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Q3 2023 REPORT

November 7, 2023

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Q3 Highlights

Regulatory filings

- In August the FDA accepted our filing for full approval of TARPEYO under priority review and provided a **PDUFA date of December 20, 2023.**

- In September, Calliditas' partner STADA **filed with the EMA** for standard marketing authorisation for Kinpeygo, submitting a Type II variation. A decision is expected in 1H 2024.

Scientific updates

- In August ***The Lancet*** published the full data from our successful Phase 3 NefIgArd clinical trial

- At the bi-annual IIgANN conference, which was held in Tokyo, Japan, we **presented 8 abstracts**, including one showing statistically significant impact with regards to resolution of microhematuria in the Nefecon treatment arm.

TARPEYO Commercial Update

- The third quarter of 2023, saw **367 new enrolments** for TARPEYO and **197 new prescribers**, reflecting the expected summer seasonality of Q3. **Robust growth in enrolments observed in early Q4.**

- **Total revenues of SEK 295 million (USD 27.3M),** out of which **TARPEYO net sales represented SEK 284M (USD 26.3M)**, reflecting a 130% growth over Q3 2022 and resulting in total product revenues of USD 68.8M to date.

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Post period events and pipeline update

Calliditas presented seven abstracts at the American Society of Nephrology's Kidney Week in Philadelphia, PA.

Numerous positive interactions with physicians emphasised the strength of our Phase 3 data and the inroads being made with the nephrologist community regarding TARPEYO.

Setanaxib was granted Orphan Drug Designation for Alport syndrome in both the USA and Europe during Q3

Calliditas' EU commercial partner STADA files with the UK MHRA for full approval for Kinpeygo in IgAN

Calliditas' China commercial partner Everest Medicines receives approval for Nefecon in Macau.

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CMO Richard Philipson

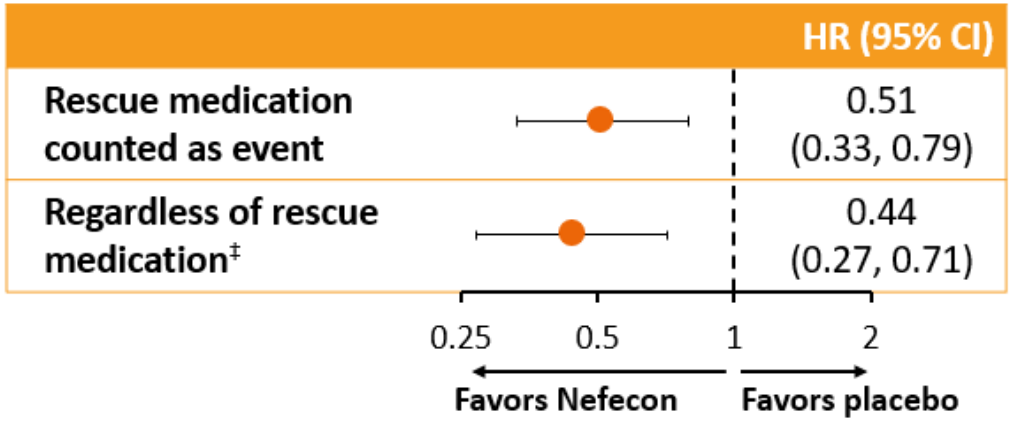
Calliditas Presence at Recent Conferences

- Calliditas has had a strong presence at two recent global nephrology conferences:
  - 17th International Symposium on IgA Nephropathy, Tokyo; 28 – 30th September 2023
  - American Society of Nephrology Annual Meeting, Philadelphia; 2 – 5th November 2023

- Over the two conferences, a total of 12 posters and 4 oral presentations have been given, in additional to educational satellite symposia, demonstrating our commitment to IgA nephropathy and rare kidney diseases

Time to 30% reduction in eGFR or kidney failure in NeflgArd Trial

- Time to 30% reduction in eGFR* or kidney failure was a secondary endpoint in the NeflgArd trial
- The time to this composite endpoint was significantly delayed with Nefecon vs placebo
  - Nefecon 16 mg/day versus placebo: HR 0.45 (95% CI 0.26, 0.75), p=0.0014 (1-sided)†
- In a *post hoc* analysis‡, the Nefecon treatment effect on the risk of 30% reduction in eGFR or kidney failure was consistent, irrespective of baseline UPCR



	Patients who experienced an event, % (n/N)
Nefecon	11.5% (21/182)
Placebo	21.4% (39/182)

