calliditas
THERAPEUTICS

Q4 2020 Report

February 18, 2021

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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 regulatory submissions for Nefecon, 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..

Company Overview

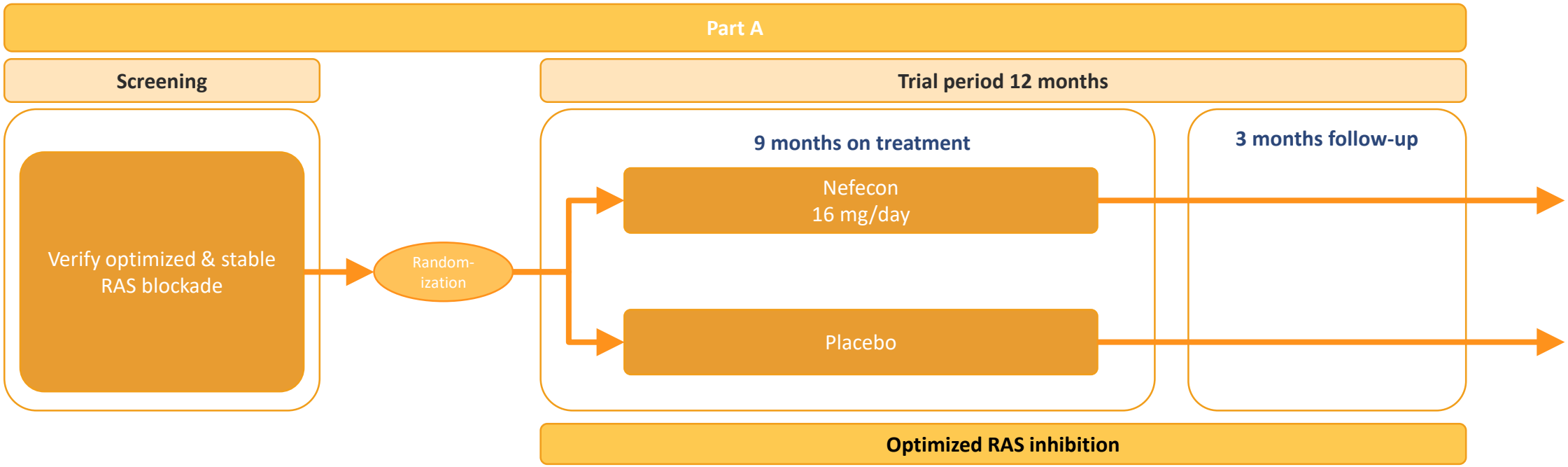
1. Calliditas is a late-stage biopharma company focused on novel treatments in orphan indications **Cash balance** of US$118M as of December 31, 2020, which provides financing into **Q3 2022**
2. Lead candidate Nefecon is a proprietary, novel investigational treatment for IgAN intended to be **disease modifying**
3. Nefecon targets the presumed **origin** of the disease – the area of the ileum where the highest concentration of Peyer's patches is located
4. Nefecon is the **most advanced** product candidate for IgAN, and is positioned to be the **first approved drug** specifically designed for IgA Nephropathy
5. Calliditas has carried out the **only successful** randomized, double-blind, placebo-controlled Phase 2B and Phase 3 clinical trials in IgAN
6. Regulatory pathway based on FDA and EMA acceptance of accelerated / conditional approval based on proteinuria as **surrogate marker** for IgAN
7. **Significant unmet medical need** in IgAN with no currently approved treatments; total market opportunity for Nefecon of US$4-5bn in the U.S alone

Pivotal Phase 3 clinical trial (NeflgArd) design

Part A: Key highlights

- → Phase 3 study identical primary endpoint as Ph 2b; decrease in UPCR at 9 months, eGFR key secondary endpoint
- → Trial fully enrolled; 360 patients, endpoint is the difference in eGFR over a 2- year period
- → Basis for accelerated approval in U.S. and conditional approval in E.U: Part A data, reported in November 2020
- → N=200, two arms; global trial in 19 countries and approximately 146 sites. Fixed 16mg Nefecon once daily dose

