
BerGenBio
A novel approach to address significant unmet medical needs in NSCLC
Q3 2023 Business Update

Forward Looking Statements

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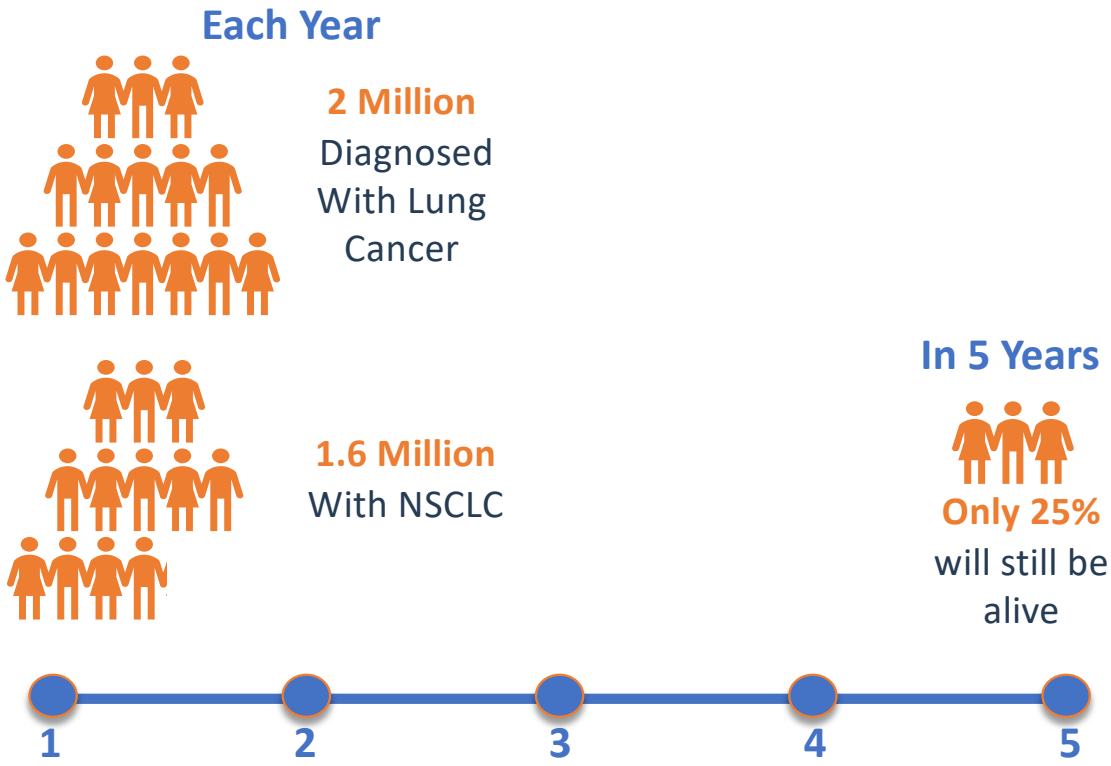
A laser focused strategy on selective AXL inhibition to improve the outcome for patients in NSCLC

- AXL a cell surface protein plays a key role in the growth and metastasis of NSCLC
- We are focused on selective inhibition AXL by our lead compound ***bemcentinib*** to delay chemoresistance and potentiate immunotherapy in NSCLC patients that respond poorly to available therapies
- ***Bemcentinib*** preclinical/clinical data demonstrate improved survival vs. expected outcome from current therapies in 2L NSCLC, particularly in:
    - AXL+ patients
    - Patients with low/negative PDL1 levels
    - Patients with difficult to treat mutations for which there are no targeted therapies today
- Our data guide focus on 1L STK11m NSCLC a significant market opportunity in which a fast-track designation has been granted by FDA
- Right-size burn and extended runway to support future value inflections
- Potential upside from additional indications and out-licensed/earlier programs

November – Lung Cancer Awareness Month reminds us of immensity of the problem



NSCLC Continues to be the Largest Cause of Cancer Deaths

- **Increasing incidence due to rise of smoking in developing countries**
- **Diagnosed late (few symptoms until metastatic)**
- **Specific molecularly defined sub-groups poorly respond to therapy**

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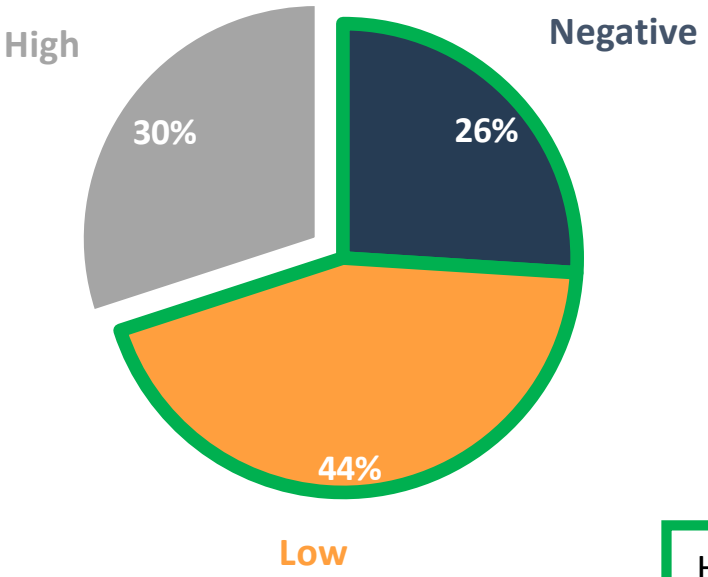
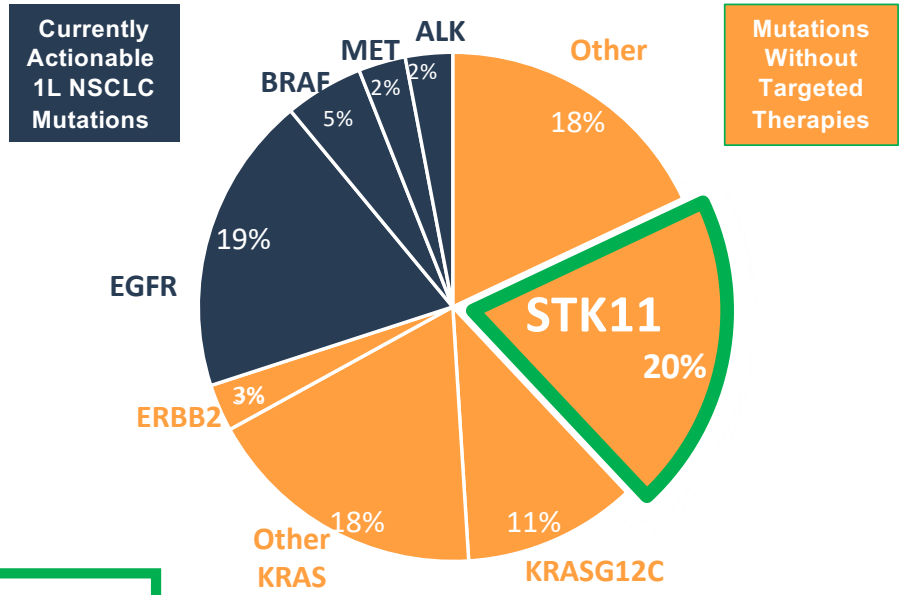
Sources: GLOBOCAN 2020, cancerresearchfoundation.org