*A 30% reduction in eGFR was confirmed by two values over ≥4 weeks. To prevent informative censoring, death from a renal-related event, patients who experienced dialysis for at least 1 month, kidney transplantation or kidney failure (defined as a sustained eGFR <15 mL/min/1.73 m^2 prior to a 30% reduction) were included as having had a clinical event occurring at that time.
†In an IPCW analysis, patients who received rescue medication or other prohibited immunosuppressive medications were censored at the time of their last eGFR measurement before receiving the medication. ‡Post hoc analysis using a standard Cox model.
CI, confidence interval; eGFR, estimated glomerular filtration rate; HR, hazard ratio; IPCW, inverse probability of censoring weights.

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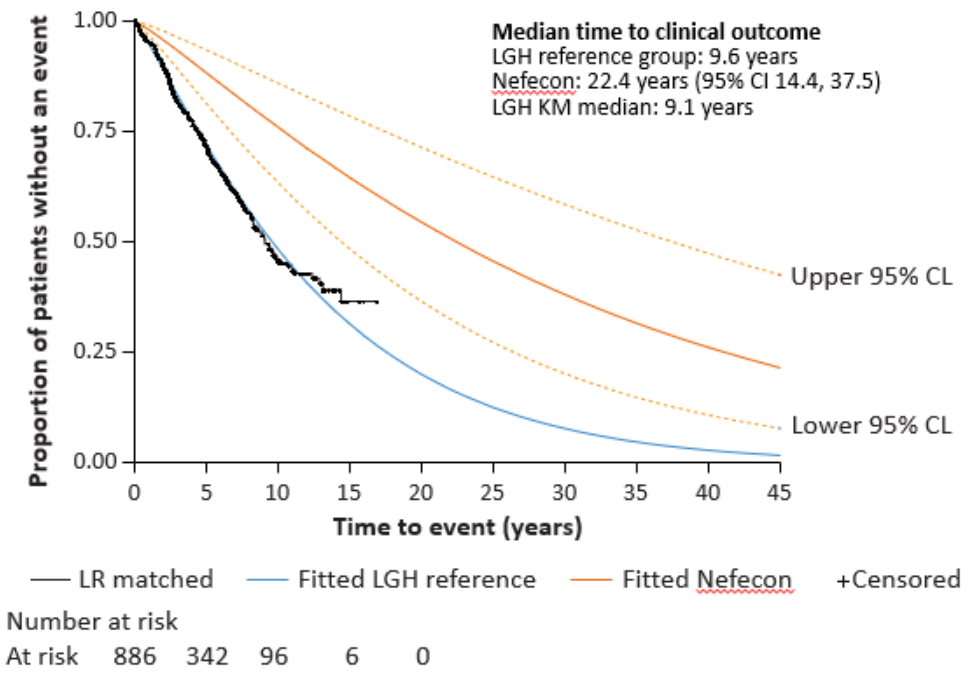
Prediction of Long-term Clinical Benefit of Nefecon in a Real-world IgAN Population

