# OSE:BGBIO Result First Quarter 2018

May 15th 2018 Richard Godfrey, CEO



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### **Corporate Snapshot**

#### **Background**



Leaders in developing selective AXL inhibitors: innovative drugs for aggressive diseases, including immune evasive, drug resistant and metastatic cancers

**Diversified pipeline**, lead drug is tested in several indications of high unmet medical need and large market potential

**Promising efficacy** with sustained treatment benefit and confirmed favourable safety

**Companion diagnostic** 

#### **Bemcentinib** (BGB324)



First-in-class highly selective oral AXL inhibitor

Broad phase II clinical programme in NSCLC, TNBC, AML/MDS, melanoma

#### **Pipeline**



Bemcentinib (BGB324)

**AXL** antibody

AXL ADC (partnered)

Immunomodulatory small molecules

#### **OSE:BGBIO**



Cash runway through to 2020

Included in the OSEBX index from 1<sup>st</sup> June 2018

+117% year to date share price increase

#### Corporate



35 staff

Headquarters and research in Bergen, Norway; Clinical Trial Management in Oxford, UK



### **Agenda**

#### 1. **Q1 2018 Highlights**

- 2. Bemcentinib's aspiring leadership position as the future cornerstone of cancer combination treatments
- 3. Q1 update on bemcentinib's global phase II development programme on track and delivering promising clinical data
- 4. Companion Diagnostic
- Finance report
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#### Q1 2018 results

#### Good progress advancing bemcentinib's phase II clinical development

- ✓ First efficacy endpoint met in Phase II trial of bemcentinib/TARCEVA® combination in NSCLC
- ✓ Recruitment completed in first stage of Phase II trial of bemcentinib/KEYTRUDA® combination in TBNC
- ✓ Bemcentinib shown to be well tolerated in all patients enrolled across three combination trials with KEYTRUDA
- ✓ Single agent therapy with bemcentinib led to increased immune activity in relapsed / refractory AML & MDS patients

#### **Post period**

Recruitment completed in first stage of Phase II trial of bemcentinib/KEYTRUDA® combination in NSCLC

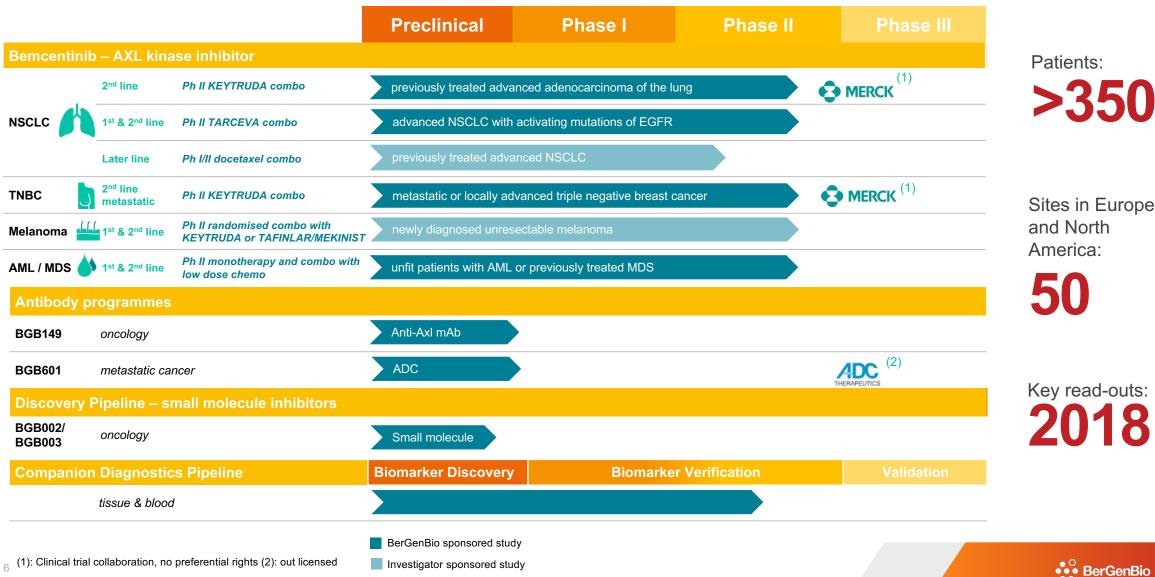
Private placement raising NOK 187.5 million