Phase 3 Part A design – NeflgArd

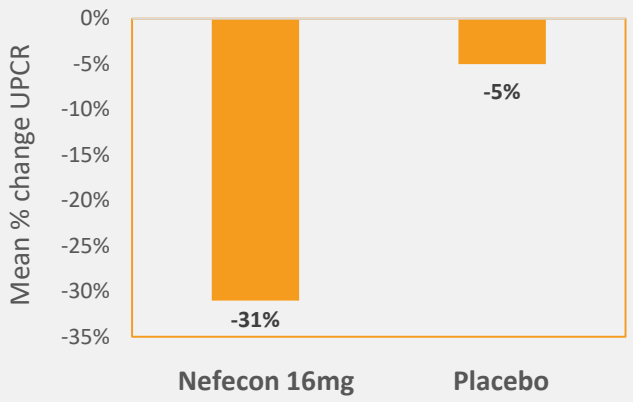


Pivotal Phase 3 Clinical Trial: Part A

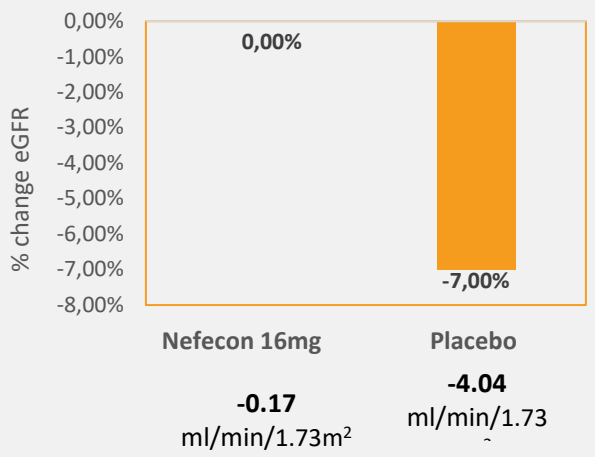
Only successful Phase 3 trial in IgAN

- Large trial population – 199 patients
- Oral dose taken daily over a nine-month period
- Randomized, double-blinded, placebo-controlled
- Global trial at 146 sites in 19 countries

Primary endpoint: Reduction in proteinuria



Secondary endpoint: Stabilization of eGFR



Efficacy findings

- ✓ Phase 3 trial of 199 patients demonstrated statistically significant and clinically meaningful reduction in proteinuria and eGFR stabilization in the 16 mg dose cohort
- ✓ Statistically significant 27% UPCR reduction with Nefecon (16 mg) compared to placebo – 9 months treatment (p=0.0005)
- ✓ Statistically significant eGFR stabilization with Nefecon (16 mg) compared to placebo – 9 months treatment (p=0.0029)

Tolerability findings

- ✓ Generally well-tolerated, with a safety profile in keeping with Phase 2b
- ✓ No severe infections
- ✓ No adverse clinical effects on the cardiovascular or metabolic system

Demographic characteristics

	Nef-301 FAS	Nef-202
	Overall (N=199)	**Overall (N=149)**
Age (years) [Median]	44	38
Sex (n, % male)	135 (67.8%)	105 (70.5%)
Race (n, % White)	171 (85.9%)	144 (97%)
Systolic BP/Diastolic BP [Mean]	126 / 79	128 / 80
UPCR (g/gram) [Median]	1.3	0.8
eGFR CKD-EPI (mL/min/1.73 m^2) [Median]	55	72