NSCLC therapy is today guided by molecular markers

1. PDL1 levels predicts response to Immunotherapy



2. Mutational status predicts response to Targeted Therapies



Highest unmet needs

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Source: Holmes, 2019, JTO; TPS Scores Neg = <1; Low 1-49; High >50

Sources: Oncogenic driver mutations in non-small cell lung cancer: Past, present and future, World J Clin Oncol. 2021 Apr 24; 12(4): 217–237Prognostic Impact of KRAS Mutation Subtypes in Metastatic Lung Adenocarcinoma, J.Thor.Onc. 2015; 10(3):431-437

1L STK11m NSCLC patients have uniquely high unmet medical needs

A vast amount of data indicate poor prognosis in STK11m NSCLC

	Real World Data n = 707 Outcomes w/ 1L CPI + chemo		
	STK11m	STK11wt	P value*
ORR	25.1%	40.5%	<0.001
PFS, mos	3.9	6.3	<0.001
OS, mos	10.4	15.2	0.004

…and many factors support potential for bemcentinib in this population

- No targeted therapies available today or in development
- STK11m pts "universally"* express AXL
- AXL inhibition improves response to checkpoint inhibition in preclinical models
- Early indications of clinical benefit of AXL inhibition in STK11m NSCLC

Alessi et al, Clinicopathologic & Genomic Factors Impacting Efficacy of First Line Chemoimmunotherapy in Advanced NSCLC, Journal of Thoracic Oncology, 2/9/23

*Based on BGB data indicating at least 88% of patients express AXL in their tumors or on immune cells

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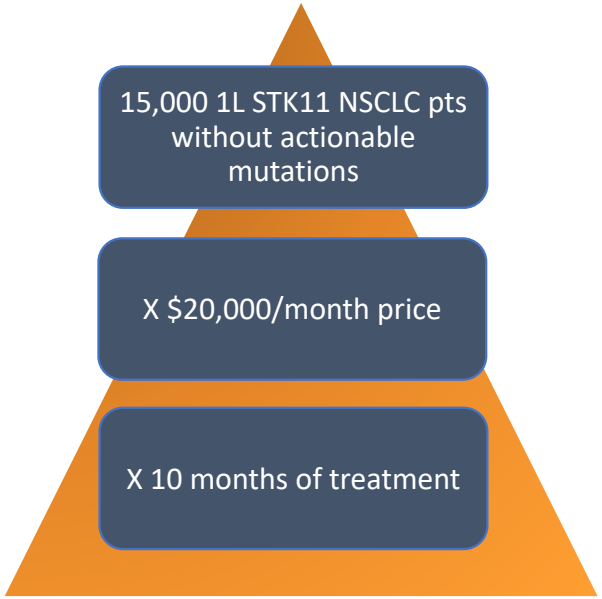
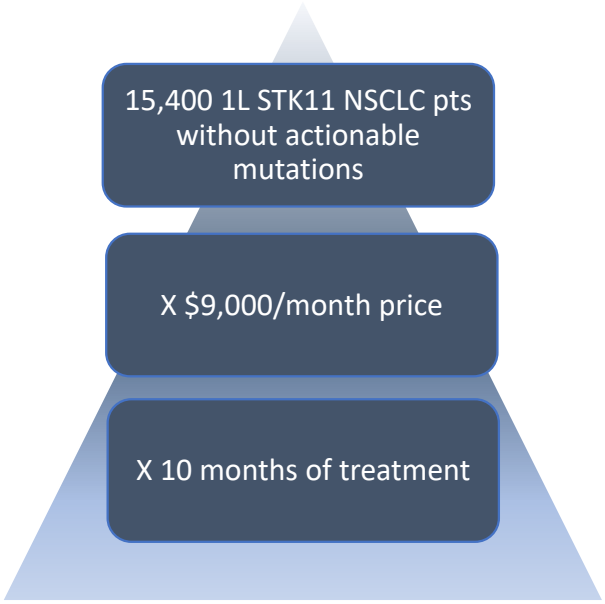
Translating into a significant potential for an effective 1L STK11m NSCLC treatment

2023 US Market Potential



= $2.9B USD/yr

2023 Market Potential in EU5



= $1.4B USD/yr.

Total market potential in major 5 territories $4.3B USD/year

Key assumptions: Patient population based on GlobalData 2023,;STK11m have a low ~4% rate of 1L actionable mutations; pricing estimates based on recent launch pricing in relevant territory; months of treatment based on real world data for wild type STK11 patients with 1L immunotherapy + doublet chemotherapy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Bemcentinib
Potential to address a significant
market need in 1L STK11m NSCLC

Bemcentinib: Differentiated AXL tyrosine kinase inhibitor

- High selectivity: precedent setting
- Improved potency: few off-target adverse events
- Concentrates in lung (40x) ; crosses BBB – brain mets common in NSCLC
- Monotherapy activity seen in multiple indications
- Proven combinations: chemotherapy, targeted therapies and CPI*
- Fast Track Designation (FDA) in STK11m NSCLC
- Extensive IP through 2042