Emerging promising pre-clinical data continues to support BerGenBio pipeline development

- Data highlighting potential of selective AXL inhibition to treat advanced non-alcoholic steatohepatitis (NASH) and idiopathic pulmonary fibrosis (IPF) presented at EASL annual meeting and pubished in American Journal of Respiratory and Critical Care Medicine, respectively
- Promising data highlighting bemcentinib's potential to reverse tumour immune suppression and enhance immune checkpoint inhibitor efficacy presented at AACR annual meeting
- Pre-clinical data supporting the clinical development of out-licensed AXL ADC BGB601 presented at AACR annual meeting



### Pipeline of innovative AXL inhibitors





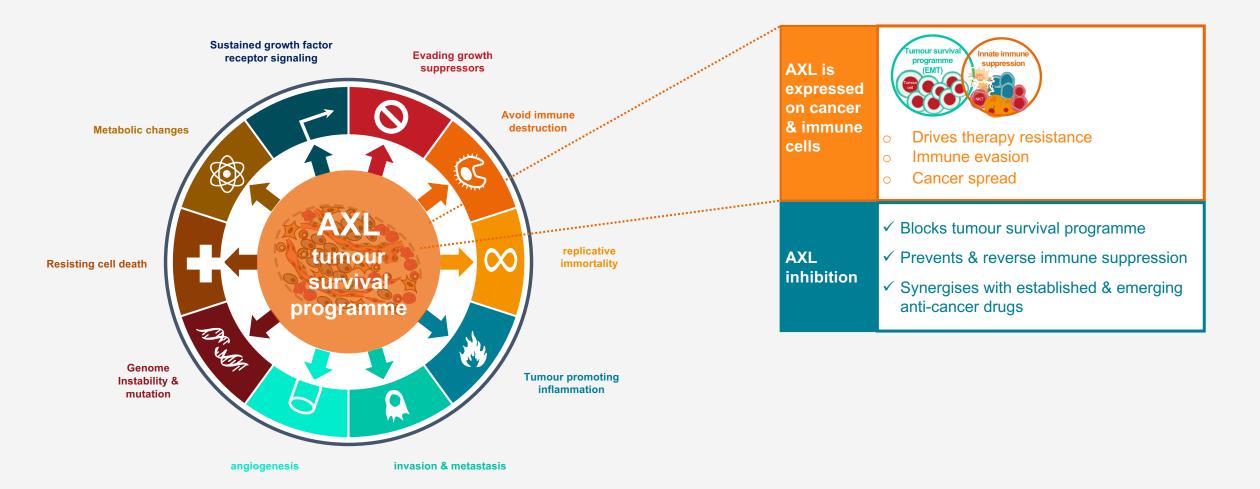
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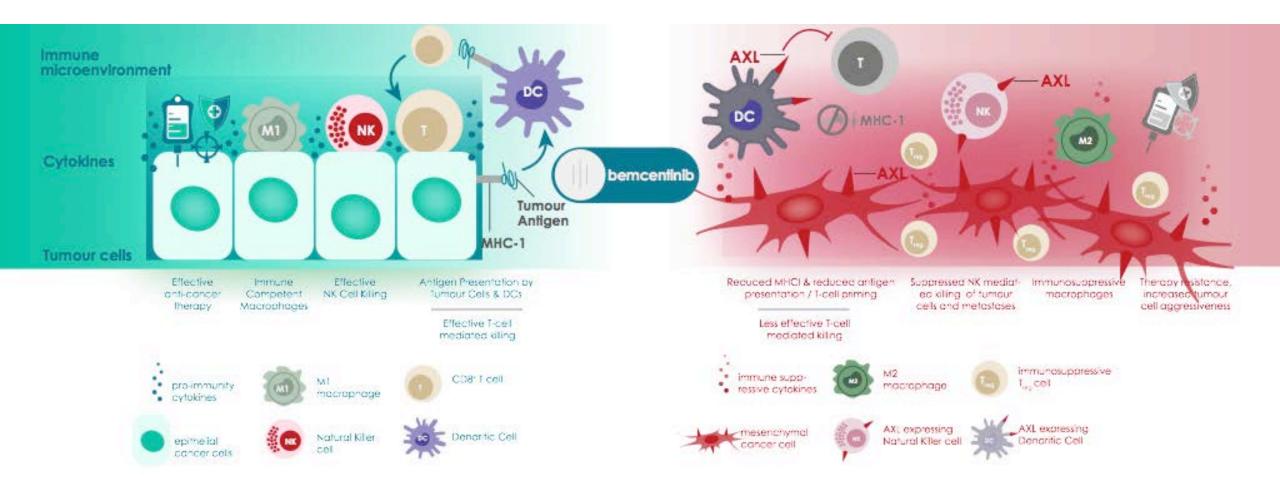


