calliditas
THERAPEUTICS

Q3 2020 Report

November 12, 2020

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Company Overview

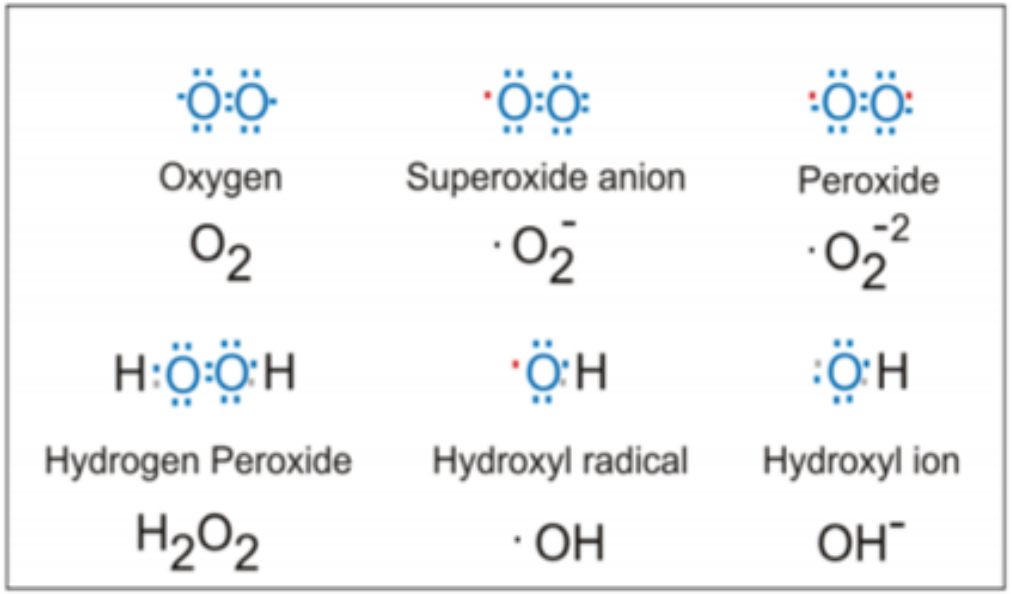
1. Calliditas is a clinical-stage biopharma company focused on novel treatments in orphan indications **Cash balance** of US$161M as of September 30, 2020, provides financing through **Q3 2022**
2. Lead candidate Nefecon is a proprietary, novel investigational treatment for IgAN intended to be **disease 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 of US$9-10bn in the U.S alone

Genkyotex Transaction Update

- Transaction overview
  - Expert opinion received by Genkyotex Board supporting the offered price as being fair in terms of the tender offer, as well as a potential squeeze out if Calliditas owns at least 90% upon closing of the tender offer
  - Genkyotex Board subsequently voted unanimously to recommend the offer to share holders
- Tender offer prospectus submitted to the French stock market regulator (AMF)
  - Clearance targeted for November 24th
  - Following acceptance by the AMF, the simplified mandatory tender offer for the remaining shares outstanding will open for 10 trading days
- Board composition changed following closing of the block trade
  - Mr Schnee, Mr Schur and Mrs Lucander elected as new Board members alongside CEO, Mr Papatheodorou
- Organisation
  - Plan is to retain staff and to continue the work related to the development of NOX inhibitors

