calliditas
THERAPEUTICS

Q3 2021 REPORT

November 18, 2021

Disclaimers

Important information

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding the regulatory pathway for Nefecon, plans for submissions for marketing approvals, plans and strategies for commercialization of Nefecon, if approved, the conduct of Part B of the NefIgArd clinical trial, Calliditas' strategy, business plans and focus. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this presentation are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this presentation, including, without limitation, any related to the potential for and timing of FDA approval of its regulatory marketing application for Nefecon, the potential for FDA's review extension on the NDA for Nefecon to lead to marketing approval, the continuation of Part B of the NefIgArd study, Calliditas' business, operations, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, and other risks identified in the section entitled "Risk Factors" in Calliditas' reports and other filings with the Securities and Exchange Commission. Calliditas cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Calliditas disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this presentation represent Calliditas' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

Q3 Highlights – Strengthening our Cash Position

Resolved on a directed share issue in the amount of 2.4 million shares, raising proceeds of approximately SEK 324 million

Signed a loan agreement of up to the Euro equivalent of $75 million with Kreos Capital. The loan facility is divided into three tranches of $25 million each.

- Drawdown of the first $25 million tranche can be made until 31 December 2021 and will be available after the satisfaction of customary closing conditions.
- Drawdown of the second tranche of $25 million can be made until 30 June 2022 and will be available subject to accelerated approval of Nefecon by the FDA.
- Drawdown of the third and final $25 million tranche can be made until 31 December 2022 and will be available subject to certain revenue milestones and coverage metrics.

Q3 Highlights – Regulatory Review Update

European Medicines Agency (EMA) decided to continue the assessment of the marketing authorization application (MAA) for Nefecon under standard procedure timelines.

- Targeted EMA opinion date Q1, 2022

The U.S Food and Drug Administration (FDA) extended the PDUFA goal date of the ongoing accelerated approval review of Nefecon to December 15th.

- Additional analyses requested categorized as Major Data Amendment

EU Partnership

- **Calliditas and STADA Arzneimittel Deal covering European Economic Area (EEA) member states, Switzerland and the UK**
- **Valued at a total of 97.5 million EUR ($115m), plus royalties**
  - Calliditas received an initial upfront payment of 20M EUR ($24m) upon signing
  - Calliditas will receive up to an additional 77.5M EUR ($91m) in future payments linked to pre-defined regulatory and commercialization milestones
  - STADA is also to pay tiered royalties on net sales in the form of a percentage between the low twenties and the low thirties

Anticipated milestones

Anticipated milestones regarding Calliditas' clinical, regulatory and commercial plans

1H 2021

- Complete recruitment of NefIgArd (Q1) ☑
- Outcome of Phase 1 high dose PK study of setanaxib (Q1) ☑
- Clinical development plan for NOX inhibitors (Q1) ☑
- Submission of regulatory filing with FDA for approval of IgA Nephropathy (Q1) ☑
- Submission of filing with EMA for approval of IgAN (Q2) ☑

2H 2021

- European commercial partnership (Q3) ☑
- FDA target PDUFA date for Nefecon in IgAN (Q4)
- Initiate pivotal Phase 2/3 TRANSFORM trial in PBC (Q4)

2022

- Initiate proof-of-concept Phase 2 trial in head and neck cancer (Q1)
- Commercial launch of Nefecon for IgAN in the US, subject to approval (Q1)
- Target date EMA opinion for conditional approval for Nefecon (Q1)
- Commercial launch of Nefecon in Europe, subject to approval (Q2/Q3)
- Interim analysis in proof-of-concept head and neck cancer trial (Q4)
- Launch additional clinical trial

2023

- Futility analysis of TRANSFORM trial in PBC
- Final readout of head and neck cancer trial
- Final readout of NefIgArd study Part B
- Filing for full approval in IgAN

Pipeline

Clinical Candidate	Indication / Trial	Research/ Preclinical	Phase 1	Phase 2	Phase 3	Phase 4 / Marketed[1]
Nefecon	IgAN/ NefIgArd					
Setanaxib	PBC					
Setanaxib	Oncology					
	Kidney					
Nefecon	IgAN Open Label Extension[1]					

