer.org/cancer/breast-cancer/understanding-a-breast-cancer-diagnosis/breast-cancer-survival-rates.html>, accessed 19 August 2018











<sup>97</sup> <https://www.sciencedaily.com/releases/2016/06/160604050637.htm>, accessed 18 August 2018

<sup>98</sup> Carey, A. & Carey, L., Understanding and Treating Triple-Negative Breast Cancer, Oncology, 2008: 22 (11): 1233-1243

been shown to be more immunogenic, but responses to CPIs have been somewhat disappointing. The increased insights are spurring clinical studies aiming to develop the first generation of targeted therapies for TNBC.

The table below provides a selected development landscape in TNBC deemed most relevant for bemcentinib. As can be seen, none of these selectively target Axl<sup>99</sup>:

#### Selected late stage development landscape in TNBC

























Drug	Lead company	Drug type	Phase	Selectively target Axl?
glembatumumab vedotin	 CellDex therapeutics	MAB-DC <sup>1</sup>	Phase IIb	No
Keytruda	 MERCK	MAB <sup>2</sup>	Phase III	No
atezolizumab	 Roche	MAB <sup>2</sup>	Phase III	No
Lynparza	 AstraZeneca	Small molecule	Phase III	No
niraparib	 TESARO	Small molecule	Phase III	No
talazoparib	 MEDIVATION	Small molecule	Phase III	No
veliparib	 abbvie	Small molecule	Phase III	No
Buparlisib	 NOVARTIS	Small molecule	Phase III	No
sacituzumab govitecan	 IMMUNOMEDICS, INC.	MAB-DC <sup>1</sup>	Phase II	No
Vinflunine	 Pierre Fabre		Phase III	No

Note: 1) MAB-DC = Monoclonal antibody drug conjugate; 2) MAB = Monoclonal antibody

<sup>99</sup> Biomedtracker. Data available at the Company, sourced through its advisor Alacrita Consulting

## 7.6 Relevant precedent transactions within oncology

M&A transactions, partnerships and licensing agreements are fairly common in the biotech industry. Large biotech and pharma companies are actively on the look-out to improve their position and be on top of key trends in the industry. Transactions can be engineered in a number of ways, but typical features include upfront payments, licensing fees, milestone fees and royalty fees. In the recent years there have been several deals in the market deemed relevant for BerGenBio's technologies. A summary of these are included in the table below:

Year	Target company	Candidate	Indication(s)	Highest phase	Acquirer/ Licensor	Deal type	Upfront (USDm)	Max (USDm)
2018		NKT-214, phase II IL-2 agonist	Cancer	Phase II		License	1 billion cash + 850mn USD in equity investment (at 36% premium)	3.6 billion USD
2018		Preclinical TAM programme, phase II entrectinib	Cancer	Phase II (entrectinib)		Acquisition		1.7bn USD (at 74% premium)
2018		Several cytokine & other IO programmes	Cancer	AM0010: Phase II (NSCLC) and phase III (pancreatic)		Acquisition		1.6bn USD (67% premium)
2017		Brigatinib Iclusig	Cancer	Market		Acquisition		5,200
2016		CLND 18.2 mAb IMAB362	Gastroesophageal, gastric and pancreatic cancers	Ph II		Acquisition	460	1,396
2016		Anti-KIT anti-Her3, TAM program	Cancer	Ph Ib		Acquisition		233
2016		Xtandi, talazoparib, pidilizumab	Prostate cancer, breast cancer, DLBCL	Market		Acquisition		13,631
2016		HM95573	Cancer	Ph I		License	80	830
2016		Pracinostat	AML, MDS	Ph III		License	15	469
2016		Multiple IO <sup>1</sup> programmes	Cancer	Pre-clinical		License	225	2,561
2016		Vyxeos	AML	Ph III		Acquisition		1,500
2014		Duvelisib	Blood cancers	Ph III		License	275	530

Note: 1) IO = Immuno-oncology

Source: Public press releases

## 8 BUSINESS OF THE COMPANY

### 8.1 Overview

**BerGenBio ASA is a clinical stage biopharmaceutical company** focused on developing a pipeline of first-in-class AXL kinase inhibitors, including the lead product bemcentinib, a selective AXL inhibitor in phase II clinical development, as a potential cornerstone of combination cancer therapy. The Company has an in-depth understanding of the role and function of AXL kinase (a receptor tyrosine kinase) in mediating cancer spread, immune evasion and drug resistance in multiple aggressive solid and haematological cancers. The Company's primary aim, either alone or in collaboration with a partner, is to develop and commercialise bemcentinib through to marketing approval by the regulatory agencies and subsequent commercialisation.

**AXL is generally accepted as a driver of many of the hallmarks of aggressive cancer and is also an essential mediator of cellular plasticity** through the pathway known as EMT (see Section 7.4 "Tumour cell plasticity and the role of AXL").

**Bemcentinib is a potentially first-in-class, highly selective, orally bio-available small molecule AXL inhibitor**, and the only selective AXL inhibitor in phase II clinical trials. The Company is currently sponsoring four Phase II clinical trials with bemcentinib as a single agent and in combination with standard-of-care drugs in patients with leukaemia (AML, MDS) and solid tumours (NSCLC, TNBC). In addition, a number of investigator-sponsored trials are underway, including a trial to investigate bemcentinib with either Mekinist™ (trametinib) plus Tafinlar™ (dabrafenib) or Keytruda™ in advanced melanoma, as well as a trial combining bemcentinib with docetaxel in advanced NSCLC.

**Preliminary interim phase II data on the trials with bemcentinib** have been presented in June 2018 during the 2018 ASCO conference and further interim data are anticipated during 2018.

**BerGenBio is simultaneously developing a companion diagnostic test** to identify patient subpopulations most likely to benefit from treatment with bemcentinib. This is anticipated to facilitate more efficient registration trials and support a precision medicine-based commercialisation strategy.

**In addition to bemcentinib, BerGenBio has developed a humanised monoclonal antibody**, which shows high affinity and selectivity for AXL, and inhibits the activation of AXL. A clinical candidate, BGB149, has been nominated and the first human studies are planned to begin in 2018.

Early stage research at BerGenBio is further expanding the understanding of the role of **novel targets** that regulate the transition of cancers into aggressive forms that acquire resistance to therapeutic intervention, while driving immunosuppression within the tumour microenvironment (processes collectively known as cellular plasticity). These findings have been translated into a **pipeline of proprietary small molecule drug candidates** targeting critical nodes in cellular plasticity and which are being evaluated as new strategies for therapeutic intervention.

Furthermore, **encouraging pre-clinical data has emerged pointing to an important role of AXL and AXL inhibition via bemcentinib in several fibrotic indications** including the rare disease idiopathic pulmonary fibrosis (IPF) and the aggressive liver disease non-alcoholic steatohepatitis (NASH). BerGenBio continues to follow AXL biology and the potential of AXL inhibition by supporting such promising research carried out by leading researchers in the field.

BerGenBio has leveraged its leading position in AXL biology to establish international commercial and research partnerships; (i) with MSD, a global pharmaceutical company, who will supply its CPI, Keytruda™ for combination clinical studies in patients with lung cancer and TNBC (ii) ADCT, a Swiss biotech company, to whom the Company has licensed preclinical AXL antibodies for the development of an antibody-drug conjugate (ADC) and (iii) leading research and clinical institutions including the MD Anderson Cancer Center, Cedars-Sinai and Harvard University / MIT.

BerGenBio's founding research was undertaken at the University of Bergen, and in 2007 the Company was established by Bergen Teknologioverføring AS (the technology transfer office of the UiB, UniResearch AS (the investment holding company of UiB), Prof. James Lorens and Dr. David Micklem. An initial public offering (IPO) of BerGenBio shares took place at the Oslo Stock Exchange on 8 April 2017 raising 400mn NOK and a private placement directed towards specialist investors was completed on 13 April 2018 raising a further 187.5mn NOK. The Company maintains its administrative and research offices in Bergen whilst its clinical development functions are the main responsibility of its fully owned UK subsidiary, BerGenBio Ltd, with offices in Oxford, UK.

## 8.2 Strategy

### 8.2.1 Overview

BerGenBio's strategy is to discover and develop novel medicines to treat aggressive diseases, including immune evasive and therapy resistant cancers, which represent a significantly high unmet medical need.

The Company is focussed on developing and commercialising bemcentinib, companion diagnostics and other pipeline assets, either alone or in collaboration with partners, through to global regulatory approval, marketing authorisation and reimbursement; potentially in defined patient populations predicted to receive most benefit from treatment with an AXL inhibitor.

Strategic near-term operational priorities therefore include (i) the demonstration of proof of concept of bemcentinib's efficacy across multiple cancer indications, including the current clinical investigations in non-small cell lung cancer lung cancer (NSCLC), triple-negative breast cancer (TNBC), melanoma and acute myeloid leukaemia (AML) / myelodysplastic syndrome (MDS), as well as (ii) the development of suitable companion diagnostics to predict patient benefit.

The Company also intends to advance BGB149, an anti-AXL antibody, into Phase I clinical trials during 2018.

BerGenBio retains all global rights to bemcentinib as well as the pipeline programmes and maintains strategic flexibility in relation to their future development and commercialisation. The Company anticipates that the innovative biological mechanism of bemcentinib plus its promising therapeutic profile make it an attractive and potentially high value target for strategic co-development and partnering opportunities. The Company may also consider a "go-to market" strategy in select indications in discrete territories.

BerGenBio remains committed to extending its worldwide leadership position in understanding AXL biology as the foundation of its differentiated pipeline of novel AXL inhibitors. Relationships with leading academic and clinical research sites are therefore being continuously established and maintained to further strengthen this advantage.

While the research and development strategy is designed in-house in BerGenBio, the Company 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 Company. To a large extent this is done by supplying, under strict contractual control, a small quantity of bemcentinib or other drug candidates to academic research institutions, giving external, third party research validation. The Company has employed experienced personnel that are skilled in directing work that is performed by collaborators and the CROs. This approach to product development is very resource efficient, allows the Company to quickly change directions and permits the rapid adoption of new technologies and expertise when necessary.

The Company intends to maintain its scientific leadership position by continued frequent publication of scientific papers in journals and by presenting posters at conferences world-wide. All intellectual property ("**IP**") is protected before any material is released or published by both the Company or collaborators.

### 8.2.2 Bemcentinib clinical development strategy

The Company intends to develop its lead product bemcentinib, a potentially first-in-class, highly selective inhibitor of the AXL receptor tyrosine kinase, either alone or in collaboration with a pharma company, through to marketing approval in a well-defined patient population informed by a broad proof-of-concept (PoC) phase II clinical development programme.

Phase II trials sponsored by the Company include first and second line indications in non-small cell lung cancer (NSCLC), acute myeloid leukaemia (AML) as well as second line settings in myelodysplastic syndrome (MDS) and triple negative breast cancer (TNBC). The trial programme includes bemcentinib monotherapy applications as well as rational combinations

Bemcentinib has the potential to treat a very wide range of additional cancer types. The Company is exploring these additional opportunities in investigator sponsored clinical trials, so to better understand the therapeutic potential, increase the clinical experience with bemcentinib while sharing development risk and develop a broad market potential.

Taken together, the PoC programme with bemcentinib aims to establish bemcentinib's safety and tolerability when taken as a monotherapy and in combination with established and emerging cancer drugs, as well as its efficacy alone

and in combination. The efficacy will be assessed across all patients enrolled in the trials as well as according to biomarker expression

#### 8.2.2.1 Selective AXL inhibition

High expression of AXL correlates with poor overall survival in most cancers. AXL is epigenetically upregulated in response to a hostile environment on tumour as well as immune cells. It drives a survival programme that renders cancer cells immune evasive, resistant to chemotherapeutic, targeted and immunotherapy drugs (see section 7.4 "Tumour cell plasticity and the role of ")<sup>100101</sup>. By inhibiting the AXL signal, bemcentinib makes cancer cells less aggressive (meaning: visible and tractable to the immune system), more sensitive to cancer drugs and less metastatic.

Inhibition of AXL signalling thus offers an exciting new therapeutic opportunity for aggressive, immune-evasive, drug-resistant and metastatic cancers both as a monotherapy and in combination with other drugs.

The ability to selectively target AXL is crucial in order to reduce potential side effects and allow combination with a wide range of therapeutics. Bemcentinib was discovered using a unique cell based screening approach that allowed for the selection of an inhibitor that was both highly potent and had minimal off-target effects.

#### 8.2.2.2 Bemcentinib monotherapy

An initial phase I healthy volunteer clinical trial demonstrated that bemcentinib could be safely administered at doses that exceeded those predicted necessary to reach clinical efficacy.

Furthermore, clinical efficacy as a monotherapy was demonstrated in patients with AML, MDS and NSCLC in phase I/II trials.

In AML and MDS, bemcentinib's potential as a monotherapy is currently studied further using phase II expansion cohorts based on the initial phase I/II results.

#### 8.2.2.3 Bemcentinib rational combinations

Since the inhibition of AXL is expected to increase tumour cells' sensitivity to cancer drugs and immune responses, bemcentinib's potential to increase the efficacy of chemotherapeutics, targeted and immunotherapy is being tested in a large phase II PoC clinical programme. Being a highly selective AXL inhibitor bemcentinib is believed to be well suited for safe and tolerable administration in combination with other cancer treatments.

In particular, bemcentinib's ability to increase the efficacy of and safe combination with immunotherapy is being investigated by combining bemcentinib with the checkpoint inhibitor pembrolizumab (Keytruda™) in NSCLC, TNBC and melanoma. The first two combination trials are conducted under a clinical collaboration agreement with MSD while the latter trial is an investigator initiated clinical trial.

Bemcentinib is further combined with targeted therapy in order to investigate its potential to reverse and prevent resistance to this class of therapeutics, respectively. In NSCLC, bemcentinib is studied in combination with the EGFR inhibitor erlotinib (TARCEVA) and in melanoma, bemcentinib is investigated in combination with the BRAF and MEK kinase inhibitor doublet dabrafenib and trametinib (Tafinlar™ and Mekinist™).

Combination trials with chemotherapy are under way in AML and NSCLC respectively.

#### 8.2.3 Biomarker strategy

BerGenBio is developing companion diagnostics to help identify cancer patients whose tumours express AXL and are more likely to respond to bemcentinib. The Company believes this has a number of advantages, including reducing the number of patients required in a registration-directed clinical trial, the potential for accelerated approval, reducing costs and speed of trials, and ultimately precision medicines often attract superior reimbursement rates.

The objectives of the broad clinical and biomarker development programme with bemcentinib is to generate data that will inform future clinical trials and support an accelerated regulatory process towards marketing authorisation and

<sup>100</sup> Carl M. Gay, Kavitha Balaji and Averett Byers; Giving AXL the axe: targeting AXL in human malignancy (<http://www.nature.com/bjc/journal/vaop/ncurrent/full/bjc2016428a.html>), accessed 27 June 2018

<sup>101</sup> Matthew Brown et al.; Gene of the month: AXL (<http://jcp.bmj.com/content/69/5/391>, accessed 27 June 2018)



commercialisation. Positive results from these studies are also anticipated to underpin the positioning of bemcentinib as potential future cornerstone of cancer combination therapy in key indications.

While the current clinical trials analyse biomarker expression, including using the BerGenBio AXL IHC and liquid biomarkers, retrospectively, future trials would aim at using these tools to select patients most likely to benefit from bemcentinib treatment.

#### 8.2.3.1 AXL immunohistochemistry

Immunohistochemistry (IHC) methods are the gold standard of cancer diagnosis and guide the choice of treatment course for most cancer patients. In order to tie in with these existing standards, BerGenBio has developed and validated an AXL IHC assay which is hoped to help future patient stratification by becoming part of the standard biomarker testing panel in selected cancer indications.

#### 8.2.3.2 Liquid biopsies and other emerging technologies

While IHC methods rely on the availability of patient tissue and thus cumbersome, invasive biopsy sampling procedures to be carried out on patients, minimally invasive techniques analysing biomarkers in blood samples allow for easier and more frequent testing. BerGenBio is actively working on identifying suited biomarkers for such a liquid biopsy in order to be able to offer cutting edge techniques alongside its first-in-class drug thus staying ahead of the curve.

#### 8.2.4 Pipeline development

BerGenBio have partnered an AXL antibody drug conjugate (ADC) to ADC Therapeutics (BGB601), are actively progressing an anti-AXL antibody into the clinic (BGB149) and are investigating additional small molecule programmes against additional novel targets that are intended for the treatment of aggressive diseases including therapy resistant and immune-evasive cancers.

Furthermore, the Company support external and internal research on the role and function of AXL biology in additional aggressive and under-served disease indications such as fibrosis. Promising results from this pre-clinical work may support and direct the development path of the pipeline programmes and/or serve bemcentinib's life-cycle management.

### 8.3 History and important events

The table below provides an overview of key events in the history of the Company:

Year	Event
2007 .....	BerGenBio established by Bergen Teknologioverføring AS (the technology transfer office of UiB), UniResearch AS (Investment holding company of UiB), Prof. James Lorens and Dr. David Micklem
2008 .....	Richard Godfrey joined as CEO AXL target patent filed Fee for service contract research business model pursued, with international clients such as Johnson & Johnson, Epizyme, & Compugen
2010 .....	Published AXL paper in Proceedings of the National Academy of Sciences (PNAS) BGB101 AXL mAb drug candidate developed and IPintellectual property ("IP") filed Seed funding of NOK 6 million from Sarsia Seed
2011 .....	In-license bemcentinib from Rigel Inc Successful closing of a NOK 54 million private placement
2012 .....	BGB002 method patent filed. Grant of NOK 11.7 million from the Research council of Norway's User-driven Research based Innovation programme (" <b>BIA</b> "). Drug discovery programme (based on BGB002) initiated bemcentinib preclinical development started
2013 .....	Successful closing of a NOK 37 million private placement Start of Phase I clinical trial for the Company's lead product, bemcentinib
2014 .....	Successful completion of private placements of NOK 165 million in total Start Phase Ib clinical trial with bemcentinib in patients with AML BIA grant of NOK 13.3 million BerGenBio received orphan drug designation from the FDA for bemcentinib treatment of AML Out-license 2 antibodies to ADCT for ADC development The Wellcome Trust Limited (the " <b>Wellcome Trust</b> ") granted the Company a convertible loan in the amount of GBP 1.605 million for the BGB002 programme
2015 .....	Start Phase Ib clinical trial with bemcentinib in NSCLC at 3 sites in U.S., including MD Andersen Cancer Center Grant of NOK 12 million from the Research council of Norway's User-driven Research based Innovation programme (BIA) International sites opened for AML study in Germany (4 sites) and U.S. (MD Andersen Cancer Center) companion diagnostic co-development collaborations established in Germany, U.S., Norway
2016 .....	Successful completion of private placements of NOK 213.5 million in total BerGenBio presented promising " <i>Phase I Clinical &amp; Biomarker Data from first-in-class AXL Inhibitor bemcentinib In AML</i> " at the 58 <sup>th</sup> ASH Annual Meeting & Exposition in San Diego 2016 Presentation on promising " <i>bemcentinib Phase I/II Monotherapy Data in Patients with Lung Cancer</i> " at the 28 <sup>th</sup> EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics Symposium Meeting in Munich Reported " <i>First-in-patient Phase 1 Data for bemcentinib in patients with Myeloid Malignancies</i> " at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting Presentation of new breast cancer research highlighting bemcentinib in overcoming immunotherapy resistance at the San Antonio Breast Cancer Symposium 2016
2017 .....	Entry into of two clinical collaboration agreements with MSD BIA grant of NOK 15.1 million. IFU grant from Innovasjon Norge of NOK 24 million related to the clinical trial in combination with Keytruda™ in NSCLC. Successful IPO and capital raise of NOK 400 million. Initial PoC data presented with bemcentinib monotherapy in AML/MDS and in combination with chemotherapy in NSCLC.
2018 .....	Official generic name for BGB324 assigned by World Health Organisation (WHO): bemcentinib. Successful private placement of NOK 187.5 million directed towards US/EU specialist investors, broaden shareholders base. First efficacy endpoint in erlotinib combination study in NSCLC met First stages of Keytruda™ combination trials in NSCLC and TNBC (MSD collaboration) fully recruited BerGenBio ASA share to be included in OSEBX index from 1 June 2018. Interim data from Phase II studies presented at ASCO including PoC data in combination with Keytruda™ in NSCLC as well as biomarker correlation.

## 8.4 Competitive strengths

The Company believes it has a number of competitive strengths that enable it to successfully execute its strategy.

- Pipeline of first-in-class selective drugs:** The Company's lead product, bemcentinib, is a potentially first-in-class, orally available, small molecule AXL inhibitor in phase II clinical development and the most selective AXL inhibitor in clinical development today. BerGenBio believes selective inhibition of AXL is essential for future success, including in combination settings, in order to reduce the risk of overlapping toxicities when cancer treatments are used together. Further first-in-class pipeline programmes comprise an AXL function blocking antibody (BGB149) that is planned to enter the clinic in late 2018 and first-in-class selective small molecule inhibitor programmes at early pre-clinical stage. An AXL ADC (BGB601) is out-licensed to ADC Therapeutics for onward clinical development.
- Compelling PoC clinical data for bemcentinib:** Interim clinical data presented in June 2018 from Company sponsored and investigator-led studies across the clinical development programme provided continued evidence that bemcentinib is well tolerated alone and in combination with the other cancer therapies used. The data show an encouraging anti-tumour effect of bemcentinib-containing regimens including monotherapy, combination with chemotherapy, targeted and immunotherapy agents; increasingly a correlation between the patient's AXL status and the anti-tumour effect.
- Parallel companion diagnostics development:** BerGenBio is pursuing a precision medicine approach with its parallel development of companion diagnostics for selection of patients with high AXL expression, who will most likely benefit from bemcentinib treatment. Precision medicine means providing the right medicine to the right patients at the right time. This will offer clear safety and efficacy benefits to the patients and cost effectiveness for provider of healthcare, such as insurance companies or governmental payers.
- MSD clinical collaboration:** BerGenBio entered into a clinical collaboration agreement with MSD in 2017 for two clinical trials of bemcentinib in combination with MSD's anti PD-1 agent Keytruda™. Keytruda™ is among the leading checkpoint inhibitor (CPI) and has been approved in a wide range of cancers. As of July 2018, it is the only immunotherapy approved in the United States to treat lung cancer patients who have not received prior treatment. The collaboration with MSD is valuable to BerGenBio as it (i) validates the role of AXL as a novel drug target, (ii) validates bemcentinib as a robust and potentially high value drug candidate, (iii) represents a substantial financial contribution through the provision of Keytruda™ (otherwise a major cost, typically USD 150,000 per patient per year), (iv) includes a provision of scientific input to the trials protocol designs by MSD, (v) provides trial oversight through participation in the joint steering committee and (vi) biomarker analysis that BerGenBio will have access to at no cost. As of July 2018, both collaboration trials had successfully completed their first stages ahead of schedule.
- Scientific leadership and expertise in AXL kinase biology and EMT:** BerGenBio has gained a deep and leading scientific expertise and knowledge of AXL and EMT biology through many years of internal R&D. Professor James Lorens, the Company's CSO is a highly regarded academic researcher and has published widely on AXL, EMT and cancer. BerGenBio has built a broad international network of academic and clinical collaborators and key opinion leaders in the field to further augment its understanding of AXL biology, its role in aggressive cancers and its potential as a novel target for cancer drug discovery. Bemcentinib is recognised as the most advanced and selective AXL inhibitor and it has been the subject of many publications by academic researchers studying the AXL target.
- Clear strategic vision:** BerGenBio's strategy is to discover and develop novel medicines to treat aggressive cancers, which represent a significant, high unmet medical need. The Company intends, either alone or in collaboration with a partner, to develop and commercialise its lead product bemcentinib through to marketing approval by the regulatory agencies. Furthermore, it is developing companion diagnostics to identify the cancer patient populations that can be expected to benefit most from treatment with, bemcentinib. The ability to select the most appropriate patients for therapy is expected to facilitate breakthrough designation for bemcentinib and accelerate its path to approval by the regulators.
- Low cost of goods (COG) of bemcentinib:** Bemcentinib is a simple stable small molecule that is administered orally. Small molecules are well established as a drug class, accounting for 90% of the global pharmaceutical market and five out of the top selling drugs. Bemcentinib is easily synthesised and manufactured and supplied in simple packaging with a three-year expiry date. This contrasts with complex biologicals, such as monoclonal antibodies, ADCs, etc, which typically cost twenty times as much to produce, have a short shelf life and are given

via injection. Bemcentinib is administered as a low dose, one-a day pill, that patients take at home, not requiring an expensive in-patient administration at a hospital as with complex biological. The low COG gives BerGenBio room to manoeuvre around possible future pricing pressure. Expensive medicines, driven by complex new technologies are a global issue facing the biopharmaceutical industry and providers of healthcare, such as insurance companies or governmental payers.

- **Ongoing clinical collaborations with leading institutions globally:** The Company is currently working with highly regarded oncologists and conducting clinical trials at top U.S. and European cancer centers. The quality of the collaborators that BerGenBio is working with reflects the interest from the global medical community in AXL inhibition and the benefits that drugs targeting AXL could provide to patients with aggressive disease.
- **A strong shareholder base:** The Company has a strong shareholder base including highly recognised leading Norwegian life-sciences investors and reputable institutions with significant assets under management. The recent private placement in 2018 added new specialist life sciences investors in the U.S. to the shareholder base.
- **Portfolio of patents:** BerGenBio has a portfolio of patents granted and pending covering the Company's product portfolio. The Company is diligent in protecting all of the IP it develops which it believes will provide protection to significant elements of its business. This includes technologies, discoveries, inventions, data and methods. Protection of proprietary rights includes seeking and maintaining patent protection intended to cover the composition of matter and use for the Company's drug candidates and back up series. IPR (patents) are filed and prosecuted and maintained worldwide (including all major pharmaceutical markets).
- **BerGenBio has an experienced management team:** The Company has an experienced executive management team with extensive expertise in drug discovery, development and commercialisation of new oncology drugs. The team has significant international experience, from top tier big pharma/biotech, including Eli Lilly, Daichi, Vertex, Reckitt Benckiser, Rigel and Roche. The team is located in Bergen (Norway) and Oxford (UK).

### 8.5 Overview of the Company’s business areas

BerGenBio’s lead product is bemcentinib, a potentially first-in-class, selective orally bioavailable small molecule inhibitor of the receptor tyrosine kinase AXL in phase II clinical development in NSCLC, AML/MDS, TNBC and melanoma.

The clinical development of bemcentinib is underpinned by the development of a parallel companion diagnostics aimed at predicting which patients may derive most benefit from bemcentinib treatment in the future.

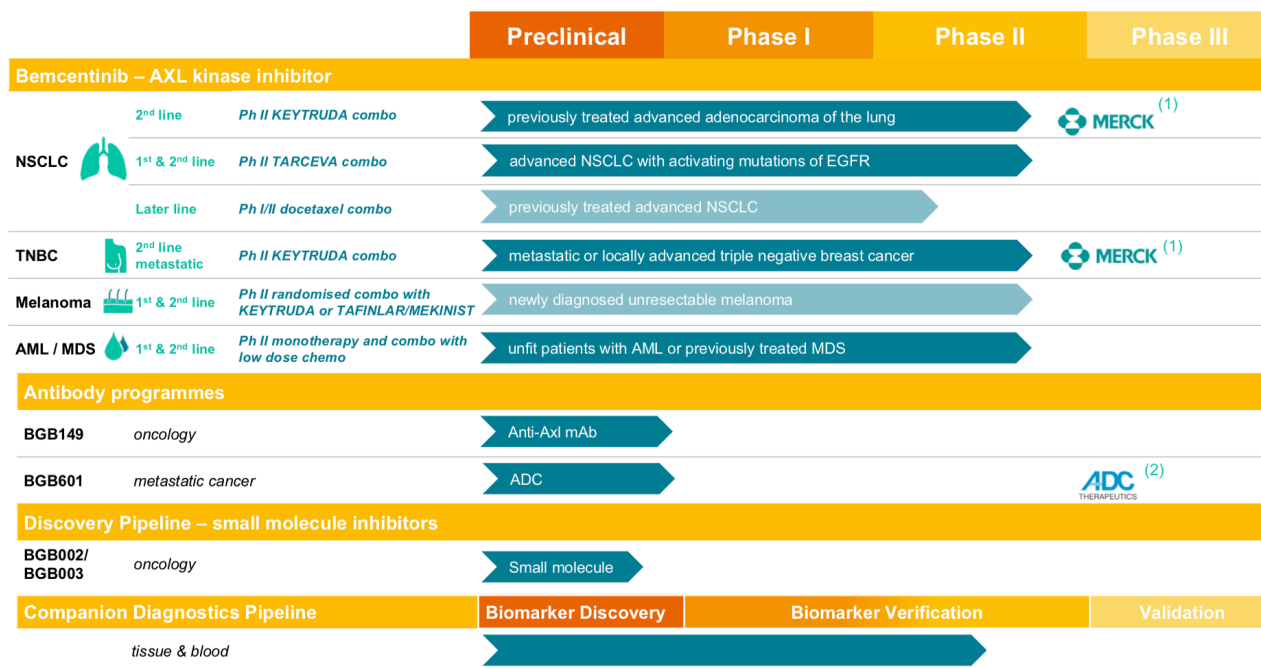
The Company also develops antibodies targeting AXL: BGB149 is a fully humanised function blocking monoclonal antibody in late stage preclinical development with first-in-man clinical trials expected to commence in 2018. The development of BGB149 is further described in Section 8.5.3.2 "Anti-AXL monoclonal antibody (mAb)". BGB601, is an anti-AXL ADC outlicensed to ADCT which is indicatively expected to enter Phase I trials in Q1 2019.

The Company also has a discovery pipeline consisting of the small molecule selective inhibitor programmes BGB002 and BGBC003 in early pre-clinical development. The development of BGB003 is further described in Section 8.5.2.2 "Phase II clinical trial in AML/MDS as a monotherapy and in combination with low dose chemotherapy: BGBC003 (NCT12488408)" and the development of BGB002 is further described in Section 8.5.3.4 "Discovery pipeline".

Additionally, BerGenBio supports pre-clinical work investigating the potential of AXL inhibition in additional oncology and non-oncology indications.

The figure below is illustrating the Company's business areas and development status as of July:

Figure 12: Clinical development overview



(1) Clinical trial collaboration, no preferential rights.

(2) BGB601 has been outlicensed for further development to ADC Therapeutics.

**8.5.1 Companion Diagnostics**

BerGenBio has proprietary antibodies and technologies to enable the detection of total AXL and the activation of the AXL pathway in patient samples. This includes sections from tumour biopsies as well as blood sample based assays. Assays under development include AXL IHC and several liquid biopsy techniques.