FAS = Full Analysis Set

Safety – AEs, Vital Signs and Metabolic Effects

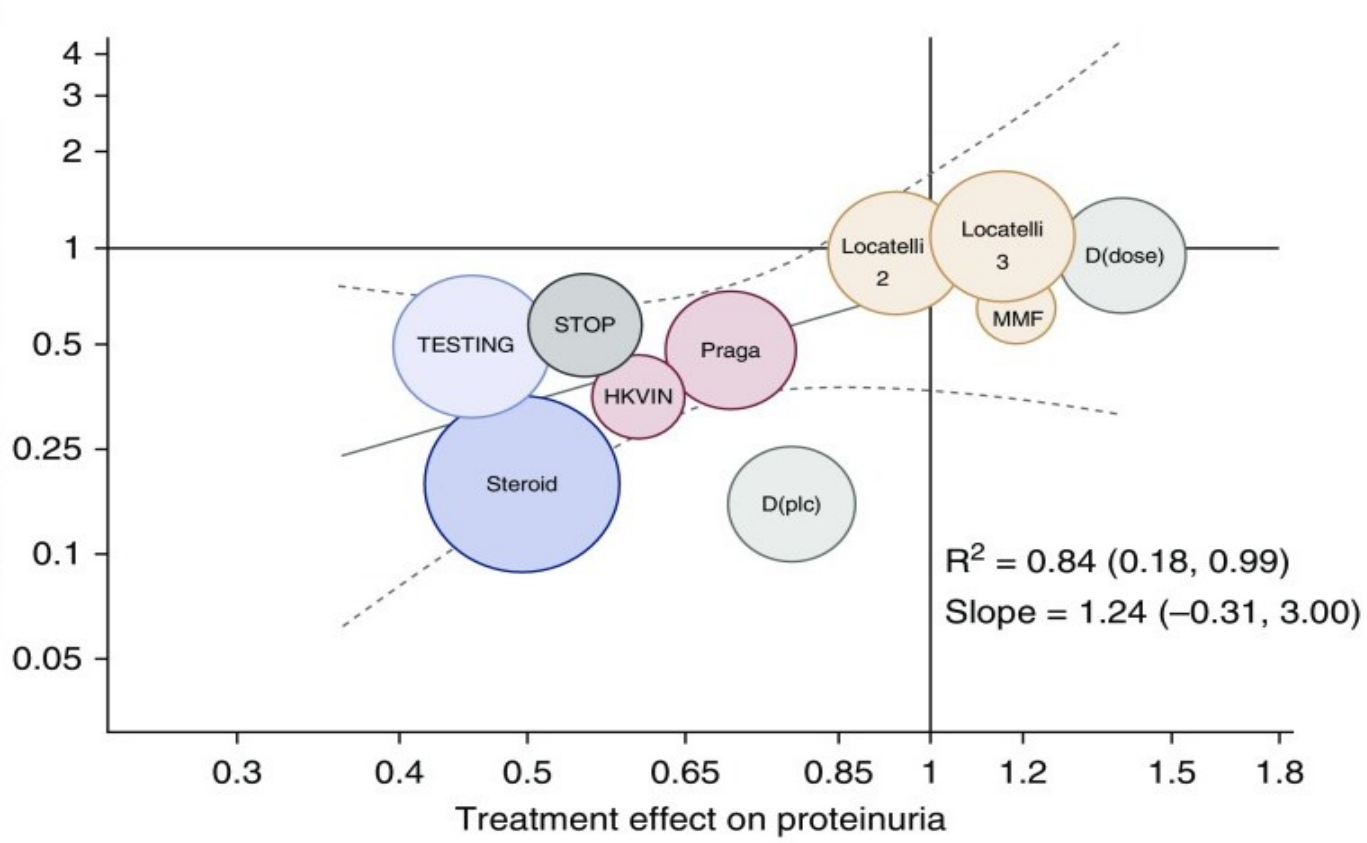
- ✓ The most common AEs were similar to those observed in Nef-202
  - Lower frequency in reporting of some AEs in Nef-301, likely due to solicitation of GCS-related and GI-related AEs in Nef-202
- ✓ No adverse clinical effects on body weight
- ✓ No adverse clinical effects on systolic or diastolic blood pressure
- ✓ No adverse clinical effects on HbA1c
  - Patients without a diagnosis of diabetes mellitus showed a pattern of HbA1c results similar to that seen in phase 2b study
  - Some patients with a diagnosis of diabetes mellitus showed clinically manageable increases in HbA1c during treatment, resolving on treatment discontinuation

Discontinuations

Discontinuation of study treatment	Total
Part A Full Analysis Set	
Total (n, %)	19 (9.5)
Due to AEs (n, %)	10 (5.1)

