calliditas
THERAPEUTICS

Q4 2023 REPORT

February 21, 2024

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 Calliditas' strategy, commercialization efforts, business plans, regulatory submissions, clinical development 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 Calliditas' business, operations, continued and additional regulatory approvals for TARPEYO and Kinpeygo, market acceptance of TARPEYO and Kinpeygo, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, revenue and product sales projections or forecasts, including 2024 revenue guidance, cash runway and other risks identified in the section entitled "Risk Factors" in Calliditas' reports filed 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.

Q4 Highlights

On December 20th the FDA granted full approval of TARPEYO based on the submission of the full Phase 3 data set in June of 2023. The Phase 3 trial showed a highly statistically significant outcome on the primary endpoint of eGFR ($p < 0.0001$). Additional supportive data; slope analysis of 3ml/min/year in favour of TARPEYO versus placebo and statistically significant impact on microhaematuria and biomarkers such as IgA1

The new indication; reduction of loss of kidney function is now also indicated for the entire IgAN population at risk of disease progression.

Conditional approval of Nefecon in China was granted in November, providing access to a very large market opportunity where IgAN is not a rare disease, with estimates of up to 5 million patients.

Initiation of a Phase 2 trial in Alport syndrome in November, 2023 with setanaxib, a rare kidney disease for which there today is no approved medication.

The US PTO issued a Notice of Allowance for a new patent covering TARPEYO until 2043 on December 11th

Refinancing of existing credit line with Athyrium Capital LP on December 27th

calliditas THERAPEUTICS

Commercial Highlights

Q4 saw record enrolment growth, quarter over quarter, with a 51% increase in enrolments over Q3. New prescribers also grew by 53% in Q4 over Q3, reflecting an improved familiarity with, and increased understanding of, the disease modifying potential of TARPEYO

Total revenues of SEK 452 M for the 4th quarter (USD 42.4M), out of which TARPEYO net sales represented SEK 347 M (USD 32.6M), reflecting a 22% growth over Q3 2023 and a 108% growth over Q4 2022.

Positive operating cashflow in the quarter; communicated target achieved

Expecting some initial disconnect between new US label and market access rules due to P&T committee processes – typical seasonality in Q1 also expected

Potential full EMA approval of Kinpeygo in 1st half 2024, providing impetus for continued European commercial growth

Targeted commercial launch in Q2 of 2024 in China

calliditas THERAPEUTICS

Post period events

Patent covering TAREPYO

January 24th - patent issued
February 13th - patent becomes valid
February 16th - FDA Orange Book is updated for TARPEYO, adding US 11,896,719

Maria Törnsen appointed as President of North America

Key Events in 2023 – A successful year!

- ✓ Successful readout of NefIgArd Phase 3 clinical study; p> 0.0001; filing for full approval with the FDA 3 months after read out
- ✓ Filing for full approval of Kinpeygo with EMA
- ✓ Phase 3 data published in The Lancet
- ✓ Interim readout of setanaxib data from Head and Neck cancer study – exciting data
- ✓ China conditional approval for Nefecon granted
- ✓ Notice of Allowance for TARPEYO patent until 2043
- ✓ Full approval of TARPEYO by the FDA – First and Only
- ✓ Product revenues of over $100m achieved in first full year of commercialization

CATEGORY LEADER IN A GROWING MARKET!

calliditas THERAPEUTICS

calliditas
THERAPEUTICS

CMO Richard Philipson

Calliditas Recent Scientific Communications

CALLIDITAS HAD A STRONG PRESENCE AT KIDNEY WEEK, A CONFERENCE ORGANISED BY ASN (AMERICAN SOCIETY OF NEPHROLOGY) IN NOVEMBER OF 2023:

American Society of Nephrology Annual Meeting, Philadelphia; 2 – 5th November 2023

7 abstracts and presentations

Select scientific communications

- 30% reduction in eGFR or kidney failure
- Prediction of Long-term Clinical Benefit of Nefecon in a Real-World IgAN population
- Suppression of IgAN circulating autoimmune complexes