## **AXL** supports the hallmarks of cancer\*

#### - it drives key tumor survival programmes



## Bemcentinib's mechanism: restore sensitivity to immune cell attack and therapy as well as prevent spread



## **AXL** inhibition as cornerstone for cancer therapy bemcentinib proof-of-concept Phase II clinical trials

BGBC008: NSCLC BGBC004: NSCLC BGBIL005: NSCLC BGBC007: TNBC **BGBC003**: **BGBIL006: Melanoma** BGBC003: AML BGBIL006: Melanoma **AML/MDS** + chemotherapy + targeted therapy + checkpoint inhibitors monotherapy Bemcentinib as a foundation therapy

## Bemcentinib clinical development summary





PoC clinical programme:
Potential cornerstone

- √ 6 global phase II trials
- ✓ Monotherapy
- ✓ Combo with IO, targeted and chmo



Monotherapy activity demonstarted

- ✓ R/R AML and MDS
- ✓ NSCLC



Activity in combination with targeted and chemo reported

- ✓ NSCLC in combo with docetaxel
- ✓ NSCLC in combo with EGFRi (TARCEVA)



Safety in combination with KEYTRUDA

- ✓ melanoma
- ✓ TNBC
- ✓ NSCLC



Companion diagnostic development

- ✓ IHC established
- ✓ Blood based candidates identified



Selected patient populations

Pivotal trials in stratified patient populations



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**BGBC003 trial in AML/MDS** 

AML and high-risk MDS patients unfit for high intensity chemotherapy remain a very challenging patient population with no treatment options when driver mutations are absent

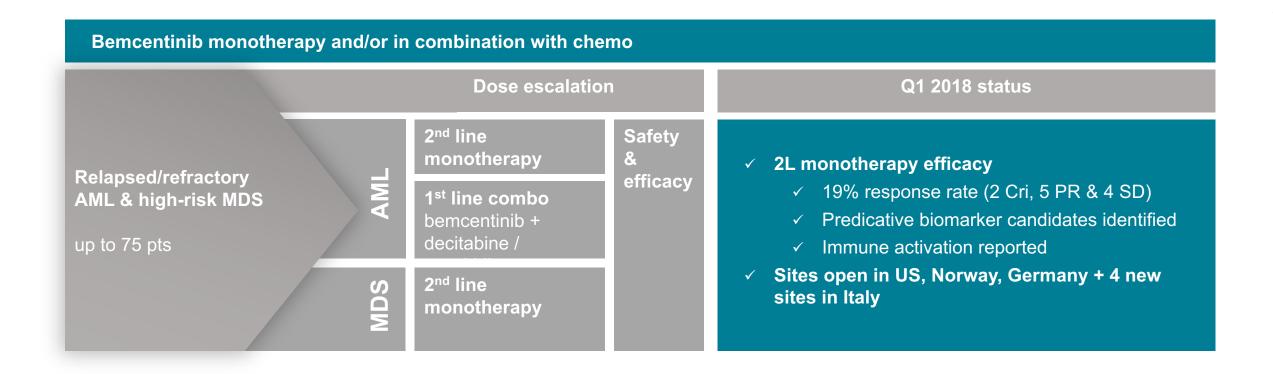
The BGBC003 trial is designed to test the hypothesis whether AXL inhibition with bemcentinib can

- Elicit single agent effect and / or
- Enhance responses to low dose chemotherapy

when given as a single agent in relapsed / refractory AML and high risk MDS or in combination with azacitidine or decitabine in treatment naïve AML patients



### BGBC003: Phase lb/II trial in AML/high risk MDS



## **BGBC004 trial in NSCLC**

NSCLC patients tend to initially respond well to targeted therapies but virtually all acquire resistance over time.