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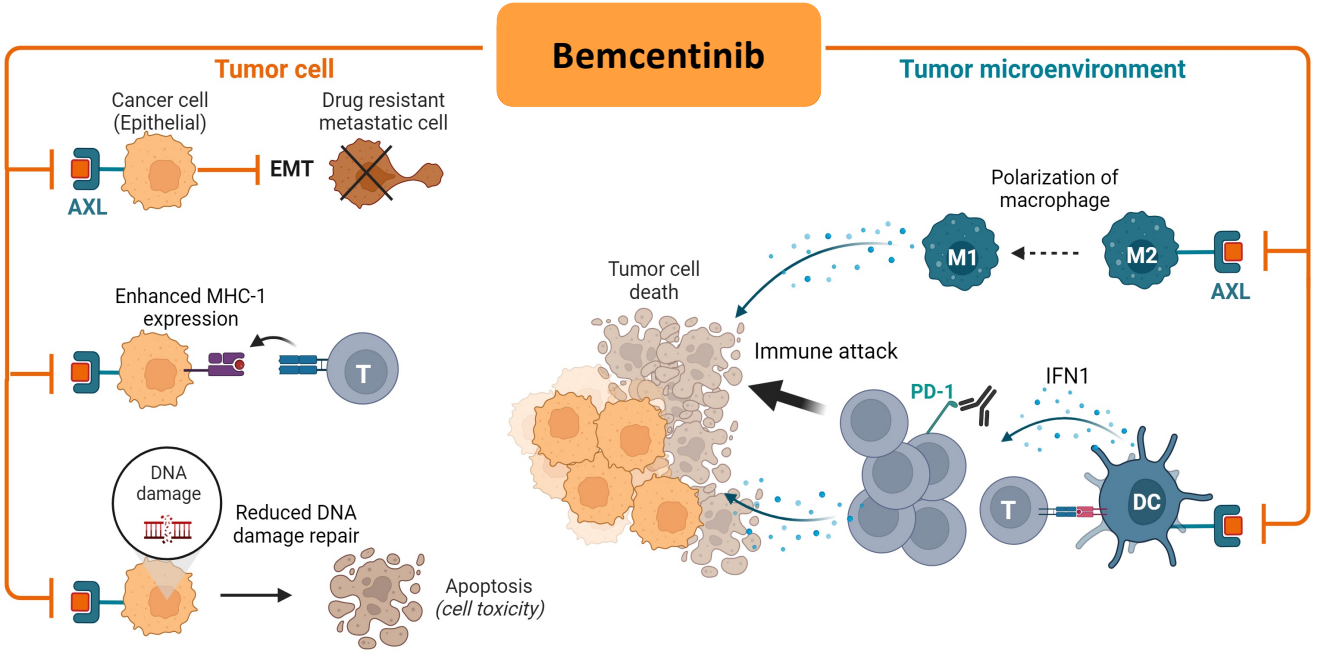
*Checkpoint inhibitors

AXL inhibition with bemcentinib sensitizes both the tumor and immune environment

Reduces immune evasion, drug resistance

Enhances antigen presentation

Reduces DNA damage and cell death



Reactivates innate immunity

Unique dual role of AXL inhibition expected to delay chemoresistance and improve checkpoint response in 1L NSCLC

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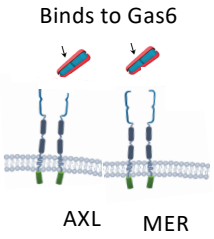
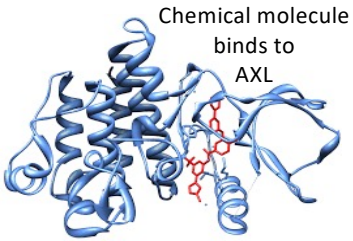
Bemcentinib: leading *selective* AXL inhibitor

AXL selectivity has been difficult for others to achieve

Approach	AXL ADC's	"Naked" AXL mAbs	Gas6 Inhibitors	AXL Inhibitors
Mechanism of action				
AXL Inhibition	None (delivery vehicle only)	**Selective**	Non-Selective	**Selective (bemcentinib)** Non-Selective (competitors)
Companies	ADCT (BGB mAb) BioAtla	BGB (tilvestamab) Servier (discovery)	Aravive (Ph3 failure)	6 ***Non-selective*** compounds in Ph1 for NSCLC

Bemcentinib: only AXL inhibitor in clinical development for 1L STK11 NSCLC

Candidate/Company/Target	Current Phase*	Specific to 1L?	Specific to STK11m pts?	Comments
BGB/bemcentinib/AXL	**Ph 1b/2a**	✓	✓	**Entire STK11m population**
AZ/anti-PD1/CTLA4	Ph 3b	✓	✓	Also KEAP-1, KRASm
Mirati/adagrasib/KRASG12C	Ph 2	✓	No	KRASG12C+STK11m
Amgen/sotorasib/KRASG12C	Ph2	✓	No	KRASG12C+STK11m
Novartis/JDQ443/KRASG12C	Ph2	✓	No	KRASG12C+STK11m
JacoBio/KRASG12C	Ph 1/2	2L	No	KRASG12C+STK11m
Regeneron/anti-IL6R + PD1	Ph 1b	1L – 4L	✓	STK11m or EGFRm
Tango/coREST inhibitor + PD1	Ph 1/2	2L	✓	STK11m