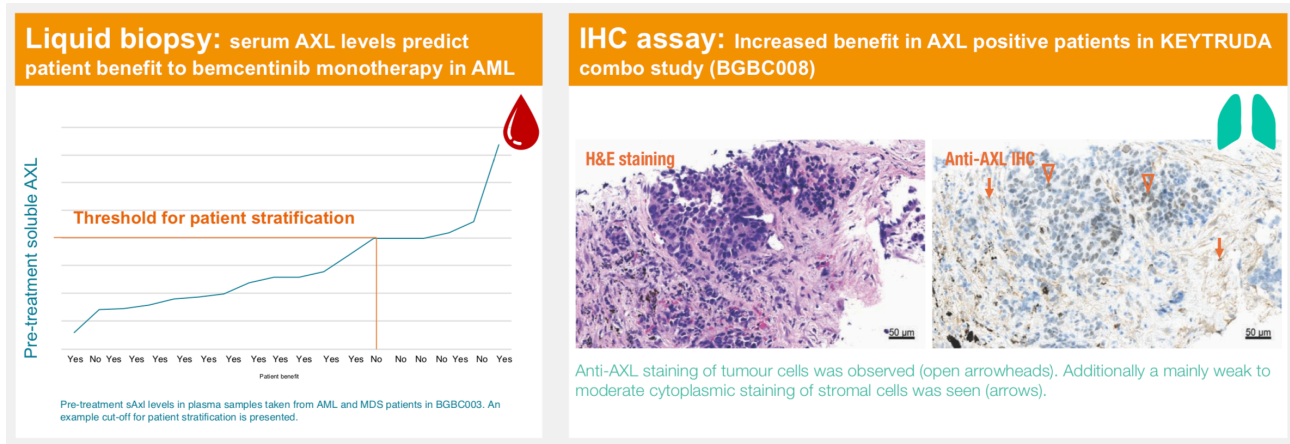
Initial clinical data retrospectively analysing the presence of AXL in patient tissue per IHC as well as AXL pathway activation in liquid biopsies has shown promise that these and other techniques may guide patient selection in the future (figure 13 “Liquid biopsy and tumour tissue biopsy”). In particular, the levels of the inactive form of AXL in plasma (plasma soluble AXL / sAXL) were shown to be predictive of response to bemcentinib monotherapy in patients with AML and MDS. A proportion of NSCLC patients who expressed AXL as measured per IHC showed benefit from the combination treatment of bemcentinib and Keytruda™, even in the absence of detectable PD-L1 expression which is the predictive biomarker for Keytruda™.

Analyses of clinical samples and assay development are being carried out in laboratories appropriately certified to carry out such tests (CLIA certification). This allows for predictive biomarker data generated during the PoC phase II clinical programme with bemcentinib to form part of a potential future regulatory submission for a companion diagnostic.

Additionally, response biomarkers indicating the effect of bemcentinib on a patient during treatment, the so called pharmacodynamic effects, are being investigated continuously and continue to provide evidence that bemcentinib has selective on-target activity.

An overview of the company’s progress regarding predictive and response biomarker development was presented during the 2018 ASCO Annual Meeting:<sup>102</sup>

Figure 13: Liquid biopsy and tumour tissue biopsy



<sup>102</sup> [https://www.bergenbio.com/wp-content/uploads/2018/06/ASCO2018\\_posters\\_reduced-file-size.pdf](https://www.bergenbio.com/wp-content/uploads/2018/06/ASCO2018_posters_reduced-file-size.pdf)

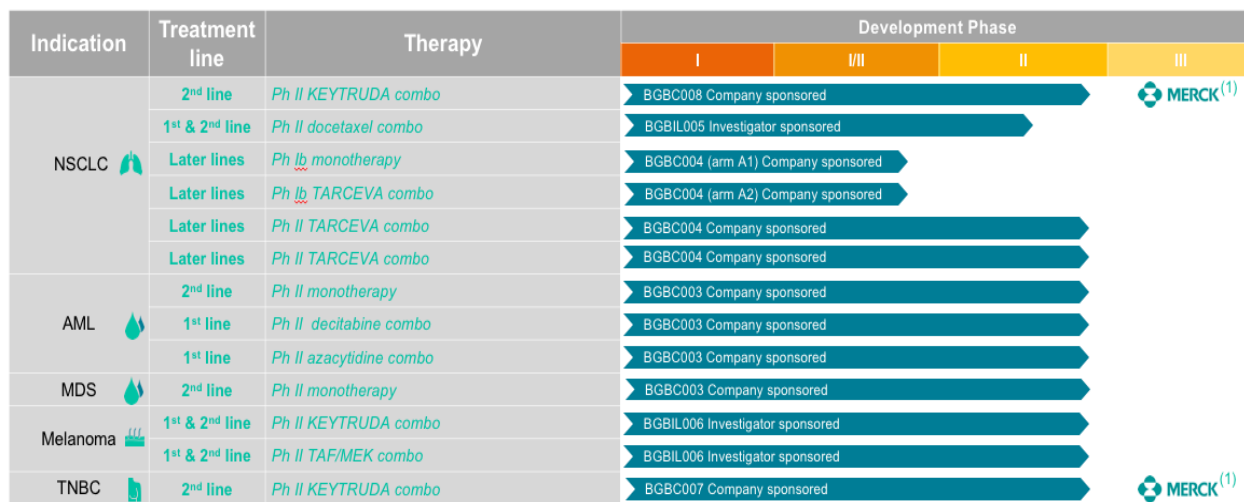
### 8.5.2 Bemcentinib clinical development

Bemcentinib is an orally available selective small molecule inhibitor of the AXL tyrosine kinase. The clinical formulation has good oral bio-availability and pharmaceutical properties that allows it to be administered once a day as an oral capsule which can be taken at home.

The clinical experience with bemcentinib so far indicates that it is well tolerated both as a single agent and in combination with targeted and immunotherapy as well as chemotherapy.

An overview of the Company’s progress regarding its PoC clinical development programme with bemcentinib was presented during the 2018 ASCO Annual Meeting:

Figure 14: Bemcentinib clinical development



(1) Clinical trial collaboration, no preferential rights.

The individual trials for the Phase II studies as described in figure 14 above do not have a specific end date. An indication of the timeline for these Phase II studies appear in Figure 25 in Section 8.5.2.8 "Registration directed studies (Phase III)".

#### 8.5.2.1 Phase I – Healthy volunteer clinical trial

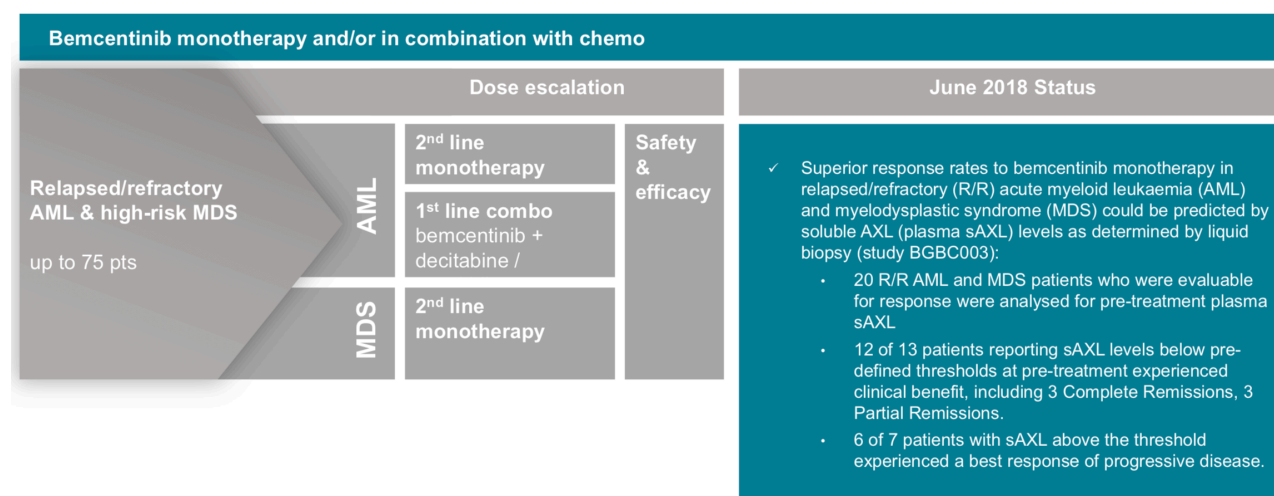
BerGenBio has completed one dose escalation study with bemcentinib in healthy volunteers. This is rather unusual for a cancer drug. The strategy was approved by regulators because bemcentinib is highly selective for AXL, AXL has no known function in healthy tissue and bemcentinib preclinical toxicology studies suggested it would be safe. The healthy volunteer study (BGBC001) involved 36 subjects who received individual doses of bemcentinib ranging from 50 mg to 1.5 g. In general drug administration was well tolerated; although gastrointestinal toxicity, particularly diarrhoea became evident at higher dose levels, but was manageable. Systemic exposure to bemcentinib increased linearly with administered dose and individual subject profiles confirmed animal observations that bemcentinib has a long terminal elimination half-life. Pharmacokinetic profiling indicated that an initial loading dose followed by a much smaller daily dose would rapidly achieve and maintain steady state concentrations in the blood stream.

### 8.5.2.2 Phase II clinical trial in AML/MDS as a monotherapy and in combination with low dose chemotherapy: BGBC003 (NCT12488408)

In total, up to 75 AML and high-risk MDS patients are expected to be enrolled in this trial (illustrated in the figure below). Patients are typically elderly and frail. The objective for this trial is to assess bemcentinib's safety profile and antileukaemic efficacy in this patient population both as a monotherapy and in combination with low-dose chemotherapy regimens. In addition, predictive biomarker candidates are being identified with a view to develop a companion diagnostic for use in conjunction with bemcentinib in this indication in the future.

Recruitment is currently ongoing in the U.S., Norway, Italy and Germany into the phase II portion of the trial: AML patients who are unfit for intensive chemotherapy receive a combination of bemcentinib with low doses of the chemotherapeutic agents cytarabine or decitabine. AML and MDS patients who have failed prior therapies (relapsed or refractory AML and MDS patients) are receiving bemcentinib monotherapy.

Figure 15: AML/MDS Phase II as monotherapy and in combination with chemotherapy



#### Summary of key results reported to date:

- (1) A range of novel predictive biomarker candidates that correlated significantly with clinical benefit were detected in blood, bone marrow plasma or bone marrow cell samples from patients as reported at the 2017 ASH meeting (Loges *et al.* ASH 2017)<sup>103</sup>.
- (2) Further translational analyses of the study of bemcentinib monotherapy, reported at the ASCO-SITC (Loges *et al.* ASCO-SITC 2018)<sup>104</sup> congress in January 2018, showed a clear immunomodulatory effect as a result of selective AXL inhibition with bemcentinib; this was evidenced in six of nine patients analysed by increased immune activity characterised by diversification of patients' T-cell receptor repertoire in peripheral blood and/or bone marrow.
- (3) Superior response rates (figure 16) to bemcentinib monotherapy in patients with low levels of plasma soluble AXL (plasma sAXL) levels as determined by liquid biopsy were reported at the 2018 ASCO Annual meeting<sup>105</sup>:
  - 20 R/R AML and MDS patients who were evaluable for response were analysed for pre-treatment plasma sAXL
  - 12 of 13 patients reporting sAXL levels below pre-defined thresholds at pre-treatment experienced clinical benefit, including 3 Complete Remissions, 3 Partial Remissions.
  - 6 of 7 patients with sAXL above the threshold experienced a best response of progressive disease.

<sup>103</sup> Loges *et al.* ASH 2017 [http://www.bergenbio.com/wp-content/uploads/2017/12/2017\\_ASH\\_final.pdf](http://www.bergenbio.com/wp-content/uploads/2017/12/2017_ASH_final.pdf) (accessed 24.08.2018)

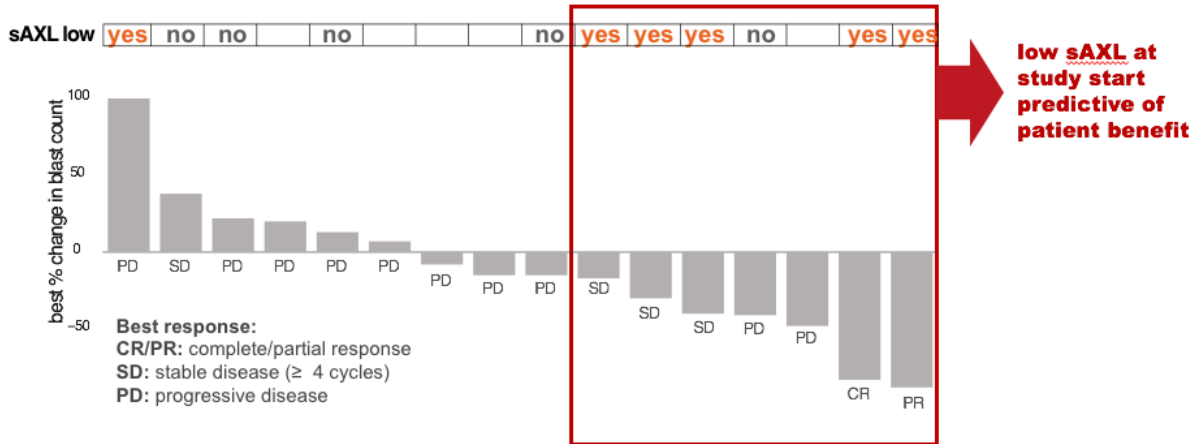
<sup>104</sup> Loges *et al.* ASCO-SITC 2018 [http://www.bergenbio.com/wp-content/uploads/2018/01/2018\\_ASCO\\_SITC-003\\_final.pdf](http://www.bergenbio.com/wp-content/uploads/2018/01/2018_ASCO_SITC-003_final.pdf)

<sup>105</sup> [https://www.bergenbio.com/wp-content/uploads/2018/06/ASCO2018\\_posters\\_reduced-file-size.pdf](https://www.bergenbio.com/wp-content/uploads/2018/06/ASCO2018_posters_reduced-file-size.pdf)

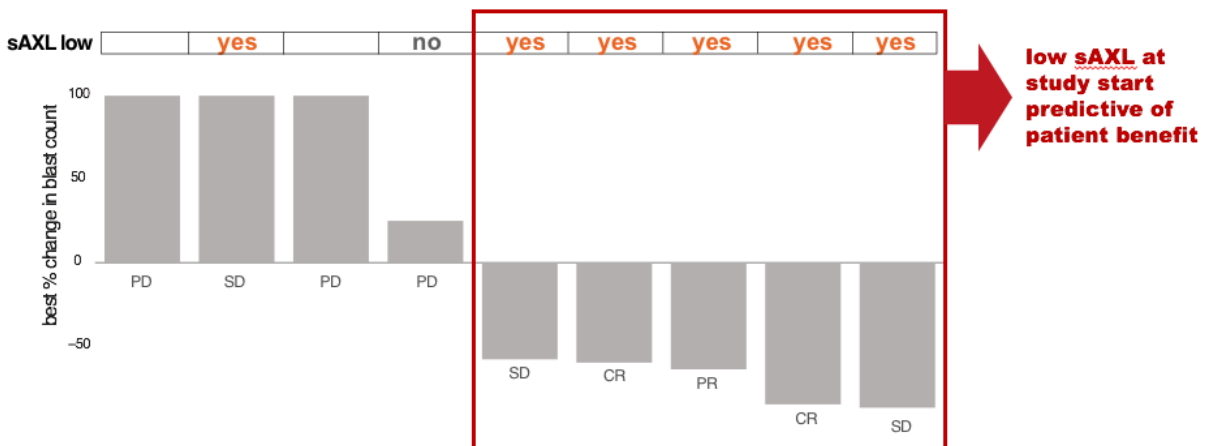


Figure 16: AML/MDS Phase II, interim response rate

## Superior efficacy in patients with low plasma soluble sAXL: AML



## Superior efficacy in patients with low plasma soluble sAXL: MDS



Displayed above in Figure 16 is the best % change in blast count for patients with available bone marrow assessments and their overall best response over the course of treatment. Furthermore, patients' sAXL status before commencement of treatment is shown (sAXL low: yes/no). The change in blast count gives an indication of the effect of bemcentinib treatment on patients' tumours and their overall response is determined taking into account such tumour response as well as haematological parameters and general health over the course of treatment. Relatively more patients with low sAXL at the beginning of treatment saw benefit from treatment as measured by a reduction in blast count and/or an overall objective response of complete or partial response (CR or PR, respectively). This suggests that a patient's sAXL status at the beginning of treatment may be a suitable biomarker to predict whether a patient will benefit from treatment with bemcentinib<sup>106</sup>.

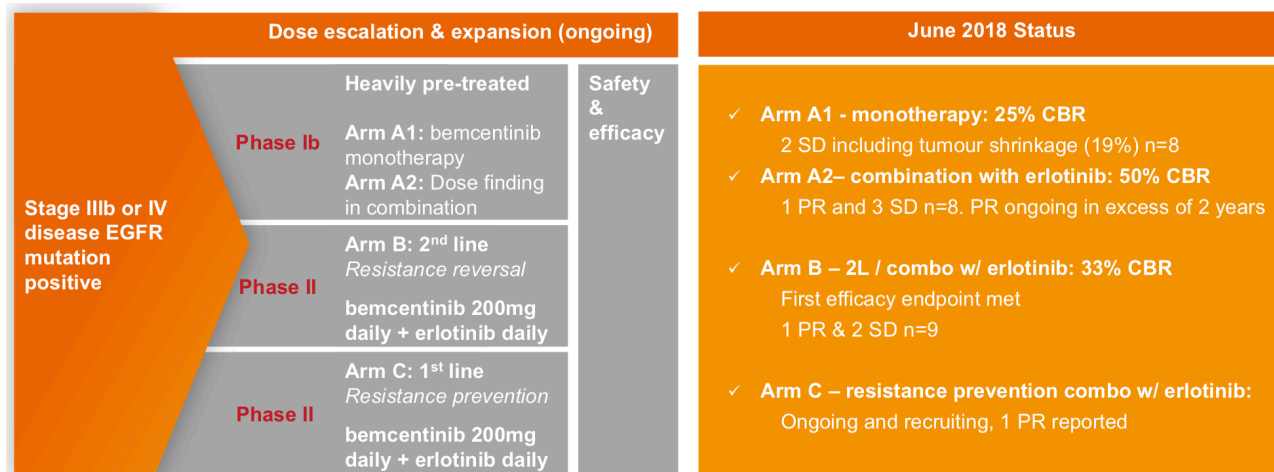
<sup>106</sup> Gjertsen et al ASCO 2018 ([https://www.bergenbio.com/wp-content/uploads/2018/06/ASCO2018\\_posters\\_reduced-file-size.pdf](https://www.bergenbio.com/wp-content/uploads/2018/06/ASCO2018_posters_reduced-file-size.pdf))

### 8.5.2.3 Phase II clinical trial in NSCLC in combination with EGFR inhibitor erlotinib (TARCEVA): BGBC004 (NCT02424617)

Up to 66 patients with NSCLC with an activating mutation of the EGFR gene (appr. 15-20% of NSCLC patients) are expected to be enrolled into this trial (as illustrated in figure 17 below). The trial includes first and second line patients who are either currently receiving the targeted EGFR inhibitor erlotinib (TARCEVA) or have previously received an EGFR inhibitor on which they experienced disease progression, respectively. Enrolment into the phase II portion of the trial is currently ongoing at centres in the U.S.

The objective for this trial is to assess bemcentinib's safety profile and efficacy at enhancing responses to EGFR directed therapy when given in combination with full doses of the AGFR inhibitor erlotinib (TARCEVA).

Figure 17: NSCLC Phase II combination with erlotinib (TARCEVA)



#### Summary of key results reported to date:

- (1) Bemcentinib monotherapy in heavily pretreated NSCLC patients led to stabilisation of the disease for approximately one year in two of eight patients indicating that bemcentinib may be effective on its own in a proportion of patients. This data was presented at the 2016 ENA Annual meeting<sup>107</sup>.
- (2) Preliminary results on the second line combination of bemcentinib and erlotinib were presented during a mini oral presentation at the World Conference of Lung Cancer 2017<sup>108</sup> indicating that the combination is well tolerated with patients ongoing for periods extending 2.5 years.
- (3) The predefined efficacy endpoint for the first stage of the bemcentinib and erlotinib second line combination was met in January 2018<sup>109</sup> and later exceeded (1 partial response, 1 stable diseases at 12 weeks, 1 stable disease at 6 weeks).
- (4) Preliminary data on the combination of bemcentinib and erlotinib in the first line setting presented during the 2018 ASCO Annual Meeting<sup>110</sup> showed that the addition of bemcentinib led to a deepening of responses in patients who had experienced optimum benefit from erlotinib monotherapy: Of a total of six RECIST evaluable patients, four had experienced tumour shrinkage including one partial response.

### 8.5.2.4 Phase I/II investigator led clinical trial in NSCLC in combination with docetaxel: BGBIL005 (NCT02922777)

Up to 30 patients with end stage NSCLC who have exhausted all available treatment options will be enrolled into this phase I/II investigator led trial. Enrolment is currently underway at clinical centres in the U.S.

<sup>107</sup> Byers *et al.* ENA 2016 <https://www.ecco-org.eu/Events/Past-conferences/ENA2016/Searchable-Programme>

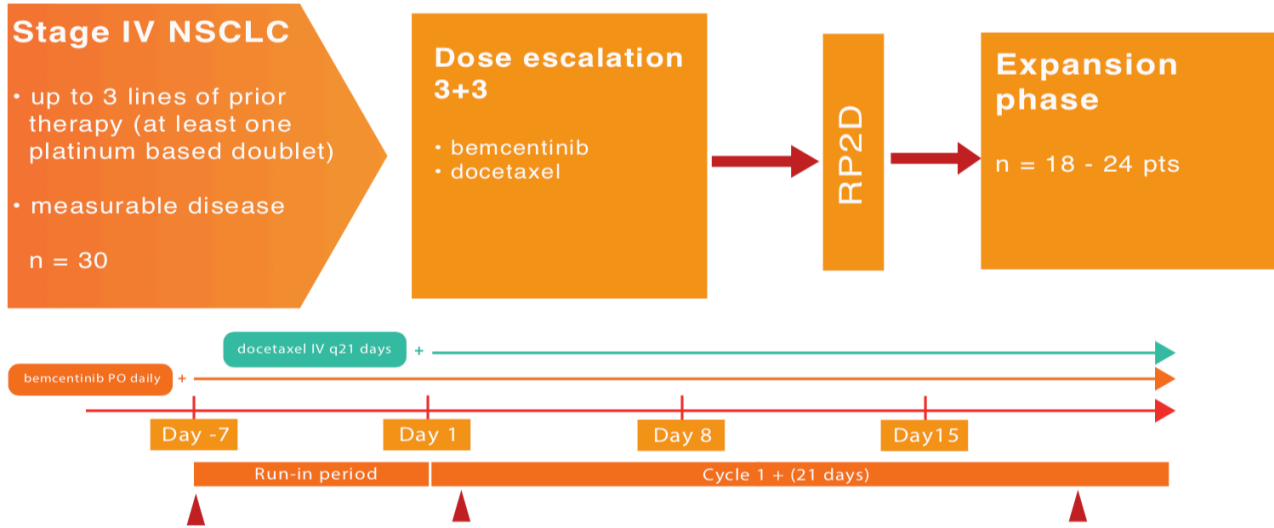
<sup>108</sup> Byers *et al.* WCLC 2017 [http://www.bergenbio.com/wp-content/uploads/2017/10/wclc2017\\_BGBC004\\_final.pdf](http://www.bergenbio.com/wp-content/uploads/2017/10/wclc2017_BGBC004_final.pdf) (accessed 24.08.2018)

<sup>109</sup> Notice 9 January 2018: <https://www.bergenbio.com/investors/stock-exchange-notices/>

<sup>110</sup> Lorens *et al.* ASCO 2018 [https://www.bergenbio.com/wp-content/uploads/2018/06/ASCO2018\\_posters\\_reduced-file-size.pdf](https://www.bergenbio.com/wp-content/uploads/2018/06/ASCO2018_posters_reduced-file-size.pdf)

The objective for this trial is to assess bemcentinib’s safety profile and efficacy at enhancing responses to chemotherapy when given in combination with docetaxel – a common chemotherapy regimen in this patient population that typically yields responses in less than 10% of patients treated with docetaxel alone.

Figure 18: NSCLC Phase I/II in combination with docetaxel



**Summary of key results reported to date:**

Presentations made at the World Conference of Lung Cancer 2017<sup>111</sup> and during the 2018 ASCO Annual Meeting<sup>112</sup> highlighted that the combination is tolerated and has shown encouraging potential at enhancing responses to docetaxel: Among the first seven evaluable patients, three experienced partial responses and three had stabilisation of their disease.

<sup>111</sup> Gibbons ACLC 2017 [http://www.bergenbio.com/wp-content/uploads/2017/10/wclc2017\\_BGBC004\\_final.pdf](http://www.bergenbio.com/wp-content/uploads/2017/10/wclc2017_BGBC004_final.pdf)

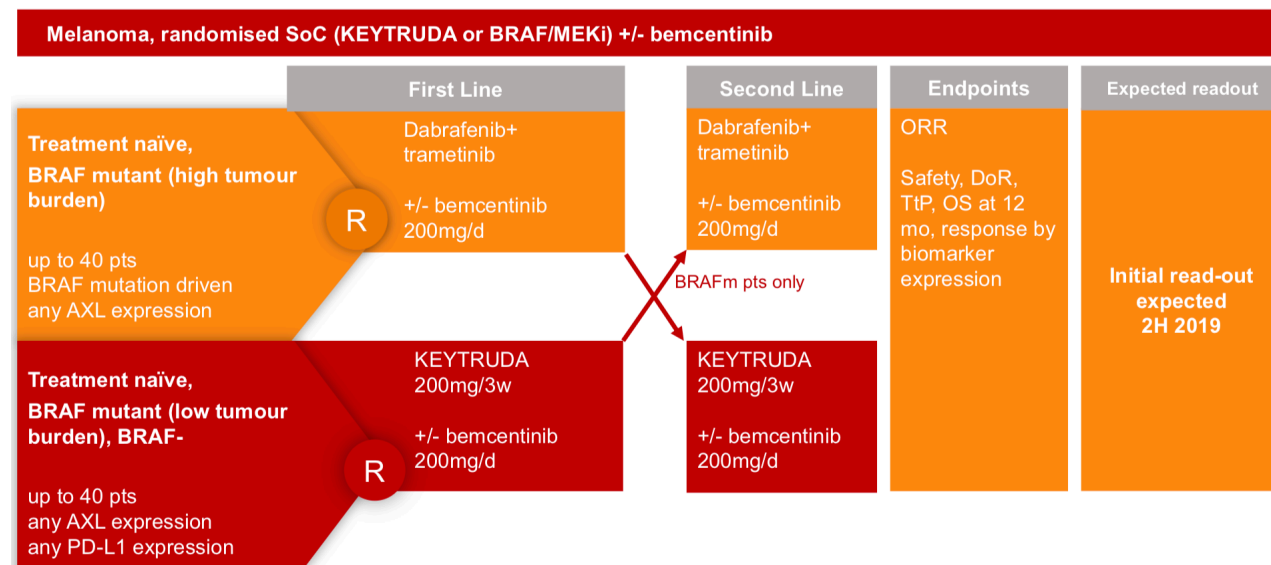
<sup>112</sup> [www.bergenbio.com/investors/presentations](http://www.bergenbio.com/investors/presentations)

### 8.5.2.5 Randomised Phase II investigator led clinical trial in melanoma in combination with targeted therapy (dabrafenib/trametinib) or immune checkpoint inhibitors (pembrolizumab): BGBIL006 (NCT02872259)

Up to 92 newly diagnosed patients with metastatic melanoma are expected to be enrolled into this phase II randomised trial. Patients are stratified to receive either targeted or immunotherapy (depending on the presence of activating BRAF mutations and their overall disease burden) and patients will be randomly assigned to receive bemcentinib in addition to these standard of care drugs (at a 2 to 1 ratio). Recruitment into the phase II portion of the trial is currently ongoing at several centres in Norway.

The objective of this trial to evaluate the overall response rate of the combination. Biomarker correlations will also be analysed.

Figure 19: Melanoma Phase II in combination with dabrafenib/trametinib or pembrolizumab



#### Summary of key results reported to date:

- (1) The phase I portion of this trial evaluating the safety of combining the three kinase inhibitors bemcentinib, dabrafenib and trametinib (Tafinlar™/Mekinist™) has successfully been completed indicating that these agents could be safely combined at full dose as reported at the World Melanoma Congress 2017.<sup>113</sup>
- (2) At the 2018 ASCO Annual Meeting, encouraging tumour responses were reported with 15 of 19 patients analysed at the time of data cut-off showing evidence of tumour shrinkage including two complete response (CR), eight partial responses (PRs) and a further six stable disease (SD).<sup>114</sup>

<sup>113</sup> Straume *et al* World Melanoma Congress 2017 [http://www.bergenbio.com/wp-content/uploads/2017/10/World-Melanoma\\_final.pdf](http://www.bergenbio.com/wp-content/uploads/2017/10/World-Melanoma_final.pdf).

<sup>114</sup> Straume *et al* ASCO 2018 [https://www.bergenbio.com/wp-content/uploads/2018/06/ASCO2018\\_posters\\_reduced-file-size.pdf](https://www.bergenbio.com/wp-content/uploads/2018/06/ASCO2018_posters_reduced-file-size.pdf).