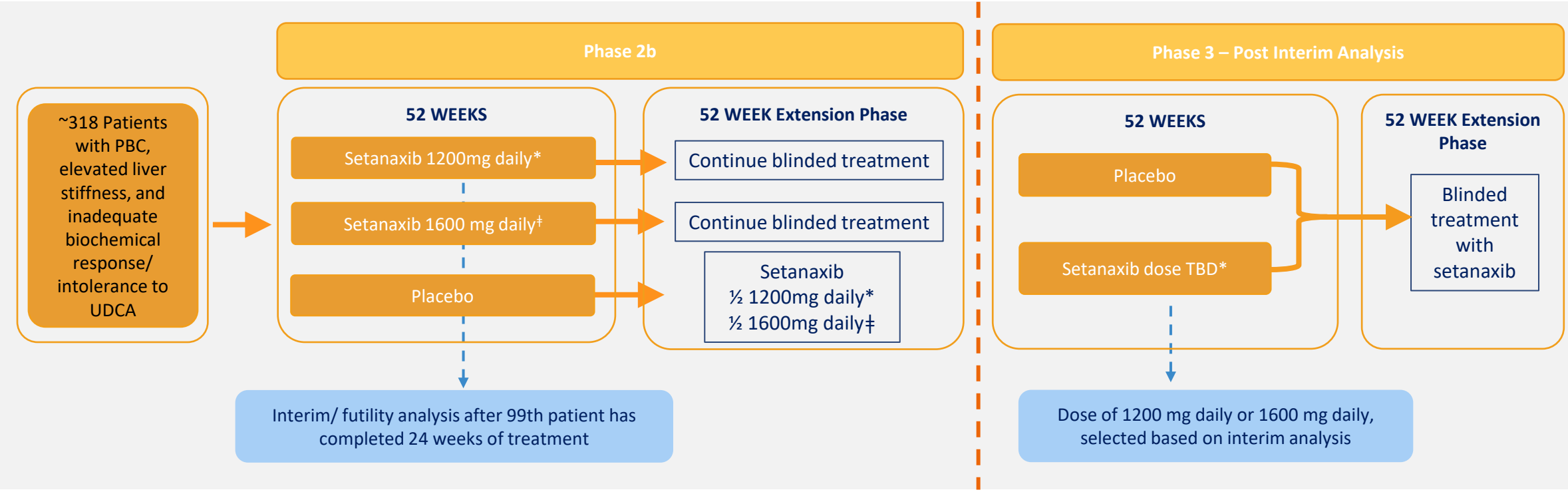
Depicts ongoing/planned clinical trial stage:

1. Clinical study primarily supporting healtheconomic and / or treatment related considerations

Setanaxib is also being evaluated in investigator led studies in IPF and DKD.

Setanaxib Phase 2b/ 3 Trial (TRANSFORM)

- Double-blind, randomized, placebo-controlled, adaptive study
  - Primary endpoint is: ALP <1.67x ULN, ***and*** ALP reduction >15%, ***and*** total bilirubin <ULN



- On-track to start in Q4 2021, with the futility analysis targeted for 2H 2023 and the final data readout expected late 2024/early 2025

- Calliditas received FDA fast track designation for setanaxib in PBC in August 2021

*Dose of 1200 mg daily administered as 800 mg AM and 400 mg PM
‡Dose of 1600 mg daily administered as 800 mg AM and 800 mg PM