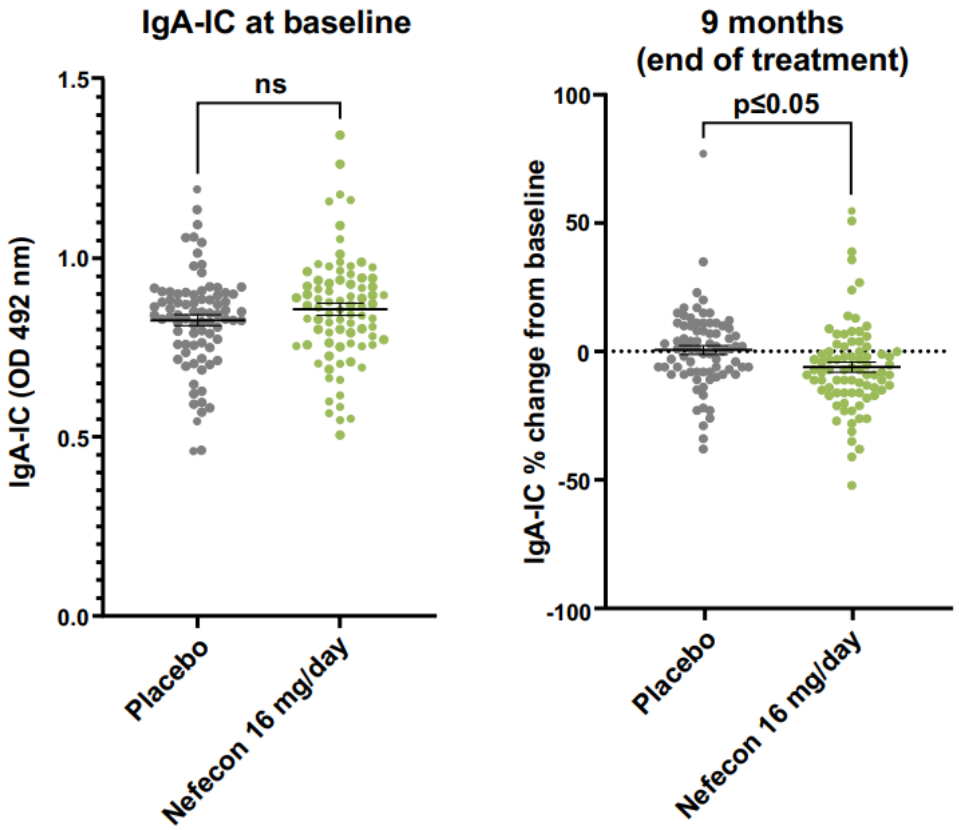
- eGFR total slope from the NefIgArd trial was used to calculate a hazard ratio (HR) for the clinical outcome, using the Inker meta-analysis[1]
  - HR = 0.38 (95% CI 0.21, 0.63)
- A matched registry cohort receiving supportive care only was used to generate a reference time to event curve
- In comparison to this matched reference cohort, using the calculated HR of 0.38, the median delay to clinical outcome attributed to Nefecon was 12.8 years (95% CI 4.8, 27.9)
- There was a relative reduction of approximately 50% in the proportion of patients expected to have a clinical outcome event within 10 years (24% vs 52%, Nefecon vs placebo)



1. Inker LA, *et al. J Am Soc Nephrol* 2019;30:1735-1745.

Suppression of Circulation IgA-containing Immune Complexes

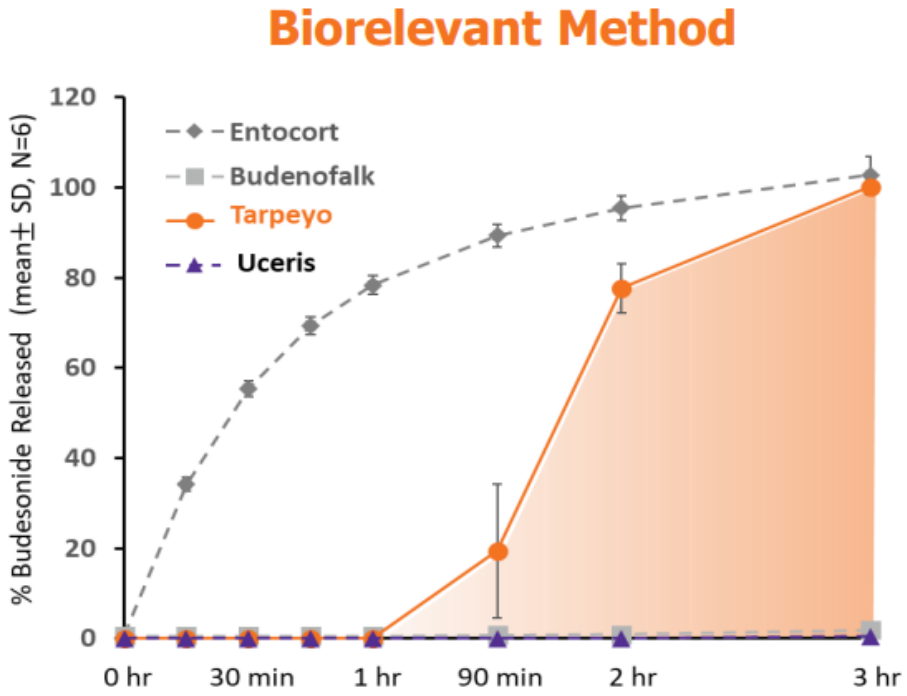
- A key contributor to IgA-containing immune complex (IgA-IC) formation is an excess of poorly *O*-galactosylated IgA1 (Gd-IgA1) in the circulation
- IgA-IC levels in 160 patients in the NefIgArd trial were measured at baseline, during and after treatment
- Levels of Ig-IC were similar in the treatment groups at baseline
- Nefecon significantly reduced levels of IgA-IC at throughout the treatment period (compared to placebo), supporting the disease-modifying effect of the treatment