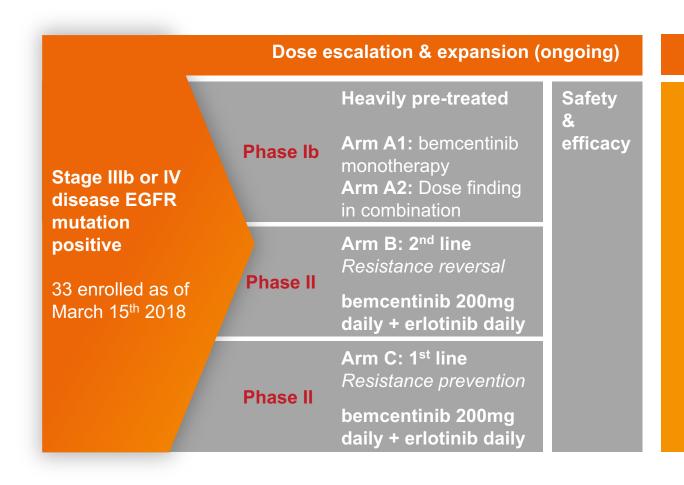
The BGBC004 trial is designed to test the hypothesis whether AXL inhibition can

- Reverse and / or
- Prevent resistance to EGFRm targeted therapies

when given in combination with erlotinib in EGFRm NSCLC patients who have either progressed on or have just started EGFRm targeted therapy



## BGBC004: Phase Ib/II trial in NSCLC of bemcentinib with TARCEVA (erlotinib)

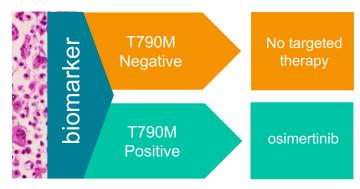


#### **Q1 2018 status**

- ✓ Arm A1 monotherapy: 25% CBR
   2 SD including tumour shrinkage (19%) n=8
- ✓ Arm A2– combination with erlotinib: 50% CBR
   1 PR and 3 SD n=8. PR ongoing in excess of 2 years
- ✓ Arm B 2L / combo w/ erlotinib: 33% CBR
  First efficacy endpoint met
  1 PR & 2 SD n=9
- Arm C resistance prevention combo w/ erlotinib:
   Ongoing and recruiting, 1 PR reported

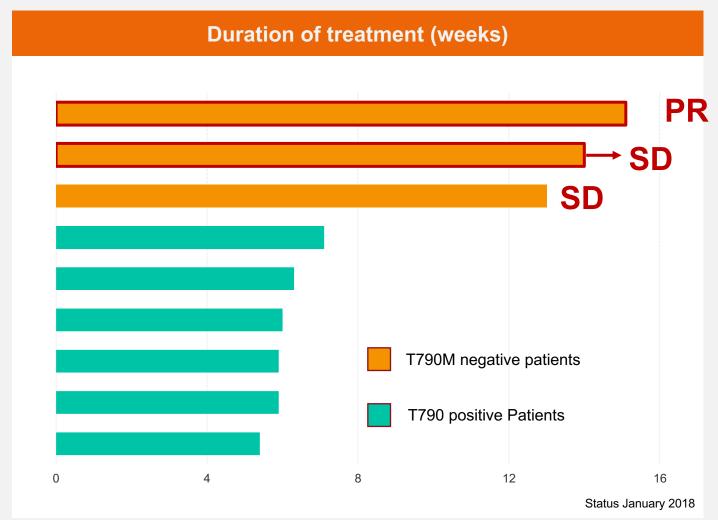
## BGBC004: Phase II Arm B, erlotinib resistance reversal Primary efficacy end point met

No targeted therapy available for 2<sup>nd</sup> line T790M negative patients\*



#### **Arm B patient population**

- Progressed on 1<sup>st</sup> line approved EGFR TKI therapy (erlotinib, afatinib, gefitinib)
- Median 3 lines (2 12) prior therapy
- Typical EGFRm population
  - > 5 of 9 pts are Asian, 6 females





## **BGBC007/8 trials in TNBC** and NSCLC

KEYTRUDA monotherapy showed 4% response rate in previously treated TNBC patients and 18% in NSCLC. PD-L1 negative patients remain particularly challenging.

The BGBC007 and 008 trials are designed to test the hypothesis whether AXL inhibition can

**Enhance** responses to immunotherapy when given in combination with KEYTRUDA (pembrolizumab) in previously treated, immunotherapy-naïve TNBC or NSCLC patients, respectively.