Reactive Oxygen Species

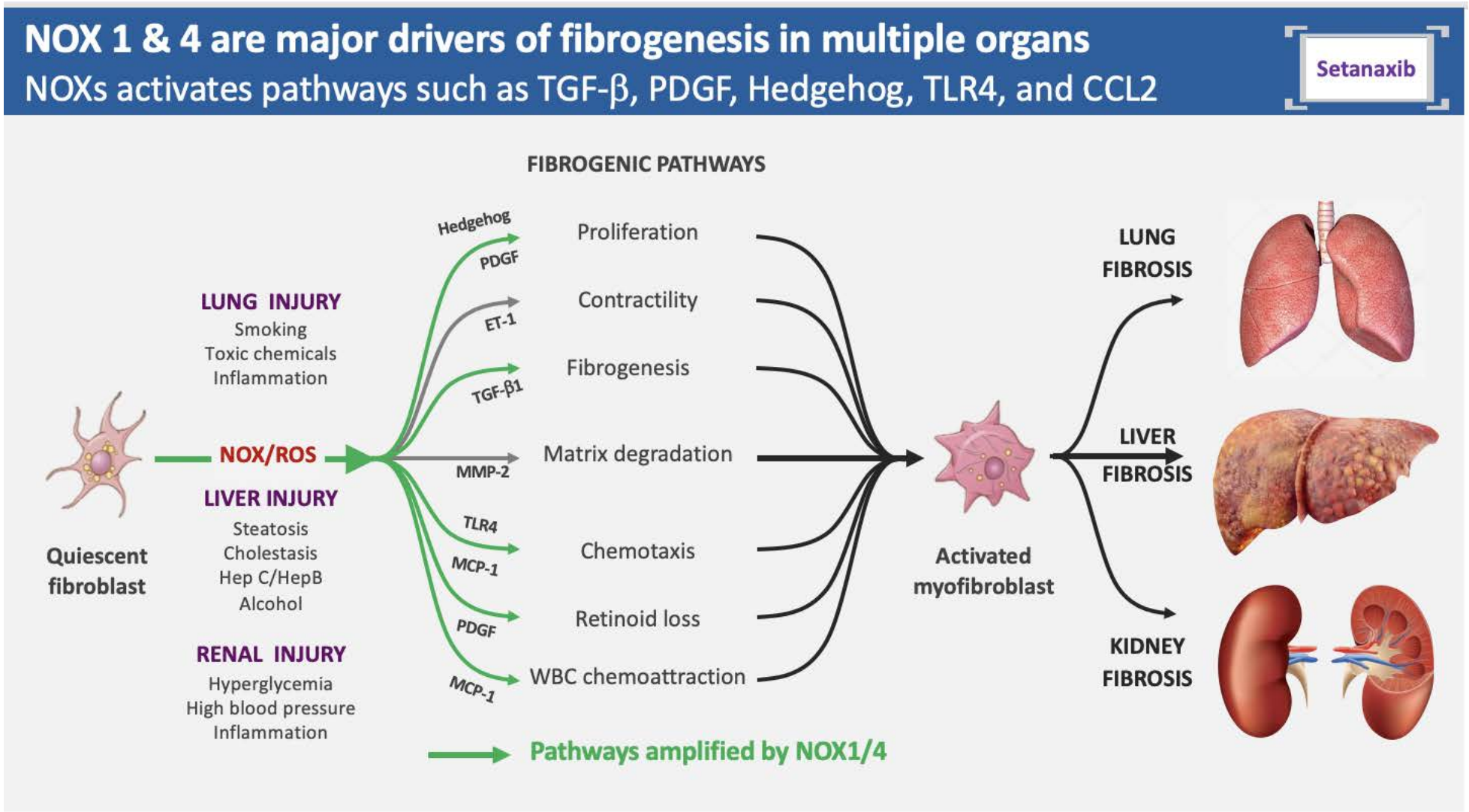
- Several enzymes in the body are capable of producing reactive oxygen species (ROS)
- The only known enzymes that are solely dedicated to producing ROS as their primary function are nicotinamide adenine dinucleotide phosphate (NADPH) oxidases and their catalytic subunits, NOX.[1]
- At appropriate concentrations, ROS have essential functions in cellular signalling processes.
  - ROS regulate cell proliferation, innate immune response, differentiation and migration, extracellular matrix dynamics, vascular tone, and inflammation.[2]
- However, the disturbance of the redox homeostasis has been implicated in multiple disease pathways.
  - Oxidative stress, an excess of ROS, is a likely common underlying mechanism for cardiovascular diseases, neurodegenerative disorders, and cancer disease pathways.[3]



Electron structures of common reactive oxygen species.[4]

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

Operational Summary

- US research coverage initiated by Citi, Jefferies and Stifel post US IPO in early June, 2020
- Green shoe (overallotment) of $6.9m exercised related to US IPO in July, 2020
- Our Chinese partner, Everest Medicines, announced recruitment of the first patient into NefIgArd on September 7th, 2020
- Appointed a General Counsel; Jonathan Schur, formerly Partner at Goodwin Proctor

Post period events

- Poster and Presentation at American Society of Nephrology Digital Kidney Week 2020 on October 22nd & 23rd
  - Poster describing the design of the NefIgArd trial
  - Presentation on the effect of Nefecon on circulating levels of BAFF and soluble BCMA and TACI in patients with IgAN
- Closing of acquisition of a controlling interest in Genkyotex on November 3rd
- Positive Topline Results from Part A of the Pivotal Phase 3 NefIgArd Trial announced on November 8th
  - Statistically significant results on both primary and key secondary endpoint