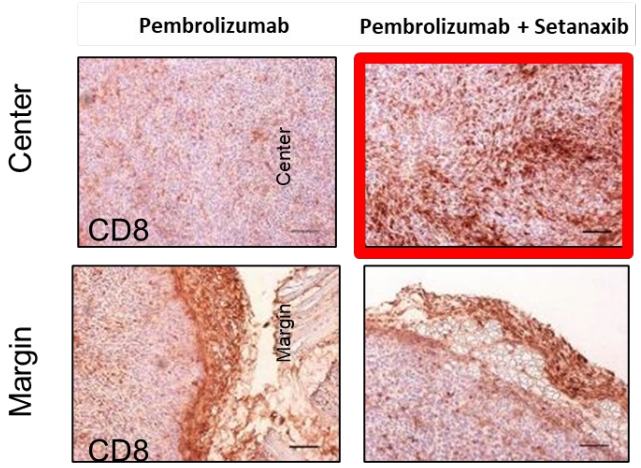
Objectives and Endpoints

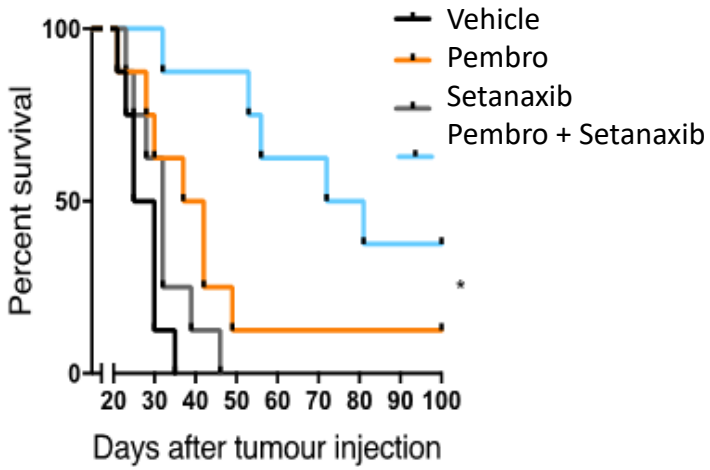
Primary Objective	Primary Endpoint
To evaluate the effect of setanaxib on **biochemical response at Week 52** in adult patients with PBC and with elevated liver stiffness and intolerance or inadequate response to UDCA	Proportion of patients achieving a biochemical response at Week 52, defined as: ○ ALP reduction to <1.67×ULN, and ○ ALP reduction ≥15% from Baseline, and ○ Total bilirubin ≤1×ULN
Secondary Objectives	**Secondary Endpoints**
To evaluate the effect of setanaxib on **liver stiffness** at Week 52	Change in liver stiffness at Week 52 compared to Baseline, as assessed by transient elastography (FibroScan®)
To evaluate the effect of setanaxib on **fatigue** at Week 52	Change in fatigue at Week 52 compared to Baseline, as assessed by relevant PROs
To evaluate the effect of setanaxib on **pruritus** at Week 52	Change in pruritis at Week 52 compared to Baseline, as assessed by relevant PROs
To evaluate the **safety and tolerability** of setanaxib over a 52-week treatment period	Adverse events, Laboratory tests, Vital signs 12-lead ECG

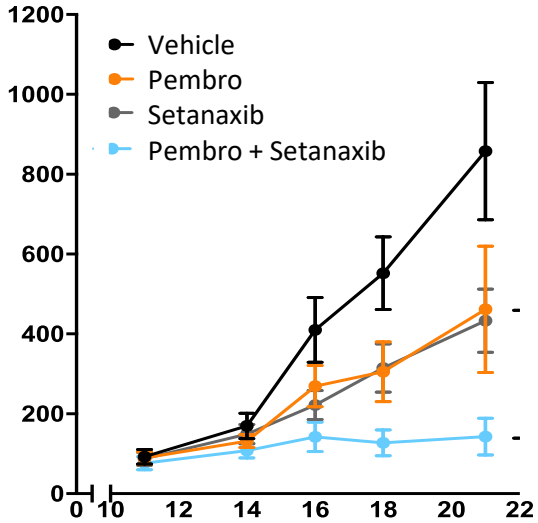
Head and Neck Cancer

- A relationship between Cancer-associated fibroblast (CAFs) and prognosis in Squamous Cell Carcinoma of the Head & Neck (SCCHN) has been established
  - There is increasing use of pembrolizumab as 1st line monotherapy in patients with relapsed or metastatic SCCHN, although response rates are low (ORR approx. 20%)

