

# BerGenBio

Developing first-in-class drugs to treat aggressive cancer

> Oslo Børs og AksjeNorge Den store selskapskvelden June 6<sup>th</sup> 2017

**Richard Godfrey - CEO** 



#### **Disclaimer**

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**BerGenBio – First-in-class Axl inhibitors for multiple aggressive cancers** 

**90%** of cancer deaths result from tumors spreading, becoming immune evasive and drug resistant

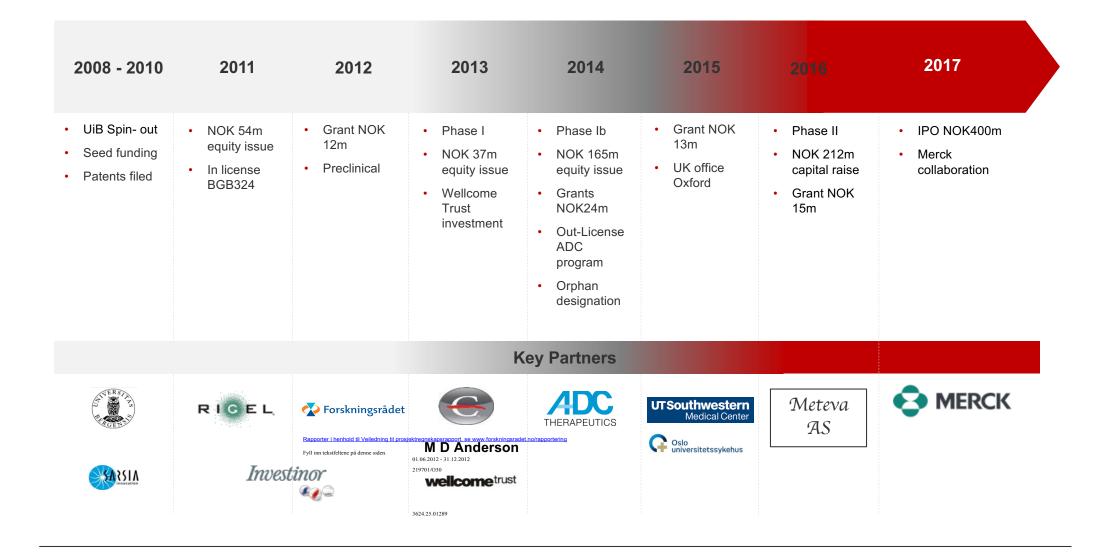
**AxI** is a **key mediator** of these traits in most cancers

BerGenBio is a **World-leader** in Axl biology and is developing an exciting **pipeline** of Axl inhibitors

BGB324 initially addressing an annual market potential of USD 11 Billion



#### Key events in BerGenBio's history



kr 0 (Konto 8913)

## Introduction to BerGenBio ASA



- Listed on Oslo Børs: BGBIO
- HQ and Administration
- Research



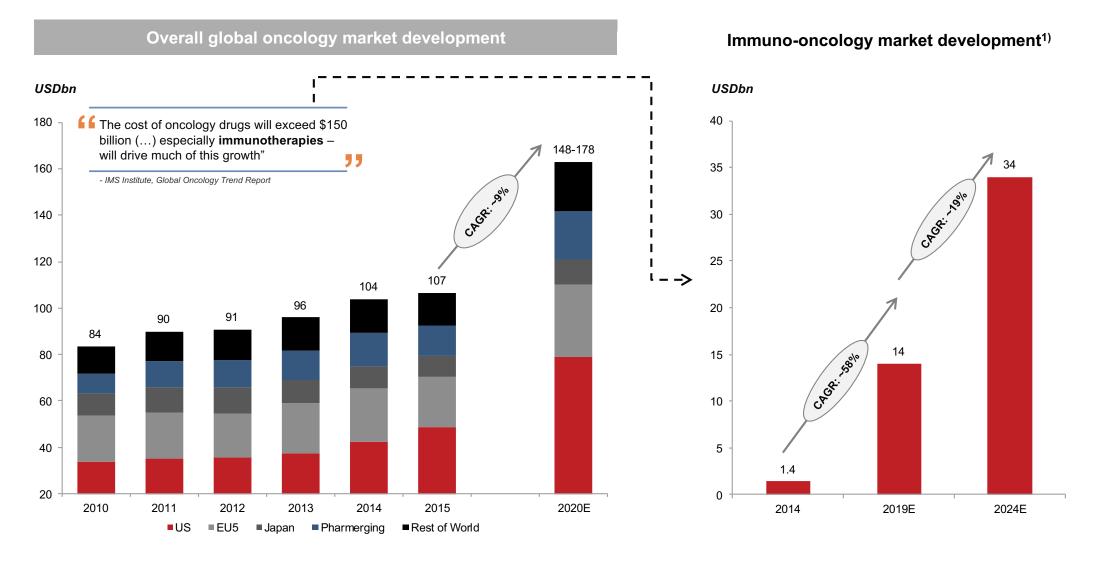
- Clinical trial management
- Drug discovery programs