Discontinuation of study	Total
Full Analysis Set (n, %)	7 (3.5)

Trial-level assessment of the validity of proteinuria as a surrogate end point



Clin J Am Soc Nephrology, Thompson et al (2019)

Estimate of translational clinical benefit – proteinuria reduction

Treatment effect versus placebo[1]	Predicted HR for ESRD[2]	Progression without intervention in years; HR=1.0[3]	Progression with intervention	Estimated delay of disease progression[2,3]
30%	0.50	12.4	23.1	11 years
40%	0.41	12.4	27.6	15 years
50%	0.33	12.4	33.5	21 years
Trend based effect at one year – Nefecon				
42-48%	0.37	12.4	30.3	18 years

1. Treatment effect on UPCR assuming placebo treated according to SOC
2. Clin J Am Soc Nephrology, Thompson et al (2019)
3. Travere R&D day, 2020, Univeristy of Leicester presentation

eGFR - clinical benefit estimates

Table 3. Application of GFR slope as surrogate end point in new RCT: predicted treatment effect on clinical end point and PPV

GFR Slope	Observed Treatment Effect on Change in GFR Slope	Infinite Sample Size in New RCT		Large RCT		Modest RCT	
		Median HR and 95% Prediction Interval	PPV	Median HR and 95% Prediction Interval	PPV	Median HR and 95% Prediction Interval	PPV
Total slope over 4 yr	0.5	0.78 (0.69 to 0.87)	1.00	0.78 (0.59 to 1.01)	0.97	0.78 (0.52 to 1.15)	0.90
	0.75	0.69 (0.61 to 0.78)	1.00	0.69 (0.52 to 0.89)	1.00	0.69 (0.46 to 1.02)	0.97
	1.0	0.61 (0.53 to 0.7)	1.00	0.61 (0.46 to 0.8)	1.00	0.61 (0.4 to 0.91)	0.99
Threshold for treatment effect on GFR slope to assure PPV≥97.5%		0.20		0.52		0.79	
Total slope over 3 yr	0.5	0.77 (0.64 to 0.90)	1.00	0.77 (0.59 to 0.99)	0.98	0.77 (0.53 to 1.11)	0.93
	0.75	0.69 (0.58 to 0.81)	1.00	0.69 (0.52 to 0.89)	1.00	0.69 (0.47 to 1.00)	0.98
	1.0	0.62 (0.52 to 0.74)	1.00	0.62 (0.47 to 0.80)	1.00	0.62 (0.42 to 0.90)	1.00
Threshold for treatment effect on GFR slope to assure PPV≥97.5%		0.24		0.48		0.74	
Total slope over 2 yr	0.5	0.75 (0.56 to 0.98)	0.98	0.75 (0.54 to 1.01)	0.97	0.75 (0.51 to 1.07)	0.95
	0.75	0.7 (0.52 to 0.91)	0.99	0.7 (0.5 to 0.94)	0.99	0.69 (0.47 to 0.99)	0.98
	1.0	0.65 (0.48 to 0.85)	1.00	0.65 (0.46 to 0.87)	1.00	0.64 (0.43 to 0.92)	0.99
Threshold for treatment effect on GFR slope to assure PPV ≥97.5%		0.42		0.54		0.72	
Total slope over 1 yr	0.5	0.74 (0.49 to 1.1)	0.94	0.74 (0.49 to 1.11)	0.94	0.74 (0.48 to 1.11)	0.93
	0.75	0.72 (0.47 to 1.06)	0.96	0.72 (0.47 to 1.07)	0.95	0.72 (0.47 to 1.07)	0.95
	1.0	0.69 (0.46 to 1.03)	0.97	0.69 (0.45 to 1.04)	0.97	0.69 (0.45 to 1.04)	0.96
Threshold for treatment effect on GFR slope to assure PPV≥97.5%		1.26		1.32		1.31	
Chronic slope	0.5	0.8 (0.66 to 0.95)	0.99	0.8 (0.6 to 1.05)	0.95	0.8 (0.54 to 1.17)	0.88
	0.75	0.72 (0.59 to 0.86)	1.00	0.72 (0.54 to 0.94)	0.99	0.72 (0.48 to 1.05)	0.96
	1.0	0.65 (0.53 to 0.78)	1.00	0.65 (0.48 to 0.85)	1.00	0.65 (0.42 to 0.94)	0.99
Threshold for treatment effect on GFR slope to assure PPV≥97.5%		0.37		0.62		0.85	