Trial Design: Phase 2b -> Phase 3

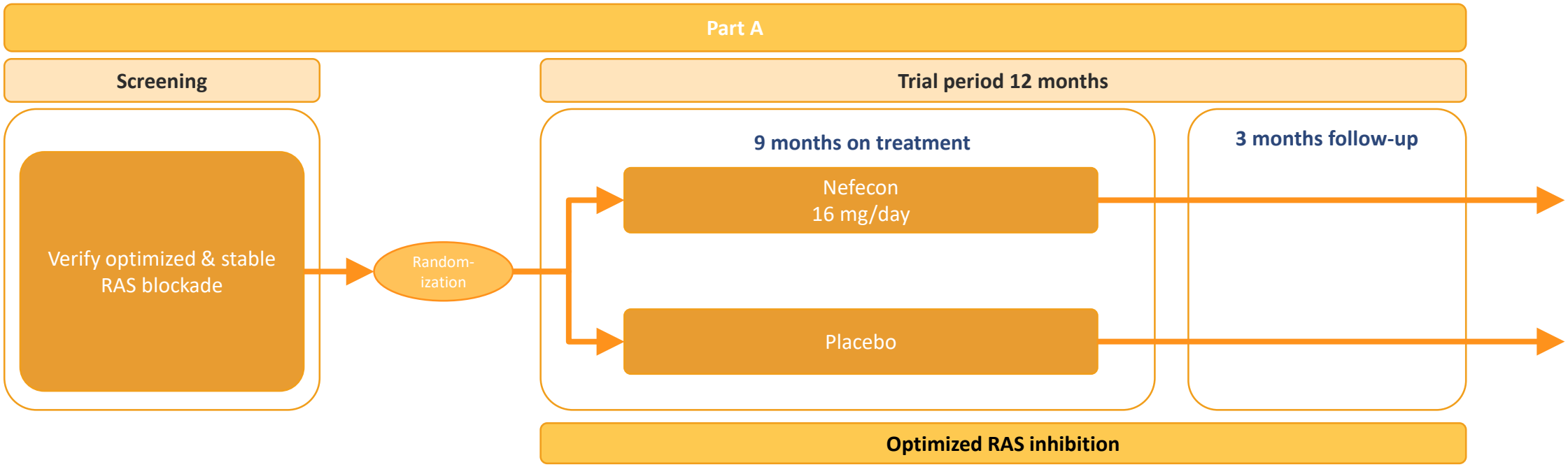
Phase 2b Trial Design	Phase 3 Trial Design
Large trial population –150 patients	Large trial population – 200 patients in Part A
Oral dose taken daily over a nine-month period	Oral dose taken daily over a nine-month period
Randomized, double-blinded, placebo-controlled	Randomized, double-blinded, placebo-controlled
European trial in 62 sites in 10 countries	Global trial in 146 sites in 19 countries
Primary endpoint: Reduction in proteinuria	Primary endpoint: Reduction in proteinuria
Key secondary endpoint: Stabilization of eGFR	Key secondary endpoint: Stabilization of eGFR

Pivotal Phase 3 clinical trial (NefIgArd) designed to confirm Phase 2b results

Part A: Key highlights

- → Phase 3 study design evaluates the same primary endpoint as Phase 2b trial: decrease in UPCR at 9 months
- → Fixed 16 mg Nefecon once daily oral dose
- → Reduction of proteinuria: Accelerated approval in U.S. and conditional approval in E.U. based on Part A data
- → N=200, two arms; global trial in 19 countries and approximately 146 sites