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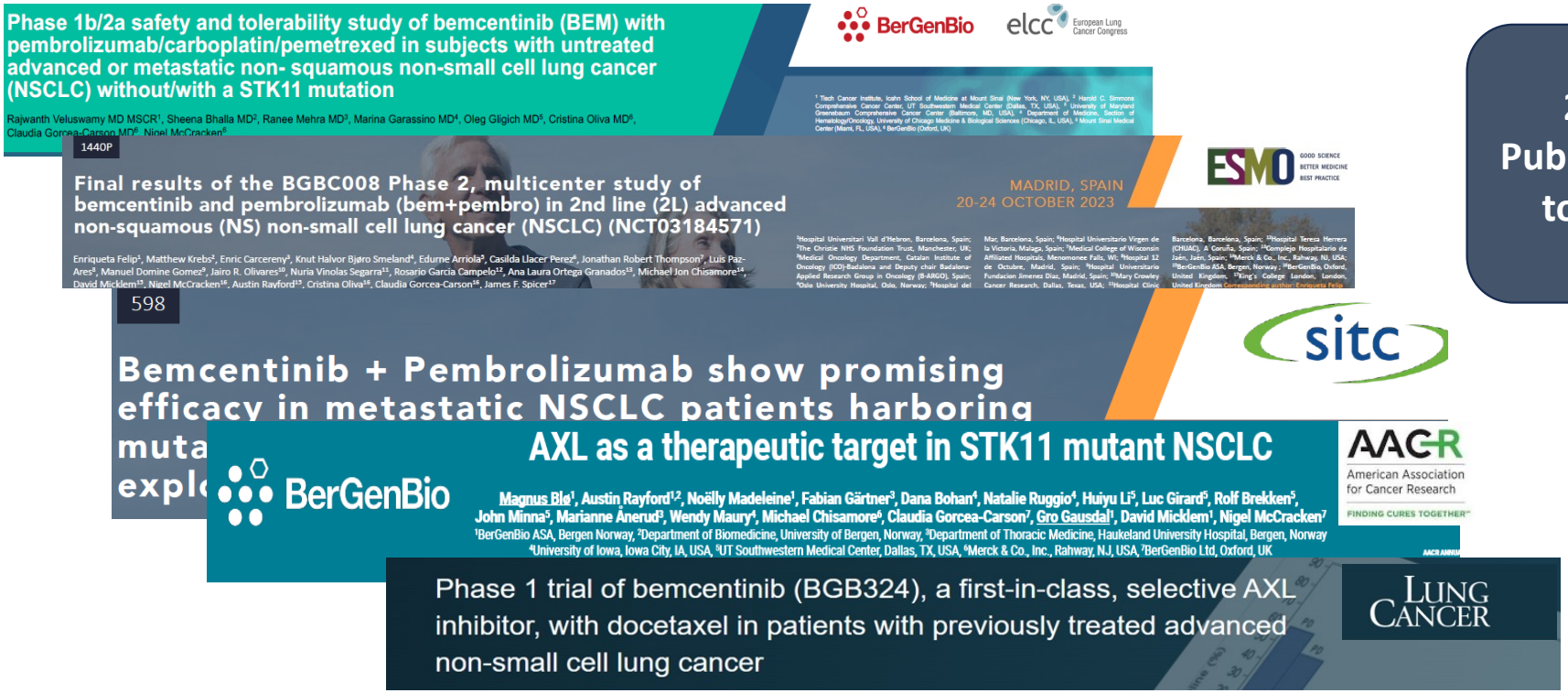
Sources: clinicaltrials.gov, EU clinical trials register, company websites
Note: does not include Investigator Sponsored Trials

Awareness of STK11m importance and bemcentinib activity in cancer is growing



2023 Publications to Date

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Strong clinical data foundation

Clinical validation of AXL inhibition

Extensive data substantiates 1L NSCLC strategy

Two phase 2 trials in 2L NSCLC >100 patients

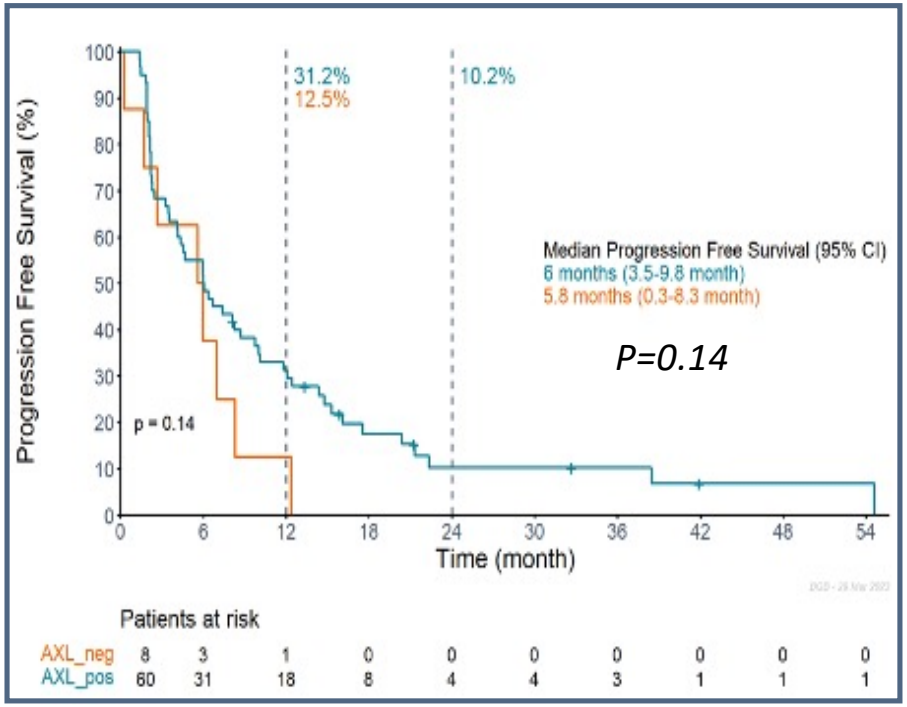
- Meaningful PFS and OS benefit from Bem + Pembro:
- AXL expressing pts live longer (bem + Pembro)
- Clinical benefit even in negative and low PD-L1 patients (bem + Pembro)
- Early evidence of potential benefit in patients with hard-to-treat mutations
- Meaningful PFS and OS benefit from Bem + docetaxel

Compelling rationale for 1L NSCLC STK11m

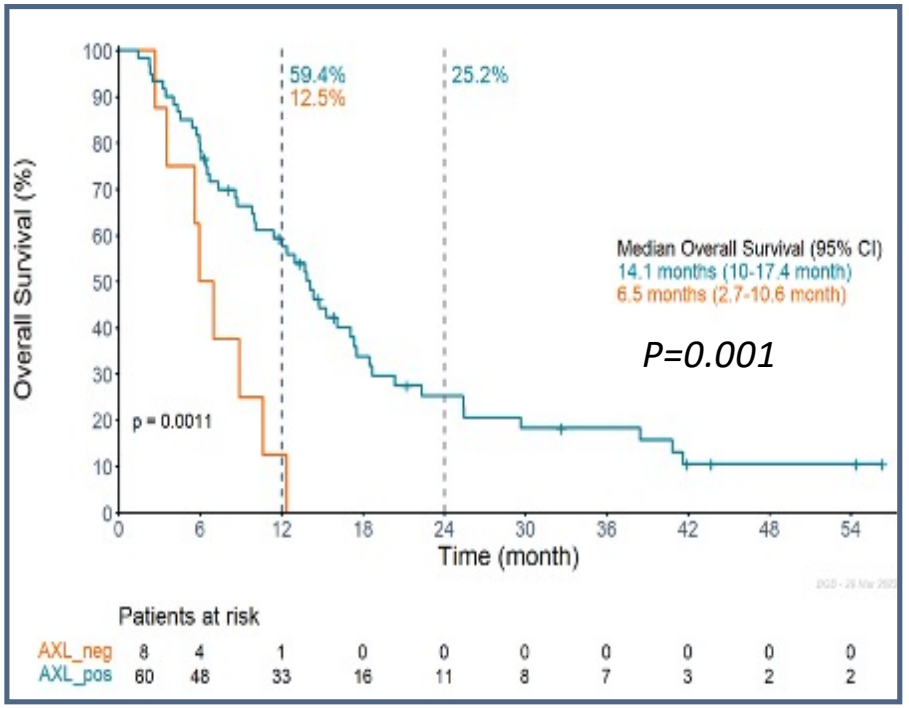
- Potential to provide significant benefits before patients develop chemo-I/O resistance
- Early evidence of similar outcomes in mutated and wild-type patients