Clinical collaboration with Merck & Co. (MSD) A MERCK

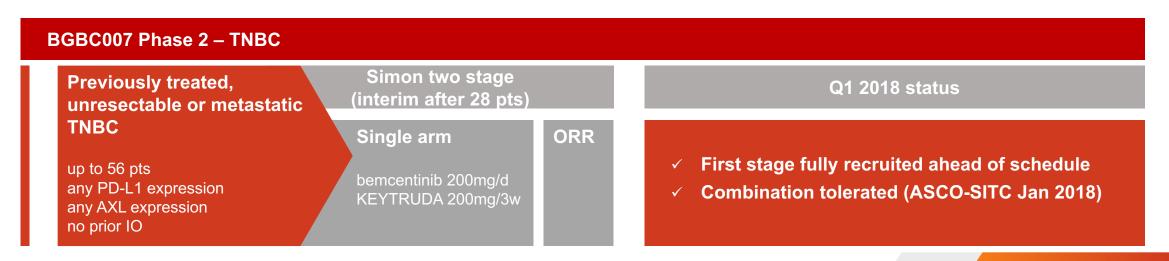




#### **Combination studies with KEYTRUDA**



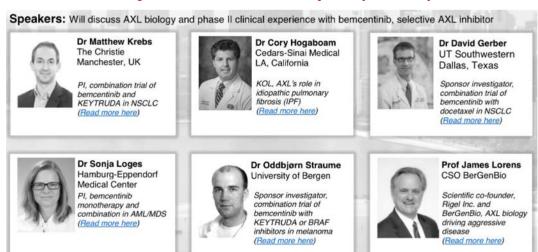
#### **BGBC008** Phase 2 – Adenocarcinoma of the lung Simon two stage Previously treated, Q1 2018 status (interim after 22 pts) unresectable adenocarcinoma of the lung ORR Single arm up to 48 pts First stage fully recruited any PD-L1 expression bemcentinib 200mg/d ✓ Combination tolerated (ASCO-SITC Jan 2018) KEYTRUDA 200mg/3w any AXL expression no prior IO



#### BerGenBio reception at *ASCO* – 2<sup>nd</sup> June 2018 Presentation of AXL biology and interim clinical data with bemcentinib



#### Saturday June 2nd 2018: 6-8 p.m. (Central)



#### **ASCO** conference and KOL reception

#### ASCO:

- 4 abstracts to be presented, interim clinical data
- ➤ NSCLC BGBC008
- ➤ AML/MDS BGBC003
- Melanoma BGBIL006
- Companion diagnostics programme
- → Full abstracts available on May 16<sup>th</sup>

#### BerGenBio KOL reception

- Short talks by KOLs and Pls
- AXL biology
- Bemcentinib interim clinical data



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- 3. Q1 update on bemcentinib's global phase II development programme on track and delivering promising clinical data

#### 4. Companion Diagnostic

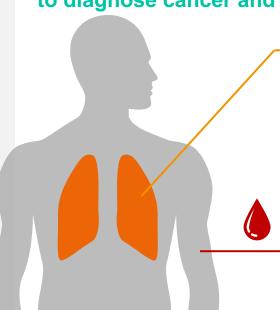
- Predictive biomarker candidates identified soluble and cellular (Dec '17)
- AXL IHC established and rolled out for BGBC007 and BGBC008 (Jan '18)
- 5. Finance report
- 6. Outlook
- 7. Q&A



## BerGenBio companion diagnostics programme aligned with gold standard & emerging practice for personalised medicine

#### **Cancer Diagnosis:**

Standard (tissue) and emerging (blood) pathology techniques are used to diagnose cancer and determine optimal, personalised treatment



Tumour tissue biopsy – "the main way cancer is diagnosed" 1

- Gold standard for diagnosing cancer & determining course of treatment
- Determine actionable driver mutations
  - eg: EGFR, ALK, KRAS, BRAF, HER2, ROS1, and RET
- Determine PD-L1 status for check point inhibitors
- → Purpose of BerGenBio tissue CDx:

  determine AXL expression as part of routine assessments

#### Liquid biopsy – emerging technology

- Minimally invasive technique, less risky and can be done more frequently
- · New technology can measure
  - ctDNA to determine mutations
  - Proteins: cytokine profiles, soluble receptors, etc.
- → Purpose of BGB blood CDx: predict and monitor response to treatment by measuring BerGenBio biomarkers

Advantages of Companion Diagnostics (CDx)

