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Q1 2023 REPORT

May 16, 2023

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Q1 Highlights

- In March the global NefIgArd Phase 3 trial successfully met its primary endpoint, estimated glomerular filtration rate (eGFR) with a p value of < 0.0001.
- In February, we received Conditional Marketing Authorization from the UK MHRA for Kinpeygo in IgA nephropathy
- In the first quarter of 2023, a record level of 408 new enrollments for TARPEYO were generated, reflecting a growth of over 30% from Q4, 2022.
- The growth in unique prescribing nephrologists was the highest to date with over 276 new prescribers in Q1, compared to 162 in Q4, 2022.
- Total revenues of SEK 191.4 million, out of which TARPEYO net sales represented SEK 185.7 (USD 17.8) million for the quarter. Our 2023 Outlook remains unchanged with Calliditas expecting revenue growth with net sales from TARPEYO estimated to be USD 120-150 million for the year ending December 31, 2023.

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Strong eGFR Data from NefIgArd Trial Readout

Our approach of targeting the origin of the disease with a locally active treatment has generated what we believe is ground-breaking data having an impressive kidney protective impact. Supportive eGFR total slope analysis show clear, clinically relevant differences on an annual basis.

Reported eGFR data we believe supports disease modification, having shown immediate kidney protective effect which endures after treatment is discontinued and remains intact even after 15 months off drug. This effect is irrespective of base line UPCR levels.

Proteinuria (UPCR) reduction of 34% versus optimized and stable standard of care (physicians' choice) at 9 months, which also importantly was durable after treatment discontinuation with similar levels being seen even after patients were off drug for 15 months

We are planning to file for full approval of the entire study population with the FDA in July, which would enable a regulatory decision in the first half of 2024. The exact timing of this decision is dependent on whether the process would be conducted under priority or standard review.

Pipeline update

We are on track to report out biomarker data of the setanaxib head and neck cancer trial around mid-year 2023 as previously disclosed. The TRANSFORM clinical trial remains challenging from a recruitment perspective.

We are launching a trial with setanaxib in Alport syndrome, a renal orphan disease in which there is nothing approved by the FDA or EMA today and where there is a substantial unmet medical need.
Our expectation is that the randomized, controlled trial will start in the second half of 2023 and will enrol around 20 patients.

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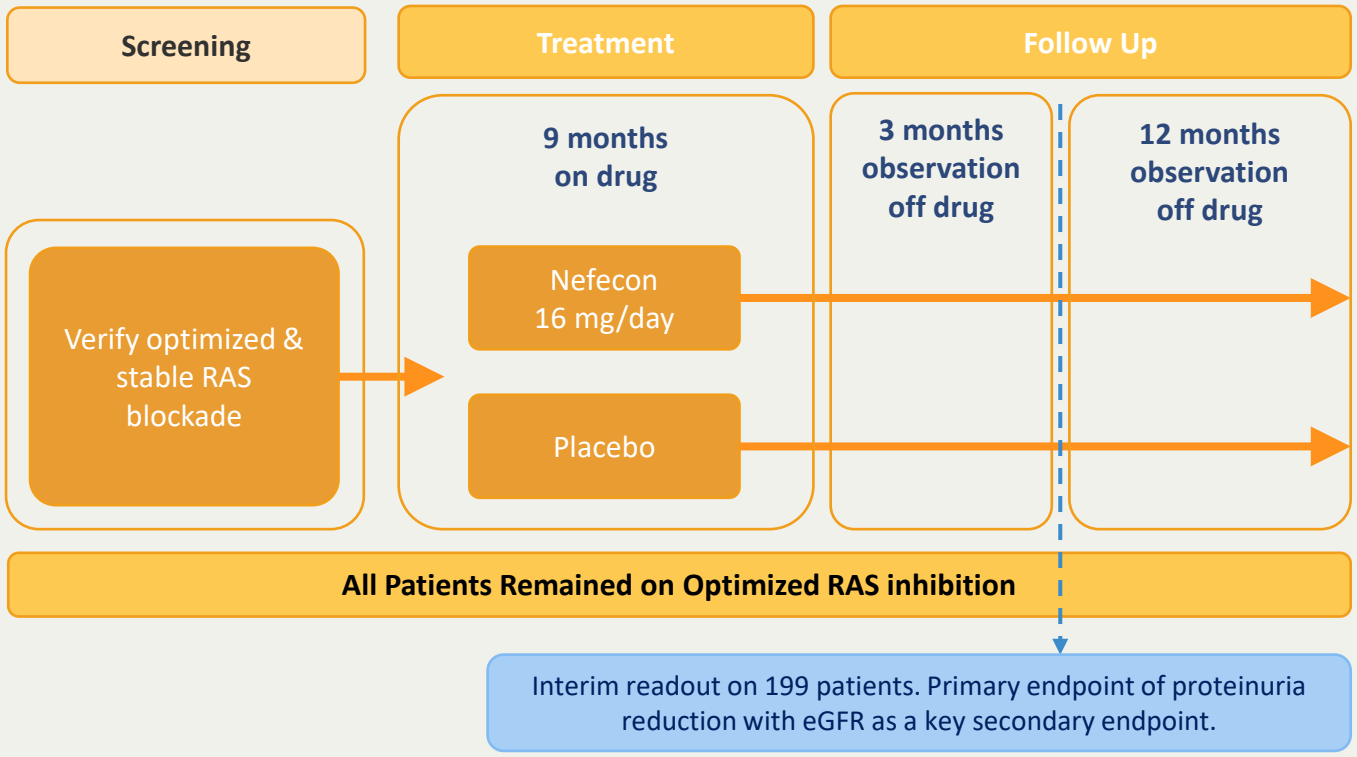
Q1 Update: NefIgArd Trial Full Readout