In Vitro Dissolution Profile of Nefecon

Implications for product interchangeability

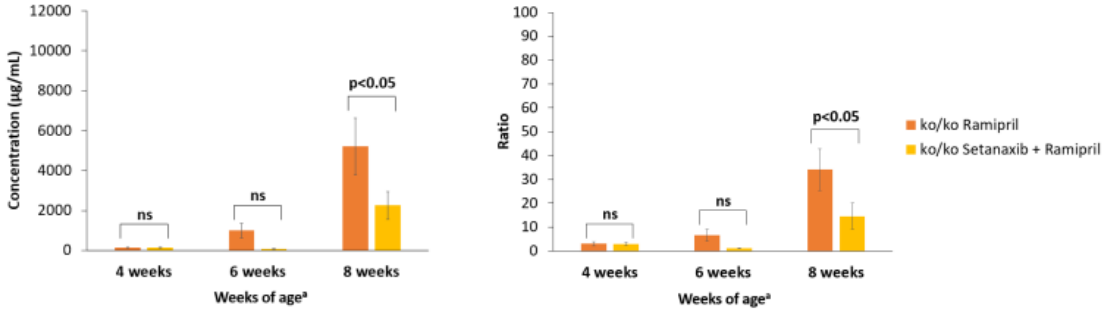
- The *in vitro* dissolution profiles of Nefecon and three other budesonide formulations (Entocort, Budenofalk and Uceris) were compared in experiments based on USP, FDA, and EMA guidelines
- Under biorelevant experimental conditions, the four different formulations had distinct dissolution profiles
  - Using Nefecon as a reference, the three other formulations of budesonide were shown to be statistically dissimilar
- The rapid release of budesonide from Nefecon after 1 hour in intestinal conditions is expected to result in a localized release of budesonide to the Peyer's patch-rich ileum, the target tissue for downregulation of galactose-deficient IgA1 production[2]
- The differing dissolution profiles, together with differences in indications, doses, duration of treatment, and dosing conditions, indicate there is no basis to consider the four products to be pharmaceutically or therapeutically interchangeable[1]

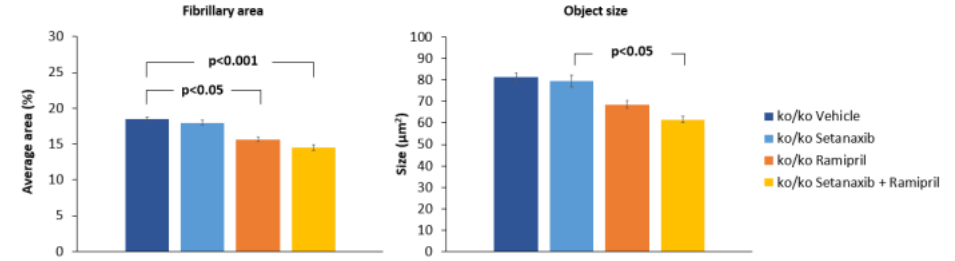


1. Dressman J, et al. Dissolution Technol 2023 (Nov) – accepted for publication
2. Barratt J et al. NeflgArd Study Steering Committee. Kidney Int Rep. 2020;5(10):1620-1624.

Setanaxib in Alport Syndrome

- Alport syndrome is a rare genetic disorder of collagen, typically presenting in childhood or adolescence, resulting in progressive kidney damage, hearing loss and vision problems
- A *Col4a3* -/- KO mouse model of Alport syndrome was used to evaluate the effects of setanaxib, ramipril (as a positive control) or a combination
- The combination of setanaxib and ramipril led to a statistically significant reduction in albuminuria and albumin-to-creatinine ratio (ACR) compared with ramipril monotherapy
- The combination of setanaxib and ramipril also significantly decreased glomerular sclerosis, which was further confirmed by Sirius red quantification of overall kidney fibrosis
- Outcomes suggestive of possible rescue of glomerular basement membrane





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President, North America Andrew Udell

Q3 2023 US Financial Metrics

367
New Patients enrolled in Q3
YTD patients enrolled: 1,198

197
New Prescribers in Q3
LTD Prescribers: 1,338

86%
Of patients enrolled in TARPEYO Touchpoints got TARPEYO* YTD

$26.3M Net sales of TARPEYO in Q3

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

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Continue to Build upon Success with A Focused Strategic Approach

FDA grants priority review for the full approval of TARPEYO - PDUFA December 20th

Full results from the NefIgArd Phase 3 trial published in The Lancet

8 Presentations at IIGaNN including NefIgArd Phase 3 trial and biomarker data

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Exciting Journey Ahead

7 abstracts presented at ASN.