Units of GFR are ml/min per 1.73 m^2. **Treatment effect on GFR slope is expressed as mean difference and in units of ml/min per 1.73 m^2/yr.** Treatment effect on the clinical end point is expressed as HR. PPVs are defined as the 97.5% probabilities for clinical benefit, defined as HR<1 for an infinite, large, or modest-sized RCT. A large RCT was defined as one in which the treatment effect on GFR slope can be estimated to within an SEM of 0.25, corresponding to a total sample size (*N*) of about 1900 for RCTs whose average follow-up accorded with the RCTs in the analysis. A modest RCT was defined as having SEM of 0.4 (*N* roughly 720).

Inker CKD analysis shows; if difference in 1-year slope is > 1.31 ml/min/1.73m^2/year there is a >97.5% probability that there will be a delay in the clinical endpoint (ESKD, eGFR<15, doubling of serum creatinine).
NefIgArd at 9m; difference between Nefecon and placebo = 3.87 ml/min/1.73m^2

1. Table 3, JASN 30: 1735-45, 2019

Conclusions

- Robust demonstration of efficacy (reduction in proteinuria and eGFR stabilization) in Nefecon treated patients
- Tolerability and safety profile in line with the poor bioavailability (10%) and hence low systemic availability as expected from the active ingredient
- Highly consistent efficacy across phase 2b and phase 3 clinical trials, in a broad range of patients with IgA nephropathy
- eGFR stabilization consistently shown across two large randomized and placebo-controlled studies provide basis for disease modification

Filing status and pre commercial preparations

- Submission to the FDA of our regulatory filing for accelerated approval of Nefecon is on track for Q1. Priority review, if granted, would position us for commercialization in the US in Q4, 2021
- Submission to EMA of our regulatory filing for conditional approval of Nefecon is on track for Q2. In case of accelerated assessment being granted, this could enable approval in Q1, 2022
- Looking forward to interactions with regulators based on our robust data package
- Continuing to build out our organization in the US in line with our communicated plans. We are excited about the feedback from nephrologists following the Phase 3 data readout.