#### **Patients:**

 Receive only treatments that are predicted o offer benefit

#### **Drug developers:**

- Patient stratification reduces clinical trial cost and time
- Defined patient populations offer regulatory and reimbursement advantages

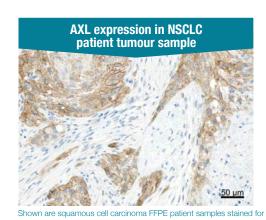


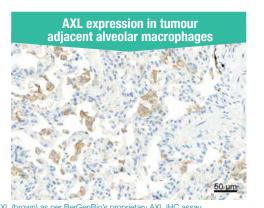
## AXL immunohistochemistry (IHC) test developed and validated, predictive blood biomarker candidates identified

## AXL immunohistochemistry (IHC) developed and validated<sup>1</sup>, used with standard tissue biopsy analysis



- ✓ AXL detected in tumour and immune cells
- ✓ Tumours were found to have a varying degree of AXL, determined by a positive stain when tested with BerGenBio IHC method, in a prospective study performed on banked tumour samples (1)

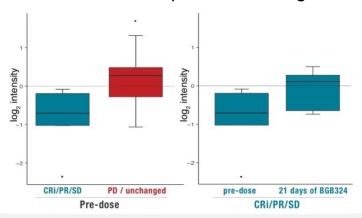




## Predictive biomarker candidates identified in relapsed & refractory AML/MDS<sup>2</sup>



- ✓ BGBM001 can be detected in blood as part of a routine blood draw
- ✓ Levels of BGBM001 were low in patients deriving benefit from bemcentinib treatment
- ✓ BGBM001 levels increase upon treatment with bemcentinib in patients deriving benefit



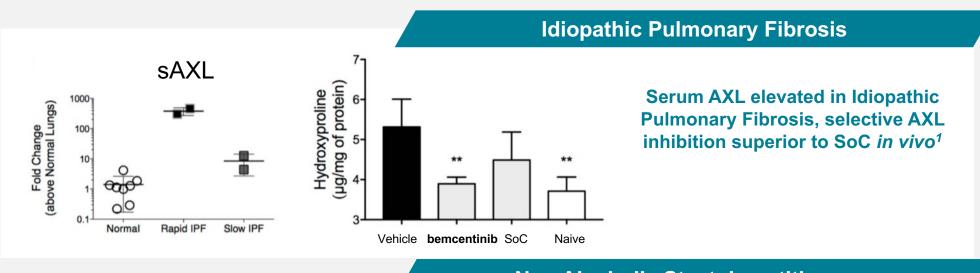
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- 5. Promising pre-clinical data supporting BerGenBio's pipeline
  - Role of AXL and AXL inhibition via bemcentinib in fibrosis presented at leading conferences
  - Pre-clinical data highlighting potential to improve efficacy of checkpoint inhibitors and chemotherapy presented at AACR
- 6. Finance report
- Outlook
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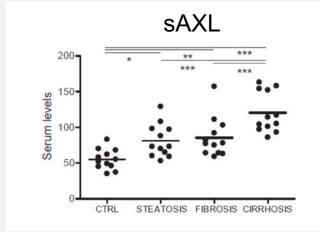


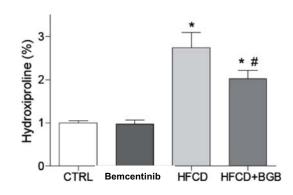
## AXL inhibition as a potential therapy in fibrotic diseases

- Pre-clinical research data presented in Q1 by international KOLs









Serum AXL elevated in NASH, selective AXL inhibition active in vivo<sup>2</sup>

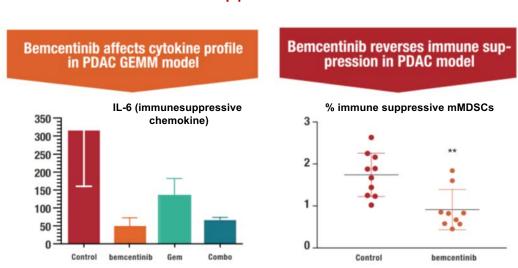
**HFCD** = high-fat, choline deficient diet Leads to NASH in animal models