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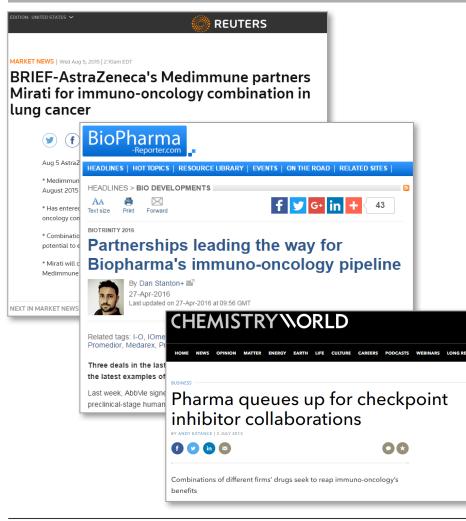
#### Global cancer drugs sales forecasted to exceed USD ~150bn by 2020



<sup>1</sup> Across the 7 major countries of the US, France, Germany, Italy, Spain, the UK and Japan Source: IMS Institute, Global Oncology Trend Report: A Review of 2015 and Outlook to 2020, DCAT, GlobalData

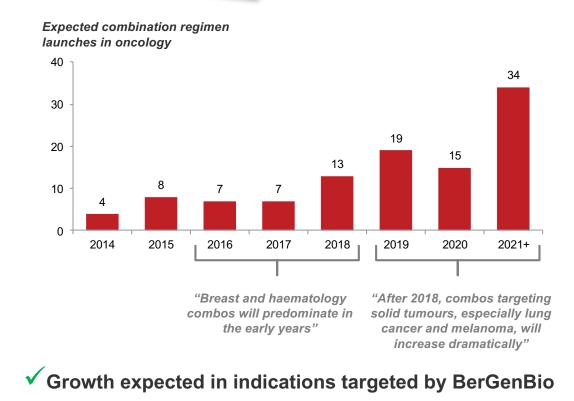
#### Combination treatments are driving clinical benefit & commercial opportunity

Multiple examples of potentially high value partnerships; trend particularly prominent within immune-oncology



Expected new combination regimen launches

"Combination treatments are becoming the treatment of choice" - Business Insights, The Cancer Market Outlook to 2016



Source: IMS Institute – Developments in Cancer Treatments, Market Dynamics, Patient Access and Value; Business Insights - The Cancer Market Outlook to 2016, Pfizer, AstraZeneca, ChemistryWorld, BioPharma-Reporter



## **Pipeline will drive value creation**

	Discovery	Preclinical	Phase I	Phase II	Phase III
BGB324 – Axl kinase inh	ibitor				
AML / MDS	Phase lb / II – Single	agent / Combination			
NSCLC (mutation driven)	Phase Ib / II – Comb	ination with TARCEVA® (ε	rlotinib)		
NSCLC (adenocarcinoma)	Phase II Combinatio	n with KEYTRUDA® (pem	brolizumab)		
TNBC	Phase II Combinatio	n with KEYTRUDA® (pem	brolizumab)		
Investigator-sponsored trials					
NSCLC	Phase II BGB324 in	combination with Docetax	el		
Melanoma	Phase II BGB324 in o	combination with current s	standard therapies, incl. CPIs		
Antibody programs					
BGB149 – Oncology	Anti-Axl mAb				
BGB601 – Metastatic cancer (Partnered)	ADC	THERAPEUTICS			
Discovery Pipeline – small mo	plecule inhibitors				
BGB002 – Oncology					
BGB003 – Oncology					