Figure 20: Melanoma Phase II - percentage change from baseline

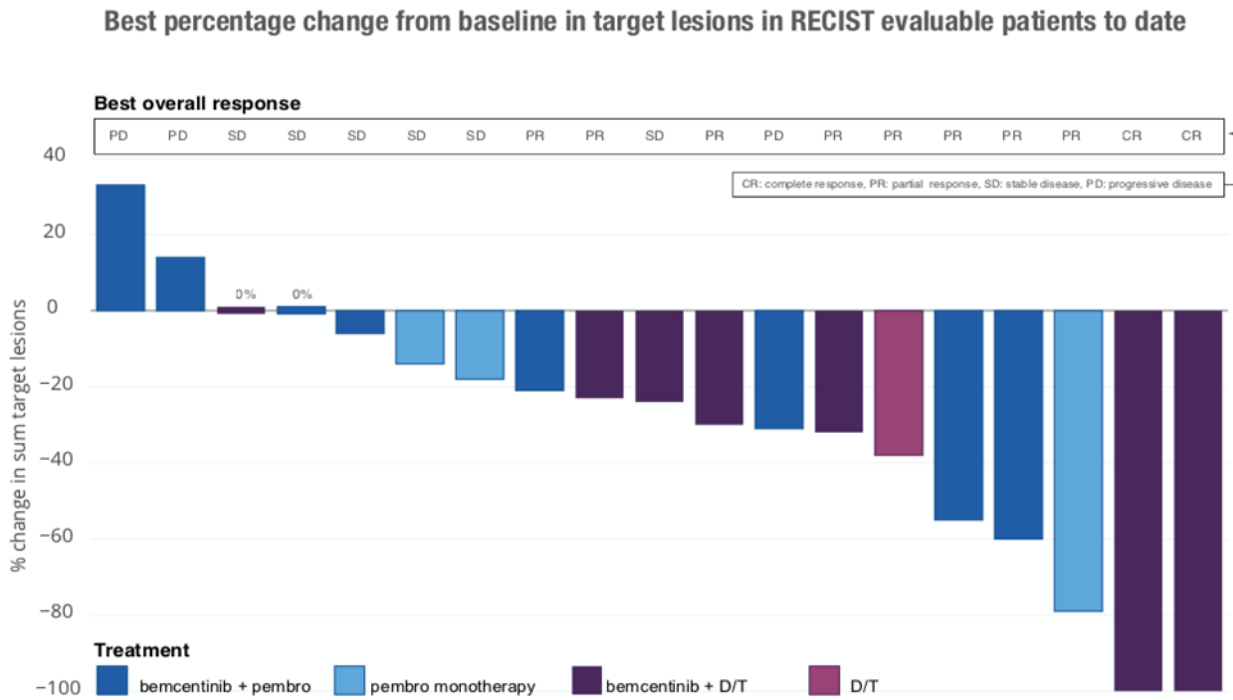
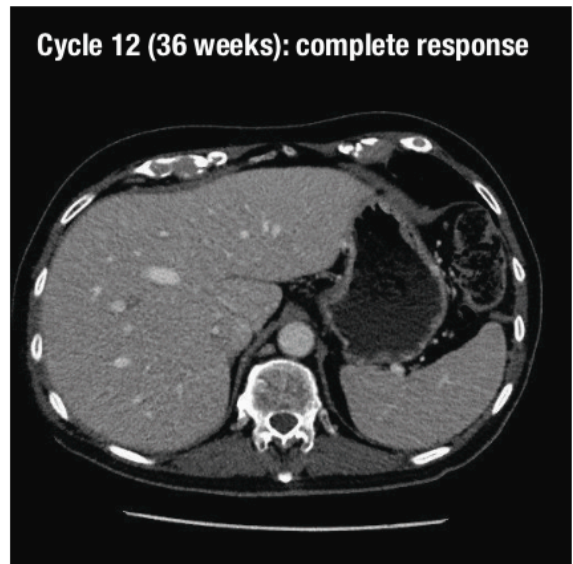
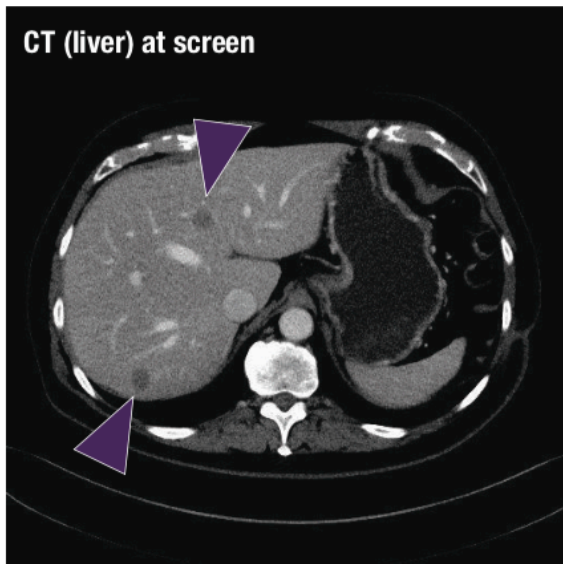


Figure 21: Melanoma- example CR on bemcentinib + dabrafenib/trametinib

### Example CR on bemcentinib + dabrafenib/trametinib

A 68 year old male was randomised to receive 200 mg/daily bemcentinib + standard dabrafenib/trametinib. At screening the patient had multiple metastases to the liver and the lungs. At cycle 12, he had a complete response.



**8.5.2.6 Phase II clinical trial in TNBC in combination with immune checkpoint inhibitor pembrolizumab (Keytruda™): BGBC007 (NCT03184558)**

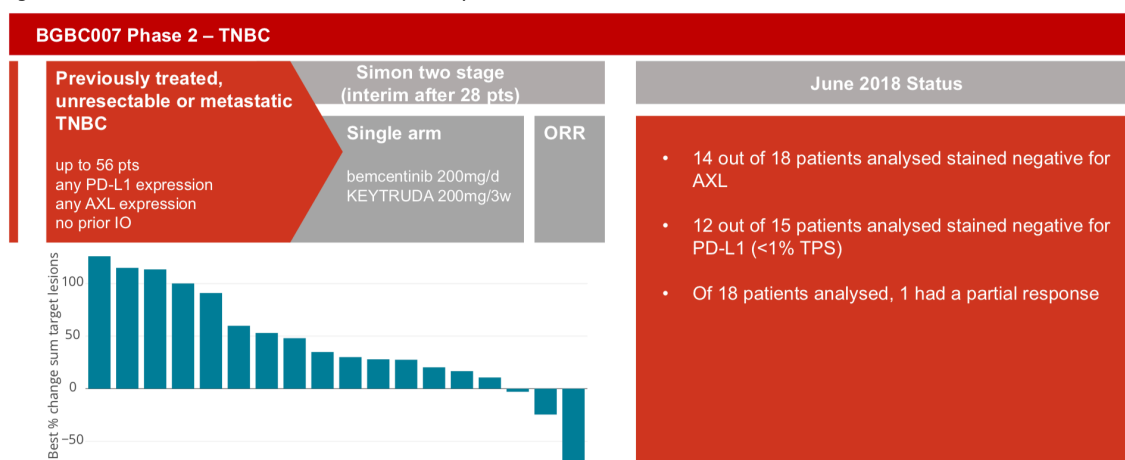
Up to 56 patients with second line metastatic TNBC were planned to be enrolled into this Simon-like two stage study. In one single treatment arm, patients are receiving full dose bemcentinib in combination with pembrolizumab (Keytruda™), an immune checkpoint inhibitor not yet approved in this indication.

The objective for the trial is to analyse the safety and overall response rate of the combination. Biomarker correlations will also be investigated.

**Summary of key results reported to date:**

The first stage of the trial has completed recruitment and as of July 2018 patients remain on study, but no patients are currently receiving treatment. 14 out of 18 patients were reported to be AXL negative as per BerGenBio’s proprietary immunohistochemistry assay. Three of 18 evaluable patients had evidence of tumour shrinkage. (www.bergenbio.com/investors/presentations).

Figure 22: TNBC Phase II in combination with Keytruda™



### 8.5.2.7 Phase II clinical trial in NSCLC in combination with immune checkpoint inhibitor pembrolizumab (Keytruda™): BGBC008 (NCT03184571)

Up to 48 patients with second line NSCLC are expected to be enrolled into this Simon-like two stage study. In one single treatment arm, patients are receiving full dose bemcentinib in combination with pembrolizumab (Keytruda™), an immune checkpoint inhibitor which is approved as a second line monotherapy in PD-L1 biomarker positive NSCLC patients.

The objective for the trial is to analyse the safety and overall response rate of the combination. Biomarker correlations will also be investigated.

Figure 23: NSCLC Phase II in combination with Keytruda™

BGBC008 Phase 2 – Adenocarcinoma of the lung		
Previously treated, unresectable adenocarcinoma of the lung up to 48 pts any PD-L1 expression any AXL expression no prior IO	Simon two stage (interim after 22 pts)	Status June 2018
	Single arm bemcentinib 200mg/d KEYTRUDA 200mg/3w	ORR
		<ul style="list-style-type: none"> <li>✓ Tumour shrinkage was reported in 8 of 15 evaluable patients to date, including three PRs and one mixed response,</li> <li>✓ Response assessment according to biomarker expression analysis available <u>thus far</u>:               <ul style="list-style-type: none"> <li>• 6 of 7 PD-L1 negative patients reported clinical benefit, including 2 PR and 2 patients with evidence of tumour shrinkage.</li> <li>• 5 of 6 patients thus far tested for AXL expression with BerGenBio's proprietary immunohistochemistry assay, were AXL positive.</li> <li>• 4 of 5 Axl positive patients reported clinical benefit including 1 PR and 2 patients with evidence of tumour shrinkage.</li> <li>• All 4 AXL positive patients reporting clinical benefit were found to be PD-L1 negative.</li> </ul> </li> <li>✓ An acceptable safety profile of the combination was reported with only a minority of patients experiencing fully reversible adverse events.</li> </ul>

#### Summary of key results reported to date:

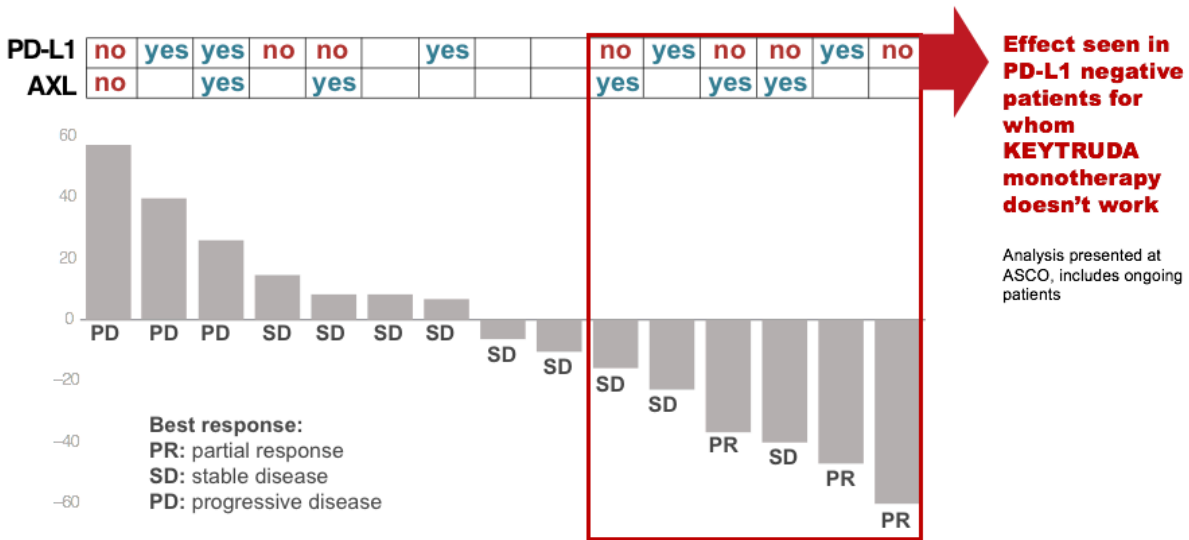
- (1) As of July 2018, the first stage of the trial had completed accrual and a proportion of patients are still undergoing treatment.
- (2) At the 2018 ASCO-SITC & ASCO annual meeting 2018 meeting, the combination was reported to be well tolerated<sup>115</sup>.
- (3) At the ASCO annual meeting 2018 meeting, encouraging early efficacy was reported including in the PD-L1 biomarker negative population which is not expected to derive significant benefit from Keytruda™ monotherapy (figure 24)<sup>116</sup>:
  - Tumour shrinkage was reported in 8 of 15 evaluable patients to date, including three Partial Responses (PR) and one mixed response,
  - Response assessment according to biomarker expression analysis available thus far:
    - 6 of 7 PD-L1 negative patients reported clinical benefit, including 2 PRs and 2 patients with evidence of tumour shrinkage.
    - 5 of 6 patients thus far tested for AXL expression with BerGenBio's proprietary immunohistochemistry assay, were AXL positive.
    - 4 of 5 AXL positive patients reported clinical benefit including 1 PR and 2 patients with evidence of tumour shrinkage.
    - All 4 AXL positive patients reporting clinical benefit were found to be PD-L1 negative.

<sup>115</sup> Yule *et al* ASCO-SITC 2018 and Lorens *et al* ASCO 2018, [http://www.bergenbio.com/wp-content/uploads/2018/02/ASCO-SITC\\_007-008\\_final.pdf](http://www.bergenbio.com/wp-content/uploads/2018/02/ASCO-SITC_007-008_final.pdf), [https://www.bergenbio.com/wp-content/uploads/2018/06/ASCO2018\\_posters\\_reduced-file-size.pdf](https://www.bergenbio.com/wp-content/uploads/2018/06/ASCO2018_posters_reduced-file-size.pdf).

<sup>116</sup> Yule *et al* ASCO-SITC 2018 and Lorens *et al* ASCO 2018, [http://www.bergenbio.com/wp-content/uploads/2018/02/ASCO-SITC\\_007-008\\_final.pdf](http://www.bergenbio.com/wp-content/uploads/2018/02/ASCO-SITC_007-008_final.pdf), [https://www.bergenbio.com/wp-content/uploads/2018/06/ASCO2018\\_posters\\_reduced-file-size.pdf](https://www.bergenbio.com/wp-content/uploads/2018/06/ASCO2018_posters_reduced-file-size.pdf)

Figure 24: NSCLC Phase II in combination with Keytruda™, interim response rate

## Encouraging activity in PD-L1 negative patients

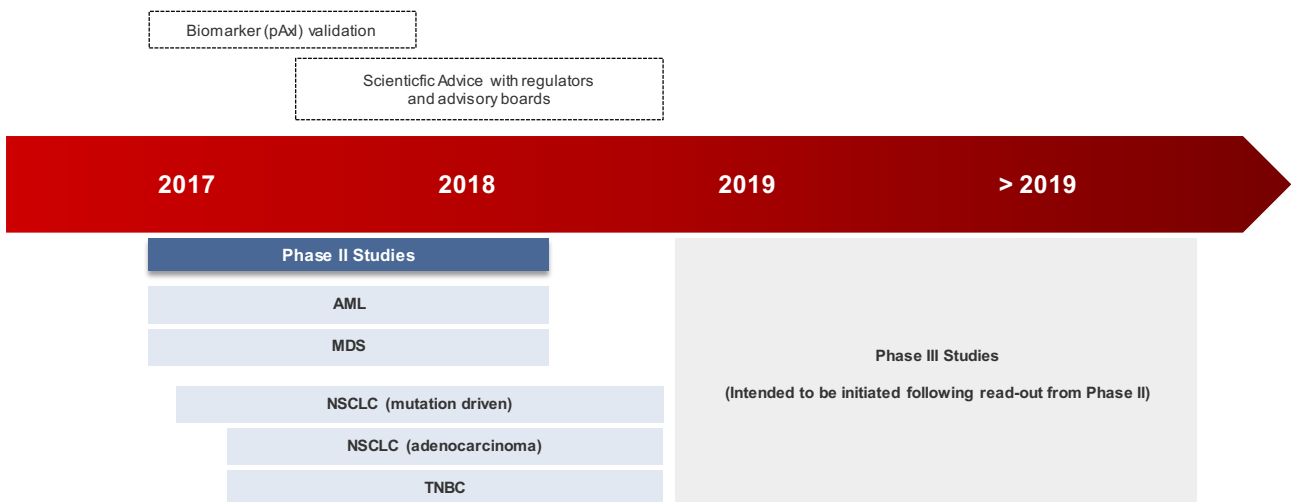


Displayed above in Figure 24 is the best % change in size of target lesions of patients with available radiographic evaluation at the time of data cut-off and their overall best response at that time point. Furthermore, it is indicated whether patients' tumours were positive for AXL or PD-L1 (AXL/PD-L1 yes/no). Relatively more patients who received benefit from the bemcentinib / KEYTRUDA combination treatment as measured by a reduction in tumour size and/or an overall objective response of partial response (PR) lacked PD-L1. Patients who lack PD-L1 expression have been shown to not derive any benefit from KEYTRUDA mono therapy. The observation of benefit in PD-L1 negative patients thus suggests that adding bemcentinib may improve KEYTRUDA response rates<sup>117</sup>.

### 8.5.2.8 Registration directed studies (Phase III)

BerGenBio's registration strategy is to pursue Phase III clinical trials following the read-out of the Phase II studies. The registration study population is anticipated to be enriched for AXL over-expressing patients, as determined by the Company's companion diagnostic tools. This enrichment strategy facilitates possibly smaller Phase II studies, an accelerated approval status will also be pursued with regulators and the combined use with a companion diagnostic could facilitate an improved reimbursement rate.

Figure 25: bemcentinib Indicative path to registration



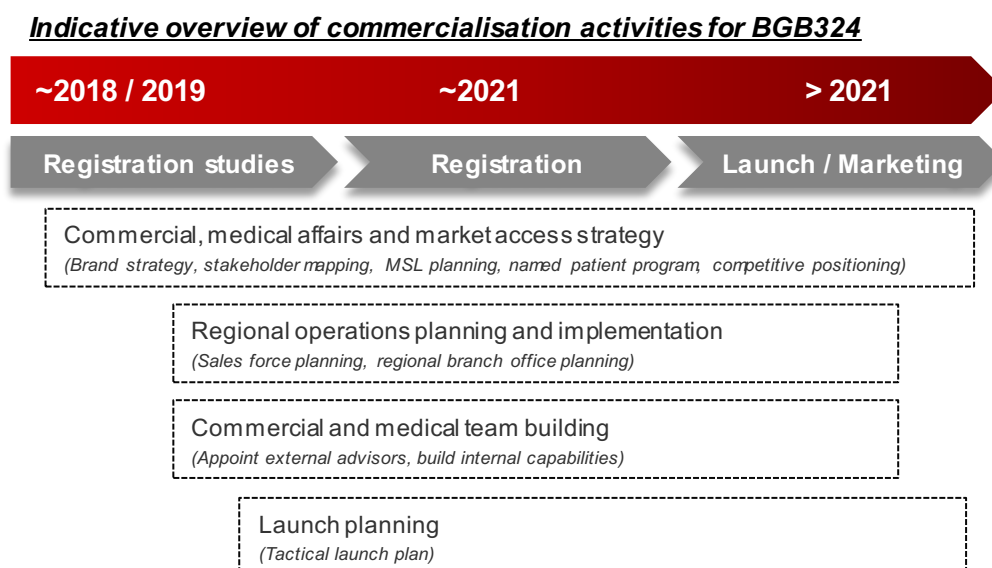
<sup>117</sup> Lorens et al ASCO 2018 ([https://www.bergenbio.com/wp-content/uploads/2018/06/ASCO2018\\_posters\\_reduced-file-size.pdf](https://www.bergenbio.com/wp-content/uploads/2018/06/ASCO2018_posters_reduced-file-size.pdf))



### 8.5.2.9 Commercialisation strategy

The Company intends, either alone or in collaboration with a partner, to develop and commercialise its lead product bemcentinib through to marketing approval by the regulatory agencies. Readiness for commercialisation needs to start well ahead of regulatory approval. BerGenBio sees opportunities to commercialise bemcentinib in certain small indications and territories itself. However, the Company is open to possibly licensing and partnering transactions with big biopharma companies to further the development and commercialisation of bemcentinib. This strategy for commercialisation will include establishing medical affairs and market access skills and competence in the Company at least 1.5 years ahead of anticipated regulatory approval. Following this detailed launch, planning and implementation of regional operations including building out a commercial and medical team required to prepare the launch of the product.

Figure 26: Commercialising bemcentinib



### 8.5.3 Pipeline development

#### 8.5.3.1 Bemcentinib, pre-clinical

BerGenBio scientists, academic collaborators and other international cancer researchers continue to explore the potential of bemcentinib to enhance responses to established and emerging therapy classes such as CPIs, targeted and chemotherapeutics in a large number of tumour animal models.

Additionally, emerging research suggests an important role for AXL in the aetiology of aggressive fibrotic diseases with large market potential such as idiopathic pulmonary fibrosis (IPF) and non-alcoholic steatohepatitis (NASH). In pre-clinical models of these diseases, bemcentinib has shown promising efficacy.

#### 8.5.3.2 Anti-AXL monoclonal antibody (mAb)

BerGenBio has developed a humanised anti-AXL monoclonal antibody. The antibody shows high affinity for AXL and selectivity over other members of the TAM receptor family. The antibody is functionally blocking and prevents the activation of the AXL receptor by Gas6 ligand binding. Pre-clinical animal models of human cancer have demonstrated that the anti-AXL antibody exhibits anti-tumour activity. In addition to oncology indications, it is anticipated that the anti-AXL antibody may have utility in other diseases. A clinical-candidate, BGB149, has been nominated and cell line development and manufacturing of the antibody has been carried out by a leading biologics CRO. It is anticipated that Phase I clinical trials of the antibody will be initiated in 2018.

#### 8.5.3.3 Anti-AXL antibody drug conjugate (ADC) – referred to as ADCT-601

BerGenBio has licensed two of its proprietary anti-AXL monoclonal antibodies to ADC Therapeutics SA for the development of an anti-AXL antibody conjugated to a toxic payload targeting metastatic cancers. Such agents are typically referred to as antibody drug conjugates. The antibody functionality targets the therapeutic to cells which express AXL on their surface. Binding of the antibody conjugate to the AXL receptor results in internalisation, release of the cytotoxic payload and ultimately tumour cell death.

Pre-clinical studies with ADCT-601 in animal models of human cancer have demonstrated dose-dependent potent anti-tumour activity with significant tumour regression and elimination. Further preclinical, presented at AACR in April by

ADC Therapeutics, described safety, tolerability and antitumour activity of ADCT-601 in vitro in human cancer cell lines and in vivo in preclinical models. The data support the anticipated clinical development of ADCT-601.

#### 8.5.3.4 Discovery pipeline

BGB002 is a program related to a novel EMT target identified by BerGenBio. Currently BerGenBio has developed potent selective small molecule inhibitors of the target. These compounds have been shown to inhibit tumour metastasis and seeding in pre-clinical animal models and a number of compounds have been selected as pre-clinical development candidates. In addition, BerGenBio has several lead candidate molecules (BGB003) to target anti-tumour immune responses. It is anticipated that these may have alternative modes of action and therefore may provide differential clinical benefit.

### 8.6 Research and development expenses

Research and development (“R&D”), including clinical research through the clinical trials and pre-clinical research, expenses for the six months ended 30 June 2018 were NOK 75.2 million, of which NOK 67.2 million are classified as other operating expenses and NOK 8.0 million are classified as payroll. Government grants of NOK 7.0 million have been recognised in the profit and loss for the first six month ended 30 June 2018 as a reduction of the related expense. A breakdown of the grants for the six months ended 30 June 2018 is included in Section 8.6.1 "Grants" below.

R&D expenses for 2017 were NOK 137.5 million, of which NOK 132.0 million are classified as other operating expenses and NOK 5.5 million are classified as payroll. Government grants of NOK 22.5 million have been recognised in the profit and loss for 2017 as a reduction of the related expense. A breakdown of the grants for 2017 is included in Section 8.6.1 "Grants" below.

As described above the R&D expenses for 2017 were the net amount deducted for government grants amounted to 137.5 million, the most significant contribution related directly to clinical trials sponsored by BerGenBio, amounting to NOK 83.7 million. NOK 1.1 million was related to investigator led clinical trials. Furthermore, a milestone payment under the terms of the Rigel licence agreement was incurred at NOK 28.1. CMC and drug production related to bemcentinib amounted to NOK 12.1 million. Clinical, regulatory and quality consultants related to the clinical trials sponsored by BerGenBio and bemcentinib amounted to NOK 12.5 million.

R&D expenses, including clinical research through the clinical trials and pre-clinical research, for 2016 were NOK 101.9 million, of which NOK 98.2 million are classified as other operating expenses and NOK 3.8 million are classified as payroll. Government grants of NOK 17.8 million have been recognised in the profit and loss for 2016 as a reduction of the related expense. A breakdown of the grants for 2016 is included in Section 8.6.1 "Grants" below.

As described above the R&D expenses for 2016 were the net amount deducted for government grants amounted to 101.9 million, costs related directly to clinical trials sponsored by BerGenBio, amounted to NOK 38.5 million. NOK 1.3 million was related to investigator led clinical trials. Furthermore, pursuant to BerGenBio's option to back up compounds under the terms of the Rigel licence agreement, the Company was taken a licence to nine back up compounds to bemcentinib such that licensing costs of NOK 31.8 million were incurred. CMC and drug production related to bemcentinib amounted to NOK 13.3 million. Clinical, regulatory and quality consultants related to the clinical trials sponsored by BerGenBio and bemcentinib amounted to NOK 17.0 million.

All expenditure on research and development activities is recognised as an expense in the period in which it is incurred.

### 8.6.1 Grants

The Company has received various government grants:

<b>Government grants recognised in the profit or loss as a reduction of expense (in NOK 1,000)</b>	<b>30 June 2018</b>	<b>2017</b>	<b>2016</b>
Payroll and related expenses	518	2,508	4,19
Other operating expenses	6,527	19,971	13,57
<b>Total</b>	<b>7,045</b>	<b>22,479</b>	<b>17,774</b>
<b>Grants receivable as at end of period, detailed as follows</b>	<b>30 June 2018</b>	<b>2017</b>	<b>2016</b>
Grants from Research Council, BiA	1,148	4,840	2,87
Grants from Research Council, PhD	0	0	257
Grants from Innovation Norway	3,600	0	0
Grants from SkatteFunn	6,958	6,958	7,70
<b>Total</b>	<b>11,707</b>	<b>11,798</b>	<b>10,839</b>

#### 8.6.1.1 BIA grants from the Research Council

The Company has been awarded with four grants from the Research Council, programs for user-managed innovation arena (BIA). The first BIA grant ("Targeting Cancer Stem Cells with AXL inhibitors to Treat Advanced Metastatic Cancer") totals to NOK 11.7 million and covers the period from June 2012 to May 2015. The first BIA grant was concluded in Q2 2015. The second 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 0.0 million in the first half 2018 (2017: NOK 1.4 million, 2016: NOK 3.9 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 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 0.7 million (2017: NOK 2.5 million, 2016: NOK 5.1 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses. The fourth 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 (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 BIA grants from the Research Council are user-driven, and reports shall be submitted to the Research Council, such as project accounting reports, progress reports and final report. Project account reports are to be submitted for each calendar year, progress reports shall be submitted semi-annually and final report shall be submitted 1 month after the conclusion of the projects. The criteria for the grants are defined by the objective of the project and include also a description and summary of the project. Project funding is based on an agreed project plan for a defined period with defined costs, on which the Company on a continual basis report to the Research Council. The progressions of the projects are in accordance with the project plans for the projects.

#### 8.6.1.2 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 0.0 million (2017: NOK 0.4 million, 2016: NOK 0.8 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses.

The Industrial Ph.D. scheme for funding for industry-oriented doctoral research fellowships was established to facilitate the recruitment of researchers to Norwegian industry. The Industrial Ph.D. scheme is designed to enhance interaction between companies and research institutions, increase research activity in industry, and equip newly-educated researchers with knowledge of relevance to their company. The scheme offers substantial benefits to all three involved parties:

- The Company acquires new expertise and expands its network of contacts in academia.
- The degree-conferring research institution obtains new, industry-relevant knowledge and connections in the business sector.
- The doctoral candidate completes a doctorate and gains research-related work experience at the same time.

Under the Industrial Ph.D. scheme, companies receive an annual grant equal to maximum 50% of the applicable rate for doctoral research fellowships for a three-year period. The candidate must be an employee of the Company and be formally admitted to an ordinary doctoral degree programme. Funding is awarded conditional to the employee's admission to an organised doctoral degree programme, will be awarded for a period of three years and is determined after completion of an application process.

#### 8.6.1.3 SkatteFunn

R&D projects have been approved for SkatteFunn for the period from 2012 until the end of 2017. The Company has not yet apply for approval for 2018, thus the Company has not recognised cost reduction in first half 2018. The Company had as of year-end 2017 recognised NOK 7.0 million (2016: NOK 7.7 million) classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses.

The SkatteFunn R&D tax incentive scheme is a government program designed to stimulate research and development (R&D) in Norwegian trade and industry. SkatteFunn provides funding to companies' R&D projects when the aim of the project is to develop a new or improved product, service or production process, the project follows a progress plan with a clear objective and a defined scope, and the results of the project will benefit the applying company.

Approved projects may receive a tax deduction of up to 20% of the eligible costs related to R&D activity. All costs must be associated with the approved project. Costs associated with certain R&D project activities are tax deductible under the scheme. To qualify as R&D, any activity must meet the definitions set out by the Research Council of Norway. If the tax deduction for the R&D expenses is greater than the amount that the firm is liable to pay in tax, the remainder is paid in cash to the firm. If the firm is not liable for tax, the entire allowance is paid in cash. SkatteFunn projects submit annual reports and an auditor must confirm the project accounts when the tax returns are submitted.

#### 8.6.1.4 Innovation Norway

In December 2014 the Company was granted an "Innovation Project" grant from Innovation Norway related to immunology. The grant amounted to NOK 400,000, all of which was recognised in 2016, classified partly as reduction of payroll and related expenses and partly as a cost reduction of other operating expenses.

The Company has been awarded a NOK 24 million grant from Innovation Norway to support the clinical development of bemcentinib in combination with Merck & Co.'s Keytruda<sup>TM</sup> (pembrolizumab) in patients with advanced lung cancer.

The grant from Innovation Norway is an Industrial Development Award (IFU). The IFU program is directed to Norwegian companies developing new products or services in collaboration with foreign companies. BerGenBio received NOK 7.2 million in Q4 2017 of this grant. The grant may be withdrawn under certain circumstances. The Group has recognized NOK 3.6 million in first half year 2018 (2017 NOK 7.2 million, 2016: NOK 0.0 million) classified as cost reduction of other operating expenses.

## 8.7 Patents

The table below shows an overview of the Company's patents and patent applications.

Subject matter	Patent / Application No	Patents/ Applications in family	Status	Priority date	Expiry date	Related products
Use of CellSelect technology	PCT/US2008/014037	4	U.S. and Singapore granted. EPO <sup>118</sup> allowed. U.S. Divisional pending.	2007-Dec-24	2027	CellSelect technology
Use of AXL as a target and biomarker and diagnostic methods	PCT/IB2010/000516	11	Australia, Russia and Singapore granted. Brazil, Canada, China, EPO, India, Japan, Russia and U.S. pending.	2009-Mar-13	2028	Bemcentinib
bemcentinib composition of matter and use	PCT/US07/089177	49	EPO <sup>119</sup> , U.S. <sup>120</sup> , Australia, Canada, China, Japan <sup>121</sup> and Hong Kong granted. India pending.	2006-Dec-29	2027 (un-extended)	Bemcentinib
Use of bemcentinib in combination with chemotherapeutic agents	PCT/US2010/021275	23	EPO <sup>122</sup> , U.S., Japan, Russia, Macau, Hong Kong and Australia granted. Brazil, Canada, China, Singapore and U.S. Divisional pending.	2009-Jan-16	2030 (un-extended)	Bemcentinib
AXL/EMT biomarker	PCT/IB2013/053488	12	Australia, Brazil, Canada, China, EPO, Eurasia, India, Japan, New Zealand, Singapore, South Korea and U.S. pending	2012-May-02	2033	bemcentinib and BGB149
bemcentinib isolation procedure	PCT/GB2015/053442	5	China, EPO, Israel, Japan and U.S. pending	2014-Nov-14	2035	bemcentinib
bemcentinib	PCT/GB2014/053548	3	U.S., EPO and Japan pending.	2013-Dec-02	2034	Bemcentinib
BGB149 antibody composition of matter and use	PCT/EP2015/080654	8	Australia, Mexico, EPO, Japan, China, Canada, South Korea and U.S. pending	2014-Dec-18	2035	BGB149
AXL antibody II composition of matter and use	PCT/EP2015/063700	8	Australia, Mexico, Japan, EPO, Canada, China, South Korea and U.S. pending.	2014-Jun-18	2035	AXL antibody II
AXL antibody III composition of matter and use	PCT/EP2015/063704	8	Australia, Mexico, Japan, EPO, Canada, China, South Korea and U.S. pending	2014-Jun-18	2035	AXL antibody III
BGB002 composition of matter and use	PCT/EP2015/081168	8	Australia, Canada, China, EPO, India, Japan, South Korea and U.S. pending	2014-Dec-23	2035	BGB002
AXL/EMT biomarker	PCT/EP2015/076603	2	EPO and U.S. pending.	2014-Nov-14	2035	bemcentinib and BGB149
Humanised AXL Antibody II	PCT/EP2016/058368	2	EPO and U.S. pending.	2015-Jul-13	2036	AXL antibody II
AXL/EMT biomarker	PCT/EP2016/066357	2	EPO and U.S. pending.	2015-Jul10	2036	bemcentinib and BGB149
Use of AXL inhibitors in combination with immune checkpoint inhibitors	PCT/GB2016/051542	3	EPO, Japan and U.S. pending.	2015-May-29	2036	bemcentinib and BGB149
BGB149 humanized	PCT/EP2017/065313	1	PCT application pending	2016-Jun-22	2037	BGB149

<sup>118</sup> Member states of the European Patent Organisation ("EPO").