Dr Richard Philipson, Chief Medical Officer

NefIgArd study design



Base inclusion criteria:

- Biopsy proven IgAN; > 1 gram of proteinuria; > 35 eGFR < 90 ml/min 36o patients, including 200 from Part A
- Patients were required to have well-controlled blood pressure of <140/90 mmHg to enter into the study, to ensure no BP confounding effects on proteinuria reduction.
- No immunosuppressive drugs were permitted during the study; changes to anti-hypertensive medications were discouraged.

Interim Readout

- 199 patients in 19 countries with >145 sites
- Primary endpoint: proteinuria
  Key secondary endpoint: eGFR
- Read out positive data in November 2020
- Basis for accelerated/conditional approval in USA/Europe, respectively

Full Phase 3 trial

- Designed to confirm the long-term renal benefit of observed proteinuria reduction
- 364 patients
- Primary endpoint: average difference in kidney function as measured by eGFR over the 2-year period
- Read out positive data in March 2023

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Disposition

	Nefecon 16 mg	Placebo	Total
All randomised	197	198	395
Safety Analysis Set [a]	195	194	389
Full Analysis Set [b]	182	182	364
Early discontinuation of study	24	19	43

[a] The Safety Analysis Set includes all randomized patients who received at least 1 dose of study treatment.

[b] The Part B Full Analysis Set excludes 29 patients enrolled for regulatory purposes in China after global recruitment was complete.

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Demographic characteristics

- Demographic characteristics are representative of the intended primary IgAN population. Disease characteristics describe a clinically relevant high-risk IgAN population.
- Treatment groups were balanced with regards to baseline characteristics.
- Blood pressure was well controlled at study entry.

	Nef-301 Phase 3 Full Analysis Set		
	Nefecon 16 mg (N=182)	**Placebo (N=182)**	**Total (N=364)**
Age (years) (Median [range])	43 [21, 69]	42 [34, 49]	43 [20, 73]
Sex (n, % male)	117 (64%)	123 (68%)	240 (66%)
Race (n, % White)	138 (76%)	137 (75%)	275 (76%)
(n, % Asian)	43 (24%)	40 (22%)	83 (23%)
Systolic BP/Diastolic BP (Median)	126/79	124/79	125/79
UPCR (g/gram) (Median)	1.28	1.25	1.26
eGFR CKD-EPI (mL/min/1.73 m^2) (Median)	56.1	55.1	55.5

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Primary analysis of eGFR: Effect of Nefecon averaged over 2 years

Time-weighted average change from baseline in eGFR during 9 months of treatment and 15 months of observation

- Averaged over the 2-year period of treatment and observation, the mean decline in eGFR was 2.47 mL/min/1.73 m^2 for patients who received Nefecon compared with 7.52 mL/min/1.73 m^2 for patients who received placebo
- Averaged over the 2-year period of treatment and observation, there was a 5.05 mL/min/1.73 m^2 eGFR treatment benefit in favour of Nefecon compared to placebo (p<0.0001)