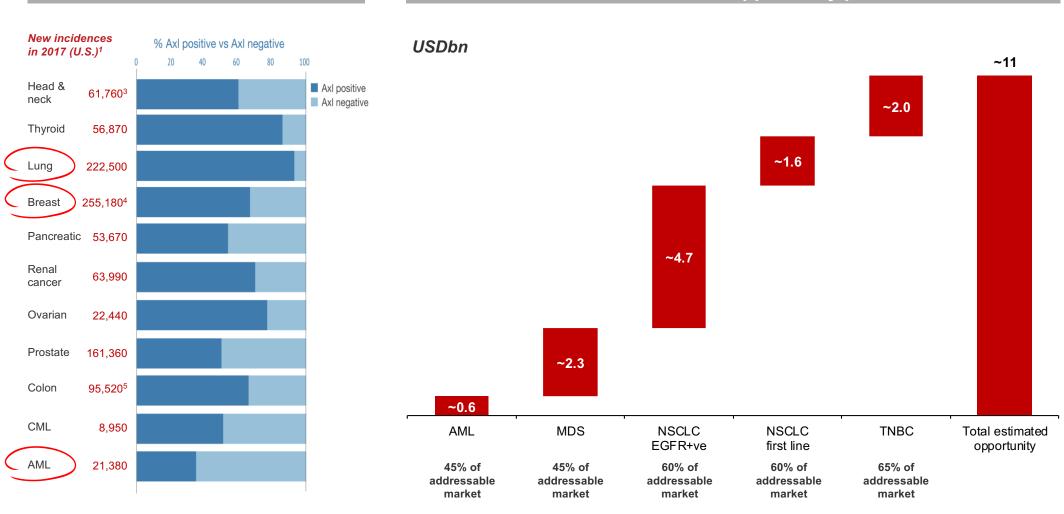
#### **BGB324 Ongoing Phase II trials**



•••• BerGenBio

#### BGB324 - Blockbuster potential – addressable market ~\$11bn in selected indications

Most common tumours express high Axl levels



Estimated annual market opportunity per indication<sup>6</sup>

1) SEER Program – National Cancer Institute (National Institute of Health) http://seer.cancer.gov/; 3) Cancer.net; 4) Figure for male and female breast cancer; 5) Excluding rectum; 6) Estimates by Alacrita Consulting

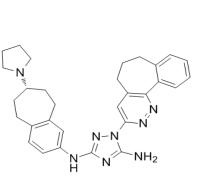
## BGB324 – First-in-class, highly selective oral Axl inhibitor

#### **Investigational Medicinal Product**

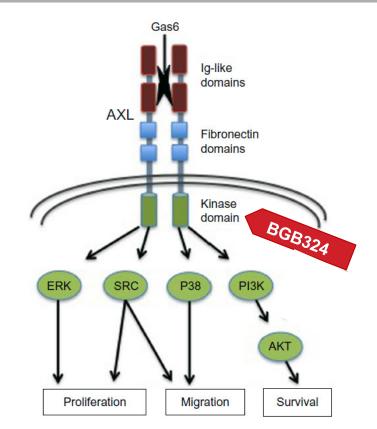
- 100mg capsules, standard pharmaceutical formulation
- 3yr shelf life
- Low 'cost of goods' (COGs)
- Patients take medicines home, one-a-day dose

#### **Drug substance**

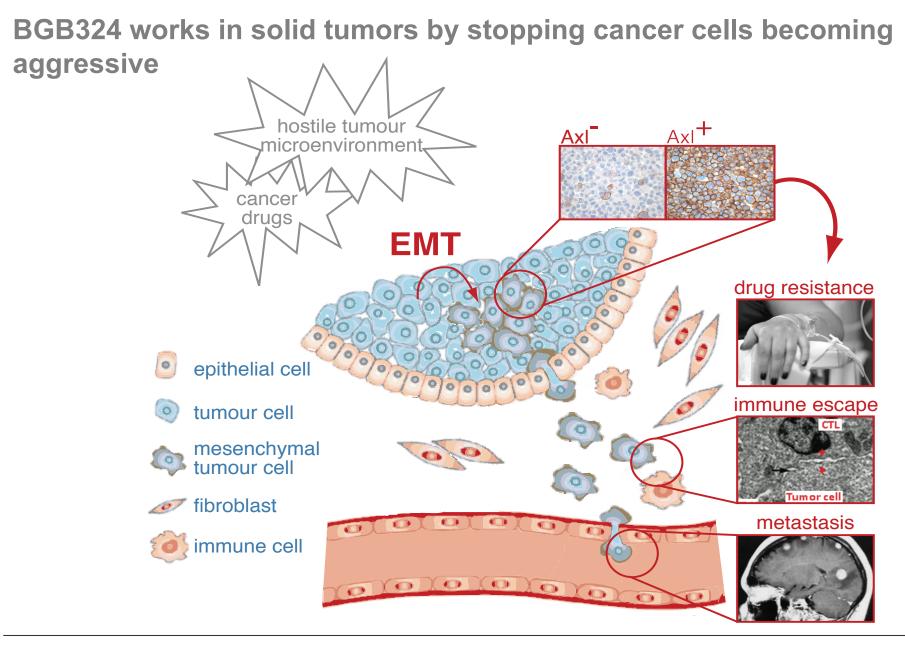
- Licensed from Rigel Inc. 2011
- Highly selective and potent
- Orally bioavailable
- Orphan status in US for AML
- Well tolerated: suitable for long term therapy
- Wide therapeutic index: suitable for combination with existing drugs