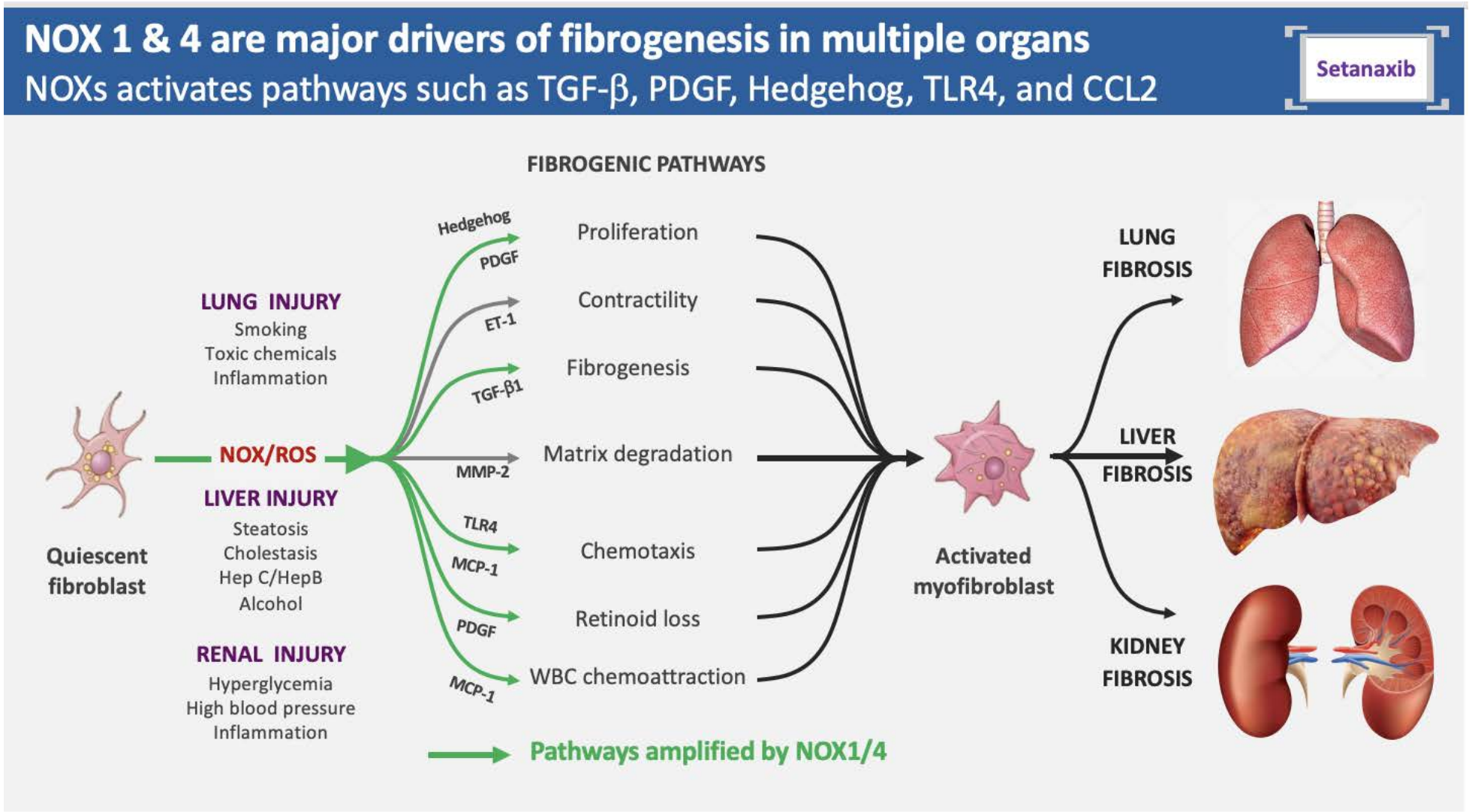
Genkyotex Transaction Update

- Transaction overview
  - Control transaction of 67.2% concluded on November 3rd, 2020, followed by a simplified mandatory tender offer which closed on December 11th, resulting in a total ownership of 86.2%
  - Calliditas plans to increase its ownership in alignment with communicated intentions
- Operations
  - The work related to the development of new generation compounds from the NOX platform continues and preparations with regards to starting of clinical trials in 2H are on track
- Publications
  - Recent forum review article NADPH Oxidase Inhibition in Fibrotic Pathologies by Karen Bernard & Victor J Thannickal[1] provides overview of the role of NOX enzymes in a variety of fibrotic diseases

1. Antioxidants & Redox Signalling, volume 33, Number 6, 2020

Setanaxib: A NOX1 and NOX4 Inhibitor

Setanaxib downregulates the activation of multiple clinically validated fibrogenic and apoptotic pathways



*Sources: Brenner DA, Hepatology 2012, Brenner DA, PLoS One, 2015, Torok N, Free Radic Biol Med, 2012. Torok N, Gastroenterology, 2015; Thannickal V, Science Trans Med, 2014; Gray SP, Circulation, 2013