Nef-301 Primary analysis of eGFR (Full Analysis Set N=364)		
	Nefecon 16 mg (N=182)	**Placebo (N=182)**
Mean change from baseline in eGFR averaged over 2 years (mL/min/1.73 m^2)	-2.47 (-3.88 to -1.02)	-7.52 (-8.83 to -6.18)
Nefecon 16 mg versus Placebo treatment effect		
Average difference in eGFR over 2 years (mL/min/1.73 m^2)	5.05 (p<0.0001)	

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Supportive eGFR Analysis

eGFR 2-year slope analysis

- Supportive analyses of eGFR 2-year slope were statistically significant and clinically relevant
- The improvement in total 2-year eGFR slope was estimated to be 1.8 to 3.0 mL/min/1.73 m^2 per year for Nefecon 16 mg once daily compared to placebo, depending on the analysis method used
- All estimates are well in excess of the difference per year in 2 year eGFR total slope required to predict clinically meaningful treatment effects on the composite endpoint of ESRD, eGFR<15 mL/min/1.73 m^2 or sustained doubling of serum creatinine (Inker et al 2019)

Nef-301 Part B eGFR 2-year Analyses (Full Analysis Set N=364)		
Difference between Nefecon 16 mg and Placebo in 2-year eGFR total slope (mL/min/1.73 m^2 per year) 1-sided p-value	Absolute change in eGFR from baseline at 24 months	
	Nefecon 16 mg (N=182)	Placebo (N=182)
1.8 – 3.0 with p-values <0.0001 - 0.0035	-6mL/min/1.73 m^2	-12mL/min/1.73 m^2

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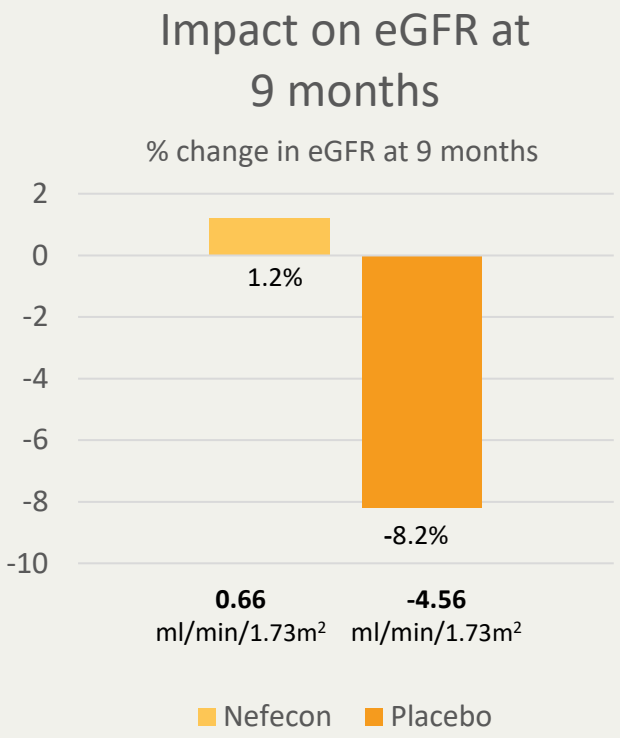
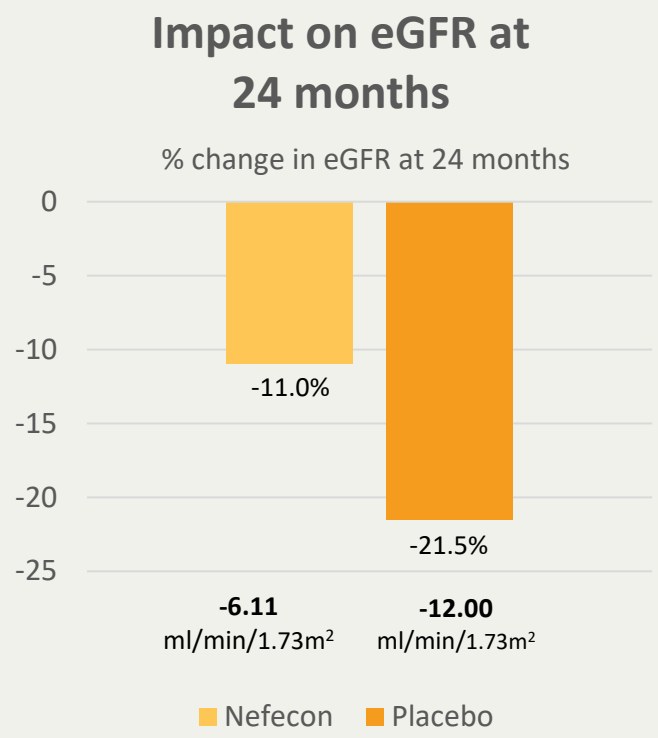
eGFR Phase 3 Data

Sustained eGFR effect observed at 24 months

9 months of dosing with 16mg Nefecon in 364 patients resulted in 50% less loss of kidney function vs placebo at 24 months.