<sup>119</sup> Validated in the following EPO member states: Albania, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Switzerland, Cyprus, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Croatia, Hungary, Iceland, Ireland, Italy, Lithuania, Luxembourg, Latvia, Monaco, Former Yugoslav Republic of Macedonia, Malta, Montenegro, Netherlands, Poland, Portugal, Romania, Serbia, Sweden, Slovenia, Turkey and Slovakia.

<sup>120</sup> Includes the following patents: US, US Divisional 1, US Divisional 1 Continuation 1, US Divisional 1 Continuation 2 and US Divisional 1 Continuation 3.

<sup>121</sup> Includes the following patents: JP and JP Divisional 1.

<sup>122</sup> Validated in the following EPO member states: United Kingdom, Germany, France, Italy, Netherlands, Spain, Switzerland, Sweden, Ireland, Poland, Portugal and Turkey.

The Company has a patent portfolio consisting of 16 patent families. The most important patents/patent applications are those pertaining to the Company's lead drug candidate, bemcentinib.

The Company is diligent in protecting all IP it develops that is regarded to be of significant importance to its business. This includes proprietary technologies, discoveries, inventions, data and methods. Protection of proprietary rights includes seeking and maintaining patent protection intended to cover the composition of matter and use for the Company's drug candidates and back up series. IPR (patents) are filed and prosecuted and maintained worldwide including all major pharmaceutical markets.

Success of the Company's business will rely to a great extent on the ability to obtain, maintain and enforce patent and other proprietary protection for commercial technology. Inventions and expertise related to its business as well as defend and enforce its patents and other proprietary rights of third parties are equally important. Intellectual capital is a key factor for continuing technological innovation as well as develop, strengthen and maintain the Company's proprietary position in the field of EMT inhibitors.

The cost of the patents, depending upon the nationality of the patent application, is usually comprised of a one-time application fee, a cost for prosecution and issuance of the patent and a yearly maintenance fee.

In 2017 the Company had patent costs amounting to NOK 4.9 million, these include renewal of patents, maintenance of patents and filing of patents. For 2016 the patent costs amounted to NOK 2.3 million.

The patent positions of biopharmaceutical companies are generally uncertain and involve complex legal, scientific and factual questions. Furthermore, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance.

#### **8.8 Dependency on contracts, suppliers and assets necessary for production**

The Company has entered into several contracts within the ordinary course of business. BerGenBio uses suppliers under the ordinary course of business, such as CROs and production facilities for the production of drugs. There are a wide range of suppliers providing these type of services and BerGenBio is not dependent on specific suppliers.

BerGenBio does not need to own production equipment.

The Company has received grants and expect to attract grant funding also in the future. The Company is not dependent on grant funding, but it does represent an additional funding to the Company although at a relatively low level compared to the equity funding that historically has been attracted and is assumed to be attracted in the future.

The Company is dependent on obtaining and maintaining its patent and other proprietary protection for its commercial technology. See Section 8.7 "Patents" above for a description of the Company's 16 patent families.

BerGenBio has three contracts or collaborations which can be regarded as material in the context of its business; in-licenses from Rigel, collaboration with MSD and out-license to ADCT. Rigel, MSD and ADCT who are all considered by the Company as organizations of high standing and repute within the industry.

The Company is dependent on the agreement with Rigel for the development and commercialisation of its lead product, bemcentinib. The Rigel agreement supports much of the value from the bemcentinib asset, although other IP and assets are of increasing value, but the right to use the licensed Rigel IP is and will remain very important to the Company.

The Company is not dependent on the ADCT agreement, but it is material in the sense that it serves to corroborates the interest in the technology of the Company, and specifically AXL as target. As described in Section 8.4 "Competitive strengths", the collaboration with MSD is valuable to BerGenBio, but the Company is not dependent on this agreement.

#### **In-License from Rigel Pharmaceuticals Inc (bemcentinib)**

29 June 2011, the Company entered into a license agreement with Rigel. It grants to BerGenBio an exclusive worldwide license under the key Rigel patent rights protecting the compound bemcentinib (including two patent families known as PCT/US07/089177 and PCT/US2010/021275, see Section 8.7 "Patents" above), and the small amount of related know-how generated by Rigel and existing at the time of the license.

The license is an exclusive sub-licensable license to research, develop, manufacture and commercialise bemcentinib and eight backup AXL inhibitors, and the exclusivity is reinforced by a provision that Rigel shall not directly or indirectly

develop or commercialise itself or with a third party any compound that "Selectively Inhibits the Activity of AXL" (this is defined technically in the agreement).

As well as bemcentinib and the backup AXL inhibitors, BerGenBio has subsequently exercised its option to add nine additional AXL inhibitors in the Rigel compound patents to the licensed compounds. As per the license agreement, the Company has made a total payment of USD 2,000,000 for these additional nine licenses.

BerGenBio has the responsibility for the conduct of all activities to be performed under the license, at its own cost, expense and liability. At law BerGenBio owns the intellectual property it develops and generates around bemcentinib – patent rights, know-how (including data), trademarks and commercial information.

Under the terms of the license, a distinction is drawn between the circumstance in which BerGenBio itself eventually commercialises the bemcentinib product, and the circumstance in which BerGenBio appoints a partner to do so, or BerGenBio as a company is sold to an acquirer.

If BerGenBio itself commercialises the bemcentinib product, BerGenBio must pay development and regulatory milestones:

<b>Milestone payment events</b>	<b>Milestone payment</b>
Commencement of the first Phase II clinical trial for the first product	USD 5,000,000
Commencement of the first Phase III clinical trial for the first product	USD 8,000,000
Submission of an NDA (or equivalent) for the first product	USD 12,000,000
First regulatory approval (or equivalent) for the first product	USD 16,000,000

The Phase II clinical milestone of USD 5 million has been reached and has been paid by BerGenBio.

Royalties are payable on Net Sales of the Products in countries where the Product is covered by a valid claim under the Rigel compound patents.

<b>Aggregate annual net sales of the products in the territory for a particular year</b>	<b>Royalty rate</b>
Net sales are less than USD 500 million	5%
Net sales are greater than USD 500 million but are less than USD1 billion	7%
Net sales are greater than USD 1 billion	9%

If BerGenBio and its Affiliates do not themselves develop and commercialise a product but instead "Out-license" different financial provisions apply. The definition of "Out-license" is complex, and requires a case-by-case analysis to ascertain if particular circumstances have triggered it. But broadly it is triggered either: (i) If there is a transaction involving a sub-license to the Rigel technology licensed or a sale of the rights of the Rigel technology licensed; or (ii) if there is a transaction involving the sale of substantially all of BerGenBio's shares resulting in the transfer of control of the principal business or operations.

When a transaction triggers the out-license provisions, if it involves other assets of BerGenBio of any description in addition to the license under the Rigel technology, there must be an analysis of: (i) the value of all the assets which are the subject of the out-license including e.g. buildings, equipment and other tangible assets as well as Rigel technology and the BerGenBio intellectual property involved, and (ii) a calculation of the value of only the Rigel technology licensed, and the fraction that this represents to the total value. That fraction is then to be multiplied by the consideration received

by BerGenBio upon the out-license, and the resulting proportion/part of the consideration on the out-license deal is then used to calculate a revenue share due to Rigel as set out below:

<b>Timing of Out-license</b>	<b>Revenue share percentage</b>
Prior to completion of a Phase Ia clinical trial	60%
After the completion of a Phase Ia clinical trial	50%
After the completion of a Phase Ib clinical trial	45%
After the completion of the first Phase 2 clinical trial	40%
After the completion of a Phase II clinical trial where sixty or more patients are enrolled; after the completion of one or more Phase II clinical trials where sixty or more patients are enrolled; or, initiation of a Phase III clinical trial	35%
After the completion of a Phase III clinical trial	30%

There are complicated provisions for the adjustment of milestone payments due from BerGenBio in the event it carries out an out-license in only part of the world.

BerGenBio has the responsibility for the prosecution and maintenance (including the cost) of the Rigel Compound Patents, in liaison with Rigel.

The license agreement remains in full force and effect until the patents protecting the licensed assets has expired, BerGenBio has terminated the agreement or Rigel has terminated the agreement due to a non-remedied breach of contract by BerGenBio.

#### **Collaboration with Merck Sharp & Dohme B.V. (MSD) for further clinical trials for bemcentinib**

There are two virtually identical contracts made with MSD on 24 November 2016. They cover the conduct by BerGenBio as sponsor of two Phase II clinical trials for a combination of bemcentinib with MSD's antibody known as pembrolizumab (Keytruda™) as follows:

- A Phase II multi center study of bemcentinib in combination with Keytruda™ in patients with previously treated advanced adenocarcinoma of the lung. Up to 48 evaluable patients will be enrolled; and
- A Phase II multi center study of bemcentinib in combination with Keytruda™ in patients with previously treated, locally advanced and unresectable or metastatic TNBC or Triple Negative Inflammatory Breast Cancer ("**TN-IBC**"). Up to 56 evaluable patients will be enrolled.

Under each collaboration MSD will supply the quantities of Keytruda™ required and will perform certain testing activities free of charge, and BerGenBio will sponsor and organise the clinical trials at its own cost, expense and liability, using a CRO for most functions. Coordination of the studies are done by a joint development committee made up of an equal number of representatives of MSD and BerGenBio.

There are no IPR license granted by either party to its background IPR save for those required for the conduct of the respective clinical trial.

Each party has access to all data generated, with BerGenBio committed to timely publication of the results of each study after study completion. Until then no disclosure or use of the clinical data can be made except for limited purposes, which in the case of BerGenBio include permission to disclose to a bona fide investor or potential investor, but not an industry strategic investor. If other disclosures are required, MSD's prior consent is necessary.

Ownership and use of the results is handled as follows:

- Except for sample testing results, the clinical data from the studies will be jointly owned and can be used by either Party. MSD can use this to obtain label changes for Keytruda™.
- Each party owns the sample testing results that it generates.
- If new inventions or discoveries are generated that do not relate solely to their compound (in which case the relevant party owns that IPR) they are to be jointly owned inventions. These can be freely exploited by either party, save that MSD may not use them in relation to an AXL inhibitor, and BerGenBio may not use them in relation to a PD-1 Antagonist.

For nine months after study completion either party can propose a Phase III registration study (or other subsequent study) for the combination. This proposal must be given to the other party within six months of study completion, with a draft protocol for the Phase III study, draft budget and cost-sharing proposal. The purpose of cost-sharing is to give



both parties a right of access and use of the study data. After the proposal is made, the parties then have three months to negotiate an extension of the agreement. The agreement expires if not extended, although certain terms survive.

There is no obligation on BerGenBio to supply quantities of bemcentinib for any subsequent study, nor such an obligation on MSD to supply quantities of Keytruda™.

If the Parties fail to agree to proceed together on a cost-sharing basis, each party can try to proceed alone at its own cost and expense but the other party has a blocking mechanism in that it can (i) object to the protocol for the study, or (ii) can refuse to supply its compound for the study; and (iii) if a party considers supplying compound for the study the parties must agree mutually acceptable amendments to the agreement for this to occur (but the transfer price is to be fully-allocated manufacturing cost).

In limited circumstances but including when MSD terminates the agreement for safety reasons or material breach of BerGenBio according to the terms of the agreement, MSD is entitled to be reimbursed the direct and indirect manufacturing costs of the MSD compound used in the study.

#### **Out-license to ADC Therapeutics SA**

The license agreement with ADCT was made on 18 July 2014 and is the basis for the out-license of the antibody program referred to elsewhere in this Prospectus BGB601. The agreement relates to two novel antibodies invented and patented by BerGenBio, each of which specifically binds to AXL.

The agreement grants ADCT an exclusive, worldwide sub-licensable (in specified circumstances) license under BerGenBio IPR, including BerGenBio owned patent rights relating to these two antibodies and modifications of them and to other antibodies that bind to AXL to research, develop, make, use, sell, offer for sale, import and otherwise commercialise therapeutic AXL ADC Products and also companion diagnostics. An "**AXL ADC Product**" is a molecule comprising an AXL antibody conjugated to a small molecule drug.

The parties are obliged to be exclusive to each other in the field of AXL ADC Products.

A key obligation on ADCT is to carry out a development plan to get at least one AXL ADC Product ready for an investigational new drug application ("**IND**") to the FDA.

ADCT is solely responsible by itself or its sub-licensees for the cost, expense and liability of the development and commercialisation of the AXL ADC Products. It must use commercially reasonable efforts to develop, obtain regulatory and pricing approvals for, and thereafter commercialise, at least one licensed product as a pharmaceutical product. ADCT is responsible for most liability to third parties arising out of ADCT activities.

Under the license a series of development, regulatory and sales-based milestones are due to BerGenBio from ADCT upon the occurrence of certain specified events. These potential milestone payments total up to USD 34,250,000 per AXL ADC Product, which are comprised of development and regulatory milestone payments of up to USD 13,250,000 and sales-based milestone payments of up to USD 21,000,000.

The first milestone payment will be triggered by the dosing of the fifth patient in a Phase I clinical study for the first AXL ADC Product. BerGenBio currently estimates that the first milestone payment could be triggered as early as Q1 2019.

Two-tiered mid-range single digit royalties are also due to BerGenBio on worldwide net sales of AXL ADC Products and related companion diagnostics. The royalties are payable for at least a minimum of 10 years from first commercial sale in each country, regardless as to whether there are valid claims of a royalty patent in such country.

ADCT is also required to pay BerGenBio a one-time low eight figure sales milestone payment in U.S. dollars if and when the worldwide net sales during a given calendar year for all AXL ADC Products and related companion diagnostics exceed USD 1,000,000,000 in the aggregate for the first time.

Under the license agreement, BerGenBio is responsible for the prosecution and maintenance of the patents it has out-licensed to ADCT, but the cost and expense in relation thereto is to be reimbursed by ADCT. Most intellectual property generated by ADCT will be owned, prosecuted and maintained by ADCT at its own cost and expense.

ADCT can terminate the license agreement at will, but if it does, and in certain specified circumstances, BerGenBio may have the right to continue the development of any licensed product under development in return for a revenue sharing arrangement.

### **8.9 Legal proceedings**

The Company is not, nor has been during the course of the preceding 12 months, involved in any legal, governmental or arbitration proceedings which may have, or has had in the recent past, significant effects on the Company's and/or the Group's financial position or profitability, and the Company is not aware of any such proceedings which are pending or threatened.

### **8.10 Property, plants and equipment**

The Company rents premises in Bergen at the University of Bergen for office and laboratory purposes under a sublease agreement. The rent is approximately NOK 225,070 per annum. The Company will in addition to this amount be charged for a proportionate share of common variable costs related to building management. The sublease agreement expires on 1 December 2020, with an option for an additional 5 plus 5 years. Both parties have the right to terminate the sublease agreement with 12 months' prior written notice. Under the same rental agreement the Company has access to the use of defined scientific equipment at a cost of NOK 41,993 (2017) per employee per year. The price is subject to a yearly adjustment of 3.0%.

From September 2015, the Company has rented an office in the Magdalen Centre, The Oxford Science Park, UK. The rental agreement can be terminated by either party with a one month's notice period. The monthly rental amount is GBP 6,100.

From January 2018 the Group has entered into a rental agreement for offices in Bergen with Helse Bergen. The rental agreement expires at 31 December 2020 with an option for an additional 1 plus 1 year.

There are currently no environmental issues that may affect the Company's utilization of the tangible fixed assets, and the Company believes that the risk of liability related to emissions or contaminations is low.

The Company does not own any assets which is necessary for production.

## 9 CAPITALISATION AND INDEBTEDNESS

### 9.1 Introduction

The information presented below should be read in conjunction with the other parts of this Prospectus, in particular the Financial Statements and the Interim Financial Statement and related notes, incorporated by reference hereto, see Section 17.3 "Incorporation by reference".

This Section provides information about the Company's unaudited capitalisation and net financial indebtedness on an actual basis as at 30 June 2018. There has been no material change to the Company's audited capitalisation and net financial indebtedness since 30 June 2018.

### 9.2 Capitalisation

*In NOK 1,000*

**As of  
30 June 2018**

#### **Indebtedness**

Total current debt	
- Guaranteed .....	0
- Secured .....	0
- Unguaranteed/unsecured .....	31,238

#### **Total non-current debt**

- Guaranteed .....	-
- Secured .....	-
- Unguaranteed/unsecured .....	-

<b>Total Indebtedness .....</b>	<b>31,238</b>
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#### **Shareholders' equity**

a. Share capital .....	5,471
b. Legal reserve.....	
c. Other reserves .....	419,207

<b>Total equity .....</b>	<b>424,678</b>
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<b>Total capitalisation .....</b>	<b>455,917</b>
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**9.3 Net financial indebtedness***In NOK 1,000***As of  
30 June 2018**

Net indebtedness	
(A) Cash.....	441,263
(B) Cash equivalents .....	0
(C) Interest bearing receivables .....	0
<b>(D) Liquidity (A)+(B)+(C) .....</b>	<b>441,263</b>
<b>(E) Current financial receivables .....</b>	<b>0</b>
(F) Current bank debt .....	0
(G) Current portion of long-term debt .....	0
(H) Other current financial liabilities .....	31,238
<b>(I) Current financial debt (F)+(G)+(H) .....</b>	
<b>(J) Net current financial indebtedness (I)-(E)-(D) .....</b>	<b>(410,025)</b>
(K) Long-term interest bearing debt .....	
(L) Bonds issued .....	
(M) Other non-current financial liabilities .....	
<b>(N) Non-current financial indebtedness (K)+(L)+(M) .....</b>	
<b>(O) Net financial indebtedness (J)+(N) .....</b>	<b>(410,025)</b>

**9.4 Working capital statement**

The Company is of the opinion that the working capital available to the Group is sufficient for the Group's present requirements, for the period covering at least 12 months from the date of this Prospectus.

**9.5 Contingent and indirect indebtedness**

The Company is not aware of any indirect or contingent indebtedness.

## 10 SELECTED FINANCIAL AND OTHER INFORMATION

### 10.1 Introduction and basis for preparation

The tables set out in this Section 10 "Selected Financial and Other Information" present selected financial information derived from the Group's audited consolidated financial statements (including the notes thereto) as of, and for the years ended, 31 December 2017 and 2016 (the Financial Statements), as well as the Group's unaudited interim consolidated financial information as of, and for the six months' periods ended, 30 June 2018 and 2017 (the Interim Financial Statements). The Financial Statements have been prepared in accordance with IFRS, while the Interim Financial Statements have been prepared in accordance with IAS 34.

EY has not audited, reviewed or produced any report on any other information provided in this Prospectus.

The selected financial information included herein should be read in connection with, and is qualified in its entirety by reference to the Financial Statements.

### 10.2 Summary of accounting policies and principles

For information regarding accounting policies and the use of estimates and judgments, please refer to note 2 and 3 of the Financial Statements which have been incorporated by reference hereto, see Section 17.3 "Incorporation by reference".

### 10.3 Statement of profit and loss and other comprehensive income

The table below sets out selected data from the Group's audited consolidated statement of profit and loss and other comprehensive income for the years ended 31 December 2017 and 2016, and the Group's unaudited consolidated interim financial statement as of and for the three (Q2) and six month (YTD) periods ended 30 June 2018 and 30 June 2017, respectively.

*In NOK 1,000*

	Year ended		Q2 Period		YTD	
	31 December		(30 June)		(30 June)	
	2017	2016	2018	2017	2018	2017
			(unaudited)	(unaudited)	(unaudited)	(unaudited)
<b>Revenues</b>						
Operating revenue .....	0	0	0	0	0	0
<b>Total operating revenue .....</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
Payroll and related expenses .....	28,827	20,561	6,300	5,895	21,972	12,189
Depreciation .....	193	207	54	51	108	101
Other operating expenses .....	154,687	110,802	44,378	27,899	83,433	87,345
<b>Total operating expenses .....</b>	<b>183,708</b>	<b>131,570</b>	<b>50,732</b>	<b>33,846</b>	<b>105,513</b>	<b>99,635</b>
<b>Operating profit (loss) .....</b>	<b>(183,708)</b>	<b>(131,570)</b>	<b>(50,732)</b>	<b>(33,846)</b>	<b>(105,513)</b>	<b>(99,635)</b>
<b>Finance income and finance expenses .....</b>						
Finance income .....	4,168	3,031	1,622	541	2,668	1,660
Finance expense .....	2,668	1,260	128	778	172	1,173
<b>Financial items, net .....</b>	<b>1,500</b>	<b>1,771</b>	<b>1,495</b>	<b>(236)</b>	<b>2,496</b>	<b>(487)</b>
<b>Loss before income tax .....</b>	<b>(182,208)</b>	<b>(129,799)</b>	<b>(49,238)</b>	<b>(34,082)</b>	<b>(103,017)</b>	<b>(99,148)</b>
Income tax .....	0	0	0	0	0	0
<b>Loss for the period .....</b>	<b>(182,208)</b>	<b>(129,799)</b>	<b>(49,238)</b>	<b>(34,082)</b>	<b>(103,017)</b>	<b>(99,148)</b>
Other comprehensive income (loss), net of income tax .....	0	(1,089)	0	0	0	0
<b>Total comprehensive income (loss) for the period .....</b>	<b>(182,208)</b>	<b>(130,888)</b>	<b>(49,238)</b>	<b>(34,082)</b>	<b>0</b>	<b>0</b>
<b>Loss for the period attributable to owners of the company .....</b>	<b>(182,208)</b>	<b>(130,888)</b>	<b>(49,238)</b>	<b>(34,082)</b>	<b>(103,017)</b>	<b>(99,148)</b>
<b>Total comprehensive income (loss) for the period attributable to owners of the Company .....</b>	<b>(182,208)</b>	<b>(130,888)</b>	<b>(49,238)</b>	<b>(34,082)</b>	<b>(103,017)</b>	<b>(99,148)</b>
Earnings (loss) per share (NOK) .....	(4,01)	(419.68)	(0.92)	(0.70)	(1.99)	(2.41)
Basic and diluted earnings (loss) per share (NOK) .....	(4,01)	(419.68)	(0.92)	(0.70)	(1.99)	(2.41)

#### 10.4 Statement of financial position

The table below sets out selected data from the Group's audited consolidated statement of financial position as of 31 December 2017 and 2016, as well as for the Group's unaudited interim consolidated statement of financial position for the three (Q2) and six month (YTD) periods ended 30 June 2018 and 30 June 2017.

As of year-end 2017 total assets amounted to NOK 384.3 million compared to NOK 174.5 million at year-end 2016. The increase reflects the capital raise as part of the IPO of the Group and the use of cash to finance the Group's development and operations. Total equity at year-end 2017 was NOK 350.4 million compared to NOK 153.3 million at the end of 2016. The change in equity reflects the capital raise as part of the IPO of the Group and the loss of the year.

	As of		Q2 Period		YTD	
	31 December		(30 June)		(30 June)	
	2017	2017	2018	2017	2018	2017
			(unaudited)	(unaudited)	(unaudited)	(unaudited)
<i>In NOK 1,000</i>						
<b>Assets</b>						
<b>Non-current assets</b>						
Research and development .....	0	0	0	0	0	0
Patents and licences .....	0	0	0	0	0	0
<b>Total intangible assets .....</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
Property, plant and equipment .....	557	410	518	467	518	467
<b>Total property, plant and equipment .....</b>	<b>557</b>	<b>410</b>	<b>518</b>	<b>467</b>	<b>518</b>	<b>467</b>
<b>Receivables</b>						
Other non-current receivables .....	0	0	0	0	0	0
<b>Total non-current receivables ...</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Current assets</b>						
Inventory .....	0	0	0	0	0	0
<b>Receivables</b>						
Other receivables .....	13,430	12,302	14,135	16,552	14,135	16,552
<b>Total receivables .....</b>	<b>13,430</b>	<b>12,302</b>	<b>14,135</b>	<b>16,552</b>	<b>14,135</b>	<b>16,552</b>
<b>Cash and cash equivalents .....</b>	<b>370,350</b>	<b>161,825</b>	<b>441,263</b>	<b>440,300</b>	<b>441,263</b>	<b>440,300</b>
<b>Total current assets .....</b>	<b>383,780</b>	<b>174,126</b>	<b>455,398</b>	<b>456,852</b>	<b>455,398</b>	<b>456,852</b>
<b>Total assets</b>	<b>384,336</b>	<b>174,536</b>	<b>455,917</b>	<b>457,319</b>	<b>455,917</b>	<b>457,319</b>
<b>Equity and liabilities</b>						
<b>Equity</b>						
Share capital .....	4,992	3,369	5,471	4,974	5,471	4,974
Share premium .....	325,018	131,875	398,521	406,142	398,521	406,142
Other paid in capital .....	20,340	18,026	20,687	18,969	20,687	18,969
Paid in, not registered capital raise	0	0	0	159	0	159
Accumulated losses .....	0	0	0	0	0	0
<b>Total equity .....</b>	<b>350,350</b>	<b>153,270</b>	<b>424,678</b>	<b>430,245</b>	<b>424,678</b>	<b>430,245</b>
<b>Liabilities</b>						
<b>Non-current liabilities</b>						
Pension liability .....	0	0	0	0	0	0
Convertible loan .....	0	0	0	0	0	0
Derivative financial liability .....	0	0	0	0	0	0
<b>Total non-current liabilities ...</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Current liabilities</b>						
Accounts payable .....	21,575	10,703	16,646	10,826	16,646	10,826
Tax payable .....	0	0	0	0	0	0
Other current liabilities .....	9,391	5,721	5,443	12,605	5,443	12,605
Provisions .....	3,020	4,843	9,150	3,643	9,150	3,643
<b>Total current liabilities .....</b>	<b>33,986</b>	<b>21,266</b>	<b>31,238</b>	<b>27,074</b>	<b>31,238</b>	<b>27,074</b>
<b>Total liabilities .....</b>	<b>33,986</b>	<b>21,266</b>	<b>31,238</b>	<b>27,074</b>	<b>31,238</b>	<b>27,074</b>
<b>Total equity and liabilities .....</b>	<b>384,336</b>	<b>174,536</b>	<b>455,917</b>	<b>457,319</b>	<b>455,917</b>	<b>457,319</b>

## 10.5 Statement of cash flow

The table below sets out selected data from the Group's audited consolidated statements of cash flows for the years ended 31 December 2017 and 2016, as well as for the Group's unaudited interim consolidated statement of cash flow for the three (Q2) and six month (YTD) periods ended 30 June 2018 and 2017. See Section 10.8 "Liquidity and capital resources" for more information on the Group's liquidity and capital resources.

<i>In NOK 1,000</i>	<b>Year ended 31 December</b>		<b>Q2 Period (30 June)</b>		<b>YTD (30 June)</b>	
	<b>2017</b>	<b>2016</b>	<b>2018 (unaudited)</b>	<b>2017 (unaudited)</b>	<b>2018 (unaudited)</b>	<b>2017 (unaudited)</b>
<b>Cash flows from operating activities</b>						
Loss for the period (before income tax) .....	(182,208)	(129,799)	(49,237)	(34,082)	(103,017)	(99,148)
Non-cash adjustments to reconcile loss before tax to net cash flows ...						
Depreciation of property, plant and equipment .....	193	207	54	51	108	101
Calculated interest element on convertible loan .....	0	19	0	0		
Share option expense .....	2,314	5,702	311	377	347	944
Movement in provisions and pensions .....	(1,823)	(2,099)	(2,299)	(876)	6,130	(1,200)
Working capital adjustments .....					(705)	(4,250)
Decrease in trade and other receivables and prepayments .....	(1,128)	(4,263)	(2,251)	(3,461)		
Increase in trade and other payables .....	14,543	5,919	(11,227)	8,257	(8,878)	7,008
<b>Cash flows from operating activities .....</b>	<b>(168,109)</b>	<b>(124,314)</b>	<b>(64,649)</b>	<b>(29,735)</b>	<b>(106,015)</b>	<b>(96,545)</b>
<b>Cash flows from investing activities</b>						
Investments in property, plant and equipment .....	(340)	(255)	(70)	0	(70)	(159)
<b>Cash flows from investing activities .....</b>	<b>(340)</b>	<b>(255)</b>	<b>(70)</b>	<b>0</b>	<b>(70)</b>	<b>(159)</b>
<b>Cash flows from financing activities</b>						
Proceeds from equity issue .....	402,296	212,220	190,284	400,159	190,525	400,690
Share issue cost .....	(25,322)	0	(13,527)	(25,511)	(13,527)	(25,511)
Proceeds from borrowings, convertible loan .....	0	(1,307)	0	0		0
Conversion of loan by issue of share capital .....	0	1,489	0	0	0	0
<b>Cash flows from financing activities .....</b>	<b>376,974</b>	<b>212,402</b>	<b>176,757</b>	<b>374,648</b>	<b>176,997</b>	<b>375,179</b>
Net change in bank deposits, cash and equivalents .....	208,525	87,832	112,040	344,913	70,913	278,475
Cash and equivalents at beginning of period .....	161,825	73,993	329,224	95,387	370,350	161,825
<b>Cash and equivalents at end of period .....</b>	<b>370,350</b>	<b>161,825</b>	<b>441,263</b>	<b>440,300</b>	<b>441,263</b>	<b>440,300</b>

**10.6 Statement of changes in equity**

The table below sets out selected data from the Group's audited consolidated statements of changes in equity for the years ended 31 December 2016 and 2017.

<i>In NOK 1,000</i>	<b>Share capital</b>	<b>Share premium</b>	<b>Convertible instruments</b>	<b>Equity-settled share-based payments</b>	<b>Accumulated losses</b>	<b>Translation effects</b>	<b>Total equity</b>
Balance at 1 January 2016	2,479	49,944		12,323			<b>64,747</b>
Loss for the year.....		(129,799)					<b>(129,799)</b>
Other comprehensive income (loss) for the year net of income tax .....		(1,089)					<b>(1,089)</b>
<b>Total comprehensive income for the year .....</b>		<b>(130,888)</b>					<b>(130,888)</b>
Recognition of share-based payments .....				5,702			<b>5,702</b>
Issue of ordinary shares – capitalisation issue ...	890	212,819					<b>213,709</b>
Issue of ordinary shares under share options .....							
<b>Balance at 31 December 2016 ...</b>	<b>3,369</b>	<b>131,875</b>		<b>18,026</b>			<b>153,270</b>
Loss for the year ...							
Other comprehensive income (loss) for the year net of income tax .....		(182,208)					<b>(182,208)</b>
<b>Total comprehensive income for the year .....</b>		<b>(182,208)</b>					<b>(182,208)</b>
Recognition of share-based payments .....				2,314			<b>2,314</b>
Issue of ordinary shares – capitalisation issue ...	1,600	398,400					<b>400,000</b>
Issue of ordinary shares under share options .....	23	2,273					<b>2,296</b>
Share issue costs ...		(25,322)					<b>(25,322)</b>
<b>Balance at 31 December 2017 ...</b>	<b>4,992</b>	<b>325,018</b>		<b>20,340</b>			<b>350,350</b>
Loss for the first half year 2018...		(103,017)					<b>(103,017)</b>
Other comprehensive income (loss) for the first half year net of income tax .....		0					<b>0</b>
<b>Total comprehensive income for the year .....</b>		<b>(103,017)</b>					<b>(103,017)</b>
Recognition of share-based payments .....				347			<b>347</b>
Issue of ordinary shares – capitalisation issue ...	16	3,024					<b>3,040</b>
Issue of ordinary shares under share options .....	463	187,022					<b>187,485</b>
Share issue costs ...		(13,527)					<b>(13,527)</b>
<b>Balance at 30 June 2018</b>	<b>5,471</b>	<b>398,520</b>		<b>20,687</b>			<b>426,678</b>



## 10.7 Sales revenues by geographic area

The Group has not had any sales revenue in 2017 or 2016.