## Bemcentinib reverses immune suppression and enhances chemotherapy and immune checkpoint blockade

preclinical data presented at AACR 2018<sup>1</sup>

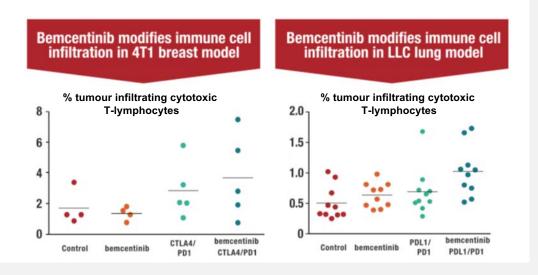
## Bemcentinib is active in combination with chemotherapy

- ✓ Increased response
- ✓ Reduced immunosuppression



## Bemcentinib is active in combination with immune checkpoint inhibitors

- ✓ Increased response
- ✓ Reduced immunosuppression





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- 5. Promising pre-clinical data supporting BerGenBio's pipeline
- 6. Finance report & business update
  - Welcome to Rune Skeie, CFO
  - Finance report
  - Cash runway
- 7. Outlook
- 8. Q&A



#### Welcome to Rune Skeie, CFO

- Joined BerGenBio in March 2018
- Registered Accountant and State Authorised Public Accountant
- 20 years experience: financial management, corporate development and governance, public and private
- Most recent positions:
  - Executive Director EY
  - CFO REMA Franchise Norge AS (Bergen)

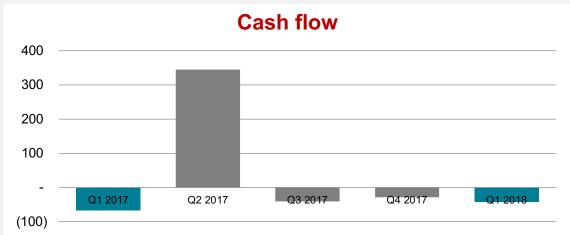


••• BerGenBio

## **Key financials**

Q1 2018	Q1 2017	FY2017
-	-	-
54,8	65,8	183,7
-54,8	-65,8	-183,7
-53,8	-65,1	-182,2
-1,08	-1,93	-4,01
-41,1 329,2	-66,4 95,4	208,5 370,3
	- 54,8 -54,8 -53,8 -1,08 -41,1	







- OPEX sequentially increased by 15% in Q118 from Q417, mainly because of increased social security tax on employee share option scheme.
- Robust cash position gives runway to deliver key clinical read outs on our ongoing clinical studies.
- Updated cash position at 11 May 2018: NOK 495 million, included fund raised from private placement announced April 13th.



### Cash runway / strengthened financial position

- ✓ Anticipated cash runway to 1H 2020 based on current burn rate
  - ✓ Cash position as at end Q1 2018 MNOK 329.2
  - ✓ Private placement completed in April gross fund raise MNOK 187.5
- ✓ Shareholder structure broadened and enhanced
  - ✓ Adding institutional investors in the US specialising in the biotechnology industry
- ✓ Strengthened financial position to execute strategy
  - ✓ To complete ongoing bemcentinib Phase II clinical development program
  - ✓ To support clinical development activities
  - ✓ To prepare regulatory strategy

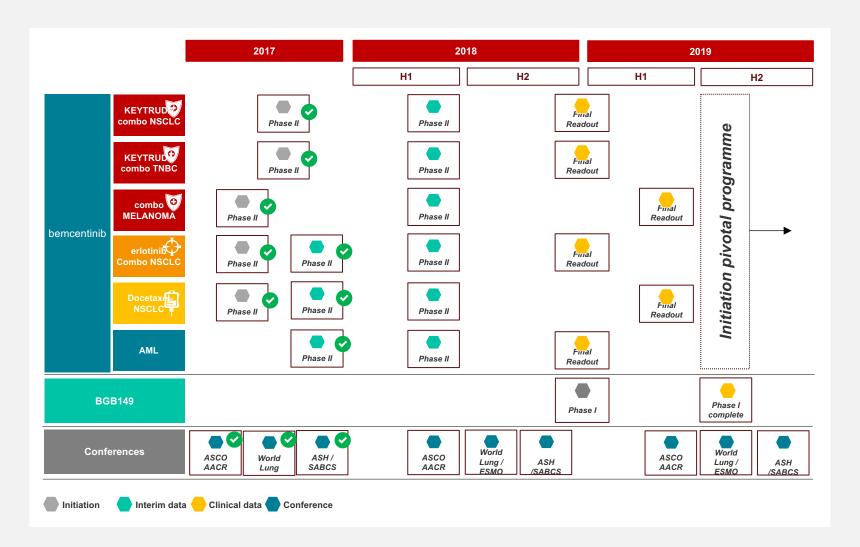


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  - Significant milestones expected in next12-18 months
- 8. Q&A