Most patients (88%) are AXL+ and live significantly longer, with statistical significance

Median progression free survival



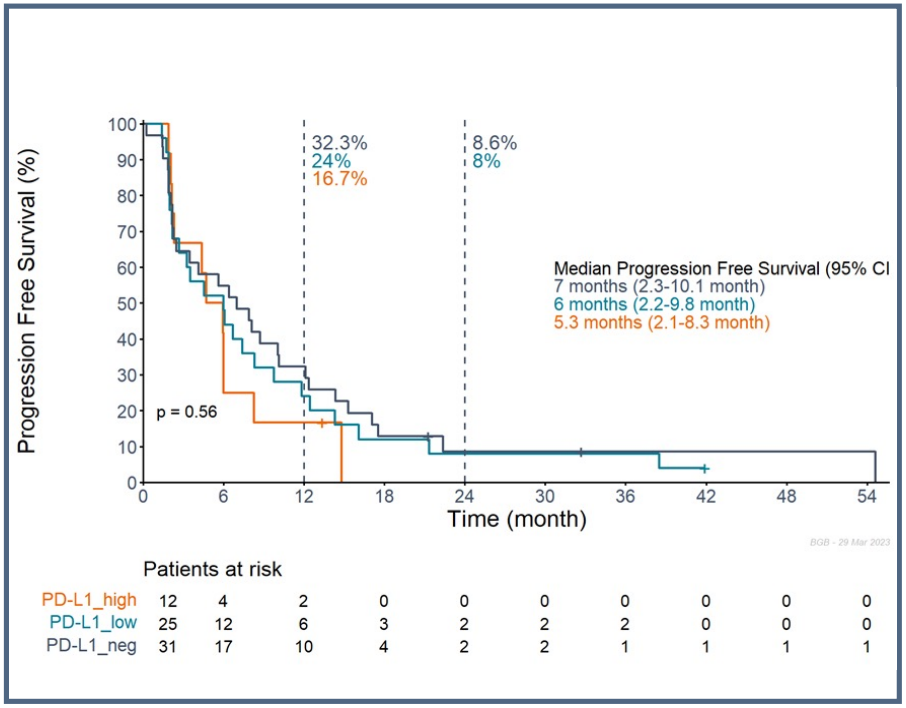
Median overall survival



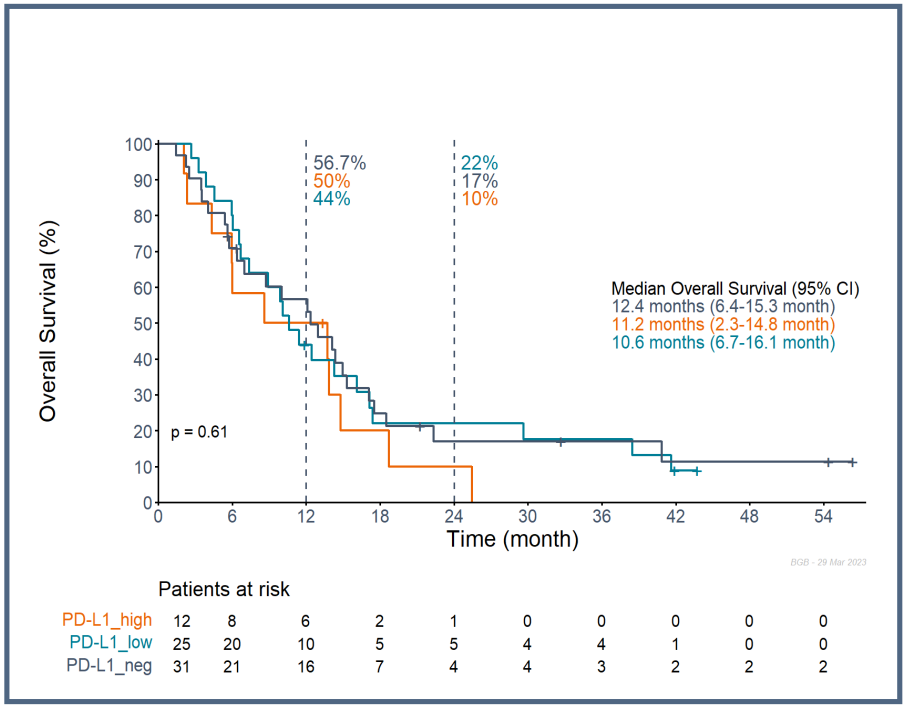
*AXL positive in tumor cells (H=>5) /or immune cells (H>1) vs. pts with no or lower AXL levels