Efficacy Findings

- Statistically significant eGFR stabilization with Nefecon (16 mg) compared to placebo following 9 months treatment ($p < 0.0001$)
- After 9 months:
  - eGFR increase for Nefecon treated patients: 0.66 ml/min/1.73m^2
  - eGFR decline for placebo: 4.56ml/min/1.73m^2
- After 24 months:
  - eGFR decline for Nefecon treated patients: 6ml/min/1.73m^2
  - eGFR decline for placebo: 12ml/min/1.73m^2

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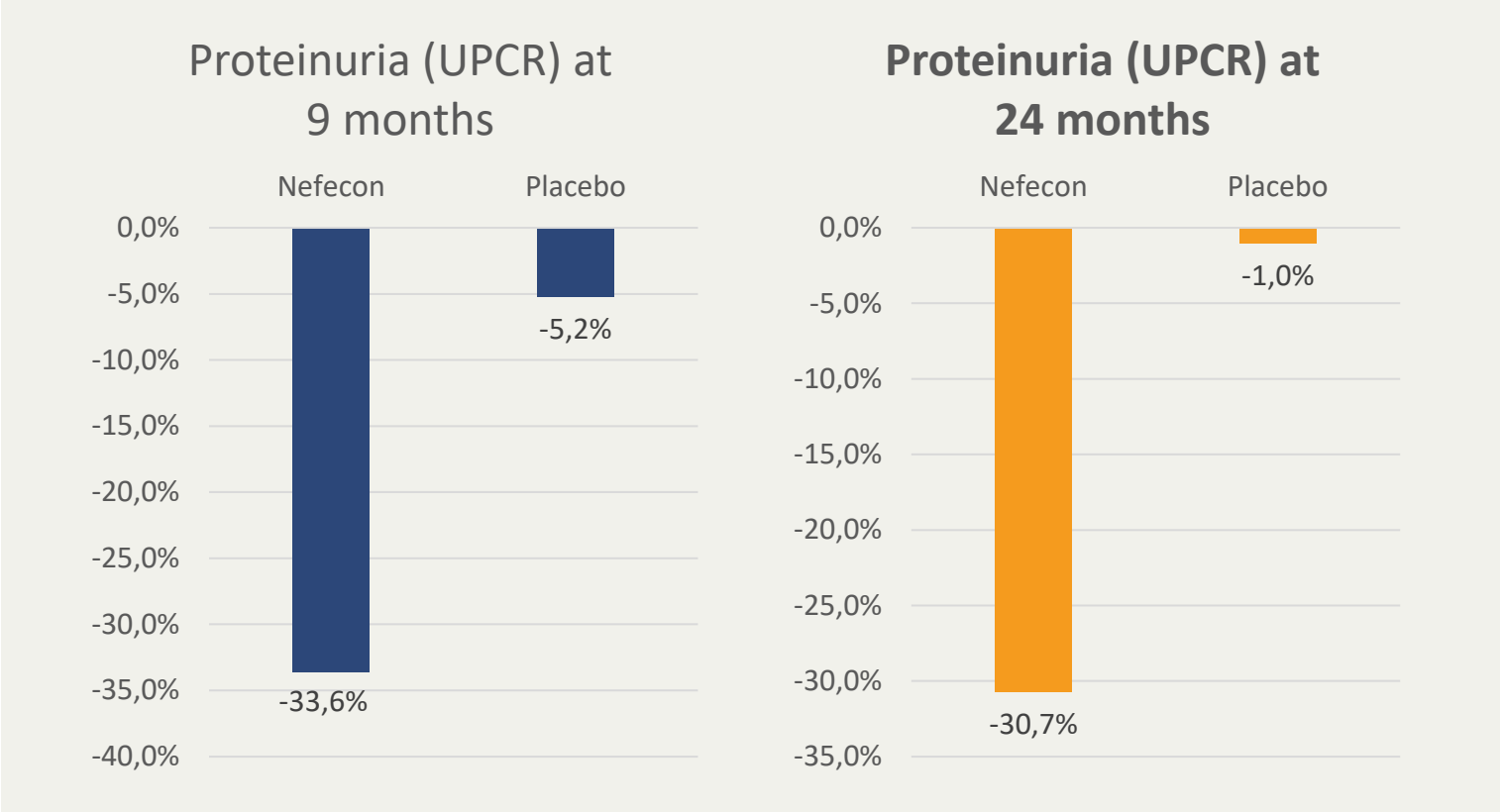
UPCR Phase 3 Data

Effect on UPCR maintained at 9 month level, or lower, from the end of treatment through 24 months

- The percent reduction in UPCR for Nefecon 16 mg versus placebo increased over time from 3 to 12 months, and thereafter returned to end of treatment (9 month) levels at the end of the follow-up period (15 months).