Clinical Activities

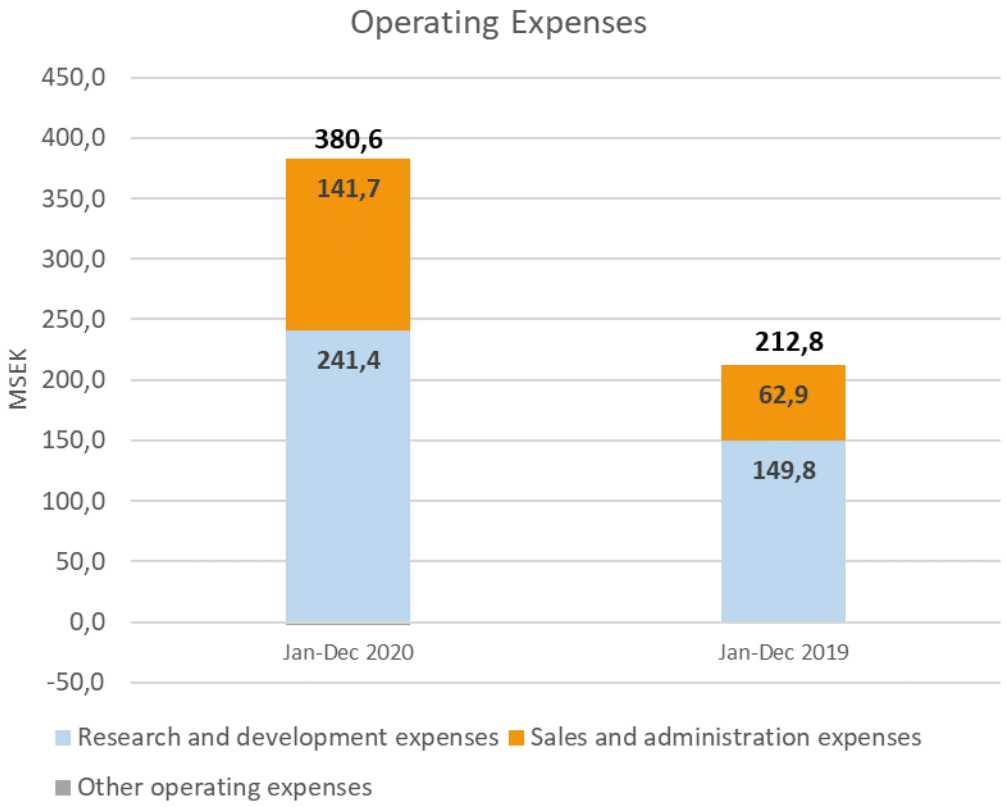
Clinical Candidate	Indication / Trial	Research/ Preclinical	Phase 1	Phase 2	Phase 3	Phase 4 / Marketed[1]
Nefecon	IgAN / NefIgArd					
Setanaxib	PBC					
Setanaxib	Oncology					
	Kidney					
Setanaxib (ILS)	IPF					
	DKD					
Nefecon	IgAN / OLE[2]					
	IgAN / NefXtend[2]					

1. We plan to submit an NDA / MAA in Q1 / Q2 2021 for accelerated / conditional approval by the FDA and EMA respectively
2. Clinical studies primarily supporting healtheconomic and / or treatment related considerations

Post period events

- Positive readout of the Genkyotex Phase 1 study providing a pathway for increased dosing of setanaxib
  - Announcement of initiation of a Phase 2/3 adaptive clinical trial in PBC in H2 based on previous Genkyotex interactions with the FDA
  - Announcement of initiation of POC Phase 2 trial in head and neck cancer in conjunction with immunotherapy treatment
- Completion of enrollment of NefIgArd on January 20th.
- Dosing of the first patient in OLE on February 4th. We expect a high level of interest from patients to roll over after their completion of the Phase 3 trial

Financial overview – full year 2020



- Revenues of SEK 0.9 M vs SEK 184.8 M for the same period last year.
- Operating loss of SEK 379.7 M vs SEK 28.0 M
  - Research and development expenses increased to SEK 241.4 M vs SEK 149.8 M, representing 63% of total operating expenses. Increase due to higher activity in the NeflgArd studies and product development.
  - Sales and administrative expenses increased to SEK 141.7 M vs SEK 62.9 M, mainly due to increase in pre-commercial activities, expenses in connection with the June NASDAQ listing and the Genkyotex acquisition.
- Cash flow used in operating activities was SEK 309.2 M vs SEK 71.0M, due increased opex in 2020 and to received 15 MUSD payment in Q3-19 for China deal upfront.
- Cash position per end of December 2020 was SEK 996.3 M vs SEK 753.5 M. The increase is mainly due to the cash flow from financing activities primarily from the June Nasdaq IPO.