Benefit even in neg/low PD-L1 pts who typically respond less well to CPI

Median progression free survival



Median overall survival



PD-L1 negative <1%;PDL1 low = 1-50%; PD-L1 high >50%

BGBC008 (2L+ NSCLC) bemcentinib + pembrolizumab

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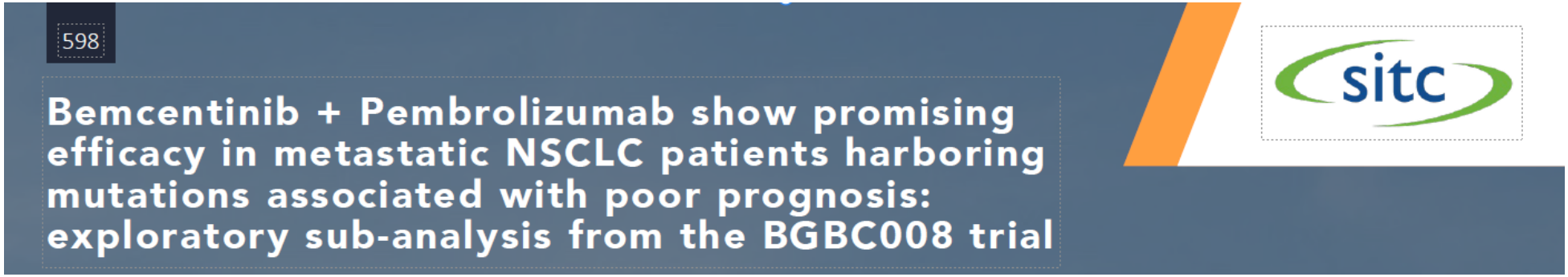
Recent SITC poster illustrates activity in difficult-to-treat mutations



Poster analyzed:

- BGBC008 results in 2L NSCLC vs.
- 2L NSCLC outcomes from Memorial Sloan Kettering MIND real-world database

Poster conclusions:

- Bemcentinib + pembrolizumab appears to eliminate liability of known poor responses to:
  - STK11m, KEAP1m, low/negative PD-L1 levels
- ~ Equal survival benefits vs. patients without these poor prognostic characteristics

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Recent ESMO cross-study data supports favorable BGBC008 survival vs. existing 2L NSCLC therapies

	BGBC008		2L Comparators	
	All Comers	AXL Positive*	KEYNOTE 189	SAPPHIRE
	Bemcentinib + Pembrolizumab	***Bemcentinib + Pembrolizumab***	***Pembrolizumab Monotherapy***	***Docetaxel following CIT***
ORR	**11.1%**	**16.4%**	**18%**	**17%**
mPFS, mos	**6.2**	**6.1**	**2.8**	**5.4**
mOS, mos	**13.0**	**14.1**	**6.9**	**10.6**

SAPPHIRE STUDY: New, highly relevant comparative data

- Prior to this, a lack of published data on 2L docetaxel (current SOC) after 1L I/O + chemo
- Docetaxel control arm after 1L I/O + chemo provides contemporary comparison supporting improved survival of bemcentinib + pembro vs. SOC

*AXL Positive = AXL H-score >5 in tumor &/or >1 in immune cells;
SOC= standard of care

Bem + pembro safety comparable to pembro alone in 2L NSCLC

	Bemcentinib 400mg Loading + 200mg fixed + pembrolizumab BGBC008	Pembrolizumab Monotherapy KEYNOTE-010
Population	2L NSCLC	2L NSCLC
Top TRAEs , all grades		
AST increase	22%	26%
ALT increase	21%	22%
Diarrhea	21%	9%
Blood creatinine increased	15%	NR
Asthenia	14%	7%
Fatigue	12%	16%
Nausea	8%	12%
Amylase increased	8%	NR
Anemia	8%	4%
Pruritis	8%	NR
Decreased appetite	8%	13%

Safety profile of combination comparable to pembro alone

- No new safety signals
- Majority of AEs grades 1-2
- Bemcentinib studied w/ 400mg loading followed by 200mg/qd
- Future studies: no loading dose + 100-150mg/qd with food

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NR= Not Reported (only AE's ≥10% reported, Source: Keytruda USPI April 2023; KEYNOTE-010 cross-over monotherapy in 2L NSCLC)

On-going global 1L STK11m NSCLC Ph1b/2a

Open label study of bemcentinib + SoC (pembrolizumab + doublet chemo)

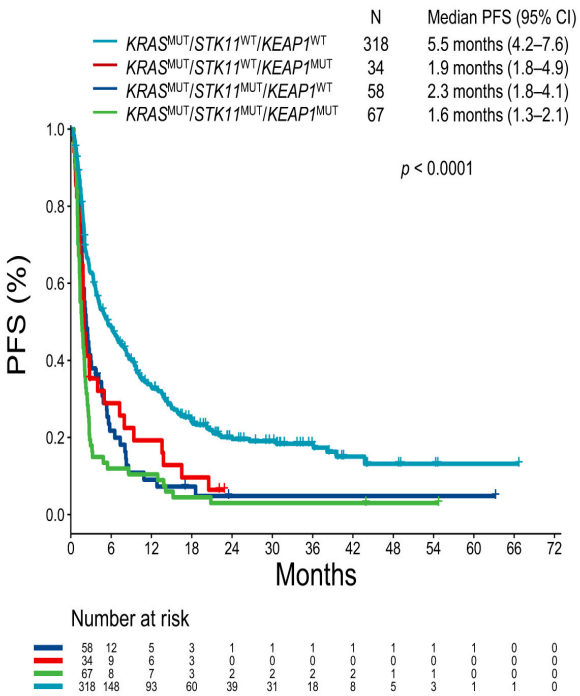
Phase 1b Safety & Feasibility (US) 3+3 design **Dose escalation (75, 100 & 150 mg)** **N=9-30**	**Phase 2a (US & EU)** **Expansion of 2 dose(s) in STK11m pts** **N=40+**
1L Advanced/ Metastatic **Non-Squamous NSCLC pts** Newly diagnosed, Any PDL1 status, no actionable mutations STK11 or AXL status not required All comers to accelerate enrollment	**40 pts. 1L Advanced/ Metastatic** **Non-Squamous STK11m NSCLC pts** 40 pts in Prospective Synthetic Control Arm: Pembro + Chemo (Same Characteristics/Mutational Status ~~based on Liquid Biopsy~~)