#### Mode of Action



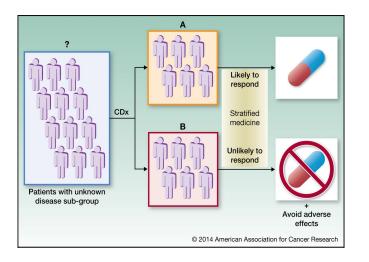




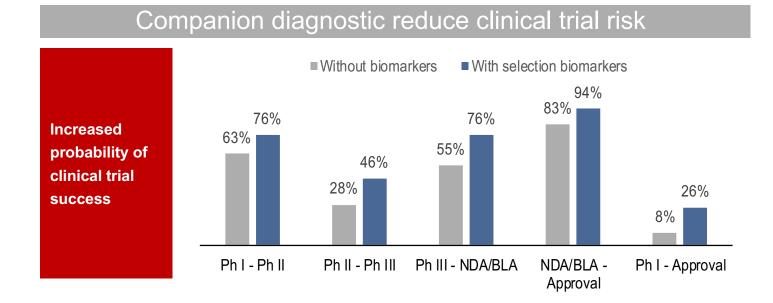
<sup>Source: Gjerdrum, 2010</sup> \* Epithelial to Mesenchymal Transition drives cell invasiveness, survival, drug resistance and immune evasion



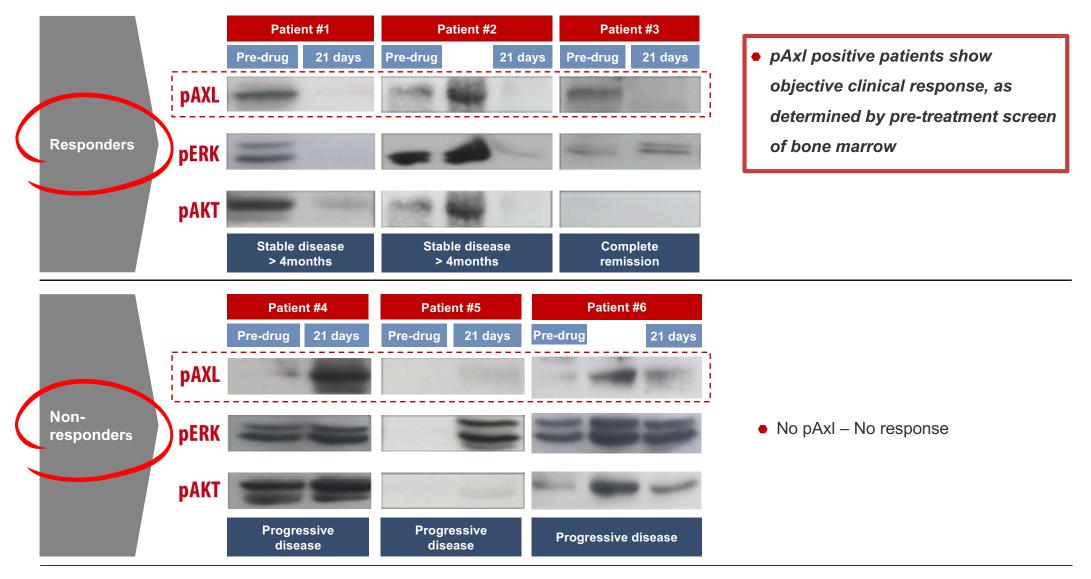
# Companion diagnostics reduce risk, add significant clinical and regulatory advantage



