

Q2 2024 REPORT

August 13, 2024

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Q2 Highlights



Conclusion of the Phase 3 NeflgArd study with the supportive read out of the Open Label Extension study as reported in April.



Positive read out of the Phase 2 Proof of Concept study in Head and Neck cancer with lead product candidate from our novel and unique NOX inhibitor platform, setanaxib.



The commercial launch of Nefecon in China by Everest Medicines in May.



Additional patent issuance by the USPTO for setanaxib for treatment in cancer, with expiry in 2039.



EMA issued positive opinion for full approval of Kinpeygo[®] for the Treatment of Primary IgA Nephropathy in Adult Patients



Presentation of additional clinical data and analysis at the ISN World congress, the European Renal Association, as well as on the R&D Day held on May 30, 2024.

Offer Announced by Asahi Kasei



Announcement on May 28, 2024 of public cash offer to acquire all shares in Calliditas for SEK 208 in cash per share (SEK 416 in cash per ADS)

Total value of the offer:
SEK 11,164 million

Premium of 83 per cent to day prior



Asahi Kasei published the offer documents on July 17, 2024

The acceptance period of the offer commenced on July 18, 2024 and will expire on August 30, 2024, subject to any extensions



Major shareholders (combined interest ~44.65% total shares) have entered into undertakings with Asahi Kasei to accept the offer, subject to customary conditions

Calliditas Board unanimously recommended that the shareholders of Calliditas accept the offer

Commercial Highlights Q2



With 750 enrolments, Q2 was another record quarter in terms of enrolments, cementing the category leadership of TARPEYO based on continued strong demand from nephrologists.

Record quarterly net TARPEYO revenues of SEK 493 million (\$46.3M) with year to date Nefecon franchise related revenues of SEK 855 million (~ \$80 M).



Operating loss of SEK 31.5 million. Excluding advisory costs related to the Offer by Asahi Kasei and incentive program provisions of approximately SEK 102 million, adjusted operating profitability¹ achieved in the ordinary course of business of approximately SEK 70 million.



Significant number of P&T committee meetings with most major plans having adjusted their rules to reflect the new label, either removing UPCR restrictions or adjusting to study criteria.



Expect updated KDIGO guidelines to further drive the acceptance, and appropriate use of TARPEYO reflecting its disease modifying potential, achieving early stabilization of eGFR.



Revenue from partners grew by SEK 49 million, reflecting growth of 286% over last quarter.

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Post period events



Positive Phase 2b data in PBC (Primary Biliary Cholangitis)

Primary endpoint of ALP reduction achieved
Positive trends for liver stiffness at 24 weeks
Generally well tolerated

European Commission grants full approval of Kinpeygo in Europe for treatment of adults with IgAN
Significant broadening of label to reflect study population
Triggering a EUR 10 million milestone payment to Calliditas in Q3