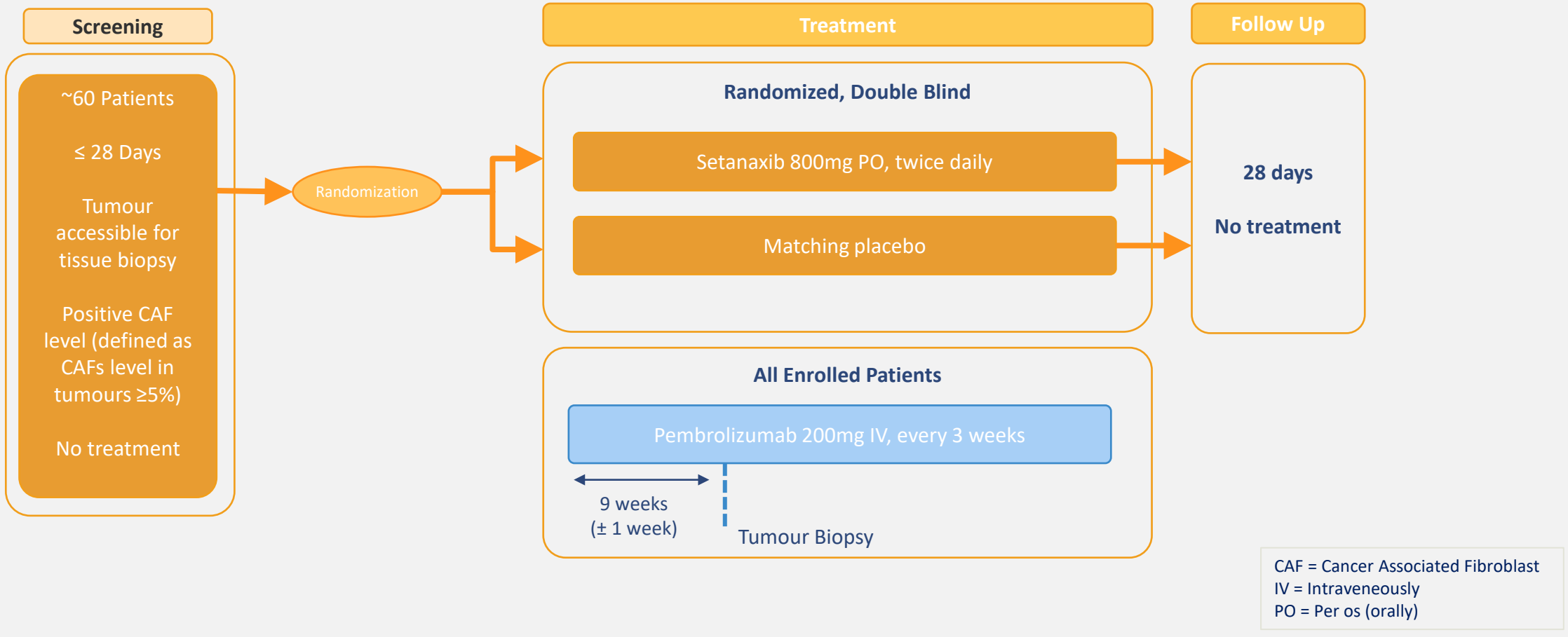
- Using a CAF-rich tumour model in mice, administration of setanaxib + pembrolizumab (versus either treatment alone) resulted in:
  - Improved penetration of tumour-infiltrating lymphocytes (TILs) into the centre of the tumour
  - Slowing of tumour growth
  - Improved survival







Proof of Concept Trial Design



- The study is targeted to start in Q1 2022, with interim biomarker analysis expected in Q4 2022
- Final readout (including PFS) is expected in 2H 2023