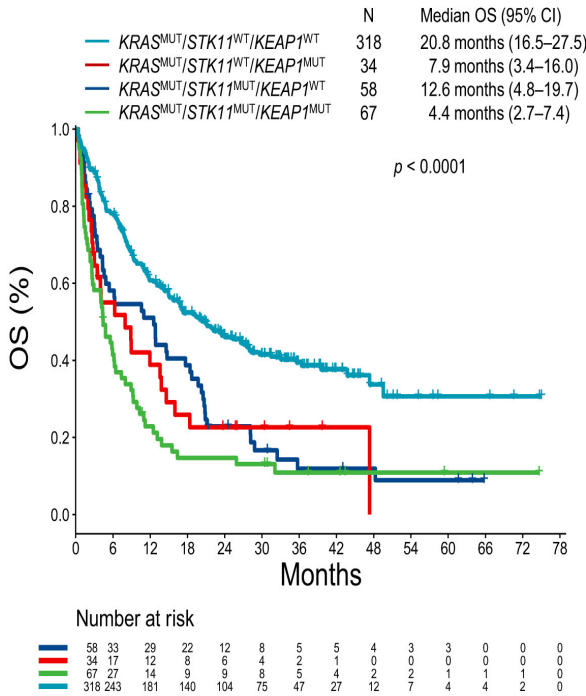
- US sites activated ; new European sites identified and coming on-line for Ph2a
- Ph 2a expansion in STK11m pts may start while last dose cohort is on-going in Ph1b
  - Primary endpoint – efficacy ; safety secondary
- Expected biomarker: STK11m (on major liquid biopsy panels); AXL will be measured but may not be required as prospective biomarker given almost universal expression in STK11m pts

Trial consideration: real-world data indicates importance of STK11 co-mutational status

Recent real-world data on 1L NSCLC I/O + chemo outcomes indicates:

- Worse survival for overall STK11m population vs. STK11wt pts
- However, patients with STK11m and co-mutations with 1 or more of KEAP-1, KRAS have even worse outcomes
- **These differential outcomes require use of a study control that takes these differences into account**





References: J Thorac Oncol. 2023 June ; JTO, March 2022

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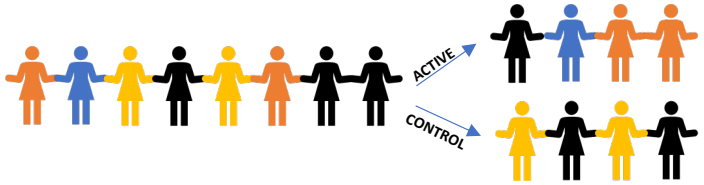
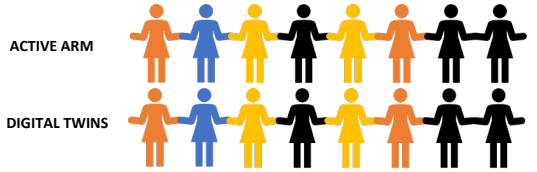
Benefits of a synthetic control arm in BGBC016





Traditional Control Arms

What: patients randomized at study entry to receive either active drug + SOC vs. placebo vs. SOC

Considerations for BGBC016:

- The regimen for bem + SOC vs SOC has to be established before conducting a randomized study
- Balancing arms for STK11m co-mutational would require more time, patients, costs

Synthetic Control Arm

What: state-of-the-art outcomes database matches patients with same mutational/disease status profiles, creating **"digital twins"** for comparison

Benefits for BGBC016:

- Improved validation of activity in active arm and positioning for pivotal trial

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Bemcentinib: a unique opportunity in 1L NSCLC STK11m

High unmet medical need

- Common non-actionable mutation (> 30,000 patients in US and EU5); poor prognosis representing a significant commercial opportunity
- No available targeted therapies; limitations of SOC

High incidence of AXL expression which can be targeted by bemcentinib

- A highly immunosuppressed and "toxic" tumor microenvironment
  - AXL expressed ~88% of patients
- AXL inhibition shown to delay chemo resistance and reactivate the anti-tumor immune response
- Strong proprietary position in STK11^{mut} NSCLC

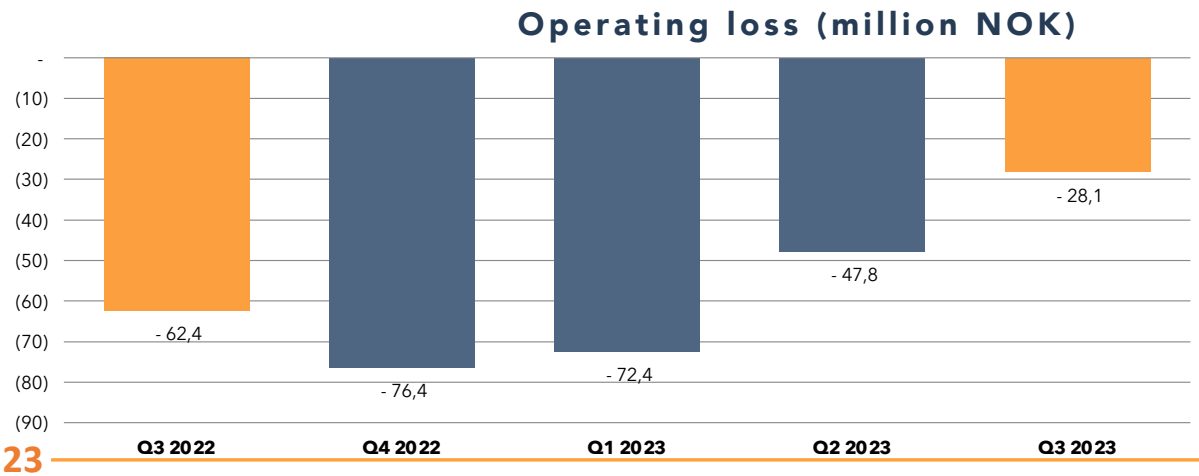
Confidence in 1L NSCLC benefit based on data in ~100 2L NSCLC

News flow expected in 2023/2024

Core Clinical Strategy	H1 2023	H2 2023 / H1 2024
1L STK11m NSCLC	✓ FPFV and additional sites activated for Ph1b/2a ✓ STK11 loss data presented at AACR ✓ Promising biomarker data from 2L study supports potential expansion of 1L NSCLC patient populations	• Ph1b data and selection of Ph2a doses • Initiation of Ph2a ✓ Additional MoA data from BGBC008 at SITC ✓ Final results from BGBC008 at ESMO 2023 • Data presentations at major oncology conferences (AACR, others)
Other News Flow	**H1 2023**	**H2 2023 / H1 2024**
	✓ Positive AML/MDS data (BGBC003) reported ✓ Data in mesothelioma presented at ASCO – primary end-point met ✓ Manuscript published by MD Anderson collaborator re: bem + docetaxel in 2L NSCLC ✓ (Bhalla et al. Lung Cancer 2023)	• BGBC003 final data to be presented at ASH 2023 • Clinical trial manuscript publications in major journals; presentations at oncology meetings (ASH, others)