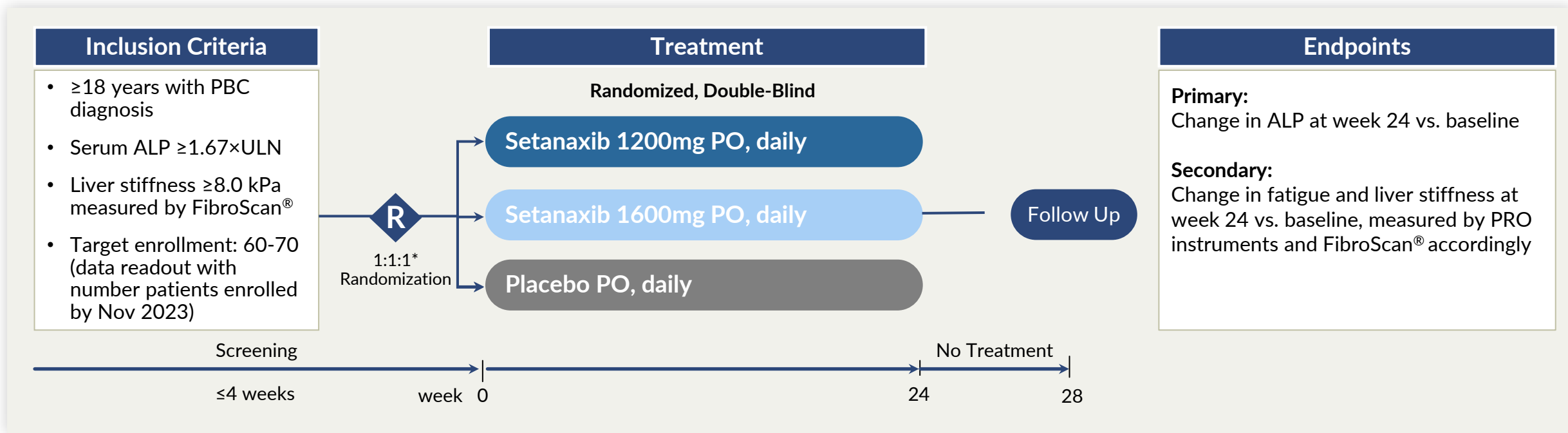
CMO Richard Philipson

Setanaxib Update

Topline results of GSN000350 (TRANSFORM) – setanaxib in Primary Biliary Cholangitis

Study Design

TRANSFORM - Phase 2b Study in Primary Biliary Cholangitis



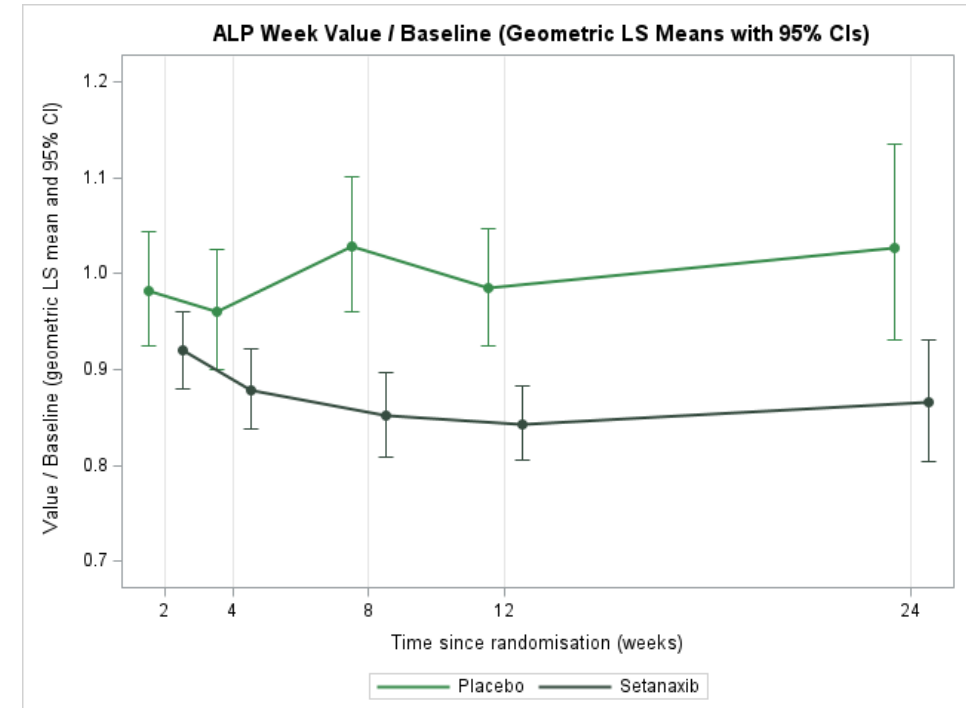
Baseline Characteristics

- 178 patients screened and 77 patients randomised
- Demography and baseline characteristics were representative of the target patient population
- Treatment arms were generally well balanced
- Heavily pre-treated population at baseline
 - 33 (43.4%) patients were receiving dual therapy (UDCA + OCA or UDCA + fibrate)
 - 10 (13.2%) patients were receiving triple therapy (UDCA + OCA + fibrate)

	All setanaxib N=49	Placebo N=27
Age, years (mean)	58.1	56.0
Sex, female (n [%])	46 (93.9)	25 (92.6)
Race, white (n [%])	42 (85.7)	23 (85.2)
Liver stiffness, kPa (geo mean)	11.6	14.0

Change from Baseline in the Ratio of ALP

- At week 24, the change from baseline in the ratio of ALP was statistically significant for both dose comparisons versus placebo*
 - 1600mg: 19% effect vs placebo, $p=0.0057$
 - 1200mg: 14% effect vs placebo, $p=0.021$
- Although week 24 was the primary comparison, significant changes observed from week 8