## 10.8 Liquidity and capital resources

### 10.8.1 Sources of liquidity

The Group's principal sources of liquidity are cash flows from equity issues and governmental grants. The Group primarily uses cash for development of novel pharmaceutical products and necessary working capital. As of 30 June 2018, cash and cash equivalents amounted to NOK 441,3 million. The Group believes that the same general combination of funds provided by governmental grants and equity issues will be sufficient to meet the Group's working capital and capital expenditure requirements for the foreseeable future.

Based on the Group's current estimate, it believes that the cash balance will be sufficient to cover the Group's activities through for the period covering at least 12 months from the date of this Prospectus.

Furthermore, the Company will continually evaluate strategic business development initiatives and partnering opportunities by way of potential licensing of the Group's assets to third parties.

### 10.8.2 Restrictions on use of capital

There are currently no restrictions on the use of the Company's capital resources that have materially affected or could materially affect, directly or indirectly, the Company's operations. The Company does not have any debt covenants, and is therefore not in breach and does not expect to be in breach of such covenants. The Company has received various grants from the government, directed towards defined projects. Generally, in order to receive the grant funding reports shall be submitted at defined milestones, such as project accounting reports, progress reports and final reports. The criteria for the grants are defined by the objective of the project and include also a description and summary of the project. Project funding is based on an agreed project plan for a defined period with defined costs, on which the Company on a continual basis reports. The projects which the Company has received grants for are, as of the date of this Prospectus, progressing in accordance with the project plans for the projects. For an overview of the grants see Section 8.6.1 "Grants".

### 10.8.3 Summarized cash flows information

The following table summarises the Group's historical cash flows, and is extracted from the Financial Statements as of, and for the years ended, 31 December 2017 and 2016, prepared in accordance with IFRS, and the Interim Financial Statements, as of and for the six months' period ended 30 June 2018 and 2017, prepared in accordance with IAS 34:

In NOK 1,000

	Period ended		Year ended	
	30 June		31 December	
	2018	2017	2017	2016
	<i>(unaudited)</i>	<i>(unaudited)</i>		
Cash from/(used in) operating activities .....	(106,015)	(96,545)	(168,109)	(124,314)
Cash from/(used in) investing activities .....	(70)	(159)	(340)	(255)
Cash from/(used in) financing activities .....	176,997	375,179	376,974	212,402
Net change in bank deposits, cash and equivalents...	70,913	278,475	208,525	87,832
Cash and cash equivalents at end of period .....	441,263	440,300	370,350	161,825

### 10.8.4 Cash flows from operating activities

Net cash outflow from operating activities for the year ended 31 December 2017 was NOK 168.1 million compared to NOK 124.3 million for the year ended 31 December 2016, an increase of NOK 43.8 million. The net cash outflow from operating activities is primarily related to the Company's R&D activities amounting in 2017 to NOK 137.5 million, in addition to employee benefit expenses of NOK 28.8 million. The R&D activities includes the increased activities related to the clinical trials, where new trials have been planned for and set up in 2017, six clinical trials have been ongoing. In addition the Company has had production costs for the drug for the clinical trials going forward, and BGB149 has been progressed to cell line development.

Net cash outflow from operating activities for the first six months ended 30 June 2018 was NOK106,0 million compared to NOK 96.5 million for the first six months ended 30 June 2017, an increase of NOK 9.5 million mainly due to an increase in clinical development activities

#### *10.8.5 Cash flows from investing activities*

Net cash inflow from investing activities for the year ended 31 December 2017 was NOK (0.34) million compared to NOK (0.26) million the year ended 31 December 2016, an increase of NOK 0.08 million. The investment in 2017 of NOK 0.34 million relates to a purchase of office furniture's.

Net cash inflow from investing activities for the first six months ended 30 June 2018 was NOK 0.1 million compared to NOK 0,2 million for the first six months ended 30 June 2017.

#### *10.8.6 Cash flows from financing activities*

Net cash inflow from financing activities for the year ended 31 December 2017 was NOK 377.0 million compared to NOK 212.4 million for the year ended 31 December 2016, an increase of NOK 164.6 million. The increase was primarily attributable to the successful IPO in 2017 amounting to NOK 400.0 million. In 2016 the cash inflow from financing activities mainly relate to private placements of NOK 213.7 in 2016.

Net cash inflow from financing activities for the first six months ended 30 June 2018 was NOK 177.0 million compared to NOK 375,2 million for the first six months ended 30 June 2017. The cash inflow from financing activities in the first six months ended 30 June 2017, primarily attributable to the successful IPO in 2017 amounting to NOK 400.0 million, and for the first six month ended 30 June 2018, to the private placement completed in April 2018 amounting to NOK 187.5 million.

### **10.9 Investments**

#### *10.9.1 Principal historical investments*

Costs associated with the development of the Company's first-in-class EMT inhibitors, and in particular the lead drug candidate (bemcentinib ), are ordinary research and development costs and are expensed as they incur, they are not capitalised in the balance sheet and included as investments. Costs of obtaining and maintaining patents are also included in the research and development costs. The Group has not had any significant historical capital expenditures, as substantially all costs incurred are research and development costs that are considered not to meet the asset recognition criteria of IAS 38 Intangible Assets and thus expensed when incurred. The investments of NOK 0.26 million in 2016 was related to laboratory equipment and the investment of NOK 0.34 million in 2017 was related to office furniture. In the first six months ended 30 June 2018 the investment of NOK 0.07 million was related to office furniture.

In 2017, expenses for research and development for the Group, including the clinical trial related costs, were expensed and amounted to NOK 137.5 million. Approximately 90-95% of the costs are attributed to the development of bemcentinib.

In 2016, expenses for research and development for the Group, including the clinical trial related costs, were expensed and amounted to NOK 101.9 million. Approximately 70-75% of the costs are attributed to the development of bemcentinib , 4-5% on BGB002 and 4-5% on BGB149. In addition, approximately 14% is attributed to BGB003 primarily due to the in-license of additional molecules from Rigel in 2016, see Section 8.8 "Dependency on contracts, suppliers and assets necessary for production".

Of the above, approximately 53% of the costs are related to the clinical development of bemcentinib, approximately 26.5% related to licensing fees, approximately 6-7% of the R&D expenses are related to personnel and approximately 2% to patent costs. The remainder is related to pre-clinical development costs for the pipeline assets.

In 2015, expenses for research and development for the Group, including the clinical trial related costs, were expensed and amounted to NOK 43.6 million. Approximately 50% of the costs were attributed to the development of bemcentinib, 25% on BGB002 and 2-3% on BGB149 and approximately 5% to patent costs. In addition, approximately 20% of the expenses were related to personnel costs within R&D activities on pre-clinical development and the pipeline assets. In 2015 the costs related to BGB002 were high as a several selective small molecule inhibitors of the target were developed and subsequently a number of compounds have been selected as pre-clinical development candidates.

### *10.9.2 Principal investments in progress and planned principal investments*

There are no significant investments in progress, but costs associated with the development of the Group's products are ordinary research and development costs, expensed as they are incurred. The Group has estimated that the cash held by the Group as of the date of this prospectus is expected to finance the Group through to 2020. The first indication for registration and commercialisation will become apparent following the Phase II studies. The Company is currently not able to quantify these future costs precisely and they will be affected by numerous factors, including amongst other the study design, results of the clinical studies, timing of regulatory approvals, the Company's chosen commercialisation strategy, the competitive landscape and the general economic climate. See note 2 of the Financial Statements incorporated by reference hereto, see Section 17.3 "Incorporation by reference", for an explanation of the accounting principles relating to research and developments costs. The Group finances the current costs related to R&D with equity and government grants.

## **10.10 Borrowings, contractual cash obligations and other commitments**

### *10.10.1 Material borrowings*

The Group has no outstanding long-term debt as of the date of this Prospectus.

On 5 September 2014, the Company entered into a convertible loan agreement with the Wellcome Trust under which Wellcome Trust granted an unsecured convertible loan in the amount of GBP 1,605,000. Wellcome Trust could at its absolute discretion require repayment or issuance of new Shares at a discounted price to be determined based on future incidents. The last tranche of the convertible loan was converted to equity in February/March 2016, and consequently from that point in time there are no further obligations under the convertible loan agreement.

Also after a full repayment of the loan, in cash or by conversion, the Wellcome Trust may take responsibility on behalf of the Company for the commercialisation of the "Product IPR" in the event the "Project IPR" has not been further developed by the Company and the Company has not been taking any material steps to commercialise the "Project IPR" within 5 years following the completion of the "Project". The final project report was approved by Wellcome Trust in December 2015.

In December 2014, the Company obtained patent protection for BGB002 composition of matter and use, and BGB002 is currently one of the main programmes in BerGenBio's pre-clinical work. The Company is thus of the opinion that it has, and in any event will within the 5 year period, have taken material steps to commercialise the "Project IPR", after which the Wellcome Trust option will lapse.

### *10.10.2 Contractual obligations and contingent liabilities*

The Group does not have any material contractual cash obligations or other commitments as of the date of this Prospectus.

### *10.10.3 No off-balance sheet arrangements*

The Group has not entered into and is not a party of any off-balance sheet arrangements.

## **10.11 Deferred tax asset**

BerGenBio has not recognised a deferred tax asset 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 the deferred tax asset. The deferred tax asset as of the 31 December 2017 was NOK 125 million due to a tax loss carry forward on NOK 543 million.

## **10.12 Related party transactions**

As per the date of this Prospectus, the Group has not entered into any related party transactions.

## **10.13 Quantitative and qualitative disclosure about financial risk and market risk**

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 Company has chosen not to put in place any measures to mitigate the potential unpredictability of the financial markets. The Group had NOK 370.4 million in cash and cash equivalents at year-end 2017. The main purpose of this is to finance the Group's activities and on-going 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.

*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 and development expenses. The Group is mainly exposed to fluctuations in euro (EUR), pounds sterling (GBP) and U.S. dollar (USD).

The Group has chosen not to hedge its operational performance as the Group's cash flow is denominated in several currencies that changes depending on where clinical trials are run. The foreign currency exposure is also mostly linked to trade payables with short payment terms. The Group might consider changing its current risk management of foreign exchange rate if it deems it necessary.

*Interest rate risk*

The Group held as at 31 December 2017 NOK 370.4 million in cash and cash equivalents and did 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. The Group had NOK 2.8 million in interest income as of 31 December 2017.

*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 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 2017 and the Company considers its credit risk as low.

**10.14 Trend information**

The Group has not experienced any changes or trends that are significant to the Group between 31 December 2017 and the date of this Prospectus, nor is the Group aware of such changes or trends that may or are expected to be significant to the Group for the current financial year.

**10.15 Significant changes**

There have been no significant changes in the financial or trading position of the Group since the date of the Financial Statements, which have been included in this Prospectus.

## 11 BOARD OF DIRECTORS, MANAGEMENT, EMPLOYEES AND CORPORATE GOVERNANCE

### 11.1 Introduction

The General Meeting is the highest authority of the Company. All shareholders in the Company are entitled to attend and vote at General Meetings of the Company and to table draft resolutions for items to be included on the agenda for a General Meeting.

The overall management of the Group is vested in the Company's Board of Directors and the Company's Management. In accordance with Norwegian law, the Board of Directors is responsible for, among other things, supervising the general and day-to-day management of the Company's business ensuring proper organisation, preparing plans and budgets for its activities ensuring that the Company's activities, accounts and assets management are subject to adequate controls and undertaking investigations necessary to perform its duties.

The Board of Directors has two sub-committees: a nomination committee and a remuneration committee. In addition, the Company has established an audit committee, with effect from the first day of Listing.

### 11.2 Board of Directors

#### 11.2.1 Overview of the Board of Directors

The Company's Articles of Association provide that the Board of Directors shall consist of a minimum of three and a maximum of seven Board Members. The current Board of Directors consists of seven Board Members, as listed in the table in Section 11.2.2 "The Board of Directors" below.

The composition of the Board of Directors is in compliance with the independence requirements of the Norwegian Code of Practice for Corporate Governance, dated 30 October 2014 (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 serves on the Board of Directors. Furthermore, pursuant to the Norwegian Public Limited Companies Act, if the board of directors of a Norwegian public limited liability company consists of six to eight members, then each gender shall be represented by at least three members.

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

The Company's registered business address, Jonas Lies vei 91, 5009 Bergen, Norway, serves as the c/o address for the Board Members in relation to their directorship of the Company. As of the date of this Prospectus, the Board Members holds only such Shares, options or other rights to acquire Shares as listed in the table under Section 11.2.2 "The Board of Directors" pursuant to the bonus and share incentive programmes described in Section 11.5 "Bonus and share incentive programmes".

#### 11.2.2 The Board of Directors

The names and positions and current term of office of the Board Members as at the date of this Prospectus are set out in the table below, including also their respective shareholdings and stock options in the Company.

<b>Name</b>	<b>Position</b>	<b>Served since</b>	<b>Term expires</b>	<b>Shares</b>	<b>Share Options</b>
Stein Holst Annexstad <sup>123</sup>	Chairman <sup>124</sup>	1 February 2016	AGM 2020	7,539	0
Susan Foden	Board Member	8 September 2011	AGM 2020	6,700	267,500
Sveinung Hole	Board Member	1 February 2016	AGM 2020	0	0
Jon Øyvind Eriksen	Board Member	30 January 2012	AGM 2020	0	0
Hilde Furberg <sup>125</sup>	Board Member	22 June 2015	AGM 2020	3,769	25,000
Stener Kvinnsland	Board Member	1 September 2015	AGM 2020	0	0
Kari Grønås <sup>126</sup>	Board Member	1 February 2016	AGM 2020	4,522	15,000

<sup>123</sup> Stein Holst Annexstad holds 7,539 shares in the Group through Holstein AS, a closely associated company of Stein H. Annexstad

<sup>124</sup> Served as chairman of the Board from 16 January 2017.

<sup>125</sup> Hilde Furberg holds 3,769 shares in the Group through J&J Future Invest AS, a closely associated company of Hilde Furberg

<sup>126</sup> Kari Grønås holds 4,522 shares in the Group through K og K AS, a closely associated company of Kari Grønås

### 11.2.3 Brief biographies of the Board Members

Set out below are brief biographies of the Board Members, including their relevant management expertise and experience, an indication of any significant principal activities performed by them outside the Company and names of companies and partnerships of which a Board Member is or has been a member of the administrative, management or supervisory bodies or partner in the previous five years (not including directorships and executive management positions in subsidiaries of such Companies).

#### Stein Holst Annexstad, Chairman

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

*Current directorships and senior management positions .....* *VEAS-Vestfjorden Avløpsselskap (chairman), Asker Kommunale Pensjonskasse (board member) and Holstein AS (managing director and board member).*

*Previous directorships and senior management positions last five years .....* *Algeta ASA (chairman), Investinor AS (chairman), Biomedisinsk Innovasjon AS (board member), Norsk Medisinsk Syklotronsenter AS (chairman), Agenda Kaupang AS (chairman) and Biotec Pharmacon ASA (chairman of the nominations committee).*

#### Susan Foden, Board Member

Dr Susan Foden holds a number of Non-Executive Directorships with both public and private companies and public funding bodies in the biotechnology and healthcare field, including Vectura plc., Source Bioscience plc, Rainbow Seed Fund, Cascade Ltd and Oxford Ancestors Ltd. Previously, Dr Foden held positions in venture capital and UK biotechnology companies. From 2000 to 2003 she was an Investor Director with the London-based VC firm Merlin Biosciences Limited, and was CEO of the technology transfer company Cancer Research Campaign Technology. She studied biochemistry at the University of Oxford from where she obtained an MA and a DPhil. She is a UK citizen, and resides in the UK.

*Current directorships and senior management positions .....* *British Technology Group Plc (board member), Vectura Group Plc (board member), Evgen Plc (board member), Oxford Ancestors Ltd (board member), BTG plc (board member) and The Cell and Gene Therapy Catapult (board member). No senior management positions.*

*Previous directorships and senior management positions last five years .....* *Rainbow Seed Fund (board member), the Cascade Fund (board member), Cizzle Biotech Ltd (chairman), Rainbow Seed Fund Ltd, Source Bioscience plc (board member), Rainbow Seed Fund (board member) and Source BioScience plc (board member).*

#### Sveinung Hole, Board Member

Mr Hole is the CEO of Bergen Research Foundation, the Kristian Gerhard Jebsen Foundation and he is at the moment employed by Meteva AS. Hole holds a number of board positions amongst others at Sarsia Seed AS, Nordic and Europe Health Invest AS and Prophylix Pharma AS. Formerly he was the CEO of the investment fund Sarsia Seed AS, board member of Bergen Hospital Trust (Helse Bergen) Norwegian Venture Capital Association, Nansen Neuroscience Network and Director of Anesthesia and Intensive Care at Haukeland University Hospital. Hole has also held various top management positions at Telenor Corporation and been Regional Managing Director/Director of Global Strategies at the

Berlitz Corporation. Hole holds a Master of International Management from BI Norwegian Business School. He is a Norwegian citizen, and resides in Norway.

*Current directorships and senior management positions .....* *Bergen Research Foundation (CEO), Stiftelsen Kristian Gerhard Jebsen (CEO), Meteva AS (employed) and Wimoh AS (employed), Sarsia Seed Fond II AS (chairman of the board) and Tromsø Forskningsstiftelse (chairman of the board), PE Helse AS (board member), Nordic and Europe Health Invest AS (board member), Sarsia Seed AS (board member), Prophylis Pharma AS (board member), Prophylis Pharma II AS (board member), Prophylis Pharma Holding AS, Volusense AS (board member).*

*Previous directorships and senior management positions last five years .....* *Sarsia Seed Management (managing partner and board member), Isentio AS (board member), Legato og Stiftelsesforvaltning AS (board member), Norwegian Venture Capital Association (board member), Bergen Hospital Trust (Helse Bergen) (board member), Nansen Neuroscience Network (board member).*

### **Jon Øyvind Eriksen, Board Member**

Jon Øyvind Eriksen holds an MSc in biotechnology from the Norwegian University of Science and Technology (NTNU), and a graduate degree in Russian and German from the University of Bergen who is currently employed as Investment Director at Investinor AS. He has been awarded an MBA with Distinction from London Business School, and he is also a CFA Charterholder. Mr Eriksen is a serial entrepreneur with a proven track record of leading technology and media companies through start-up, growth, expansion and exits, mergers, acquisitions, corporate spin-offs and turnarounds. Mr Eriksen has previously served as CEO of Kantega, Mogul Technology and Internet Aksess, and also held positions as chairman and member of the board of directors in several companies. He is a Norwegian citizen and resides in Norway.

*Current directorships and senior management positions .....* *Boostcom Group AS (board member), Northern.tech AS (board member), Northern.tech Holding AS (board member), Novelda AS (board member), Numascale AS (board member and deputy director) Signicat AS (board member), Signicat AB (board member and deputy director), Sonstad AS (chairman), Unacast, Inc. (board member) and Swarm64 AS (board member).*

*Previous directorships and senior management positions last five years .....* *Numascale AS (deputy board member), Signicat AS (chairman) and Norwegian University of Science and Technology (NTNU) (board member and deputy board member).*

### **Hilde Furberg, Board Member**

Hilde Furberg has over 30 years of commercial experience in pharma and biotech, she is currently Senior Vice President Rare Diseases EMEA at Sanofi Genzyme. Previously her roles were Vice President and General Manager of Nordic Benelux and Nordic General Manager at Sanofi Genzyme. Prior to joining Sanofi Genzyme, Ms Furberg was Managing Director and part-owner of Pharmalink and held a number of roles at Baxter including Managing Director Sweden. She is currently a board member at Pharmalink and has held board positions at Algeta, Clavis, Pronova and Probi. She is a Norwegian citizen, and resides in de Naarden, Netherlands.

*Current directorships and senior management positions .....* *Sanofi Genzyme (European head of Rare Diseases), Calliditas AB (board member) and J&J Future Invest AS (board member).*

*Previous directorships and senior management positions last five years .....* *Algeta ASA (board member), Clavis Pharma ASA (board member), and Pronova Biopharma ASA (board member).*

### **Stener Kvinnsland, Board Member**

Dr Stener Kvinnsland has more than 30 years of experience as specialist in medical oncology and radiotherapy who has served as Board member since September 2015, and who is also currently the chairman of the board of directors of Oslo University Hospital. Kvinnsland has extensive experience from the oncology space within both public and private sector. 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. He is a Norwegian citizen, and resides in Norway.

*Current directorships and senior management positions .....* *Helse Stavanger Hf (chairman), Akershus University Hospital HF (chairman), Health Faculty at Tromsø University (chairman), Pluvia Therapeutics AS (chairman), the Bergen Research Foundation (chairman) and APIM Pharmaceuticals AS (board member).*

*Previous directorships and senior management positions last five years .....* *Oslo Universitetssykehus Hf (chairman) and Health Faculty at Tromsø University (chairman).*

### **Kari Grønås, Board Member**

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

*Current directorships and senior management positions .....* *K og K AS (managing director and board member), SoftOx Solutions AS (board member) and Spago Nanomedical SE*

*Previous directorships and senior management positions last five years .....* *Algeta ASA/Bayer Norge AS (SVP Operations and SVP Executive Advisor), Lytix Biopharma AS (board member), Norwegian Pharmaceutical Society (chairman of the board) and The Federation of Norwegian Industry (member of board of representatives).*

## **11.3 Management**

### *11.3.1 Overview*

The Management is responsible for the day-to-day management of the Company's operations in accordance with Norwegian law and instructions set out by the Board of Directors. Among other responsibilities, the Company's chief executive officer ("CEO") is responsible for keeping the Company's accounts in accordance with prevailing Norwegian legislation and regulations and for managing the Company's assets in a responsible manner. In addition, the CEO must according to Norwegian law brief the Board of Directors about the Company's activities, financial position and operating results at a minimum of one time per month.

The Company's senior management team consists of nine individuals. The names of the members of Management as at the date of this Prospectus, and their respective positions, are presented in the table below, including also their respective shareholdings and stock options in the Company:

<b>Name</b>	<b>Current position with the Company</b>	<b>Employed with the Company since</b>	<b>Shares</b>	<b>Share Options</b>
Richard Godfrey	Chief Executive Officer	20 January 2009	158,900	1,067,484
Rune Skeie	Chief Financial Officer	5 March 2018	0	24,090
James Lorens	Chief Scientific Officer	1 January 2009	250,000 <sup>127</sup>	710,707
Steven Murray Yule <sup>128</sup>	Clinical Development Officer	1 November 2016	0	190,797
Tone Bjaaland	Director of Clinical Operations	9 June 2018	0	0
Anthony Brown	Director of Research	1 September 2015	0	176,499
Sonia Rodrigues	Director of Regulatory Affairs	8 May 2018	0	26,499
Endre Kjærland	Associate Director of IP and Contracts	2011	0	85,225
Julia Schölermann	Associate Director Business Development and Partnering	2015	0	80,418

<sup>127</sup> Pursuant to an agreement dated 21 December 2009, compensating the employees for their rights as co-inventors of certain early IPR of the Company, entered into with Bergen Teknologioverføring AS, later assigned to Norsk Innovasjonskapital II AS, James Lorens has a right and an obligation to purchase 200 additional Shares (20,000 Shares after the share split resolved by the General Meeting 22 March 2017) at an agreed price per Share of NOK 0.10. There is no expiry date to the call/put options, and the Shares may be purchased/sold when called or put by James Lorens or Norsk Innovasjonskapital II AS, respectively.

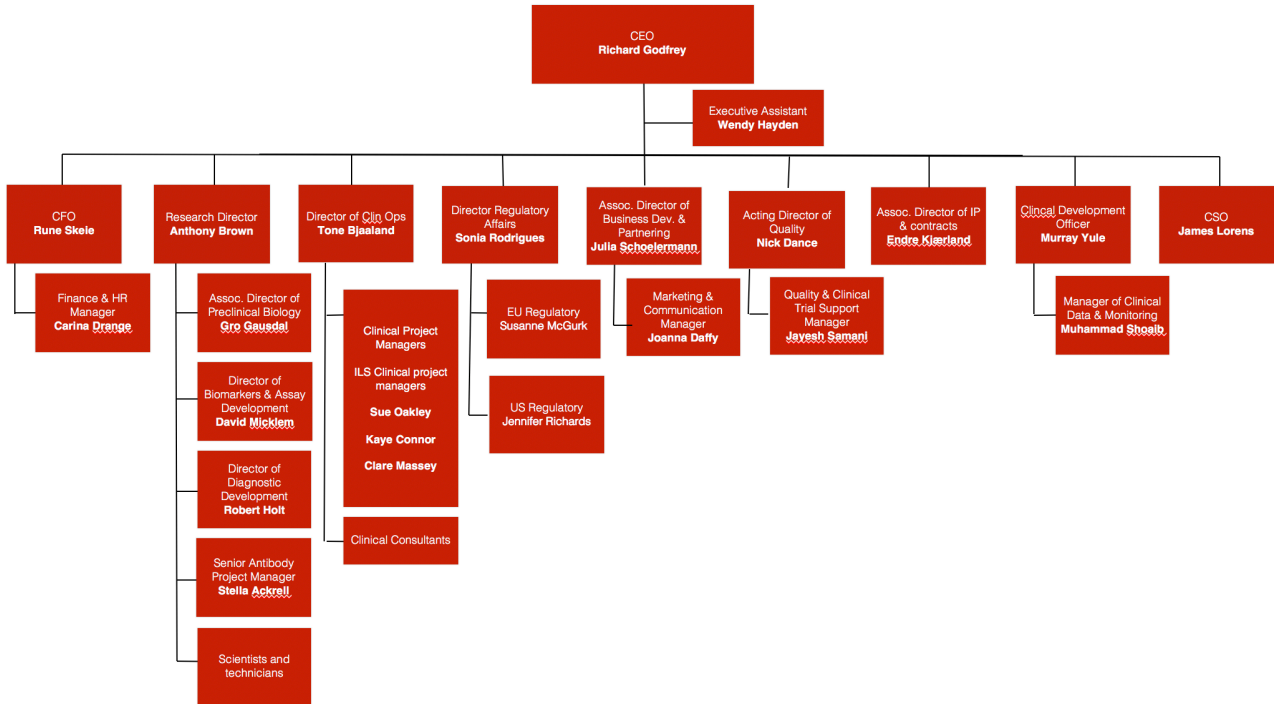
<sup>128</sup> Previously engaged by the Company as consultant from 2011



The Company’s registered business address, Jonas Lies vei 91, 5009 Bergen, Norway, serves as the business address for the members of the Management in relation to their employment with the Company.

The following chart sets out the Management’s organisational structure:

Figure 27: Organogram



11.3.2 Brief biographies of the members of Management

Set out below are brief biographies of the members of Management, including their relevant management expertise and experience, an indication of any significant principal activities performed by them outside the Company and names of companies and partnerships of which a member of Management is or has been a member of the administrative, management or supervisory bodies or partner the previous five years (not including directorships and executive management positions in subsidiaries of such companies).

**Richard Godfrey, Chief Executive Officer**

Richard Godfrey joined the Company as Chief Executive Officer in 2008. He has more than 28 years’ industry experience leading many international drug development and commercialisation partnerships. Formerly he served as Chief Executive Officer of Aenova Inc.. Prior to this he was the Managing Director of DCC Healthcare Ltd and previously he held positions of increasing responsibility at Catalant, Eli Lilly and Reckitt Benckiser in R&D and commercial roles. He qualified as a Pharmacist from Liverpool University and received his M.B.A. from Bath University. Mr Godfrey is a UK citizen, and resides in Norway.

*Current directorships and senior management positions .....* *Gnist Holding AS (managing director and chairman), Uni Targeting Research AS (chairman), Petosan AS (chairman) and Gnist Ltd (director).*

*Previous directorships and senior management positions last five years .....* *Sarisa Venture management (board member and partner), Ayanda Group AS (board member) and Captech AS (board member) Square One Holding AS (board member), Magnet Strategy and marketing Partners AS (board member), Biotec Pharmacon ASA (board member) and Balter Medical AS (board member),.*

**Rune Skeie, Chief Financial Officer**

Rune Skeie joined BerGenBio ASA in 2018 as CFO. Previously he held the position of CFO at REMA Franchise Norge AS (region Bergen), the multinational supermarket business. Skeie 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. Skeie is a Registered Accountant and a State Authorized Public Accountant. Mr. Skeie is a Norwegian citizen, and resides in Norway.

*Current directorships and senior management positions .....* Hølen Småbåtlag (chairman)  
*Previous directorships and senior management positions last five years .....* RF Bergen 2 AS, RF Bergen 3 AS, RF Bergen 4 AS, RF Bergen 5 AS, RF Bergen 6 AS, RF Bergen 7 AS, RF Bergen 8 AS, RF Bergen 9 AS and RF Bergen 10 AS (chairman)

### **James Lorens, Chief Scientific Officer**

Professor James Lorens is the co-founder of the Company with 26 years academic and biotech research experience. He 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 biotech company, as a founding scientist and research director. Professor Lorens has managed several large scientific collaborations in cancer research and development with major pharmaceutical and biotech companies. In addition to BerGenBio, he leads a large internationally active research laboratory comprising 22 researchers. His group is active in EMT, angiogenesis and cancer research. Professor Lorens is an author of more than 100 peer-reviewed articles and patents. Mr Lorens is a U.S. citizen, and resides in Norway.

*Current directorships and senior management positions .....* Lorn Holding AS (chairman) and Norwegian Research Council, Division of Innovation (board member).  
*Previous directorships and senior management positions last five years .....* None.

### **Steven Murray Yule, Clinical Development Officer**

Dr Steven Murray Yule joined BerGenBio in 2011 as a consultant and became employed as Clinical Development Officer in 2016. He began his career in the pharmaceutical industry in 1998 after completing his medical training in oncology at Addenbrookes Hospital, Cambridge. Whilst working in the United Kingdom's National Health Service, Murray supervised multiple early phase clinical studies of novel anticancer products and completed a PhD in experimental pharmacology. In the last ten years, whilst working in several top-ten pharmaceutical companies, he has planned and executed global development strategies for several anticancer drugs, which has led to licensing approvals for novel tubulin binders in solid tumours and epigenetic therapies in acute leukaemia. Dr Murray Yule also provides clinical development consulting to Incanthera Limited, Bicycle Therapeutics and the British Therapeutics Group. Mr Murray Yule is a UK citizen, and resides in the UK.