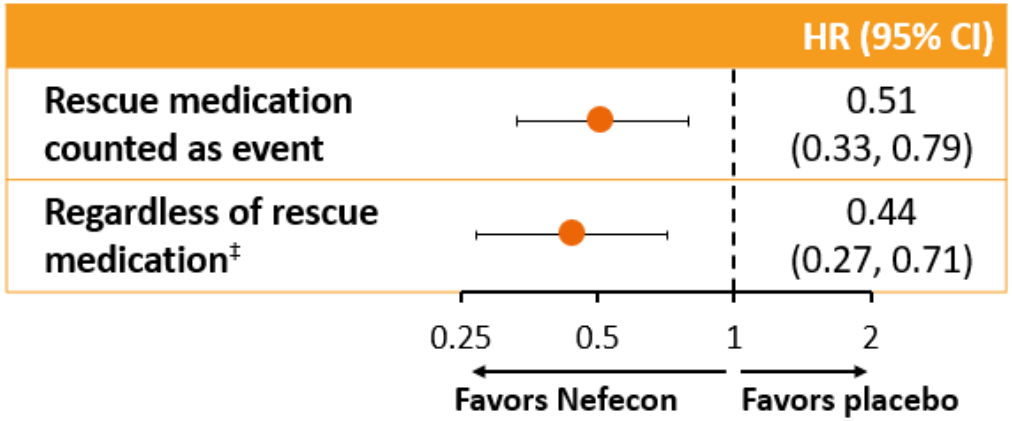
Time to 30% reduction in eGFR or kidney failure in NeflgArd Trial

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.

calliditas THERAPEUTICS

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

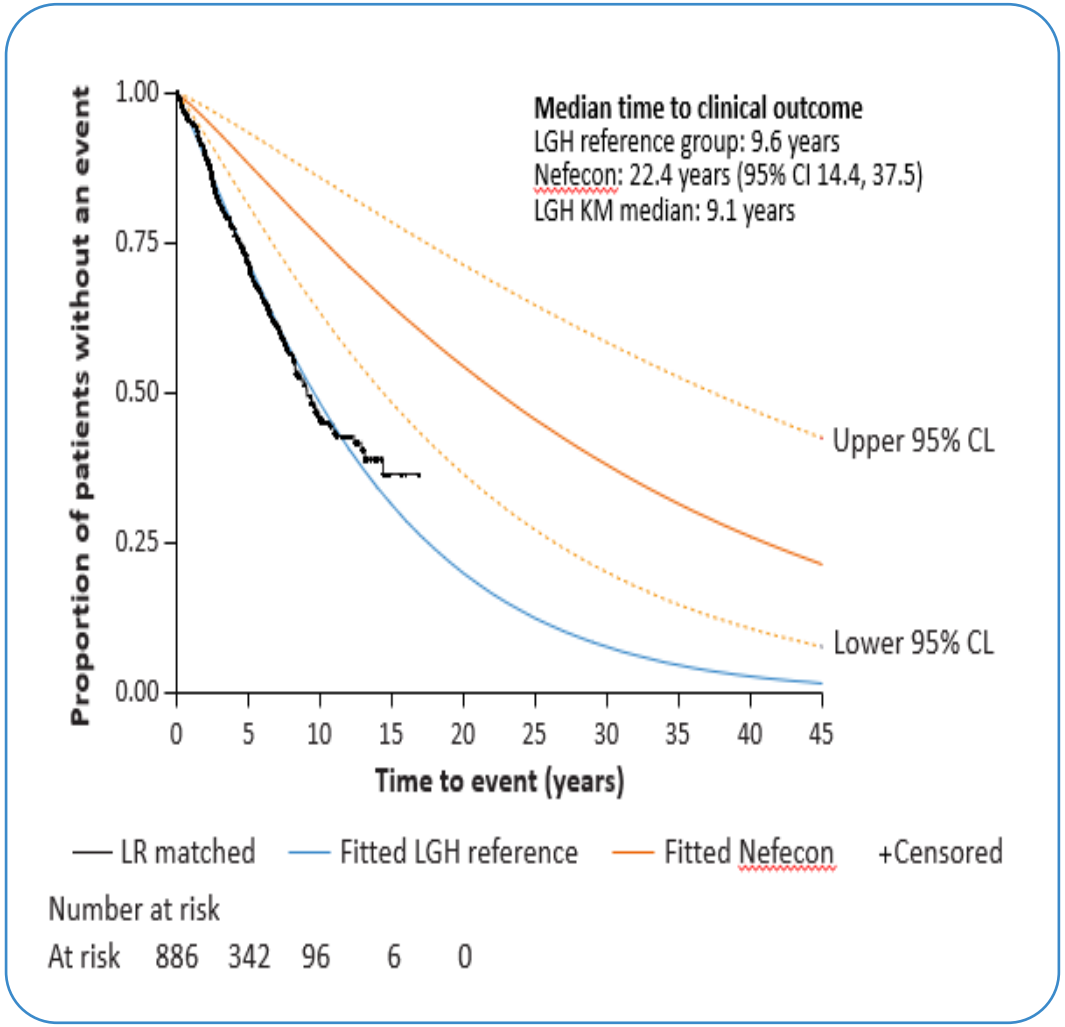
eGFR total slope from the NefIgArd trial was used to calculate a hazard ratio (HR) for the clinical outcome, using the Inker meta-analysis[1]