Phase 3 Part A design – NefIgArd

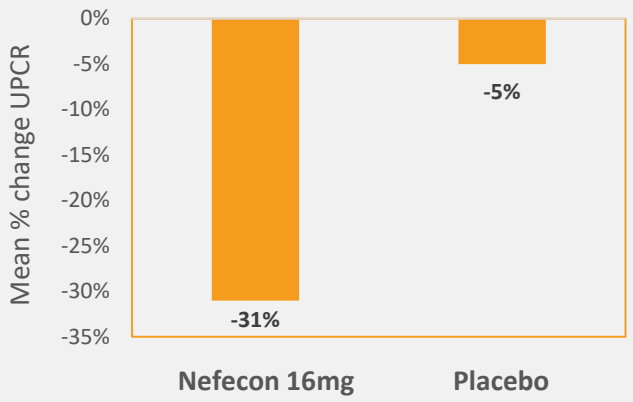


Pivotal Phase 3 Clinical Trial: Part A

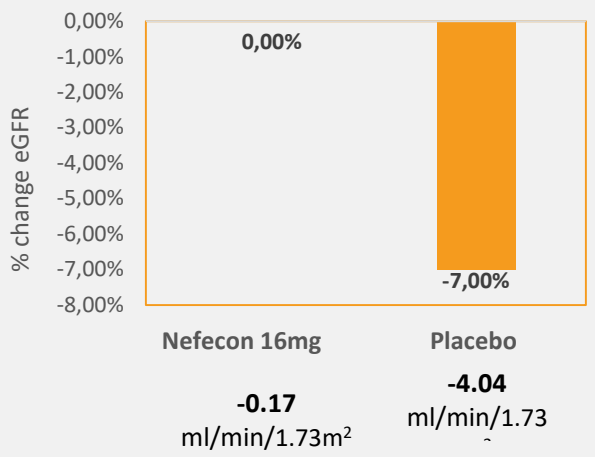
Only successful Phase 3 trial in IgAN

- 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

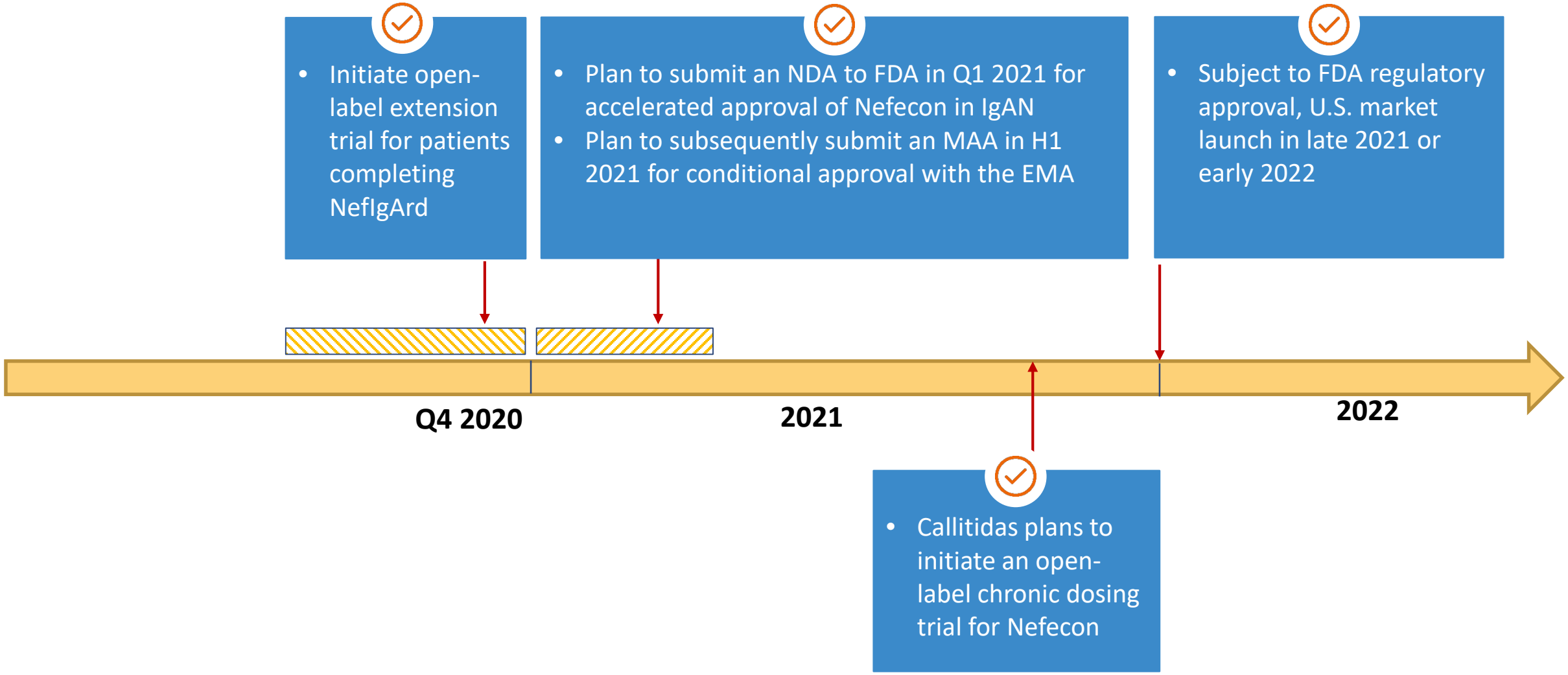
- ✓ Phase 3 trial of 199 patients demonstrated statistically significant and clinically meaningful reduction in proteinuria and eGFR stabilization in the 16 mg dose cohort
- ✓ Statistically significant 27% UPCR reduction with Nefecon (16 mg) compared to placebo – 9 months treatment (p=0.0005)
- ✓ Statistically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