- Companion diagnostics are used to select patients that are expected to benefit from a particular drug
  - Significantly increases the likelihood of a positive response
- Allows for smaller and faster clinical trials
  - Significant value added to NPV calculations
- Targeted therapies with patient selection diagnostic more likely to achieve a premium price



#### **Prototype test identifies patients that respond to BGB324**



Source: Abstract presentation at ASH, 2016



#### Funded to deliver high value milestones

	2017	2018	
		Phase II	Phase II Clinical Data
	Ongoing	$\checkmark$	
BGB324	Ongoing	NSCLC (mutation driven) – Combination with erlotinib	$\checkmark$
		NSCLC (adenocarcinoma) – Combination with KEYTRUDA	$\checkmark$
		TNBC – Combination with KEYTRUDA	$\checkmark$
Companion diagnostic	Ongoing	Method validation validation and collection of reference data set	Validated CDx
BGB149	Ma	anufacture and IND enabling work First-in-man trials	Phase I Clinical Data



#### **BerGenBio – value drivers**

USD 11bn defined market opportunity	<ul> <li>90% of cancer deaths result from tumors spreading, becoming immune evasive and drug resistant</li> <li>Axl is a key mediator of these traits in most cancers</li> <li>World leader in Axl biology</li> </ul>
Pipeline	<ul> <li>BGB324 – first in class - orally bioavailable, highly selective Axl inhibitor</li> <li>BGB149 – anti-Axl monoclonal antibody</li> <li>BGB601 – anti-Axl ADC</li> <li>Proprietary companion diagnostics for personalized medicine approach</li> </ul>
BGB324 exciting lead candidate	<ul> <li>Well tolerated by patients</li> <li>Efficacy signal reported: single agent, combination with chemo, targeted therapies</li> <li>Potentiates check point inhibitors</li> <li>Low cost drug</li> </ul>
Strategic flexibility for value creation	<ul> <li>Funded through Phase II inflection point</li> <li>Clinical collaborations with Merck &amp; Co.,</li> <li>Out-licensed ADC candidate to world-class biotech ADC Therapeutics Sarl</li> </ul>
Corporate	<ul> <li>Extensive expertise in oncology drug development, teams in Bergen, Norway and Oxford, UK</li> <li>Strong news flow</li> <li>Defined commercialization strategy</li> </ul>

1) Known as MSD outside the U.S. and Canada

#### Successful IPO in April 2017 – solid foundation to build value

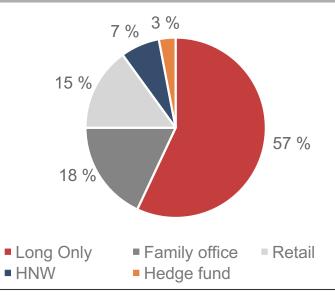
 Through the IPO raising gross proceeds of NOK 400 million to fund the next stage of its development

SHAREHOLDER	# SHARES	%
METEVA AS	14,923,000	30.00
INVESTINOR AS	6,609,800	13.29
SARSIA SEED AS	2,117,900	4.26
VERDIPAPIRFONDET ALFRED BERG GAMBA	1,852,500	3.72
MP PENSJON PK	1,780,300	3.58
NORSK INNOVASJONSKAPITAL II AS	1,273,100	2.56
JPMORGAN CHASE BANK, N.A., LONDON	1,272,000	2.56
DATUM INVEST AS	1,209,200	2.43
SARSIA DEVELOPMENT AS	1,195,000	2.40
BERA AS	1,084,800	2.18
VPF NORDEA AVKASTNING	972,354	1.95
VERDIPAPIRFONDET ALFRED BERG NORGE	845,000	1.70
KLP AKSJENORGE	835,394	1.68
VERDIPAPIRFONDET HANDELSBANKEN	720,000	1.45
VPF NORDEA KAPITAL	700,000	1.41
KOMMUNAL LANDSPENSJONSKASSE	627,188	1.26
VERDIPAPIRFONDET ALFRED BERG AKTIV	552,500	1.11
BIRK VENTURE AS	552,063	1.11
STATOIL PENSJON	440,000	0.88
VERDIPAPIRFONDET NORDEA NORGE PLUS	360,000	0.72