Efficacy Summary

The Phase 3 **Primary Endpoint of average change from baseline in eGFR over the 2 year treatment and observation period was met,** showing **high statistical significance** of Nefecon (TARPEYO / Kinpeygo) compared to placebo ($p<0.0001$)

Supportive **analyses of 2-year eGFR total slope were statistically significant and clinically relevant**, showing a magnitude ranging from approximately 1.8 – 3.0mL/min/1.73 m^2 per year (active compared to placebo), with p-values ranging from <0.0001 to 0.0035

All estimates are **well in excess of the threshold required** to predict clinically meaningful treatment effects

A **treatment benefit** on eGFR was apparent **across baseline UPCR subgroups**

Sustained proteinuria effects and **long lasting eGFR treatment benefit** even after 15 months after discontinuation, **supporting disease modification**

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Safety summary –Safety Analysis Set (treatment period)
(≥5% Nefecon-treated patients and ≥2% higher than placebo)

	Safety Analysis Set	
Adverse event N (%)	**Nefecon 16 mg (N=195)**	**Placebo (N=194)**
Peripheral edema	33 (16.9)	10 (5.2)
Hypertension	23 (11.8)	6 (3.1)
Muscle spasms	23 (11.8)	8 (4.1)
Acne	22 (11.3)	2 (1.0)
URTI	16 (8.2)	12 (6.2)
Face edema	15 (7.7)	1 (0.5)
Weight increased	13 (6.7)	6 (3.1)
Dyspepsia	13 (6.7)	4 (2.1)
Arthralgia	12 (6.2)	4 (2.1)
WBC increased	11 (5.6)	1 (0.5)

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Safety Summary

- **Nefecon was generally well tolerated**
  - Objective measures of mean weight and BP showed non-clinically relevant, fully reversible changes

- **The adverse event profile was similar to that reported in the interim analysis:**
  - The most commonly reported TEAEs observed with an increased frequency compared to placebo were oedema peripheral, hypertension, muscle spasms, and acne**.**
  - **The majority of TEAEs were of mild or moderate severity.**
  - TEAEs led to discontinuation of study drug in <10% of Nefecon-treated patients.

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Q1 Update: TARPEYO

Andrew Udell, President North America

Record new patient enrollments and new prescribers…

- $17.8M net revenues from TARPEYO sales
- Records for the quarter:
  - 408 new patient enrollments in Q1 2023 – 30% growth from Q4 2022
  - 276 new prescribers during the quarter
- 85% of patients enrolled in TARPEYO Touchpoints during Q1 received TARPEYO*
- Majority of patients that have received 9 months of treatment, remained on therapy beyond 9 months
- Nephrologist research continues to support their belief and goal of eGFR stabilization when treating IgA nephropathy patients

*Does not include patients that are still waiting final insurance decision

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Late-Breaking Presentations ERA Congress June 2023

Data presentations and posters of the NefIgArd Phase 3 Study at European Renal Association (ERA) Congress June 2023

- **Oral Presentations:**
  - **Title:** Long-term renal benefit over 2 years with Nefecon verified: The NefIgArd Phase III full trial results
  - **Title:** Nefecon Treatment Likely Modulates Downstream Pathways of Kidney Inflammation and Fibrosis in IgA Nephropathy
- **<u>e-Poster Details:</u>**
  - **Title:** Durable proteinuria reduction over 2 years with Nefecon treatment: A secondary analysis of the full NefIgArd Phase III trial results
  - **Title:** Hematuria reduction in patients with IgAN following Nefecon treatment: A secondary analysis of the full 2-year NefIgArd Phase III trial results


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Calliditas Announces Late-Breaking Presentations at the 60th European Renal Association (ERA) Congress 2023

MAY 5, 2023 14:30 CET - Non Regulatory

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") announced upcoming data presentations from the NefIgArd Phase 3 Study at the European Renal Association (ERA) Congress 2023.