## Significant milestones expected in 2018 & 2019



# Significant milestones expected over the next 12 months:

#### **Bemcentinib**

- Interim clinical data from 6 ph II trials at ASCO
- Final readout from 4 phase 2 trials in H2

#### **BGB149**

 Initiation of AXL antibody BGB149 clinical trials in H2



### **BGBIO** Investment case

First-in-class AXL inhibitors for aggressive cancers with addressable market in excess of \$20bn

Axl mechanism now widely accept by Pharma industry as a 'hot' target of great interest

Well funded & experienced organisation to deliver milestones

Bemcentinib preliminary Phase II proof-of-concept data already reported

Bemcentinib additional Phase II proof-of-concept data anticipated June 2018



## **Appendix**



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

(NOK 1000) Unaudited	Note	Q1 2018	Q1 2017	Full year 2017
Revenue		_	_	_
Cost				
Employee benefit expenses	3	15 672	6 294	28 827
Depreciation		54	50	193
Other operating expenses	6	39 055	59 445	154 686
Total operating expenses		54 781	65 789	183 707
Operating profit		-54 781	-65 789	-183 707
Finance income		1 046	1 119	4 168
Finance expense		44	395	2 668
Financial items, net		1 001	724	1 500
Profit before tax		-53 780	-65 065	-182 207
Income tax expense			-	-
Profit after tax		-53 780	-65 065	-182 207
Other comprehensive income				
Items which will not be reclassified over profit and loss				
Actuarial gains and losses on defined benefit pension plans		-	-	-
Total comprehensive income for the period		-53 780	-65 065	-182 207
Earnings per share:				
- Basic and diluted per share	7	-1,08	-1,93	-4,01



## Condensed consolidated statement of financial position

	Note	31 MAR 2018	31 MAR 2017	31 DEC 2017
(NOK 1000) Unaudited				
ASSETS				
Non-current assets				
Property, plant and equipment		503	518	557
Total non-current assets		503	518	557
Current assets				
Other current assets	5, 8	11 884	13 090	13 430
Cash and cash equivalents		329 224	95 387	370 350
Total current assets		341 108	108 477	383 780
TOTAL ASSETS		341 610	108 996	384 336
EQUITY AND LIABILITIES				
Equity				
Paid in capital				
Share capital	9	4 993	3 374	4 992
Share premium	9	271 478	67 336	325 018
Other paid in capital	4, 9	20 376	18 593	20 340
Total paid in capital		296 846	89 303	350 350
Total equity		296 846	89 303	350 350
Non-current liabilities				
Pension liability	10	-	-	_
Total non-current liabilities		-	0	0
Current liabilities				
Accounts payable		19 314	10 654	21 575
Other current liabilities		14 001	4 520	9 391
Provisions		11 449	4 519	3 020
Total current liabilities		44 764	19 693	33 986
Total liabilities		44 764	19 693	33 986
TOTAL EQUITY AND LIABILITIES		341 610	108 996	384 336



## Condensed consolidated statement of cash flow

(NOK 1000) Unaudited	Note	YTD 2018	YTD 2017
Cash flow from operating activities			
Loss before tax		-53 780	-65 065
Non-cash adjustments to reconcile loss before tax to net cash flows			
Depreciation of property, plant and equipment		54	50
Calculated interest element on convertible loan		-	-
Share-based payment expense	3, 4	36	567
Movement in provisions and pensions		8 429	- 324
Working capital adjustments:			
Decrease in trade and other receivables and prepayments		1 546	- 789
Increase in trade and other payables		2 348	-1 249
Net cash flow from operating activities		-41 366	-66 810
Cash flows from investing activities			
Purchase of property, plant and equipment			- 159
Net cash flow used in investing activities		-	- 159
Cash flows from financing activities			
Proceeds from issue of share capital	9	240	531
Net cash flow from financing activities		240	531
Net increase/(decrease) in cash and cash equvivalents		-41 126	-66 438
Cash and cash equivalents at beginning of period		370 350	161 825
Cash and cash equivalents at end of period		329 224	95 387