- 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

calliditas THERAPEUTICS

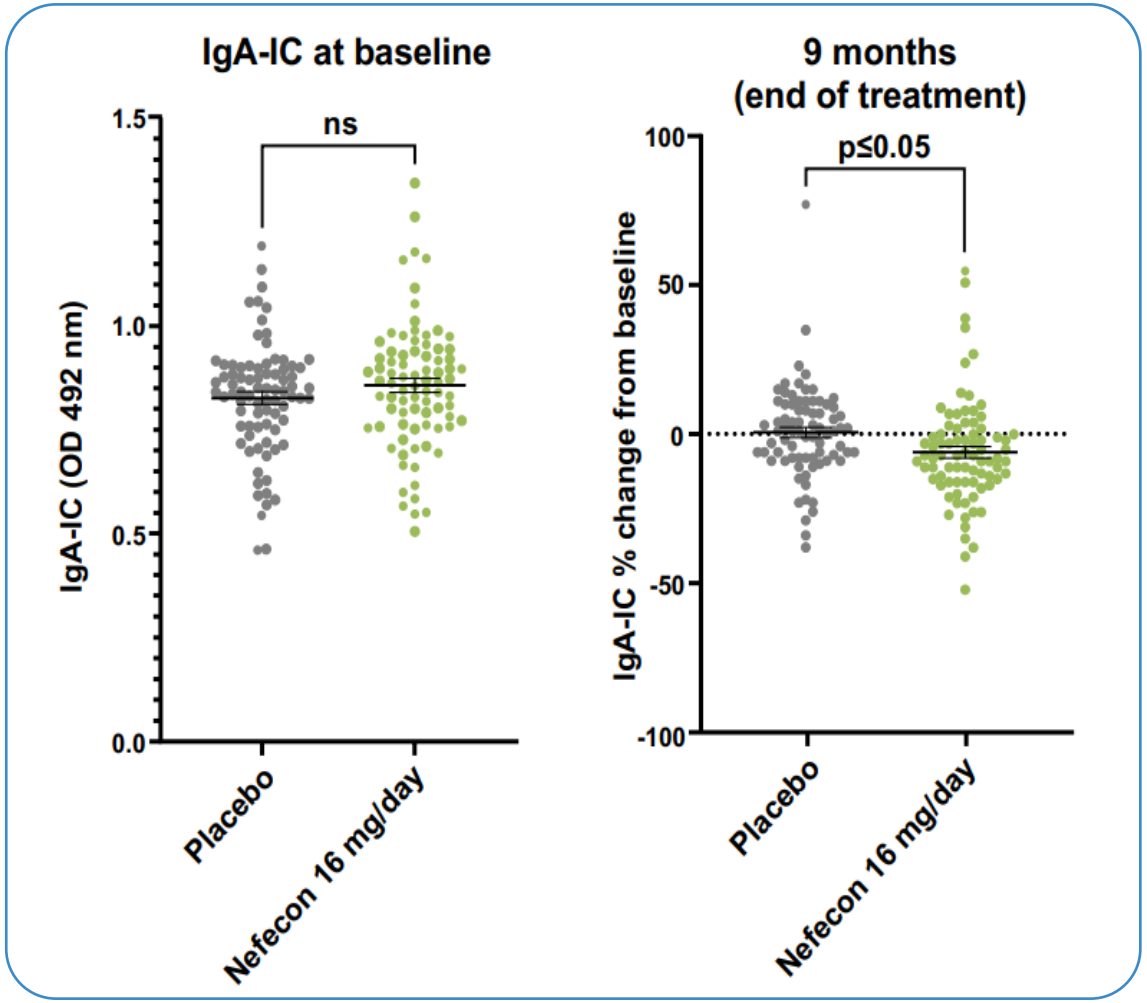
Suppression of Circulation IgA-containing Immune Complexes