These data presentations will feature data and analyses from the NefIgArd Phase 3 clinical trial evaluating Nefecon (TARPEYO (budesonide) delayed release capsules/Kinpeygo®) in patients with IgA nephropathy (IgAN). ERA will be held virtually and in Milan, Italy, June 15-18, 2023.

"We are delighted that these data presentations have been selected for the upcoming ERA Congress 2023 and extend ou congratulations to all the authors involved. The data build on trial results from the successful Phase 3 NefIgArd study ar provide additional evidence supporting the effect of Nefecon on the underlying pathophysiology of IgAN," said Calliditt medical officer, Richard Philipson.

Poster presentation details are below and will be available on the Investor page on the Calliditas' corporate websit the meeting.

Oral Presentation Details:

Title: Long-term renal benefit over 2 years with Nefecon verified: The NefIgArd Phase III full trial results

Presenter: Richard Lafayette, M.D., F.A.C.P., Stanford Healthcare

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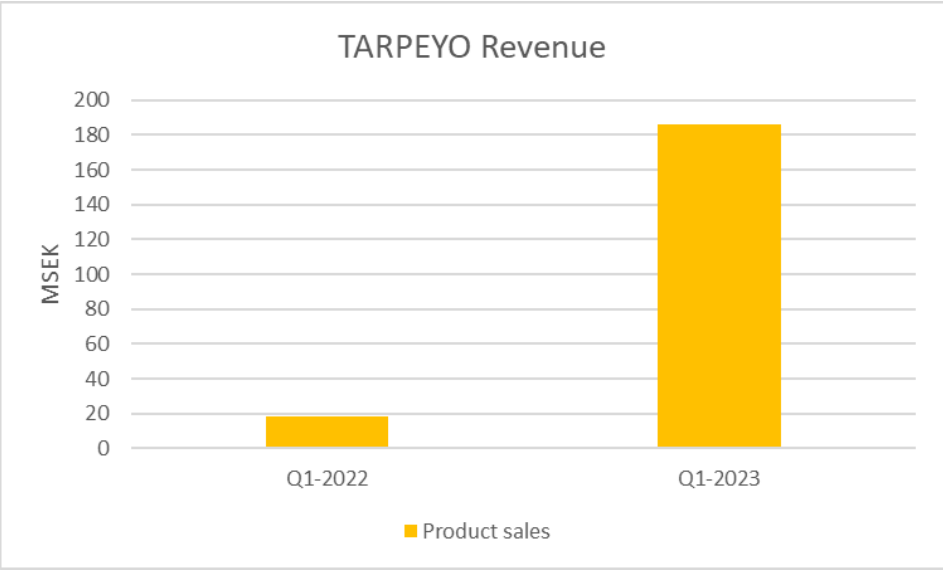
Q1 Update: Financial Overview

Fredrik Johansson, Chief Financial Officer

Financial Overview – First Quarter 2023



MSEK	Jan-Mar 2023	Jan-Mar 2022
Net sales	191,4	49,7
Gross profit	182,3	49,1
Operating loss	180,1	208,4
Loss for the period	187,5	207,0
Cash Position	1013,6	825,4

- Revenues for Q1 2023 of SEK 191.4 M vs SEK 49.7 M for Q1 2022.
  - Whereof SEK 185.7 M in net sales from TARPEYO vs SEK 18.0 M for Q1 2022.
  - Whereof SEK 5.7 M from partners vs SEK 31.7 M for Q1 2022.
- Operating expenses Q1 2023 amounted to SEK 362.4 M vs SEK 257.5 M for Q1 2022.
- Operating loss Q1 2023 amounted to SEK 180.1 M vs SEK 208.4 M for Q1 2022.
- Cash used in operating activities for Q1 2023 amounted to SEK 231.9 M vs SEK 191.4 for Q1 2022.
- The cash position per end of Q1 2023 was SEK 1,013.6 M vs SEK 825.4 M per end of Q1 2022

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Key takeaways

- **Very strong eGFR data from positive readout of Phase 3 NefIgArd trial supporting disease modification from treatment with Nefecon (TARPEYO/Kinpeygo). Filing with the FDA for full approval for the entire study population planned for July 2023. STADA expected to file with EMA for full approval in 2H 2023.**
- **Record number of 408 enrollments for the quarter, and highest growth to date of new prescribers with 276 added in Q1.**
- **MHRA conditional approval of Nefecon received, providing the first and only approved medication for IgAN in the UK.**
- **Revenues of SEK 191.4M, of which net revenues for TARPEYO were SEK 185.7M (USD 17.8M), for the quarter.**