Tolerability findings

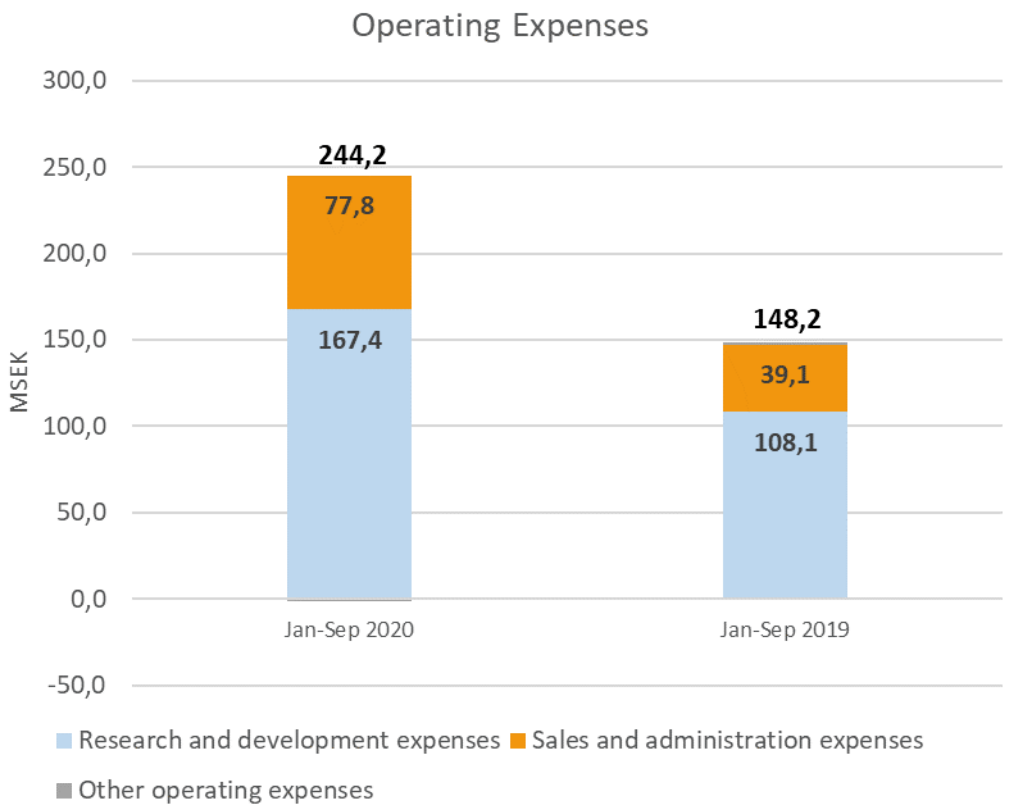
- ✓ Generally well-tolerated, with a safety profile in keeping with Phase 2b
- ✓ No severe infections
- ✓ Significantly lower withdrawal rate compared to Phase 2b

Next Steps

- Calliditas' Nefecon development and regulatory program overview



Financial overview - first nine months of 2020



- Revenues of SEK 0.5 M vs SEK 138.2 M for the same period last year.
- Operating loss of SEK 243.8 M vs SEK 10.0 M
  - Research and development expenses increased to SEK 167.4 M vs SEK 108.1 M, representing 69% of total operating expenses. Increase due to higher activity in the NeflgArd study and product development.
  - Sales and administrative expenses increased to SEK 77.8 M vs SEK 39.1 M, mainly due to increase in pre-commercial activities, expenses in connection with the June NASDAQ listing and the ongoing Genkyotex acquisition.
- Cash flow from operating activities was SEK -189.1 M vs SEK -25.6 M, due to received 15 MUSD payment in Q3 for Q2-19 China deal upfront.
- Cash position per end of September 2020 was SEK 1,396.9 M vs SEK 805.1 M. The increase is mainly due to the cash flow from financing activities primarily from the Nasdaq IPO.

Investment highlights

1. Nefecon is a proprietary, novel treatment for IgAN intended to be **disease modifying**
2. Nefecon targets the presumed **origin** of the disease – the area of the ileum where the highest concentration of Peyer's patches is located
3. Nefecon is the **most advanced** product candidate for IgAN. The **only successful** randomized, double-blind, placebo-controlled Phase 3 clinical trials carried out in IgAN to date
4. Statistically significant readout of Phase 3 across both primary and key secondary endpoint **confirms** previously successful Phase 2b trial
5. Regulatory pathway based on discussions with FDA and EMA of our seeking accelerated / conditional approval based on proteinuria as **surrogate marker** for IgAN
6. **Significant unmet medical need** in IgAN with no currently approved treatments; total market opportunity of US$9-10bn in the U.S alone, target market opportunity $4-5bn.
7. Additional potential for **pipeline development** and **in-licensing** of product candidates targeting orphan diseases