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



calliditas THERAPEUTICS

calliditas
THERAPEUTICS

President, North America Maria Törnsén

Q4 2023 US Financial Metrics

555
New Patients enrolled in Q4
FY 2023 patients enrolled: 1,753

301
New Prescribers in Q4
LTD Prescribers: 1,639

>90%
Payor coverage of US lives

$32.6M Net sales of TARPEYO in Q4

Q4 Achievements

December 20th FDA granted full approval of TARPEYO: indicated to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression

Commercial and Medical Affairs expansion to meet the increased demand and growing IgAN nephropathy market opportunity

Dedicated field reimbursement and payor team

Exciting Journey Ahead

KDIGO guidelines

Update expected in 2024

Ability to promote full approval label with recently increased field organization

Open Label Expansion (OLE) data from patients with a second 9M treatment expected in H1 2024

calliditas
THERAPEUTICS

CFO, Fredrik Johansson

Financial Overview – Fourth Quarter 2023

MSEK	Oct-Dec 2023	Oct-Dec 2022
Net sales	451,6	429
Gross profit	429,3	421,2
Operating income	41,8	32,5
Loss for the period	18,4	3,7
	Dec 31 2023	**Dec 31 2022**
Cash Position	973,7	1249,1

Total revenues for Q4 2023 of SEK 451.6 M vs SEK 429.0 M for Q4 2022

- Whereof SEK 347.3 M (USD 32.6 M) in Q4 2023 net sales from TARPEYO vs SEK 167.3 M (USD 16.1 M) for Q4 2022, a growth of 108%.
- Whereof SEK 104.3 M from partners vs SEK 261.8 M for Q4 2022.

Operating expenses in Q4 2023 amounted to SEK 387.5 M vs SEK 388.7 M for Q4 2022.

Operating income in Q4 2023 amounted to SEK 41.8 M vs SEK 32.5 M for Q4 2022.

Cash from operating activities for Q4 2023 amounted to SEK 22.8 M (appr. USD 2.2 M) vs SEK 230.0 for Q4 2022.

The cash position per end of December 2023 was SEK 973.7 M (appr. USD 93.6 M) vs SEK 1,249.1 M per end of December 2022.

Outlook 2024 - Total net sales are estimated to be USD 150-180 million for the year ending December 31, 2024

calliditas THERAPEUTICS

Key Takeaways

- Full approval of TARPEYO in the US reflecting a new label incorporating eGFR
- Data supporting disease modification, the local mode of action and long term patient benefits of treatment with TARPEYO shared at recent nephrology conference
- Q4 net TARPEYO revenues of SEK 347M (USD 32.6M) and record enrolment numbers
- Positive cash flow from operations with a strong cash position of SEK 974M
- Positive momentum from the nephrology market focused on eGFR data, increased awareness of longitudinal data related to progression of IgAN patients and positive patient experiences including their ability to choose an intermittent treatment
- Total revenue guidance for 2024 reflecting strong growth expectations of USD 150 – 180M
- **Category leader – Disease modification**

calliditas THERAPEUTICS