*Current directorships and senior management positions .....* Pentlands Oncology Consulting Ltd (board member).  
*Previous directorships and senior management positions last five years .....* Pentlands Clinical Resourcing Limited (board member) and Astex Therapeutics Limited (medical director).

### **Tone Bjaaland, Director of Clinical Operations**

Tone Bjaaland joined BerGenBio in July 2018 and serves as Director of Clinical Operations, based in Oxford, UK. She brings over 25 years' experience in the management of clinical programmes from pharma, biotech and CRO companies. She completed her doctorate from King's College, London in 1986 and has held several management positions within the pharma industry. She has worked in a number of therapeutic areas including cardiovascular, gastroenterology, neurology, oncology, and across phases 1-4. Tone Bjaaland is a Norwegian citizen, residing in the UK since 1974.

*Current directorships and senior management positions .....* None  
*Previous directorships and senior management positions last five years .....* (Director) Phase I-IV Ltd

### **Anthony Brown, Director of Research**

Dr. Anthony Brown joined BerGenBio as Research Director in October 2015. He is founder and Director of Drug Discovery Limited and currently also Scientific Director at CellCentric. He has over 25 years of experience in the drug discovery of both small molecule and biological therapeutics from research through to the clinic. This has covered multiple therapeutic areas, including Oncology, Immune/Inflammation and Cardiovascular Disease. He completed his doctorate from the University of Oxford in 1993 and has held Senior Management and Director level positions at British Biotech, OSI

Pharmaceuticals, Piramed Pharma and Cancer Research Technology. He has managed strategic alliances with pharma and biotech and lead several novel programmes in Oncology, from early research through to clinical studies. In addition, he has held Scientific Advisory Board positions and acted as a drug discovery consultant for biotechs and academic institutions. He holds an MBA from Oxford Brookes University. Dr Anthony Brown is a UK citizen and resides in the UK.

*Current directorships and senior management positions .....* *Cerebellum Limited (director) and Drug Discovery Limited (director).*  
*Previous directorships and senior management positions last five*  
*years .....* *CellCentric Limited (scientific director).*

**Sonia Rodrigues, Director of Regulatory Affairs**

Sonia Patricia Abreu Rodrigues joined BerGenBio in 2018 and serves as Director of Regulatory Affairs, based in Oxford, UK. She brings over 10 years’ experience in Regulatory Affairs across all development stages from pharma, biotech and CRO companies across a number of therapeutic areas and phases, more recently focused on immunology and oncology. She qualified as MSc and PhD in Biochemistry and Cell Biology from McGill University in Montreal, Canada. Sonia Rodrigues is a Portuguese citizen, and resides in the UK.

*Current directorships and senior management positions .....* *None*  
*Previous directorships and senior management positions last five*  
*years .....* *SML Consulting Ltd (Director).*

**Endre Kjærland, Associate Director of IP and Contracts**

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

*Current directorships and senior management positions .....* *None*  
*Previous directorships and senior management positions last five*  
*years .....* *None*

**Julia Schölermann, Associate Director Business Development and Partnering**

Dr Julia Schölermann joined BerGenBio AS She is responsible for the Company's Business Development and Partnering activities. She has a solid academic background in biotechnology and cell biology paired with many years work and supervision experience within leading academic institutions across Europe. She holds an MSc in biotechnology and biophysics from the University of Heidelberg, Germany, a PhD in cell biology from the University of Bergen, Norway, and a dual-degree MBA from Brown University, USA, and i.e. business school in Madrid, Spain.

*Current directorships and senior management positions .....* *None*  
*Previous directorships and senior management positions last five*  
*years .....* *None*

## 11.4 Remuneration and benefits

### 11.4.1 Remuneration of the Board of Directors

The total remuneration paid to the Board Members in 2017 was NOK 1,415,000. The table below sets out the remuneration paid to the Board Members in such period.

<u>Name and position</u>	<u>In NOK (1000)</u>	<u>Remuneration in 2017</u>
Stein Holst Annexstad (Chairman)		365
Jon Øyvind Eriksen (Board Member)		190
Hilde Furberg (Board Member)		175
Stener Kvinnsland (Board Member)		160
Sveinung Hole (Board Member)		190
Susan Foden (Board Member)		160
Kari Grønås (Board Member)		175

### 11.4.2 Remuneration of Management

The Board of Directors has established guidelines for the remuneration of the members of the Management. It is a policy of the Company to offer the Management competitive remuneration based on current market standards, company and individual performance. The remuneration consists of the basic salary element as set out below, combined with a performance based bonus programme and participation in the share incentive programme described in Section 11.5 "Bonus and share incentive programmes". The Management participates in the Company's insurances and medical coverage, and is entitled to certain fringe benefits, such as telephone and newspaper. The Company may, in the future, make individual agreements for early retirement for individuals in the Management.

The remuneration paid to the members of the current Management in 2017 was NOK 7,260,082. The table below sets out the remuneration of the current Management in 2017 (in NOK):

<u>Name</u>	<u>Salary</u>	<u>Bonus</u>	<u>Other benefits</u>	<u>Estimated pensions costs</u>	<u>Total remuneration</u>
Richard Godfrey (Chief Executive Officer)	2,269,644	288,970	10,884	178,618	2,748,116
Rune Skeie (Chief Financial Officer, from 5 March 2018)	0	0	0	0	0
James Lorens (Chief Scientific Officer)	463,382	143,130	6,492	36,324	649,328
Murray Yule <sup>129</sup> (Clinical Development Officer)	2,216,608	-	-	155,163	2,371,771
Tone Bjaaland (Director of Clinical Operations, from 9 July 2018)	0	0	0	0	0
Anthony Brown (Director of Research)	1,277,188	124,276	-	89,403	1,490,867
Sonia Rodrigues (Director of Regulatory Affairs, from 8 May 2018)	0	0	0	0	0

## 11.5 Bonus and share incentive programmes

### 11.5.1 Bonuses

The members of the Management are eligible for a non-pensionable annual bonus with a target bonus opportunity of 20% of annual base salary. With exceptionally performance, the target bonus can maximum be doubled, up to a 40% bonus. Any bonus awarded will be discretionary and subject to the achievement of performance conditions which in consultation with the, remuneration committee, will be set by the chairman of the Board, and finally approved by the Board.

### 11.5.2 Share Option Programmes

The Company has granted share options in 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017 and 2018 (the "**Share Option Programmes**"). The current terms of the share option programme is regulated by the "Standard Terms under the Share Incentive Programme of BerGenBio AS" as resolved by the Board of Directors 23 February 2012.

Each option gives the right to acquire one share of the Company on exercise. Since the start of the Share Option Programmes 500 options have been exercised. The Share Option Programmes are intended to ensure focus and align

<sup>129</sup> Mr Murray Yule was previously hired-in as a consultant, and employed by the Company as employee as from 1 November 2016.

the Company's long-term performance with shareholder values and interest. Most of the employees in the Company take part in the Share Option Programmes, in addition to some Board Members. The Share Option Programmes 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. In 2016, the Board of Directors reviewed and amended the vesting criteria's for granted options to employees. The revised vesting criteria was set as the earlier of IPO or annually in equal tranches over a three-year period following the date of grant.

Overview of options as of the date of the Prospectus:

<b>Time of grant</b>	<b>Number of options</b>	<b>Expiry date</b>	<b>Exercise price</b>
September 2010	225,000	December 2017/2019	5.65
May 2011	175,000	December 2017/2019	7.56
June 2012	285,000	December 2017/2019	10.615
June 2012	225,000	June 2020	10.615
June 2013	360,000	June 2021	10.615
September 2013	400,000	September 2021	10.615
June 2014	280,000	June 2022	11.15
May 2015	650,000	May 2023	16.01
September 2015	260,000	September 2023	16.01
January 2016	400,000	January 2024	24.00
February 2016	122,500	February 2024	24.00
December 2017	50,000	Dec 2025	22.00
May 2018	385,027	May 2026	46.70
Forfeited in 2015	-7,500		10.615
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		
<b>Total</b>	<b>3,150,027</b>		

As of the date of this Prospectus, there were 3,150,027 options outstanding under the Share Option Programmes of which 2,715,000 have been vested and could be exercised at present. The vested options have expiry dates varying from May 2018 to May 2026. The remaining options will vest annually in equal tranches over a three-year period following the date of grant.

Each option granted gives the holder a conditional right to acquire one Share in the Company. The exercise price under the Share Option Programme is equal to the market price of the shares at the date of the grant, the vested share options have been granted at an exercise price between NOK 5.65 and NOK 24.00, and the remaining options at an exercise price between NOK 22.00 and NOK 46.70.

As of the date of this Prospectus, members of the Board of Directors and Management have been granted share options under the Share Option Programmes and holds such share options as set out below:

Name (position)	Date granted	Expiry date	Options outstanding as of 28 March 2017	Exercise price range in NOK
<b>Susan Foden (Board Member)</b>				
	June 2012	June 2020	100,000	10.615
	June 2013	June 2021	25,000	10.615
	September 2013	September 2021	55,000	10.615
	June 2014	June 2022	50,000	11.15
	February 2016	February 2024	37,500	24.00
			<b>267,500</b>	
<b>Hilde Furberg (Board Member)</b>				
	February 2016	February 2024	25,000	24.00
			<b>25,000</b>	
<b>Kari Grønås (Board Member)</b>				
	February 2016	February 2024	15,000	24,00
			<b>15,000</b>	
<b>Richard Godfrey (CEO)</b>				
	September 2010	December 2019	50,000	5.65
	May 2011	December 2019	100,000	7.56
	June 2012	December 2019	75,000	10.615
	June 2013	June 2021	75,000	10.615
	September 2013	September 2021	150,000	10.615
	June 2014	June 2022	120,000	11.15
	May 2015	May 2023	275,000	16.01
	January 2016	January 2024	100,000	24.00
	May 2018	May 2026	122,484	46.70
			<b>1,067,484</b>	
<b>James Lorens (Chief Scientific Officer)</b>				
	September 2010	December 2019	50,000	5.65
	May 2011	December 2019	25,000	7.56
	June 2012	December 2019	75,000	10.615
	June 2013	June 2021	100,000	10.615
	September 2013	September 2021	55,000	10.615
	June 2014	June 2022	70,000	11.15
	May 2015	May 2023	275,000	16.01
	January 2016	January 2024	50,000	24.00
	May 2018	May 2026	10,707	46.70
			<b>710,707</b>	
<b>Rune Skeie (CFO)</b>				
	May 2018	May 2026	24,090	46.70
			<b>24,090</b>	
<b>Steven Murray Yule (Clinical Development Officer)</b>				
	September 2013	September 2021	100,000	10.615
	January 2016	January 2024	50,000	24.00
	May 2018	May 2026	40,797	46.70
			<b>190,797</b>	
<b>Anthony Brown (Director of Research)</b>				
	September 2015	September 2023	100,000	16.01
	January 2016	January 2024	50,000	24.00
	May 2018	May 2026	26,499	46.70
			<b>176,499</b>	

### 11.6 Benefits upon termination

No employee, including any member of Management, has entered into employment agreements which provide for any special benefits upon termination. None of the Board Members or the members of the nomination committee has a service contract and none will be entitled to any benefits upon termination of office.

### 11.7 Pensions and retirement benefits

The Company operates a defined contribution benefit pension plan, effective as of 1 October 2016.

Until 30 September 2016 the Company operated a defined benefit pension plan in, which requires contributions to be made to a separately administered fund. The Company also provides certain additional post employment healthcare benefits to employees. These benefits are unfunded.

The cost of the defined benefit pension plan and other post-employment medical benefits and the present value of the pension obligation are determined using actuarial valuations. An actuarial valuation involves making various assumptions that may differ from actual developments in the future. These include the determination of the discount rate, future salary increases, mortality rates and future pension increases. Due to the complexities involved in the valuation and its long-term nature, a defined benefit obligation is highly sensitive to changes in these assumptions.

The mortality rate is based on publicly available mortality tables for the specific countries. Those mortality tables tend to change only at intervals in response to demographic changes. Future salary increases and pension increases are based on expected future inflation rates for the respective countries.

The Company has no pension or retirement benefits for its Board Members.

For more information regarding pension and retirement benefits, see note 10 to the Financial Statements for the year ended 31 December 2016, incorporated by reference hereto, see Section 17.3 "Incorporation by reference".

### 11.8 Loans and guarantees

The Company has not granted any loans, guarantees or other commitments to any of its Board Members or to any member of Management.

### 11.9 Employees

As at the date of this Prospectus, the Company had 24 employees. Of these employees, 4.5 are working with the Company's clinical trials, 4 are working as laboratory technicians, 10.7 as scientists or scientific and research managers/leaders and the remaining 4.8 within administration, accounting, contracts, IP and management.

Save for the Management as is presented above, the Company considers the following as key employees:

*David Robert Micklem, Director of Diagnostics and Biomarkers*

Dr David Micklem is co-founder of BerGenBio and currently serves as Director of Diagnostics and Biomarkers. He has co-authored numerous scientific publications and patents and brings over 25 years of experience of research in molecular biology and genetics. He holds a BA in Biochemistry from the University of Oxford and a PhD in Developmental Biology and Genetics from the University of Cambridge.

*Gro Gausdal, Associate Director of Preclinical Biology*

Dr Gro Gausdal joined BerGenBio AS in 2013 and holds now the position as Associate Director of Preclinical Biology. Prior to joining BerGenBio, she has gained more than 10 years of experience in academic science and supervision. She completed a MSc in micro biology and PhD in cell biology from the University of Bergen.

The table below shows the development in the numbers of full-time employees over the last two years in total and by geographic region and main category of activity.

	As of the date of the Prospectus	Year ended 31 December	
		2017	2016
<b>Total</b> .....	<b>25.8</b>	<b>24.8</b>	<b>25</b>
By geographic region:			
- Norway .....	15	14	19
- UK .....	10.8	10.8	6
By main category of activity:			
- Clinical .....	5.8	5.8	4.5
- Research and development .....	12.2	12.2	15.7
- Administration/IPR/commercialisation .....	7.8	6.8	4.8

The employees working in the UK are employed by BerGenBio Limited, a UK subsidiary of the Company, see Section 12.2 "Legal structure".

**11.10 Nomination committee**

The Company's Articles of Association provide for a nomination committee composed of up to 3-4 members who are shareholders or representatives of shareholders. The current members of the nomination committee are Ann-Tove Kongsnes (chairman), Hans Peter Bøhn and Masha P.N Le Gris Strømme. The nomination committee will be responsible for nominating the shareholder-elected Board Members and members of the nomination committee and making recommendations for remuneration to the Board Members and members of the nomination committee.

**11.11 Audit committee**

The Board of Directors has established an audit committee, with effect from the first day of Listing, composed of three Board Members. The current members of the audit committee are Jon Øyvind Eriksen (chairman), Kari Grønås and Stein Holst Annexstad.

The primary purposes of the audit committee are to:

- assist the Board of Directors in discharging its duties relating to the safeguarding of assets; the operation of adequate system and internal controls; control processes and the preparation of accurate financial reporting and statements in compliance with all applicable legal requirements, corporate governance and accounting standards; and
- provide support to the Board of Directors on the risk profile and risk management of the Company.

The audit committee reports and makes recommendations to the Board of Directors, but the Board of Directors retains responsibility for implementing such recommendations.

**11.12 Remuneration committee**

The Board of Directors has established a remuneration committee amongst the Board Members. The remuneration committee comprises Sveinung Hole (chairman), Stein Holst Annexstad and Hilde Furberg.

The primary purpose of the remuneration committee is to assist the Board of Directors in discharging its duty relating to determining Management's compensation. The remuneration committee shall report and make recommendations to the Board of Directors, but the Board of Directors retains responsibility for implementing such recommendations.

**11.13 Corporate governance**

The Company has, with effect from the Listing, adopted and implemented a corporate governance regime which complies with the Corporate Governance Code. Prior to the Company being subject to the Corporate Governance Code, the Company has granted share options to Susan Foden, Hilde Furberg and Kari Grønås (Board Members) as set out in Sections 11.2.2 "The Board of Directors". Furthermore, the Company has, prior to being subject to the Corporate Governance Code, granted share options to the Management. The abovementioned share options are further described in Section 11.5.2 "Share Option Programmes".

**11.14 Conflicts of interests etc.**

During the last five years preceding the date of this Prospectus, none of the Board Members and members of the Management has, or had, as applicable:

- any convictions in relation to indictable offences or convictions in relation to fraudulent offences;
- received any official public incrimination and/or sanctions by any statutory or regulatory authorities (including designated professional bodies) or was disqualified by a court from acting as a member of the administrative, management or supervisory bodies of a company or from acting in the management or conduct of the affairs of any company; or
- been declared bankrupt or been associated with any bankruptcy, receivership or liquidation in his or her capacity as a founder, director or senior manager of a company.

Jon Øyvind Eriksen (Board member) is currently employed as Investment Director at Investinor AS, who is the second largest shareholder of the Company, Sveinung Hole is employed by Meteva AS and serves as member of the board of Sarsia Seed AS, both major shareholder of the Company, and Richard Godfrey (CEO) is a minority shareholder in Sarsia Development AS who is also a shareholder in the Company. To the Company's knowledge, there are currently no other



actual or potential conflicts of interest between the Company and the private interests or other duties of any of the Board Members and members of the Management, including any family relationships between such persons.

## 12 CORPORATE INFORMATION AND DESCRIPTION OF THE SHARE CAPITAL

The following is a summary of certain corporate information and material information relating to the Shares and share capital of the Company and certain other shareholder matters, including summaries of certain provisions of the Company's Articles of Association and applicable Norwegian law in effect as at the date of this Prospectus. The summary does not purport to be complete and is qualified in its entirety by the Company's Articles of Association, included in Appendix A to this Prospectus, and applicable law.

### 12.1 Company corporate information

The Company's legal and commercial name is BerGenBio ASA, commonly known as BerGenBio. The Company is a public limited company organised and existing under the laws of Norway pursuant to the Norwegian Public Limited Companies Act. The Company's registered office is in the municipality of Bergen, Norway. The Company was incorporated in Norway on 21 December 2007. The Company's registration number in the Norwegian Register of Business Enterprises is 992 219 688, and the Shares are registered in book-entry form with the VPS under ISIN 0010650013. The Company's register of shareholders in the VPS is administrated by DNB Bank ASA. The Company's registered office is located at Jonas Lies Vei 91, 5009 Bergen, Norway and the Company's main telephone number at that address is +47 53 50 15 64. The Company's website can be found at [www.bergenbio.com](http://www.bergenbio.com). The content of [www.bergenbio.com](http://www.bergenbio.com) is not incorporated by reference into and does not otherwise form a part of this Prospectus.

### 12.2 Legal structure

The Company, as of year-end 2017 has one wholly-owned subsidiary, BerGenBio Limited. BerGenBio Limited was incorporated 10 January 2017 in the UK with company number 10555293.

### 12.3 Share capital and share capital history

As of the date of this Prospectus, the Company's share capital is NOK 5,471,144.60 divided into 54,711,446 Shares, with each Share having a nominal value of NOK 0.10. All the Shares have been created under the Norwegian Public Limited Companies Act, and are validly issued and fully paid.

The Company has one class of shares. Except as set out in Sections 11.2.2 "The Board of Directors" and 11.5 "Bonus and share incentive programmes", there are no share options or other rights to subscribe or acquire Shares issued by the Company. The Company does not own, directly or indirectly, any Shares in the Company.

The table below shows the development in the Company's share capital for 2016 and 2017 and to the date hereof:

Date of resolution	Type of change	Change in share capital (NOK)	Nominal value (NOK)	New number of Shares	New share capital (NOK)
01.02.2016	Share capital increase <sup>1</sup>	437,500	0.10	4,375,000	2,916,740
18.02.2016	Share capital increase <sup>2</sup>	5,730	0.10	57,300	2,922,470
01.02.2016	Share capital increase <sup>3</sup>	9,250	0.10	92,500	2,931,720
21.06.2016	Share capital increase <sup>4</sup>	437,500	0.10	4,375,000	3,369,220
06.02.2017	Share capital increase <sup>5</sup>	5,000	0.10	50,000	3,374,220
22.03.2017	Share capital increase <sup>6</sup>	1,600,000	0.10	16,000,000	4,974,220
12.06.2017	Share capital increase <sup>7</sup>	1,500	0.10	15,000	4,975,720
16.11.2017	Share capital increase <sup>8</sup>	16,500	0.10	165,000	4,992,220
12.02.2018	Share capital increase <sup>9</sup>	1,000	0.10	10,000	4,993,220
05.04.2018	Share capital increase <sup>10</sup>	15,000	0.10	150,000	5,008,220
13.04.2018	Share capital increase <sup>11</sup>	462,924.60	0.10	4,629,246	5,471,144.60

1 The Shares were subscribed at a price of NOK 24 each.

2 The Shares were subscribed at a price of NOK 24 each.

3 The Shares were subscribed at a price of NOK 21.60 each through a conversion of a convertible loan.

4 The Shares were subscribed at a price of NOK 24 each.

5 The Shares were subscribed at a price of NOK 10.62 each through exercise of options from an employee

6 The Shares were subscribed at a price of NOK 25 each in connection with the initial public offering of shares and the related listing of the Company's shares on Oslo Børs

7 The Shares were subscribed at a price of NOK 10.62 each through exercise of options from an employee

8 The Shares were subscribed at a price of NOK 9.73 each through exercise of options from an employee

9 The Shares were subscribed at a price of NOK 24 each through exercise of options from an employee

10 The Shares were subscribed at a price of NOK 18.67 each through exercise of options from an employee

11 The Shares were subscribed at a price of NOK 40.50 per share in connection with a private placement of new shares

In the period from 01.01.2016 to the date of this Prospectus, NOK 9,250 of the share capital has been paid with assets other than cash (corresponding to approximately 0.17% of the current share capital).

## 12.4 Ownership structure

As at the date of this Prospectus, the Company has 3,076 shareholders. The Company's 20 largest shareholders as of the date of this Prospectus are shown in the table below.

Shareholders	Number of Shares	Per cent
Meteva AS	14,923,000	27.28
Investinor AS	6,609,800	12.08
Sarsia Seed AS	2,117,900	3.87
Verdipapirfondet Alfred Berg Gamba	1,757,942	3.21
Euroclear Bank S.A./N.V. (NOM)	1,493,893	2.73
Datum Invest AS	1,485,467	2.72
Sarsia Development AS	1,175,000	2.15
VPF Nordea Avkastning	1,125,902	2.06
MP Pensjon PK	1,117,455	2.04
Bera AS	1,084,800	1.98
KLP Aksje Norge	1,029,279	1.88
VPF Nordea Kapital	913,187	1.67
Norsk Innovasjonskapital II AS	856,170	1.56
Verdipapirfondet Alfred Berg Norge	801,556	1.47
JPMorgan Chase Bank, N.A., London (NOM)	775,236	1.42
JPMorgan Chase Bank, N.A., London (Sweden) (NOM)	733,752	1.34
Kommunal landspensjonskasse	719,520	1.32
Clearstream Banking S.A.	625,867	1.14
Verdipapirfondet Alfred Berg aktiv	574,391	1.05
Nordea ASA	536,281	0.98
<b>Others<sup>1</sup></b> .....	<b>14,255,048</b>	<b>26.05</b>
<b>Total</b> .....	<b>54,711,446</b>	<b>100.00</b>

1 Remaining 3,056 shareholders.

There are no differences in voting rights between the shareholders.

Shareholders owning 5% or more of the Shares have an interest in the Company's share capital which is notifiable pursuant to the Norwegian Securities Trading Act. See Section 13.7 "Disclosure obligations" for a description of the disclosure obligations under the Norwegian Securities Trading Act. As of the date of this Prospectus, three shareholders hold more than 5% or more of the issued Shares.

Following the completion of issuance of the New Shares, the Company is not aware of any persons or entities who, directly or indirectly, jointly or severally, will exercise or could exercise control over the Company. The Company is not aware of any arrangements the operation of which may at a subsequent date result in a change of control of the Company.

The Shares have not been subject to any public takeover bids.

## 12.5 Authorisation to increase the share capital and to issue Shares

The Board of Directors has been granted an authorisation to increase the share capital by up to NOK 547,114, corresponding to approximately 10% of the Company's current share capital. The authorisation may be used in connection with issuance of shares to employees and board members in accordance with the Company's Share Option Programmes, See Section 11.5.2 "Share Option Programmes".

The authorisation is valid until 30 June 2019. The preferential rights of the existing shareholders to subscribe for the new shares pursuant to Section 10-4 of the Norwegian Public Limited Companies Act may be deviated from. The authorisation does not permit share capital increases against contribution in kind or in connection with mergers.

## 12.6 Authorisation to acquire treasury shares

The Board of Directors does not have an authorisation to repurchase Shares.

## **12.7 Other financial instruments**

Except as set out in Section 11.5 “Bonus and share incentive programmes” the Company has not issued any options, warrants, convertible loans or other instruments that would entitle a holder of any such instrument to subscribe for any Shares. Further, the Company has not issued subordinated debt or transferable securities other than the Shares.

## **12.8 Shareholder rights**

The Company has one class of Shares in issue, and in accordance with the Norwegian Public Limited Companies Act, all Shares in that class provide equal rights in the Company, including the right to any dividends. Each of the Shares carries one vote. The owners of Shares in the Company do not assume any obligation to participate in future capital increases in the Company. The rights attaching to the Shares are described in Section 12.9 “The Articles of Association and certain aspects of Norwegian law”.

## **12.9 The Articles of Association and certain aspects of Norwegian law**

### *12.9.1 The Articles of Association*

The Company’s Articles of Association are set out in Appendix A to this Prospectus. Below is a summary of provisions of the Articles of Association.

#### 12.9.1.1 Objective of the Company

The objective of the Company is to undertake research and development in biotechnology with a focus on new pharmaceutical therapeutics.

#### 12.9.1.2 Registered office

The Company’s registered office is in the municipality of Bergen, Norway.

#### 12.9.1.3 Share capital and nominal value

The Company’s share capital is NOK 5,471,144.60 divided into 54,711,446 Shares, each with a nominal value of NOK 0.10.

#### 12.9.1.4 Board of Directors

The Company’s Board of Directors shall consist of three to seven members according to the resolution of the General Meeting. The Chairman of the Board of Directors shall be appointed by the General Meeting.

#### 12.9.1.5 Restrictions on transfer of Shares

The Articles of Association do not provide for any restrictions on the transfer of Shares, or a right of first refusal for the Company. Share transfers are not subject to approval by the Board of Directors.

#### 12.9.1.6 General Meetings

Documents relating to matters to be dealt with by the Company’s General Meeting, including documents which by law shall be included in or attached to the notice of the General Meeting, do not need to be sent to the shareholders if such documents have been made available on the Company’s website. A shareholder may nevertheless request that documents which relate to matters to be dealt with at the General Meeting are sent to him/her. The shareholders may cast their votes in writing, including through electronic communication (provided that a satisfactory method to authenticate the sender is available), in a period prior to the General Meeting. The Board of Directors can establish specific guidelines for such advance voting. The notice of the General Meeting shall describe the adopted guidelines. Shareholders shall pre-register their attendance at General Meetings within a deadline set forth in the notice of the General Meeting.

#### 12.9.1.7 Nomination committee

The Company shall have a nomination committee. See Section 11 “Board of Directors, Management, Employees and Corporate Governance”.

### *12.9.2 Certain aspects of Norwegian corporate law*

#### 12.9.2.1 General meetings

Through the general meeting, shareholders exercise supreme authority in a Norwegian public limited company. In accordance with Norwegian law, the annual general meeting of shareholders is required to be held each year on or prior to 30 June. Norwegian law requires that written notice of annual general meetings setting forth the time of, the venue

for and the agenda of the meeting be sent to all shareholders with a known address no later than 21 days before the annual general meeting of a Norwegian public limited company listed on a stock exchange or a regulated market shall be held, unless the articles of association stipulate a longer deadline, which is not currently the case for the Company.

A shareholder may vote at the General Meeting either in person or by proxy appointed at their own discretion. In notices to General Meetings, the Company will include the procedure to vote by proxy and which proxy form to be used. The Company will include a proxy form with its notices of General Meetings. All of the Company's shareholders who are registered in the register of shareholders maintained with the VPS the fifth business day prior to the day of the General Meeting (record date) are entitled to participate and vote at General Meetings. Further, the Company's Articles of Association do include a provision requiring shareholders to pre-register in order to participate at General Meetings. The expiry of the deadline to pre-register, which may not be set earlier than five days prior to the meeting, shall be stated in the notice to the General Meeting. A shareholder who has not given notice before the expiry of the deadline may be refused access.

Apart from the AGM, extraordinary general meetings of shareholders may be held if the Board of Directors considers it necessary. An extraordinary general meeting of shareholders must also be convened if, in order to discuss a specified matter, the auditor or shareholders representing at least 5% of the share capital demands this in writing. The requirements for notice and admission to the annual general meeting also apply to extraordinary general meetings. However, the general meeting of a Norwegian public limited company may with a majority of at least two-thirds of the aggregate number of votes cast as well as at least two-thirds of the share capital represented at a general meeting resolve that extraordinary general meetings may be convened with a 14 days' notice period until the next annual general meeting provided the company has procedures in place allowing shareholders to vote electronically.

#### 12.9.2.2 Voting rights – amendments to the Articles of Association

Each of the Shares carries one vote. In general, decisions that shareholders are entitled to make under Norwegian law or the Company's Articles of Association may be made by a simple majority of the votes cast. In the case of elections or appointments, the person(s) who receive(s) the greatest number of votes cast is (are) elected. However, as required under Norwegian law, certain decisions, including resolutions to waive preferential rights to subscribe new Shares in connection with any share issue in the Company, to approve a merger or demerger of the Company, to amend the Articles of Association, to authorise an increase or reduction in the share capital, to authorise an issuance of convertible loans or warrants by the Company or to authorise the Board of Directors to purchase Shares and hold them as treasury shares or to dissolve the Company, must receive the approval of at least two-thirds of the aggregate number of votes cast as well as at least two-thirds of the share capital represented at a General Meeting. Norwegian law further requires that certain decisions, which have the effect of substantially altering the rights and preferences of any shares or class of shares, receive the approval by the holders of such shares or class of shares as well as the majority required for amending the Articles of Association.

Decisions that (i) would reduce the rights of some or all of the Company's shareholders in respect of dividend payments or other rights to assets or (ii) restrict the transferability of the Shares, require that at least 90% of the share capital represented at the General Meeting in question vote in favour of the resolution, as well as the majority required for amending the Articles of Association.

In general, only a shareholder in the Company registered in the VPS is entitled to vote for such Shares. Beneficial owners of Shares that are registered in the name of a nominee are generally not entitled to vote under Norwegian law, nor is any person who is designated in the VPS register as the holder of such Shares as nominees. Investors should note that there are varying opinions as to the interpretation of the right to vote on nominee registered shares. In the Company's view, a nominee may not meet or vote for Shares registered on a nominee account ("**NOM-account**"). A shareholder must, in order to be eligible to register, meet and vote for such Shares at the General Meeting, transfer the Shares from such NOM-account to an account in the shareholder's name.

There are no quorum requirements that apply to the General Meetings.