#### Share facts

Currency	NOK
Market	Oslo (NOK)
ISIN code	NO0010650013
Ticker code	BGBIO
Industry	Biotechnology
Market Capitalization	NOK 1.2 bn
Number of Shares	49,742,200
Number of shareholders	1,884

#### Shareholding by investor type in IPO



Updated as of 29<sup>th</sup> May 2017

## Financial summary – end of first quarter 2017

(NOK million)	Q1 2017	Q1 2016	FY 2016
Operating revenues	-	-	-
Operating expenses	65.8	20.7	131.6
Operating profit (loss)	(65.8)	(20.7)	(131.6)
Profit (loss) after tax	(65.1)	(20.3)	(129.8)
Basic and diluted earnings (loss) per share (NOK)	(1.93)	(75.21)	(419.68)
Cash position end of period	95.4	163.2	161.8

The share	BGBIO
Market cap	$\approx$ NOK 1.2 billion
Daily turnover (avg. since IPO 7 <sup>th</sup> Apr)	NOK 3.4 million
Financial debt	NOK 0
Number of shares	49.7 million
Analysts	ABG Sundal Collier, Arctic Securities and DNB



# Thank you.

# For further information please visit www.bergenbio.com

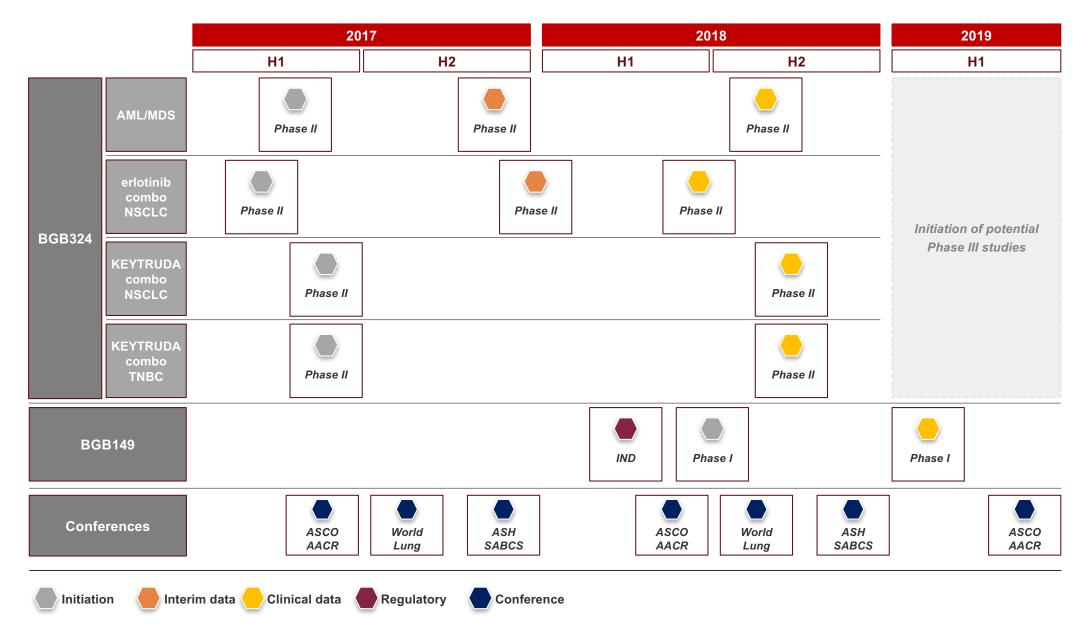
Developing first-in-class drugs to treat aggressive cancer

## Glossary

AA	Accelerated approval	FDA	US Food and Drug Administration
ADC	Antibody drug conjugate	GLP	Good Laboratory Practice
ALK	Alkaline phosphatase	IHC	Immunohistochemistry
AML	Acute myeloid leukemia	mAb	Monoclonal antibody
BLA	Biologic license application	MDS	Myeloid dysplastic syndrome
BT	Breakthrough therapy	NDA	New drug application
CAB	Clinical advisory board	NSCLC	Non-small cell lung cancer
CBR	Clinical benefit rate	pAxl	Phosphorylated Axl (activated Axl)
CDx	Companion diagnostic	PD	Progressive disease
CLIA	Clinical Laboratory Improvement Amendments	PR	Partial response
CLL	Chronic lymphocytic leukemia	RCC	Renal carcinoma
CPI	Checkpoint inhibitor	RP2D	Recommended Phase II Dose
CR	Complete response	RTK	Receptor tyrosine kinase
CTL	Cytotoxic T-lymphocytes	TAM	Tyro, Axl, Mer (family of kinases)
ECG	Electrocardiogram	TNBC	Triple negative breast cancer
EGFR	Epidermal growth factor receptor	sAxl	Soluble Axl
ELISA	Enzyme-linked immunosorbent assay	SD	Stable disease
EMT	Epithelial-to-mesenchymal transition	SoC	Standard of Care
EU5	France, Germany, Italy, Spain, United Kingdom	QTcF	QT inverval, a measure of time in the heart's electrical cycle