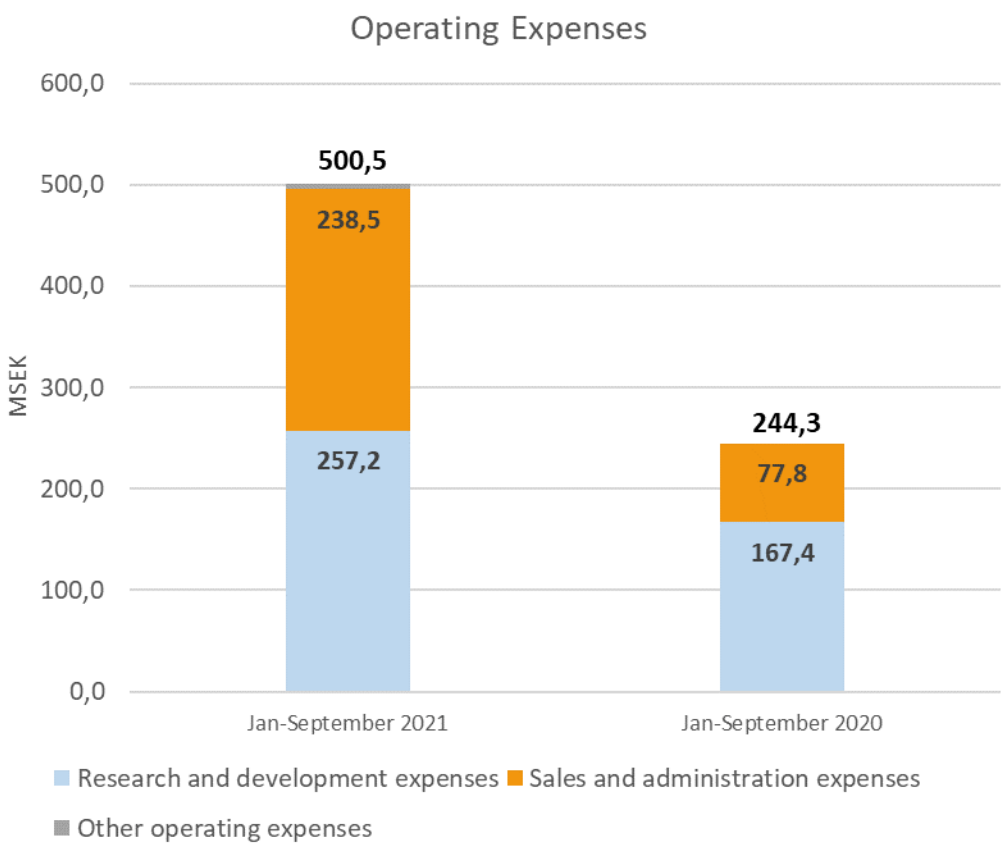
Primary Objective and Endpoint

Primary Objective	Primary Endpoint
To compare the ***change in tumour size per Response Evaluation Criteria in Solid Tumours Version 1.1 (RECIST v1.1)*** in recurrent or metastatic SCCHN patients treated with setanaxib and pembrolizumab versus patients treated with placebo and pembrolizumab	Best percentage change in tumour size, defined as the best percentage change from Baseline in the sum of diameters of target lesions, as assessed by RECIST v1.1

Key Secondary Objectives

- Clinical measures of response and treatment outcome
  - overall response rates (ORR), durability of response (DoR), PFS per RECIST v1.1 and overall survival
- Biological measures of tumour tissue response
  - Change from Baseline in CAFs level in tumour tissue, Change from Baseline in CD8+ TILs numbers in tumour tissue, Change from Baseline in patterns of gene expression and differential gene expression in tumour tissue using RNA sequencing
- Safety and tolerability

Financial overview – first nine months 2021



- Revenues of SEK 198.2 M reported originating from the EUR 20 M upfront fee from the Stada outlicensing vs SEK 0.4 M for the same period last year.
- Operating loss of SEK 302.3 M vs SEK 243.8 M
  - Research and development expenses increased to SEK 257.2 M vs SEK 167.4 M, representing 51% of total operating expenses. Increase due to higher activity in the NeflgArd studies and preparations for the upcoming setanaxib trials.
  - Administration and selling expenses increased to SEK 238.5 M vs SEK 77.8 M, mainly due to intensified preparations for commercial and medical affairs activities in the US and cost for administration.
- Cash flow used in operating activities was SEK 300.3 M vs SEK 189.1 M.
- Cash flow from financing activities was 476.5 M vs 847.9 M
- The cash position per end of September 2021 was SEK 1,163.8 M vs SEK 1,396.9 M.