#### 12.9.2.3 Additional issuances and preferential rights

If the Company issues any new Shares, including bonus share issues, the Company's Articles of Association must be amended, which requires the same vote as other amendments to the Articles of Association. In addition, under Norwegian law, the Company's shareholders have a preferential right to subscribe for new Shares issued by the Company. Preferential rights may be deviated from by resolution in a General Meeting passed by the same vote required to amend the Articles of Association. A deviation of the shareholders' preferential rights in respect of bonus issues requires the approval of all outstanding Shares.

The General Meeting may, by the same vote as is required for amending the Articles of Association, authorise the Board of Directors to issue new Shares, and to deviate from the preferential rights of shareholders in connection with such issuances. Such authorisation may be effective for a maximum of two years, and the nominal value of the Shares to be issued may not exceed 50% of the registered nominal share capital when the authorisation is registered with the Norwegian Register of Business Enterprises.

Under Norwegian law, the Company may increase its share capital by a bonus share issue, subject to approval by the General Meeting, by the same vote as is required for amending the Articles of Association, by transfer from the Company's distributable equity and thus the share capital increase does not require any payment of a subscription price by the shareholders. Any bonus issues may be affected either by issuing new shares to the Company's existing shareholders or by increasing the nominal value of the Company's outstanding Shares.

Issuance of new Shares to shareholders who are citizens or residents of the United States upon the exercise of preferential rights may require the Company to file a registration statement in the United States under United States securities laws. Should the Company in such a situation decide not to file a registration statement, the Company's U.S. shareholders may not be able to exercise their preferential rights. If a U.S. shareholder is ineligible to participate in a rights offering, such shareholder would not receive the rights at all and the rights would be sold on the shareholder's behalf by the Company.

#### 12.9.2.4 Minority rights

Norwegian law sets forth a number of protections for minority shareholders of the Company, including, but not limited to, those described in this section and the description of General Meetings as set out above. Any of the Company's shareholders may petition Norwegian courts to have a decision of the Board of Directors or the Company's shareholders made at the General Meeting declared invalid on the grounds that it unreasonably favours certain shareholders or third parties to the detriment of other shareholders or the Company itself. The Company's shareholders may also petition the courts to dissolve the Company as a result of such decisions to the extent particularly strong reasons are considered by the court to make necessary dissolution of the Company.

Minority shareholders holding 5% or more of the Company's share capital have a right to demand in writing that the Board of Directors convenes an extraordinary general meeting to discuss or resolve specific matters. In addition, any of the Company's shareholders may in writing demand that the Company place an item on the agenda for any General Meeting as long as the Company is notified in time for such item to be included in the notice of the meeting. If the notice has been issued when such a written demand is presented, a renewed notice must be issued if the deadline for issuing notice of the General Meeting has not expired.

#### 12.9.2.5 Rights of redemption and repurchase of Shares

The share capital of the Company may be reduced by reducing the nominal value of the Shares or by cancelling Shares. Such a decision requires the approval of at least two-thirds of the aggregate number of votes cast and at least two-thirds of the share capital represented at a General Meeting. Redemption of individual Shares requires the consent of the holders of the Shares to be redeemed.

The Company may purchase Shares provided that the Board of Directors has been granted an authorisation to do so by a General Meeting with the approval of at least two-thirds of the aggregate number of votes cast and at least two-thirds of the share capital represented at the meeting. The aggregate nominal value of treasury shares so acquired and held by the Company must not exceed 10% of the Company's share capital, and treasury shares may only be acquired if the Company's distributable equity, according to the latest adopted balance sheet, exceeds the consideration to be paid for the shares. The authorisation by the General Meeting cannot be granted for a period exceeding 18 months.

#### 12.9.2.6 Shareholder vote on certain reorganisations

A decision of the Company's shareholders to merge with another company or to demerge requires a resolution by the General Meeting passed by at least two-thirds of the aggregate votes cast and at least two-thirds of the share capital represented at the General Meeting. A merger plan, or demerger plan signed by the Board of Directors along with certain other required documentation, would have to be sent to all the Company's shareholders, or if the Articles of Association stipulate that, made available to the shareholders on the Company's website, at least one month prior to the General Meeting to pass upon the matter.

#### 12.9.2.7 Liability of Board Members

Members of the Board of Directors owe a fiduciary duty to the Company and its shareholders. Such fiduciary duty requires that the Board Members act in the best interests of the Company when exercising their functions and exercise a general duty of loyalty and care towards the Company. Their principal task is to safeguard the interests of the Company. A Board Member may not participate in the discussion or decision of any matter which is of such particular importance to him-/herself or any related parties that he/she must be deemed to have a special or prominent personal or financial interest in the matter.

Board Members may each be held liable for any damage they negligently or wilfully cause the Company. Norwegian law permits the General Meeting to discharge any such person from liability, but such discharge is not binding on the Company if substantially correct and complete information was not provided at the General Meeting passing upon the matter. If a resolution to discharge the Board Members from liability or not to pursue claims against such a person has been passed by a General Meeting with a smaller majority than that required to amend the Articles of Association, shareholders representing more than 10% of the share capital or, if there are more than 100 shareholders, more than 10% of the shareholders may pursue the claim on the Company's behalf and in its name. The cost of any such action is not the Company's responsibility but can be recovered from any proceeds the Company receives as a result of the action. If the decision to discharge any of the Board Members from liability or not to pursue claims against the Board Members is made by such a majority as is necessary to amend the Articles of Association, the minority shareholders of the Company cannot pursue such claim in the Company's name.

#### 12.9.2.8 Indemnification of Board Members

Neither Norwegian law nor the Articles of Association contains any provision concerning indemnification by the Company of the Board of Directors. The Company is permitted to purchase insurance for the Board Members against certain liabilities that they may incur in their capacity as such.

#### 12.9.2.9 Distribution of assets on liquidation

Under Norwegian law, the Company may be wound-up by a resolution of the Company's shareholders at the General Meeting passed by at least two-thirds of the aggregate votes cast and at least two-thirds of the share capital represented at the meeting. In the event of liquidation, the Shares rank equally in the event of a return on capital.

#### 12.9.3 *Shareholders' agreement*

The Company is not aware of any shareholders' agreements related to the Shares.

## **13 SECURITIES TRADING IN NORWAY**

*Set out below is a summary of certain aspects of securities trading in Norway. The summary is based on the rules and regulations in force in Norway as at the date of this Prospectus, which may be subject to changes occurring after such date. The summary does not purport to be a comprehensive description of securities trading in Norway. Shareholders who wish to clarify the aspects of securities trading in Norway should consult with and rely upon their own advisors.*

### **13.1 Introduction**

The Oslo Stock Exchange was established in 1819 and is the principal market in which shares, bonds and other financial instruments are traded in Norway. As of 31 December 2016, the total capitalisation of companies listed on the Oslo Stock Exchange amounted to approximately NOK 2,121 billion. Shareholdings of non-Norwegian investors as a percentage of total market capitalisation as at 31 December 2016 amounted to approximately 36.6%.

The Oslo Stock Exchange has entered into a strategic cooperation with the London Stock Exchange group with regard to, *inter alia*, trading systems for equities, fixed income and derivatives.

### **13.2 Trading and settlement**

Trading of equities on the Oslo Stock Exchange is carried out in the electronic trading system Millennium Exchange. This trading system is in use by all markets operated by the London Stock Exchange, including the Borsa Italiana, as well as by the Johannesburg Stock Exchange.

Official trading on the Oslo Stock Exchange takes place between 09:00 hours (CET) and 16:20 hours (CET) each trading day, with pre-trade period between 08:15 hours (CET) and 09:00 hours (CET), closing auction from 16:20 hours (CET) to 16:25 hours (CET) and a post-trade period from 16:25 hours (CET) to 17:30 hours (CET). Reporting of after exchange trades can be done until 17:30 hours (CET).

The settlement period for trading on the Oslo Stock Exchange is two trading days (T+2). This means that securities will be settled on the investor's account in the VPS two days after the transaction, and that the seller will receive payment after two days.

Oslo Clearing ASA, a wholly owned subsidiary of SIX x-clear AG, a company in the SIX group, has a license from the Norwegian FSA to act as a central clearing service, and has from 18 June 2010 offered clearing and counterparty services for equity trading on the Oslo Stock Exchange.

Investment services in Norway may only be provided by Norwegian investment firms holding a license under the Norwegian Securities Trading Act, branches of investment firms from an EEA member state or investment firms from outside the EEA that have been licensed to operate in Norway. Investment firms in an EEA member state may also provide cross-border investment services into Norway.

It is possible for investment firms to undertake market-making activities in shares listed in Norway if they have a license to this effect under the Norwegian Securities Trading Act, or in the case of investment firms in an EEA member state, a license to carry out market-making activities in their home jurisdiction. Such market-making activities will be governed by the regulations of the Norwegian Securities Trading Act relating to brokers' trading for their own account. However, such market-making activities do not as such require notification to the Norwegian FSA or the Oslo Stock Exchange, except for the general obligation of investment firms that are members of the Oslo Stock Exchange to report all trades in stock exchange listed securities.

### **13.3 Information, control and surveillance**

Under Norwegian law, the Oslo Stock Exchange is required to perform a number of surveillance and control functions. The Surveillance and Corporate Control unit of the Oslo Stock Exchange monitors all market activity on a continuous basis. Market surveillance systems are largely automated, promptly warning department personnel of abnormal market developments.

The Norwegian FSA controls the issuance of securities in both the equity and bond markets in Norway and evaluates whether the issuance documentation contains the required information and whether it would otherwise be unlawful to carry out the issuance.

Under Norwegian law, a company that is listed on a Norwegian regulated market, or has applied for listing on such market, must promptly release any inside information directly concerning the company. Inside information means precise



information about financial instruments, the issuer thereof or other matters which are likely to have a significant effect on the price of the relevant financial instruments or related financial instruments, and which are not publicly available or commonly known in the market. A company may, however, delay the release of such information in order not to prejudice its legitimate interests, provided that it is able to ensure the confidentiality of the information and that the delayed release would not be likely to mislead the public. The Oslo Stock Exchange may levy fines on companies violating these requirements.

#### **13.4 The VPS and transfer of Shares**

The Company's principal share register is operated through the VPS. The VPS is the Norwegian paperless centralised securities register. It is a computerised book-keeping system in which the ownership of, and all transactions relating to, Norwegian listed shares must be recorded. The VPS and the Oslo Stock Exchange are both wholly owned by Oslo Børs VPS Holding ASA.

All transactions relating to securities registered with the VPS are made through computerised book entries. No physical share certificates are, or may be, issued. The VPS confirms each entry by sending a transcript to the registered shareholder irrespective of any beneficial ownership. To give effect to such entries, the individual shareholder must establish a share account with a Norwegian account agent. Norwegian banks, Norges Bank (being, Norway's central bank), authorised securities brokers in Norway and Norwegian branches of credit institutions established within the EEA are allowed to act as account agents.

As a matter of Norwegian law, the entry of a transaction in the VPS is *prima facie* evidence in determining the legal rights of parties as against the issuing company or any third party claiming an interest in the given security. A transferee or assignee of shares may not exercise the rights of a shareholder with respect to such shares unless such transferee or assignee has registered such shareholding or has reported and shown evidence of such share acquisition, and the acquisition is not prevented by law, the relevant company's articles of association or otherwise.

The VPS is liable for any loss suffered as a result of faulty registration or an amendment to, or deletion of, rights in respect of registered securities unless the error is caused by matters outside the VPS' control which the VPS could not reasonably be expected to avoid or overcome the consequences of. Damages payable by the VPS may, however, be reduced in the event of contributory negligence by the aggrieved party.

The VPS must provide information to the Norwegian FSA on an ongoing basis, as well as any information that the Norwegian FSA requests. Further, Norwegian tax authorities may require certain information from the VPS regarding any individual's holdings of securities, including information about dividends and interest payments.

#### **13.5 Shareholder register**

Under Norwegian law, shares are registered in the name of the beneficial owner of the shares. As a general rule, there are no arrangements for nominee registration and Norwegian shareholders are not allowed to register their shares in the VPS through a nominee. However, foreign shareholders may register their shares in the VPS in the name of a nominee (bank or other nominee) approved by the Norwegian FSA. An approved and registered nominee has a duty to provide information on demand about beneficial shareholders to the company and to the Norwegian authorities. In case of registration by nominees, the registration in the VPS must show that the registered owner is a nominee. A registered nominee has the right to receive dividends and other distributions, but cannot vote in general meetings on behalf of the beneficial owners.

#### **13.6 Foreign investment in shares listed in Norway**

Foreign investors may trade shares listed on the Oslo Stock Exchange through any broker that is a member of the Oslo Stock Exchange, whether Norwegian or foreign.

#### **13.7 Disclosure obligations**

If a person's, entity's or consolidated group's proportion of the total issued shares and/or rights to shares in a company listed on a regulated market in Norway (with Norway as its home state, which will be the case for the Company) reaches, exceeds or falls below the respective thresholds of 5%, 10%, 15%, 20%, 25%, 1/3, 50%, 2/3 or 90% of the share capital or the voting rights of that company, the person, entity or group in question has an obligation under the Norwegian Securities Trading Act to notify the Oslo Stock Exchange and the issuer immediately. The same applies if the disclosure thresholds are passed due to other circumstances, such as a change in the company's share capital.

**13.8 Insider trading**

According to Norwegian law, subscription for, purchase, sale or exchange of financial instruments that are listed, or subject to the application for listing, on a Norwegian regulated market, or incitement to such dispositions, must not be undertaken by anyone who has inside information, as defined in Section 3-2 of the Norwegian Securities Trading Act. The same applies to the entry into, purchase, sale or exchange of options or futures/forward contracts or equivalent rights whose value is connected to such financial instruments or incitement to such dispositions.

**13.9 Mandatory offer requirement**

The Norwegian Securities Trading Act requires any person, entity or consolidated group that becomes the owner of shares representing more than one-third of the voting rights of a company listed on a Norwegian regulated market (with the exception of certain foreign companies) to, within four weeks, make an unconditional general offer for the purchase of the remaining shares in that company. A mandatory offer obligation may also be triggered where a party acquires the right to become the owner of shares that, together with the party's own shareholding, represent more than one-third of the voting rights in the company and the Oslo Stock Exchange decides that this is regarded as an effective acquisition of the shares in question.

The mandatory offer obligation ceases to apply if the person, entity or consolidated group sells the portion of the shares that exceeds the relevant threshold within four weeks of the date on which the mandatory offer obligation was triggered.

When a mandatory offer obligation is triggered, the person subject to the obligation is required to immediately notify the Oslo Stock Exchange and the company in question accordingly. The notification is required to state whether an offer will be made to acquire the remaining shares in the company or whether a sale will take place. As a rule, a notification to the effect that an offer will be made cannot be retracted. The offer and the offer document required are subject to approval by the Oslo Stock Exchange before the offer is submitted to the shareholders or made public.

The offer price per share must be at least as high as the highest price paid or agreed by the offeror for the shares in the six-month period prior to the date the threshold was exceeded. If the acquirer acquires or agrees to acquire additional shares at a higher price prior to the expiration of the mandatory offer period, the acquirer is obliged to restate its offer at such higher price. A mandatory offer must be in cash or contain a cash alternative at least equivalent to any other consideration offered.

In case of failure to make a mandatory offer or to sell the portion of the shares that exceeds the relevant threshold within four weeks, the Oslo Stock Exchange may force the acquirer to sell the shares exceeding the threshold by public auction. Moreover, a shareholder who fails to make an offer may not, as long as the mandatory offer obligation remains in force, exercise rights in the company, such as voting in a general meeting, without the consent of a majority of the remaining shareholders. The shareholder may, however, exercise his/her/its rights to dividends and pre-emption rights in the event of a share capital increase. If the shareholder neglects his/her/its duty to make a mandatory offer, the Oslo Stock Exchange may impose a cumulative daily fine that runs until the circumstance has been rectified.

Any person, entity or consolidated group that owns shares representing more than one-third of the votes in a company listed on a Norwegian regulated market (with the exception of certain foreign companies) is obliged to make an offer to purchase the remaining shares of the company (repeated offer obligation) if the person, entity or consolidated group through acquisition becomes the owner of shares representing 40%, or more of the votes in the company. The same applies correspondingly if the person, entity or consolidated group through acquisition becomes the owner of shares representing 50% or more of the votes in the company. The mandatory offer obligation ceases to apply if the person, entity or consolidated group sells the portion of the shares which exceeds the relevant threshold within four weeks of the date on which the mandatory offer obligation was triggered.

Any person, entity or consolidated group that has passed any of the above-mentioned thresholds in such a way as not to trigger the mandatory bid obligation, and has therefore not previously made an offer for the remaining shares in the company in accordance with the mandatory offer rules is, as a main rule, obliged to make a mandatory offer in the event of a subsequent acquisition of shares in the company.

**13.10 Compulsory acquisition**

Pursuant to the Norwegian Public Limited Companies Act and the Norwegian Securities Trading Act, a shareholder who, directly or through subsidiaries, acquires shares representing 90% or more of the total number of issued shares in a Norwegian public limited company, as well as 90% or more of the total voting rights, has a right, and each remaining minority shareholder of the company has a right to require such majority shareholder, to effect a compulsory acquisition

for cash of the shares not already owned by such majority shareholder. Through such compulsory acquisition, the majority shareholder becomes the owner of the remaining shares with immediate effect.

If a shareholder acquires shares representing more than 90% of the total number of issued shares, as well as more than 90% of the total voting rights, through a voluntary offer in accordance with the Norwegian Securities Trading Act, a compulsory acquisition can, subject to the following conditions, be carried out without such shareholder being obliged to make a mandatory offer: (i) the compulsory acquisition is commenced no later than four weeks after the acquisition of shares through the voluntary offer, (ii) the price offered per share is equal to or higher than what the offer price would have been in a mandatory offer, and (iii) the settlement is guaranteed by a financial institution authorised to provide such guarantees in Norway.

A majority shareholder who effects a compulsory acquisition is required to offer the minority shareholders a specific price per share, the determination of which is at the discretion of the majority shareholder. However, where the offeror, after making a mandatory or voluntary offer, has acquired more than 90% of the voting shares of a company and a corresponding proportion of the votes that can be cast at the general meeting, and the offeror pursuant to Section 4-25 of the Norwegian Public Limited Companies Act completes a compulsory acquisition of the remaining shares within three months after the expiry of the offer period, it follows from the Norwegian Securities Trading Act that the redemption price shall be determined on the basis of the offer price for the mandatory/voluntary offer unless specific reasons indicate another price.

Should any minority shareholder not accept the offered price, such minority shareholder may, within a specified deadline of not less than two months, request that the price be set by a Norwegian court. The cost of such court procedure will, as a general rule, be the responsibility of the majority shareholder, and the relevant court will have full discretion in determining the consideration to be paid to the minority shareholder as a result of the compulsory acquisition.

Absent a request for a Norwegian court to set the price or any other objection to the price being offered, the minority shareholders will be deemed to have accepted the offered price after the expiry of the specified deadline.

#### **13.11 Foreign exchange controls**

There are currently no foreign exchange control restrictions in Norway that would potentially restrict the payment of dividends to a shareholder outside Norway, and there are currently no restrictions that would affect the right of shareholders of a company that has its shares registered with the VPS who are not residents in Norway to dispose of their shares and receive the proceeds from a disposal outside Norway. There is no maximum transferable amount either to or from Norway, although transferring banks are required to submit reports on foreign currency exchange transactions into and out of Norway into a central data register maintained by the Norwegian customs and excise authorities. The Norwegian police, tax authorities, customs and excise authorities, the National Insurance Administration and the Norwegian FSA have electronic access to the data in this register.

## 14 TAXATION

Set out below is a summary of certain Norwegian tax matters related to an investment in the Company. The summary regarding Norwegian taxation are based on the laws in force in Norway as of the date of this Prospectus, which may be subject to any changes in law occurring after such date. Such changes could possibly be made on a retrospective basis.

The following summary does not purport to be a comprehensive description of all the tax considerations that may be relevant to a decision to purchase, own or dispose of Shares. Shareholders who wish to clarify their own tax situation should consult with and rely upon their own tax advisors. Shareholders resident in jurisdictions other than Norway and shareholders who cease to be resident in Norway for tax purposes (due to domestic tax law or tax treaty) should specifically consult with and rely upon their own tax advisors with respect to the tax position in their country of residence and the tax consequences related to ceasing to be resident in Norway for tax purposes.

Please note that for the purpose of the summary below, a reference to a Norwegian or non-Norwegian shareholder refers to the tax residency rather than the nationality of the shareholder.

### 14.1 Norwegian taxation

#### 14.1.1 Taxation of dividends

##### Norwegian Personal Shareholders

Dividends distributed to shareholders who are individuals resident in Norway for tax purposes ("**Norwegian Personal Shareholders**") are taxable in Norway for such shareholders at an effective tax rate of 30.59% to the extent the dividend exceeds a tax-free allowance; i.e. dividends received, less the tax free allowance, shall be multiplied by 1.33 which are then included as ordinary income taxable at a flat rate of 23%, increasing the effective tax rate on dividends received by Norwegian Personal Shareholders to 30.59%

The allowance is calculated on a share-by-share basis. The allowance for each share is equal to the cost price of the share multiplied by a risk free interest rate based on the effective rate after tax of interest on treasury bills (*Nw.: statskasserveksler*) with three months' maturity plus 0.5 percentage points, after tax. The allowance is calculated for each calendar year, and is allocated solely to Norwegian Personal Shareholders holding shares at the expiration of the relevant calendar year.

Norwegian Personal Shareholders who transfer shares will thus not be entitled to deduct any calculated allowance related to the year of transfer. Any part of the calculated allowance one year exceeding the dividend distributed on the share ("excess allowance") may be carried forward and set off against future dividends received on, or gains upon realisation of, the same share. Any excess allowance will also be included in the basis for calculating the allowance on the same share in the following years.

##### Norwegian Corporate Shareholders

Dividends distributed to shareholders who are limited liability companies (and certain similar entities) resident in Norway for tax purposes ("**Norwegian Corporate Shareholders**"), are effectively taxed at rate of 0.69% (3% of dividend income from such shares is included in the calculation of ordinary income for Norwegian Corporate Shareholders and ordinary income is subject to tax at a flat rate of 23%).

##### Non-Norwegian Personal Shareholders

Dividends distributed to shareholders who are individuals not resident in Norway for tax purposes ("**Non-Norwegian Personal Shareholders**"), are as a general rule subject to withholding tax at a rate of 25%. The withholding tax rate of 25% is normally reduced through tax treaties between Norway and the country in which the shareholder is resident. The withholding obligation lies with the company distributing the dividends and the Company assumes this obligation.

Non-Norwegian Personal Shareholders resident within the EEA for tax purposes may apply individually to Norwegian tax authorities for a refund of an amount corresponding to the calculated tax-free allowance on each individual share (please refer to "Taxation of dividends – Norwegian Personal Shareholders" above). However, the deduction for the tax-free allowance does not apply in the event that the withholding tax rate, pursuant to an applicable tax treaty, leads to a lower taxation on the dividends than the withholding tax rate of 25% less the tax-free allowance.

If a Non-Norwegian Personal Shareholder is carrying on business activities in Norway and the shares are effectively connected with such activities, the shareholder will be subject to the same taxation of dividends as a Norwegian Personal Shareholder, as described above.

Non-Norwegian Personal Shareholders who have suffered a higher withholding tax than set out in an applicable tax treaty may apply to the Norwegian tax authorities for a refund of the excess withholding tax deducted.

### **Non-Norwegian Corporate Shareholders**

Dividends distributed to shareholders who are limited liability companies (and certain other entities) not resident in Norway for tax purposes ("**Non-Norwegian Corporate Shareholders**"), are as a general rule subject to withholding tax at a rate of 25%. The withholding tax rate of 25% is normally reduced through tax treaties between Norway and the country in which the shareholder is resident.

Dividends distributed to Non-Norwegian Corporate Shareholders resident within the EEA for tax purposes are exempt from Norwegian withholding tax provided that the shareholder is the beneficial owner of the shares and that the shareholder is genuinely established and performs genuine economic business activities within the relevant EEA jurisdiction.

If a Non-Norwegian Corporate Shareholder is carrying on business activities in Norway and the shares are effectively connected with such activities, the shareholder will be subject to the same taxation of dividends as a Norwegian Corporate Shareholder, as described above.

Non-Norwegian Corporate Shareholders who have suffered a higher withholding tax than set out in an applicable tax treaty may apply to the Norwegian tax authorities for a refund of the excess withholding tax deducted. The same will apply to Non-Norwegian Corporate Shareholders who have suffered withholding tax although qualifying for the Norwegian participation exemption.

Nominee registered shares will be subject to withholding tax at a rate of 25% unless the nominee has obtained approval from the Norwegian Tax Directorate for the dividend to be subject to a lower withholding tax rate. To obtain such approval the nominee is required to file a summary to the tax authorities including all beneficial owners that are subject to withholding tax at a reduced rate.

From 1 January 2019, new rules will apply with respect to the documentation of the applicability of reduced withholding tax rates. According to the new rules, all Non-Norwegian Corporate Shareholders must document their entitlement to a reduced withholding tax rate by either (i) presenting an approved withholding tax refund application or (ii) present an approval from the Norwegian tax authorities confirming that the recipient is entitled to a reduced withholding tax rate. Such documentation must be provided to either the nominee or the account operator (VPS).

The withholding obligation in respect of dividends distributed to Non-Norwegian Corporate Shareholders and on nominee registered shares lies with the company distributing the dividends and the Company assumes this obligation.

#### *14.1.2 Taxation of capital gains on realisation of shares*

### **Norwegian Personal Shareholders**

Sale, redemption or other disposal of shares is considered a realisation for Norwegian tax purposes. A capital gain or loss generated by a Norwegian Personal Shareholder through a disposal of shares is taxable or tax deductible in Norway. The effective tax rate on gain or loss related to shares realised by Norwegian Personal Shareholders is currently 30,59 %; i.e. capital gains (less the tax free allowance) and losses shall be multiplied by 1.33 which are then included in or deducted from the Norwegian Personal Shareholder's ordinary income in the year of disposal. Ordinary income is taxable at a flat rate of 23%, increasing the effective tax rate on gains/losses realised by Norwegian Personal Shareholders to 30,59%.

The gain is subject to tax and the loss is tax deductible irrespective of the duration of the ownership and the number of shares disposed of.

The taxable gain/deductible loss is calculated per share as the difference between the consideration for the share and the Norwegian Personal Shareholder's cost price of the share, including costs incurred in relation to the acquisition or realisation of the share. From this capital gain, Norwegian Personal Shareholders are entitled to deduct a calculated allowance provided that such allowance has not already been used to reduce taxable dividend income. Please refer to "Taxation of dividends – Norwegian Personal Shareholders" above for a description of the calculation of the allowance. The allowance may only be deducted in order to reduce a taxable gain, and cannot increase or produce a deductible loss, i.e. any unused allowance exceeding the capital gain upon the realisation of a share will be annulled.

If the Norwegian Personal Shareholder owns shares acquired at different points in time, the shares that were acquired first will be regarded as the first to be disposed of, on a first-in first-out basis.

#### **Norwegian Corporate Shareholders**

Norwegian Corporate Shareholders are exempt from tax on capital gains derived from the realisation of shares qualifying for participation exemption, including shares in the Company. Losses upon the realisation and costs incurred in connection with the purchase and realisation of such shares are not deductible for tax purposes.

#### **Non-Norwegian Personal Shareholders**

Gains from the sale or other disposal of shares by a Non-Norwegian Personal Shareholder will not be subject to taxation in Norway unless the Non-Norwegian Personal Shareholder holds the shares in connection with business activities carried out or managed from Norway.

#### **Non-Norwegian Corporate Shareholders**

Capital gains derived by the sale or other realisation of shares by Non-Norwegian Corporate Shareholders are not subject to taxation in Norway.

##### *14.1.3 Net wealth tax*

The value of shares is included in the basis for the computation of net wealth tax imposed on Norwegian Personal Shareholders. Currently, the marginal net wealth tax rate is 0.85% of the value assessed. The value for assessment purposes for listed shares is currently equal to ninety percent of the listed value as of 1 January in the year of assessment (i.e. the year following the relevant fiscal year). The value of debt allocated to the listed shares for Norwegian wealth tax purposes is reduced correspondingly (i.e. to 80%).

Norwegian Corporate Shareholders are not subject to net wealth tax.

Shareholders not resident in Norway for tax purposes are not subject to Norwegian net wealth tax. Non-Norwegian Personal Shareholders can, however, be taxable if the shareholding is effectively connected to the conduct of trade or business in Norway.

##### *14.1.4 VAT and transfer taxes*

No VAT, stamp or similar duties are currently imposed in Norway on the transfer or issuance of shares.

##### *14.1.5 Inheritance tax*

A transfer of shares through inheritance or as a gift does not give rise to inheritance or gift tax in Norway.

## **15 THE NEW SHARES**

### **15.1 Overview**

This Prospectus is personal to each Option Holder and does not constitute or form a part of any public offer or solicitation to purchase or subscribe for securities in the Company. The New Shares may only be subscribed by Option Holders pursuant to the terms of the Share Option Programmes of the Group.

See Section 11.5.2 “Share Option Programmes” for more information regarding the Share Option Programmes.

### **15.2 The rights conferred by the New Shares**

The New Shares will in all respects carry full shareholders’ rights in the Company on an equal basis as any other Shares in the Company, including the right to any dividends, from the date of registration of the share capital increase pertaining to the issuance of the New Shares in the Norwegian Register of Business Enterprises. For a description of rights attached to the Shares, see Section 12 “Corporate Information and Description of Share Capital”.

### **15.3 VPS registration**

Any existing Shares have been, and the New Shares will be, created under the Norwegian Public Limited Companies Act. Any existing Shares have been, and the New Shares will be, registered in book-entry form with the VPS and have ISIN NO 001 0650013. The Company’s register of shareholders with the VPS is administrated by DNB Bank ASA, Dronning Eufemias gate 30, N-0191 Oslo, Norway.

### **15.4 Dilution**

If all New Shares are issued and subscribed by the Option Holders, the resulting dilution is estimated to be approximately 5%, based on the assumption that the Company issues 2,860,012 New Shares.

### **15.5 Expenses**

The gross proceeds to the Company will be up to approximately NOK 44 million and the Company’s total costs and expenses of, and incidental to, this Prospectus are estimated to amount to NOK 0.5 million (excluding VAT).

No expenses or taxes will be charged by the Company in connection with the New Shares.

### **15.6 Governing law and jurisdiction**

This Prospectus shall be governed by and construed in accordance with Norwegian law. Any dispute arising out of, or in connection with this Prospectus shall be subject to the exclusive jurisdiction of the courts of Norway, with the Oslo District Court as the legal venue.

**16 SELLING AND TRANSFER RESTRICTIONS**

The issue of New Shares upon exercise of option rights under the Share Option Programmes by Option Holders resident in, or who are citizens of countries other than Norway, may be affected by the laws of the relevant jurisdiction. Option Holders should consult their professional advisors as to whether they require any governmental or other consents or need to observe any other formalities to enable them to exercise option rights.