Key financials Q3 2023

(NOK million)	Q3 2023	Q3 2022	YTD 2023	YTD 2022	FY 2022
Operating revenues	0,0	0,0	0,0	0,0	0,4
Operating expenses	28,1	62,4	148,3	229,2	306,0
Operating profit (-loss)	-28,1	-62,4	-148,3	-229,2	-305,6
Profit (-loss) after tax	-27,9	-59,8	-148,8	-224,9	-302,1
Basic and diluted earnings (loss) per share (NOK)	-0.01	-0.67	-0.15	-2.54	-3.41
Net cash flow in the period	-55,4	-65,1	14,7	-206,9	-282,1
Cash position end of period	169,3	225,1	169,3	225,1	150,8



Focused strategy, and cost savings initiatives has reduced burn

- Operational loss in Q3 2023: 28.1 mNOK/2.7 mUSD
- Average operational loss Q3 2022 to Q3 2023: 57.4 mNOK/5.6 mUSD

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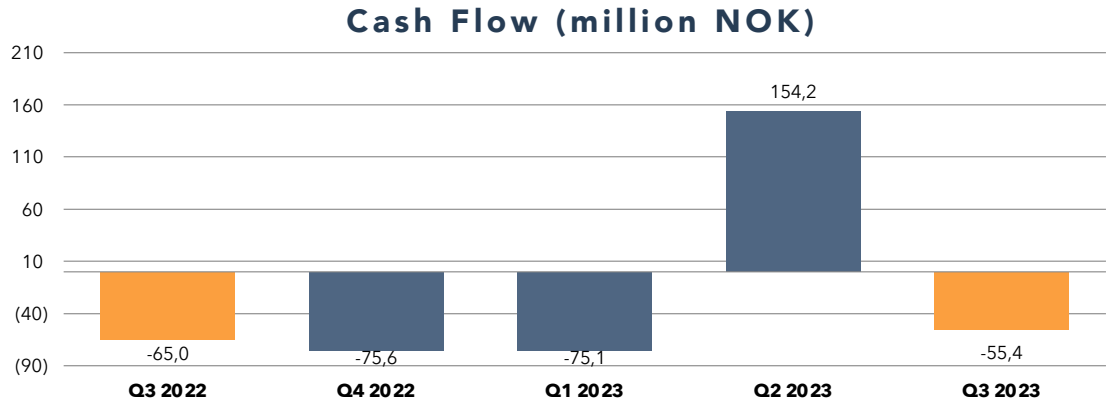
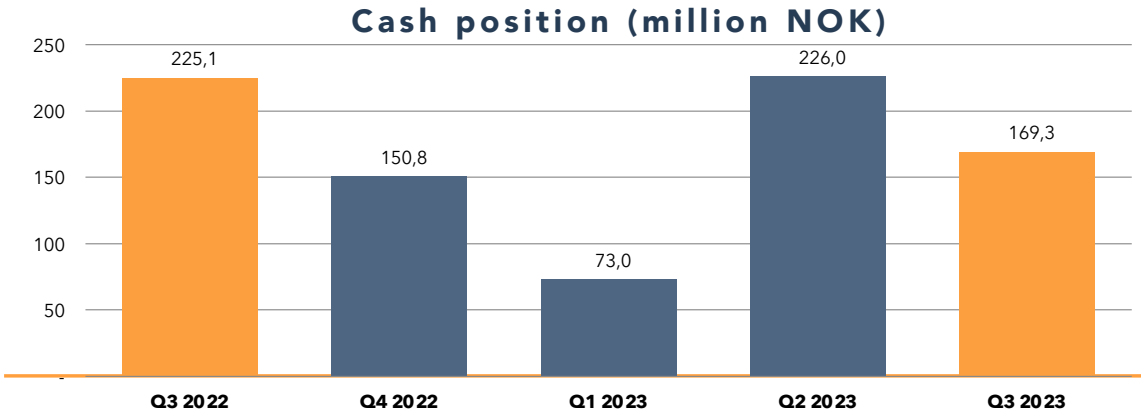
Key financials Q3 2023





Net cash flow Q3 2023
- 55.4 / - 5.3
NOK million / USD million

Quarterly average operating cash burn (Q3 2022 – Q3 2023)
- 67.5 /- 6.5
NOK million / USD million

Cash position Q3 2023
169.3 / 15.9
NOK million / USD million

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Warrants – opening of exercise window

Warrants issued to subscribers in the June 2023 Rights Issue are listed on Oslo Stock Exchange (ticker: BGBIS)

- The first exercise period for the Warrants opens on 15 November 9am CET and closes on 28 November 2023 4:30pm CET
- The exercise price in this window for the Warrants is the VWAP calculated on the share price 10 – 14 November 2023 less 30% (however with a minimum price of NOK 0.10 and a maximum price of NOK 0.13)
- The exercise price for the Warrants in this window will be announced before the exercise period opens 15 November.

Timeline for the first exercise period

- Exercise period: 15 – 28 November 2023 (both days included)
- Allocation: 30 November 2023
- Settlement: 5 December 2023
- Delivery of shares: On or about 7 December 2023

The Warrants needs to be on the investors VPS account 28 November 2023 to be allocated new shares.

Warrants – how to exercise

Alternative procedures on how to exercise the Warrants:

1. Subscribers who are Norwegian residents with a Norwegian personal identification are encouraged to exercise the Warrants through the VPS online subscription system. This can be found by following the link on www.carnegie.no/ongoing-prospectuses-and-offerings/ or www.arctic.com/secno/en/offerings, which will redirect the subscriber to the VPS online subscription system. Information will also be available on the Company's website from 15 November.

2. Complete and return an exercise form before the end of an exercise period. The exercise form will be made available on the Company's and the managers (Arctic or Carnegie) websites on the first day of the first exercise period.

For additional information: https://www.bergenbio.com/investors/investor-relations/warrants

Strategy to unlock value potential

- Focused approach in NSCLC
  - Singular focus: development of bemcentinib in 1L NSCLC STK11m
  - Strong IP and differentiated clinical approach in 1L NSCLC STK11m
- Ph1b data readout and initiation of Ph2a in H1 2024
- Cash position Q3 2023 of NOK 169M / USD 16M
  - Significantly reduced burn; runway towards the end of 2024
  - Warrant element may extend runway into H2 2025

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