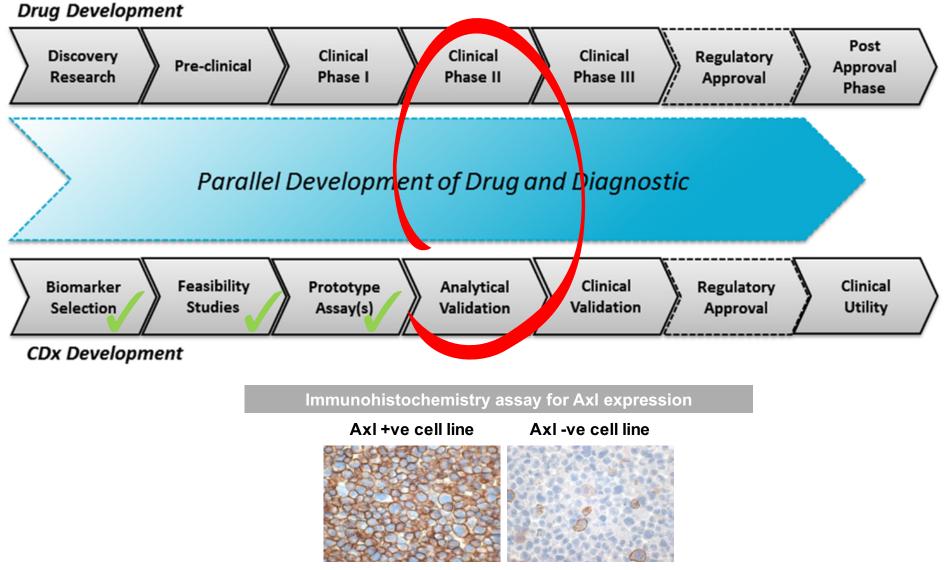


#### Multiple value-creating milestones 2017 – 2019<sup>1</sup>





#### Parallel development of companion diagnostic A high value product in its own

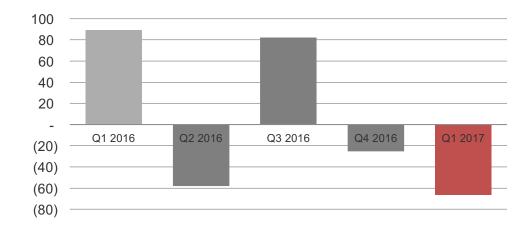


H-score validation during phase II

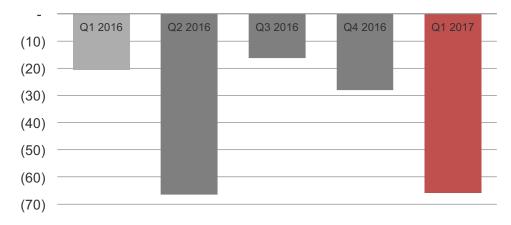
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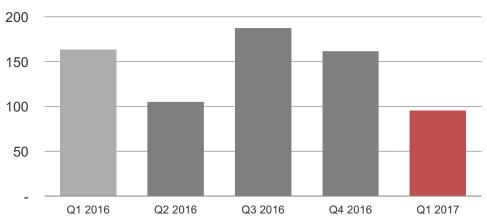
#### Cash flow



#### **Operating loss**



#### Cash position



- Operating expenses in Q1 2017 impacted by NOK 27.8 million (USD 3.3 million) Phase II milestone payment to Rigel Pharmaceuticals Inc.
- Net proceeds from the IPO approximately NOK 375 million received in April
- NOK 15.7 million grant awarded from the Research Council of Norway to support investigator-led studies terms being negotiated

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