The options and the New Shares have not been and will not be registered under the U.S. Securities Act or under the securities laws of any state or jurisdiction of the United States, and may not be offered, sold, pledged, resold, granted, delivered, allocated, taken up, transferred or delivered, directly or indirectly, within the United States except pursuant to an exemption from, or in a transaction not subject to, the registration requirements under the U.S. Securities Act and in compliance with the applicable securities laws of any state or jurisdiction of the United States. Receipt of this Prospectus will not constitute an offer in those jurisdictions in which it would be illegal to make an offer and, in those circumstances, this Prospectus is for information only and should not be copied or redistributed. Except as otherwise disclosed in this Prospectus, if an Option Holder receives a copy of this Prospectus in any territory, such Option Holder may not treat this Prospectus as constituting an invitation or offer to it, nor should the Option Holder in any event deal in the option and New Shares, unless, in the relevant jurisdiction, such an invitation or offer could lawfully be made to that Option Holder, or the option and New Shares could lawfully be dealt in without contravention of any unfulfilled registration or other legal requirements. Accordingly, if an Option Holder receives a copy of this Prospectus, the Option Holder should not distribute or send the same, or transfer the option and New Shares to any person or in or into any jurisdiction where to do so would or might contravene local securities laws or regulations. If the Option Holder forwards this Prospectus into any such territories (whether under a contractual or legal obligation or otherwise), the Option Holder should direct the recipient's attention to the contents of this Section.

Except as otherwise noted in this Prospectus and subject to certain exceptions: (i) the option and New Shares being granted or offered, respectively, may not be offered, sold, resold, transferred or delivered, directly or indirectly, in or into, Member States of the EEA that have not implemented the Prospectus Directive, Australia, Canada, Japan, the United States or any other jurisdiction in which it would not be permissible to offer the option and/or the New Shares "**Ineligible Jurisdictions**"; and (ii) this Prospectus may not be sent to any person in any Ineligible Jurisdiction.

If an Option Holder exercises its option to obtain New Shares or trades or otherwise deals in the New Shares pursuant to this Prospectus, unless the Company in its sole discretion determines otherwise on a case-by-case basis, that Option Holder will be deemed to have made or, in some cases, be required to make, the following representations and warranties to the Company and any person acting on the Company's or its behalf:

- (i) the Option Holder is not located in an Ineligible Jurisdiction;
- (ii) the Option Holder is not acting, and has not acted, for the account or benefit of a person resident in an Ineligible Jurisdiction;
- (iii) the Option Holder acknowledges that the Company is not taking any action to permit a public offering of the New Shares.

The Company and their affiliates and others will rely upon the truth and accuracy of the above acknowledgements, agreements and representations, and agree that, if any of the acknowledgements, agreements or representations deemed to have been made by its purchase of New Shares is no longer accurate, it will promptly notify the Company. Any provision of false information or subsequent breach of these representations and warranties may subject the Option Holder to liability.

If an Option Holder (including, without limitation, its nominees and trustees) is located outside Norway and wishes to exercise its option for New Shares, the Option Holder must satisfy itself as to full observance of the applicable laws of any relevant territory including obtaining any requisite governmental or other consents, observing any other requisite formalities and paying any issue, transfer or other taxes due in such territories.

The information set out in this Section is intended as a general guide only. If the Option Holder is in any doubt as to whether it is eligible to exercise its option or subscribe for the New Shares, such Option Holder should consult its professional advisor without delay.

Neither the Company nor any of its representatives, is making any representation to any Option Holder regarding the legality of an investment in the New Shares under the laws applicable to such Option Holder. Each Option Holder should



consult its own advisors before subscribing for New Shares. Option Holders are required to make their independent assessment of the legal, tax, business, financial and other consequences of a subscription for New Shares.

## 17 ADDITIONAL INFORMATION

### 17.1 Auditor and advisors

The Company's independent auditor is Ernst & Young AS with registration number 976 389 387, and business address at Dronning Eufemias gate 6, N-0191 Oslo, Norway. The partners of Ernst & Young AS are members of Den Norske Revisorforening (The Norwegian Institute of Public Accountants).

EY has been the Company's auditor since the incorporation of the Company. The Financial Statements for the years ended 31 December 2017 and 2016 have been audited by EY, and the auditor's reports are included together with the Financial Statements.

Advokatfirmaet Thommessen AS, Vestre Strømkaie 7, P.O. Box 43 Nygårdstangen, N-5838 Bergen, Norway is acting as Norwegian legal counsel to the Company.

### 17.2 Documents on display

Copies of the following documents will be available for inspection at the Company's offices at Jonas Lies vei 91, 5009 Bergen, Norway, during normal business hours from Monday to Friday each week (except public holidays) for a period of twelve months from the date of this Prospectus:

- The Company's certificate of incorporation and Articles of Association;
- All reports, letters, and other documents, historical financial information, valuations and statements prepared by any expert at the Company's request any part of which is included or referred to in this Prospectus;
- The historical financial information of the Company for each of the two financial years preceding the publication of this Prospectus; and
- This Prospectus.

### 17.3 Incorporation by reference

The information incorporated by reference in this Prospectus should be read in connection with the cross reference table set out below. Except as provided in this Section, no information is incorporated by reference in this Prospectus.

The Company incorporates by reference the Company's unaudited consolidated interim financial statements as of and for the six month periods ended 30 June 2018 and the Company's audited consolidated financial statements as of and for the years ended 31 December 2017 and 2016 (the Financial Statements), as well as certain other documents set out below.

Section in the Prospectus	Disclosure requirement	Reference document and link	Page (P) in reference document
Section 9	Audited historical financial information (Annex XXV, section 20.1)	<b>Financial statements 2017:</b> <a href="https://www.bergenbio.com/wp-content/uploads/2018/04/BerGenBio-Annual-Report-2017.pdf">https://www.bergenbio.com/wp-content/uploads/2018/04/BerGenBio-Annual-Report-2017.pdf</a>	70-99
		<b>Financial statements 2016:</b> <a href="http://www.bergenbio.com/wp-content/uploads/2017/03/Annual-Report-BerGenBio-2016.pdf">http://www.bergenbio.com/wp-content/uploads/2017/03/Annual-Report-BerGenBio-2016.pdf</a>	12-17
Section 9	Audit report (Annex XXV, section 20.1)	<b>Auditor's report 2017:</b> <a href="https://www.bergenbio.com/wp-content/uploads/2018/04/BerGenBio-Annual-Report-2017.pdf">https://www.bergenbio.com/wp-content/uploads/2018/04/BerGenBio-Annual-Report-2017.pdf</a>	120-122
		<b>Auditor's report 2016:</b> <a href="http://www.bergenbio.com/wp-content/uploads/2017/03/Annual-Report-BerGenBio-2016.pdf">http://www.bergenbio.com/wp-content/uploads/2017/03/Annual-Report-BerGenBio-2016.pdf</a>	36-38
Section 9	Interim financial information (Annex XXV, section 20.5)	<b>Interim Report Second Quarter 2017:</b> <a href="http://www.bergenbio.com/wp-content/uploads/2017/08/BerGenBio-Q2-report-2017.pdf">http://www.bergenbio.com/wp-content/uploads/2017/08/BerGenBio-Q2-report-2017.pdf</a>	11-23
		<b>Interim Report Second Quarter 2018:</b> <a href="https://www.bergenbio.com/wp-content/uploads/2018/08/BGBIO_2018-Q2-Report_reduced-file-size.pdf">https://www.bergenbio.com/wp-content/uploads/2018/08/BGBIO_2018-Q2-Report_reduced-file-size.pdf</a>	14-18

References in the table above to "Annex" and "Items" are references to the disclosure requirements as set forth in the Norwegian Securities Trading Act cf. the Norwegian Securities

**18 DEFINITIONS AND GLOSSARY****18.1 General definitions and glossary**

In the Prospectus, the following defined terms have the following meanings:

2010 PD Amending Directive	Directive 2010/73/EU amending the EU Prospectus Directive.
AA	Accelerated approval.
ADC	Antibody drug conjugate. A substance made up of a monoclonal antibody chemically linked to a drug. The monoclonal antibody binds to specific proteins or receptors found on certain types of cells, including cancer cells. The linked drug enters these cells and kills them without harming other cells.
ADCT	ADCT Therapeutics SA
AGM	Annual General Meeting of the Company.
AML	Acute myeloid leukaemia, a type of cancer that affects the bone marrow and blood as further described under Section 7.5.1.
Anti-Money Laundering Legislation	The Norwegian Money Laundering Act of 6 March 2009 no. 11 and the Norwegian Money Laundering Regulations of 13 March 2009 no. 302, collectively.
Articles of Association	The Company's articles of association.
AXL ADC Product	A molecule comprising an Axl antibody conjugated to a small molecule drug.
BerGenBio	BerGenBio ASA
BGBIO	The Company's ticker at the Oslo Stock Exchange.
BIA	The Norwegian Research council's User-driven Research based Innovation programme.
Board Members	The members of the Board of Directors.
Board of Directors	The board of directors of the Company.
CAGR	Compound aggregate growth rate.
CEO	The Company's chief executive officer.
CET	Central European Time.
CHF	Swiss Franc, the lawful currency of Switzerland.
CISA	Swiss Federal Act on Collective Investment Schemes.
CMC	Chemistry, manufacturing and control.
COG	Cost of goods.
Company	BerGenBio ASA.
Corporate Governance Code	The Norwegian Code of Practice for Corporate Governance dated 30 October 2014.
CPIs	Immune-oncology therapeutics, called immune 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.
CRO's	Contract research organisations. They provide clinical trial and other research support services for the pharmaceutical, biotechnology, medical device industries and also serve government institutions, foundations, and universities.
CTL	Cytotoxic T-lymphocytes. Key effector cells of the body's immune response to cancer acting as the immune system's "warhead".
DNB Markets	DNB Markets, a part of DNB Bank ASA.
EEA	The European Economic Area.
EGFR	Epithelial growth factor receptor. A molecule which is found at high levels in various forms of cancer.
EGFR gene	The gene that controls tumour growth.
ELISA	Enzyme-linked immunosorbent assay platform which is able to detect the presence of activated Axl
EMA	European Medicines Agency.
EMT	Epithelial-mesenchymal transition, a cellular process that makes cancer cells evade the immune system, escape the tumour and acquire drug resistant properties.
EPO	European Patent Organisation.
EU	The European Union.
EU5	The five major EU markets (France, Germany, Italy, Spain and the UK).

EU Prospectus Directive	Directive 2003/71/EC of the European Parliament and of the Council of 4 November 2003, and amendments thereto, including the 2010 PD Amending Directive to the extent implemented in the Relevant Member State.
EUR	Euro, the lawful common currency of the member states of the European Union
EY	Ernst & Young AS, the Company's auditor.
FDA	U.S. Food and Drug Administration.
Financial Information	The Financial statements and the Interim Financial Statements of the Company.
Financial Statements	The audited financial statements for the Company as of, and for the years ended, 31 December 2016 and 2015.
FSMA	The Financial Services and Markets Act 2000.
GBP	British pound sterling, the lawful currency of United Kingdom.
General Meeting	The general meeting of the shareholders in the Company.
GMP	Good manufacturing practices are the practices required in order to conform to guidelines recommended by agencies that control authorization and licensing for manufacture and sale of food, drug products, and active pharmaceutical products. These guidelines provide minimum requirements that a pharmaceutical or a food product manufacturer must meet to assure that the products are of high quality and do not pose any risk to the consumer or public. Good manufacturing practices, along with good laboratory practices and good clinical practices, are overseen by regulatory agencies in the United States, Canada, Europe, China, in addition to other countries.
Group	The Company together with BerGenBio Limited, incorporated in the UK with company number 10555293.
IAS 34	International Accounting Standard 34 "Interim Financial Reporting" as adopted by the EU.
IFRS	International Financial Reporting Standards as adopted by the EU.
IND	Investigational new drug application to the FDA.
Interim Financial Statements	The Company's unaudited consolidated interim financial statements as of and for the six month periods ended 30 June 2018.
IP	intellectual property.
IPR	Intellectual property rights.
Listing	The listing of the Shares on the Oslo Stock Exchange.
Lock-up Undertaking	The Lock-Up Undertaking to be entered into by the Managers, under which the members of the Board of Directors and Management owning Shares and the largest shareholders has agreed that neither it, nor any other party acting on its behalf, will for a period of twelve months for the Board of Directors and Management owning Shares and for a period of twelve months for largest shareholders (and six months for Sarsia Development AS) from the first day of Listing (7 April 2017), directly or indirectly, without the prior written consent of the Managers: offer, sell, contract to sell, pledge, mortgage, deposit, assign, lend, transfer, issue options or warrants in respect of, grant any option to purchase or otherwise dispose of, directly or indirectly, any Shares owned as of the date of this Prospectus (or any other securities convertible into Shares) or enter into any transaction (including a derivative transaction) having an effect on the market in the Shares similar to that of a sale of Shares, or publicly to announce any intention to do any of such things, without the prior written consent of the Managers.
MAA	Market authorisation application to the EMA.
Management	The senior management team of the Company.
MDS	Myelodysplastic syndrome. A group of cancers in which immature blood cells in the bone marrow do not mature and become healthy blood cells, as further described in Section 7.5.1.
MSD	Merck Sharp & Dohme B.V.
NDA	New drug application to the FDA.
New Shares	Up to 2,860,012 new shares to be issued by the Company to Option Holders.
NOK	Norwegian Kroner, the lawful currency of Norway.
NOM-account	Nominee account.
Non-Norwegian Corporate Shareholders	Shareholders who are limited liability companies (and certain other entities) not resident in Norway for tax purposes.
Non-Norwegian Personal Shareholder	Shareholders who are individuals not resident in Norway for tax purposes.
Norwegian Act on Overdue Payment	The Norwegian Act on Overdue Payment of 17 December 1976 no. 100 ( <i>Nw.: forsinkelsesrenteloven</i> ).

Norwegian Corporate Shareholders	Shareholders who are limited liability companies and certain similar corporate entities resident in Norway for tax purposes.
Norwegian FSA	The Financial Supervisory Authority of Norway ( <i>Nw.: Finanstilsynet</i> ).
Norwegian Personal Shareholder	Shareholders who are individuals resident in Norway for tax purposes.
Norwegian Public Limited Companies Act	The Norwegian Public Limited Companies Act of 13 June 1997 no. 45 ( <i>Nw.: allmennaksjeloven</i> ).
NOM-account	Nominee account
Norwegian Securities Trading Act	The Norwegian Securities Trading Act of 29 June 2007 no. 75 ( <i>Nw.: verdipapirhandelloven</i> ).
NSCLC	Non-small cell lung cancer. NSCLC is one of the two main types of lung cancer, the other being small cell lung cancer.
Oncology	Medical studies on cancer and treatment of cancer.
Option Holder	Holders of option rights under the Company's Share Option Program.
Order	The Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended.
Oslo Stock Exchange	Oslo Børs ASA, or, as the context may require, Oslo Børs, a Norwegian regulated stock exchange operated by Oslo Børs ASA.
pAxl	Phosphorylated Axl, being an activated Axl receptor.
PhRMA	Pharmaceutical Research and Manufacturers of America
Prospectus	This Prospectus dated 28 March 2017.
QA	Quality assurance.
QIBs	Qualified institutional buyers as defined in Rule 144A.
R&D	Research and development.
Regulation S	Regulation S under the U.S. Securities Act.
Relevant Implementation Date	In relation to each Relevant Member State, the date on which the EU Prospectus Directive is implemented in that Relevant Member State.
Relevant Member State	Each Member State of the European Economic Area which has implemented the EU Prospectus Directive.
Relevant Persons	Persons in the UK that are (i) investment professionals falling within Article 19(5) of the Order or (ii) high net worth entities, and other persons to whom the Prospectus may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order.
Rigel	Rigel Pharmaceuticals Inc
RSA	The New Hampshire Revised Statutes.
RTK	Receptor tyrosine kinase. Axl is one of the member of this class of proteins called RTKs. RTKs have proven to be valuable cancer drug targets, with several important drugs acting through RTK modulation.
Rule 144A	Rule 144A under the U.S. Securities Act.
SFA	The Singaporean Securities and Futures Act
Share(s)	Means the shares of the Company, each with a nominal value of NOK 0.10, or any one of them.
Share Option Programmes	The Company's share option programmes for Management and Board Members
SIX	The Swiss Exchange
TNBC	Triple negative breast cancer. TNBC is considered the most aggressive type of breast cancer and associated with a shorter median time to relapse, including an increased risk of spread beyond the breast, and death.
TN-IBC	Triple Negative Inflammatory Breast Cancer.
UiB	University of Bergen.
UK	The United Kingdom
U.S. or United States	The United States of America.
U.S. Exchange Act	The U.S. Securities Exchange Act of 1934, as amended.
U.S. Securities Act	The U.S. Securities Act of 1933, as amended.
USD or U.S. Dollar	United States Dollars, the lawful currency of the United States.
VPS	The Norwegian Central Securities Depository ( <i>Nw.: Verdipapirsentralen</i> ).
VPS account	An account with VPS for the registration of holdings of securities.
Wellcome Trust	Wellcome Trust Limited
WHO	World Health Organization.

## 18.2 Medical and biological terms

In the Prospectus, the following medical and biological terms (not defined under Section 18.1 above) have the following meanings:

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.
ALK inhibitors	An orally available inhibitor of the receptor tyrosine kinase anaplastic lymphoma kinase (ALK) with antineoplastic activity. Upon administration, ALK inhibitor RO5424802 binds to and inhibits ALK kinase, which leads to a disruption of ALK-mediated signalling and eventually inhibits tumour cell growth in ALK-overexpressing tumour cells.
Antibody	Proteins produced by the B Lymphocytes of the immune system in response to foreign proteins called antigens. Antibodies function as markers, binding to the antigen so that the antigen molecule can be recognized and destroyed.
Axl	A protein expressed on the surface of cells. It is a member of the class of proteins called RTKs. Axl is an essential mediator of the EMT programme. Axl is up-regulated in a variety of malignancies and associated with immune evasion, acquired drug resistance and correlates with poor clinical prognosis.
Axl ADC	Antibody-drug-conjugate. New class of highly potent biopharmaceutical drugs designed as a targeted cancer therapy. Complex molecules composed of an antibody linked to a biological active cytotoxic drug.
Bemcentinib	BerGenBio's lead drug candidate a highly selective inhibitor of Axl currently undergoing a Phase Ib/II clinical trial showing promising clinical results.
Biotech	The biotechnological segment
BGB101	BGB101 is BerGenBio's program for the development of antibodies targeting Axl. BGB149, is a fully humanised function blocking monoclonal antibody in late stage preclinical development.
BGB002	BerGenBio's program related to a novel EMT target identified by BerGenBio..
BGB149	Anti-AXL monoclonal antibody
BGBC003	The Phase Ib/II studies of bemcentinib in AML and high risk MDS.
BGBC004	The Phase Ib/II studies of bemcentinib in advanced NSCLC.
BGBC007	A Phase II multi-centre study of bemcentinib in combination with Keytruda™ (from MSD) in patients with previously treated, locally advanced or unresectable TNBC.
BGBC008	A Phase II multi-centre study of bemcentinib in combination with Keytruda™ (from MSD) in patients with previously treated unresectable adenocarcinoma of the lung.
BGBIL005	A Phase II study of bemcentinib in combination with chemotherapy docetaxel in patients with NSCLC.
BGBIL006	A Phase II randomised study of systemic melanoma therapy alone compared to the addition of bemcentinib.
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.
CBR	Clinical Benefit Rate
CellSelect	A technology platform patented by the Company used to identify and validate novel drug targets.
Clinical research	The research phases involving human subjects.
Clinical trials	Clinical trials are conducted with human subjects to allow safety and efficiency data to be collected for health inventions (e.g., drugs, devices, therapy protocols). These trials can only take place once satisfactory information has been gathered on the quality of the non-clinical safety, and Health Authority/Ethics Committee approval is granted in the country where the trial is taking place.
CML	Chronic myelogenous leukaemia. A slow-growing cancer in which too many myeloblasts are found in the blood and bone marrow. Myeloblasts are a type of immature blood cell that makes white blood cells called myeloid cells.
CR	Complete response on treatment
Cytarabine	A chemotherapy agent used mainly in the treatment of cancers of white blood cells such as AML, also known as "Ara-C".

Decitabine	A cancer treatment drug used for AML.
Docetaxel	A clinically well-established anti-mitotic chemotherapy medication that works by interfering with cell division.
DoR	Duration of Response
Epithelial state	A state of the cell where the cells are stationary, typically forming layers and tightly connected and well ordered. They lack mobility tending to serve their specific bodily function by being anchored in place.
EGFR inhibitors	Epidermal growth factor receptor inhibitors. EGFRs play an important role in controlling normal cell growth, apoptosis and other cellular functions, but mutations of EGFRs can lead to continual or abnormal activation of the receptors causing unregulated EGFR inhibitors are either tyrosine kinase inhibitors or monoclonal antibodies that slow down or stop cell growth.
EMT 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 NSCLC, pancreatic cancer and several other types of cancer. It is a reversible tyrosine kinase inhibitor, which acts on epidermal growth factor receptor (EGFR). Erlotinib is also known by its brand name, Tarceva.
First-in-class	Drugs which, for example, use a new and unique mechanism of action for treating a medical condition.
First line therapy	Therapy which is adequate to cure cancer when cancer is detected on an early stage. First-line therapy is usually chemotherapy, hormone therapy, surgery, radiotherapy or a combination of these.
Hypomethylating agents	Existing anticancer agents which are licensed for the treatment of AML and MDS.
Impaired immune synapse	An immune synapse is the interface between an antigen-presenting cell or target cell and a lymphocyte such as an effector T-cell or a natural killer cell. When a cell goes through a epithelial to mesenchymal the synapse formation is abrogated and impaired, hindering cytotoxic T Lymphocytes from reaching the cancer cell, evading immune response.
Large cell carcinoma	Large cell carcinoma of the lung, a form of NSCLC.
mAb	Monoclonal antibodies. Monospecific antibodies that are made by identical immune cells that are all clones of a unique parent cell, in contrast to polyclonal antibodies which are antibodies obtained from the blood of an immunized animal and thus made by several different immune cells.
Mesenchymal state	A state of the cell where the cells have loose or no interactions, do not form layers and are less well ordered. They are mobile, can have invasive properties and have the potential to differentiate into more specialised cells with a specific function.
Mesenchymal cancer cells	Cancer cells in a mesenchymal state, meaning that they are aggressive with stem-cell like properties.
Metastatic cancers	A cancer that has spread from the part of the body where it started (the primary site) to other parts of the body.
Myeloid leukaemia	A type of leukaemia affecting myeloid tissue. Includes AML and chronic myelogenous leukaemia.
NK cells	Natural Killer cells. A type of immune cell that has granules (small particles) with enzymes that can kill tumour cells or cells infected with a virus. A natural killer cell is a type of white blood cell.
ORR	Overall Response Rate
OS	Overall Survival
Qtc	Q-T Corrected (corrected Q-T interval). The corrected QT interval (QTc) estimates the QT interval (the time taken for ventricular depolarisation and repolarisation) at a heart rate of 60 bpm. This allows comparison of QT values over time at different heart rates.
pAKT	An activated downstream protein from Axl.
PD	Progressive disease
PD-1 Antagonist	An antagonist that blocks the action of PD-1. Usually an antibody. One of a group of CPIs such as Pembrolizumab/Keytruda™.
PD-1 blockade	Inhibition of PD-1 function.
Pembrolizumab	A humanized monoclonal immunoglobulin antibody directed against human cell surface receptor PD-1 with potential immune checkpoint inhibitory and antineoplastic activities.
Peripheral neuropathy	Damage to or disease affecting nerves.
pERK	An activated downstream protein from Axl.
Phase I	The phase I clinical trials where the aim is to show that a new drug or treatment, which has proven to be safe for use in animals, may also be given safely to people.

Phase Ib	Phase Ib is a multiple ascending dose study to investigate the pharmacokinetics and pharmacodynamics of multiple doses of the drug candidate, looking at safety and tolerability.
Phase II	The phase II clinical trials where the goal is to provide more detailed information about the safety of the treatment and its effect. Phase II trials are performed on larger groups than in Phase I.
Phase III	In the phase III clinical trials data are gathered from large numbers of patients to find out whether the drug candidate is better and possibly has fewer side effects than the current standard treatment.
PR	Partial response on 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 processes but also to have a critical role in the development and progression of many types of cancer.
RP2D	Highest dose with acceptable toxicity.
SD	Stable disease.
Second line therapy	Therapy which are administered to patients when prior therapy (first line therapy as defined above) is not effective.
Small molecule	A small molecule is a low molecular weight (<900 daltons) organic compound that may help regulate a biological process, with a size on the order of 10 <sup>-9</sup> m.
Stem-cell	Undifferentiated biological cells that can differentiate into specialized cells and can divide to produce more stem cells.
Squamous cell carcinoma	Is an uncontrolled growth of abnormal cells arising in the squamous cells, which compose most of the skin's upper layers. Squamous cell carcinoma is the second most common form of skin cancer.
TAM	The Tyro Axl Mer receptor tyrosine kinase family.
TtP	Time to Progression
Unresectable	Cannot be completely removed by surgery.



**APPENDIX A:**  
**ARTICLES OF ASSOCIATION OF BERGENBIO ASA**

(OFFICE TRANSLATION)

## **VEDTEKTER**

**for**

### **BERGENBIO ASA**

**Sist endret 13. april 2018**

#### **§ 1 - Foretaksnavn**

Selskapets navn er BerGenBio ASA. Selskapet er et allmennaksjeselskap.

#### **§ 2 - Forretningskontor**

Selskapets forretningskontor er i Bergen kommune.

#### **§ 3 - Virksomhet**

Selskapets virksomhet er å drive forskning og utvikling innen bioteknologi med fokus på nye farmasøytiske terapeutika.

#### **§ 4 - Aksjekapital**

Selskapets aksjekapital er på kr 5 471 144,60 fordelt på 54 711 446 aksjer hver pålydende kr 0.10.

#### **§ 5- Styre**

Selskapets styre skal bestå av 3 til 7 medlemmer etter generalforsamlingens nærmere beslutning. Styrets leder velges av generalforsamlingen.

#### **§ 6 – Signatur**

Selskapets firma tegnes av daglig leder og et styremedlem i fellesskap. Styret kan tildele prokura.

## **ARTICLES OF ASSOCIATION**

**for**

### **BERGENBIO ASA**

**Last amended 13 April 2018**

#### **§ 1 – Company name**

The name of the company is BerGenBio ASA. The company is a public limited liability company.

#### **§ 2 – Registered office**

The company's registered office is in the municipality of Bergen.

#### **§ 3 – The business activities**

The company's objective is to undertake research and development in biotechnology with a focus on new pharmaceutical therapeutics.

#### **§ 4 – Share capital**

The Company's share capital is NOK 5 471 144,60 divided into 54 711 446 shares, each with a nominal value of NOK 0.10.

#### **§ 5 – The board of directors**

The board of directors shall consist of 3 to 7 members according to the resolution of the general meeting. The chairman of the board of directors is elected by the general meeting.

#### **§ 6 – Authority to sign on behalf of the company**

The managing director together with a board member, have the authority to sign on behalf of the company. The board of directors may grant power of procuration.

## § 7 – Generalforsamling

På den ordinære generalforsamling skal følgende spørsmål behandles og avgjøres:

- Godkjenning av årsregnskapet og årsberetningen, herunder utdeling av utbytte.
- Styrets erklæring om fastsettelse av lønn og annen godtgjørelse til ledende ansatte etter § 6-16 a
- Andre saker som etter loven eller vedtektene hører under generalforsamlingen.

Aksjeeiere som vil delta i generalforsamlingen, skal meddele dette til selskapet innen en frist som angis i innkallingen til generalforsamlingen, og som ikke kan utløpe tidligere enn fem dager før generalforsamlingen. Aksjeeier som ikke har meldt fra innen fristens utløp, kan nektes adgang.

Retten til å delta og stemme på generalforsamlingen kan bare utøves når ervervet er innført i aksjeeierregisteret den femte virkedagen før generalforsamlingen (registreringsdatoen).

Styret kan beslutte at aksjeeier kan avgi skriftlig forhåndsstemme i saker som skal behandles på generalforsamlinger i selskapet. Slike stemmer kan også avgis ved elektronisk kommunikasjon. Adgangen til å avgi forhåndsstemme er betinget av at det foreligger en betryggende metode for å autentisere avsenderen. Styret kan fastsette nærmere retningslinjer for skriftlige forhåndsstemmer. Det skal fremgå av innkallingen til generalforsamlingen om det er gitt adgang til skriftlig stemmegivning før generalforsamlingen, og hvilke retningslinjer som eventuelt er fastsatt for slik stemmegivning.

## § 7 – General meeting

The annual general meeting shall consider the following:

- Approval of the annual accounts and the directors' report, including distribution of dividend;
- The board of directors' declaration concerning the fixing of salaries and other remuneration of leading personnel pursuant to section 6–16a;
- Any other business that, by law or pursuant to the articles of association, is to be transacted at the general meeting.

Shareholders wishing to attend a general meeting shall inform the company within a deadline which shall be stated in the notice to the general meeting. The expiry of the deadline may not be set earlier than five days prior to the meeting. A shareholder who has not given notice before the expiry of the deadline may be refused access.

The right to participate and vote at the general meeting can only be exercised when the acquisition has been entered into the shareholder register the fifth business day prior to the day of the general meeting (record date).

The board of directors can decide that shareholders can be allowed to cast their votes in writing in advance on items on the published agenda for the Company's general meetings. Such votes may also be cast by electronic communication. The access to cast votes in advance is contingent on that a satisfactory method to authenticate the sender is available. The board of directors can establish specific guidelines for advance votes in writing. The notice of the general meeting shall describe whether it will be possible to vote in writing prior to the general meeting, and what guidelines, if any, have been established for such voting.

## **§ 8 – Innkalling til generalforsamling**

Når dokumenter som gjelder saker som skal behandles på generalforsamlingen er gjort tilgjengelig for aksjeeierne på selskapets internettsider, gjelder ikke allmennaksjelovens krav om at dokumentene skal sendes til aksjeeierne. Dette gjelder også dokumenter som etter lov skal inntas i eller vedlegges innkallingen til generalforsamlingen.

## **§ 9 – Valgkomité**

Selskapet skal ha en valgkomité som skal fremme forslag for generalforsamlingen om styremedlemmer og styremedlemmenes godtgjørelse. Valgkomitéen skal bestå av tre medlemmer som utpekes og sammensattes av generalforsamlingen for en periode på to år. Generalforsamlingen skal også fastsette godtgjørelse til valgkomitéens medlemmer. Generalforsamlingen kan vedta instruks for valgkomitéens arbeid.

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## **§ 8 – Notice to the general meeting**

Documents related to matters that are to be discussed at the company's general meeting, including documents which pursuant to law shall be included in or enclosed to the notice of the general meeting, are not required to be sent to the shareholders if such documents are available at the company's website.

## **§ 9 – Nomination committee**

The company shall have a nomination committee to nominate board members and recommend the board remuneration to the general meeting. The nomination committee shall consist of three members elected by the general meeting for a period of two years. The general meeting shall also approve the remuneration to the members of the nomination committee. The general meeting may adopt an instruction to the work of the nomination committee.

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**BerGenBio ASA**

Jonas Lies vei 91  
5009 Bergen  
Norway

**Legal Adviser to the Company**

*(as to Norwegian law)*

**Advokatfirmaet Thommessen AS**

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