Live education and scientific data exchange at ASN, November 1-4 2023, in Philadelphia

December 20, 2023

PDUFA Date

Potential for full approval.

Commercial and medical affairs expansion to meet the increased demand and growing IgA Nephropathy market opportunity

*Subject to review and approval by the FDA

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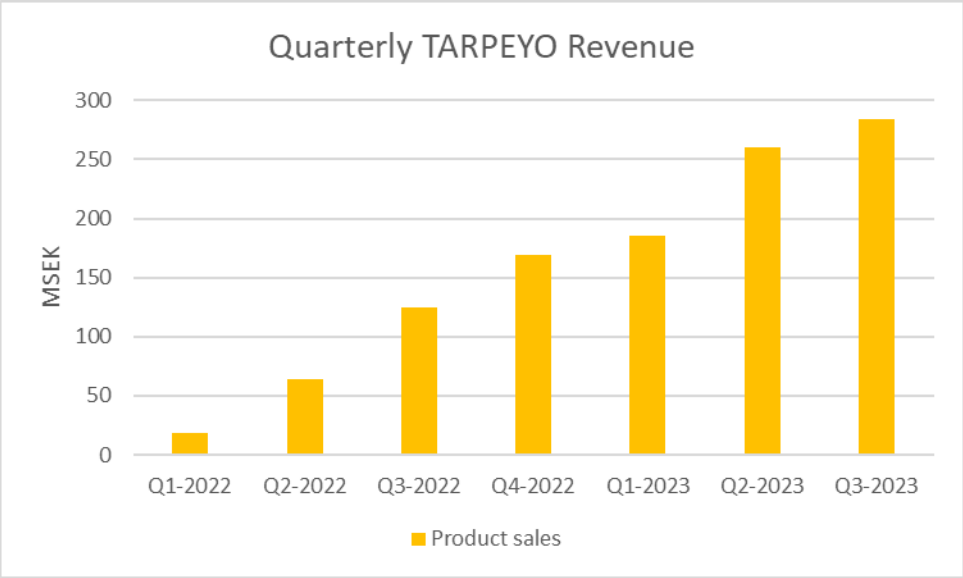
CFO, Fredrik Johansson

Financial Overview – Third Quarter 2023



MSEK	Jul-Sep 2023	Jul-Sep 2022
Net sales	294,6	260,1
Gross profit	279,7	255,7
Operating loss	159,6	36,2
Loss for the period	168,4	9,1
	Sep 30 2023	**Sep 30 2022**
Cash Position	786,9	736,2

- Revenues for Q3 2023 of SEK 294.6 M vs SEK 260.1 M for Q3 2022.
  - Whereof SEK 283.6 M (USD 26.3 M) in net sales from TARPEYO vs SEK 123.4 M (USD 12.1 M) for Q3 2022, a growth of 130%.
  - Whereof SEK 11.0 M from partners vs SEK 136.7 M for Q3 2022.
- Operating expenses Q3 2023 amounted to SEK 439.2 M vs SEK 292.0 M for Q3 2022.
- Operating loss Q3 2023 amounted to SEK 159.6 M vs SEK 36.2 M for Q3 2022.
- Cash used in operating activities for Q3 2023 amounted to SEK 62.5 M (appr. USD 5.8 M) vs SEK 124.7 for Q3 2022.
- The cash position per end of September 2023 was SEK 786.9 M (appr. USD 72.6 M) vs SEK 736.2 M per end of September 2022.

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Key Takeaways

- Impact starting to be seen from publication of full Phase 3 data in The Lancet
- Data supporting the local mode of action and long term benefits of treatment with TARPEYO shared at two recent global nephrology conferences based around 12 posters and 4 oral presentations
- Q3 TARPEYO revenues of SEK 284M (USD 26.3M) and somewhat softer prescription numbers reflecting summer seasonality as expected, followed by strong growth observed in early Q4.
- Continued low cash burn of SEK 73M (~ USD 6.8M) during the quarter, resulting in strong cash position of SEK 787M.
- Positive momentum from ASN focused on increased awareness of longitudinal data related to progression of IgAN patients and increased sense amongst nephrologists of need to treat.
- Confirming revenue guidance for 2023 of USD 100 – 120M