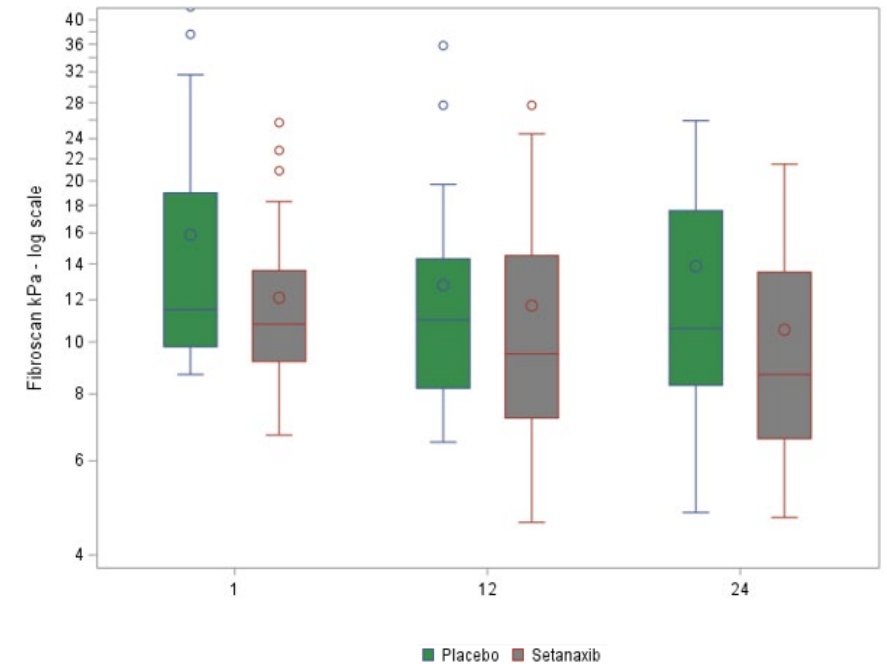


Significant difference (nominal $p=0.0039$) between the combined dose and placebo observed from week 4

*adjusted for multiple comparisons

Change in Liver Stiffness Over 24 Weeks Using Fibroscan®

- Favourable improvements in liver stiffness observed at 24 weeks in patients treated with setanaxib, compared to placebo
- Clinically relevant changes in liver stiffness typically detectable by Fibroscan® over a 52 week observation period



Safety

- TEAEs were balanced across treatment groups overall
- 76% of setanaxib patients and 85% of placebo patients experienced at least one TEAE
 - Most TEAEs were considered unrelated to treatment
- Serious TEAEs occurred in 12% of setanaxib patients and 11.5 % of placebo patients
- TEAEs leading to study treatment discontinuation occurred in 14% of setanaxib patients and 7.7% of placebo patients

	All setanaxib N=50	Placebo N=26
Any TEAE, n (%)	38 (76.0)	22 (84.6)
Any CTCAE grade ≥ 3	5 (10.0)	2 (7.7)
Any TESAЕ	6 (12.0)	3 (11.5)
Any TEAE leading to treatment discontinuation	7 (14.0)	2 (7.7)

Safety

- Of the adverse events occurring at a frequency of $\geq 10\%$ in the overall study population:
 - Nausea, headache and pruritus occurred at a higher frequency in placebo-treated patients
 - Arthralgia and fatigue occurred at similar frequencies in the combined setanaxib treatment group and placebo-treated patients
 - Nasopharyngitis occurred at a higher frequency in the combined setanaxib treatment group

Event $\geq 10\%$ in total study population n (%)	All setanaxib N=50	Placebo N=26	Total N=76
Nausea	3 (6.0)	7 (26.9)	10 (13.2)
Arthralgia	6 (12.0)	3 (11.5)	9 (11.8)
Fatigue	6 (12.0)	3 (11.5)	9 (11.8)
Headache	4 (8.0)	5 (19.2)	9 (11.8)
Nasopharyngitis	7 (14.0)	1 (3.8)	8 (10.5)
Pruritus	2 (4.0)	6 (23.1)	8 (10.5)

Conclusions

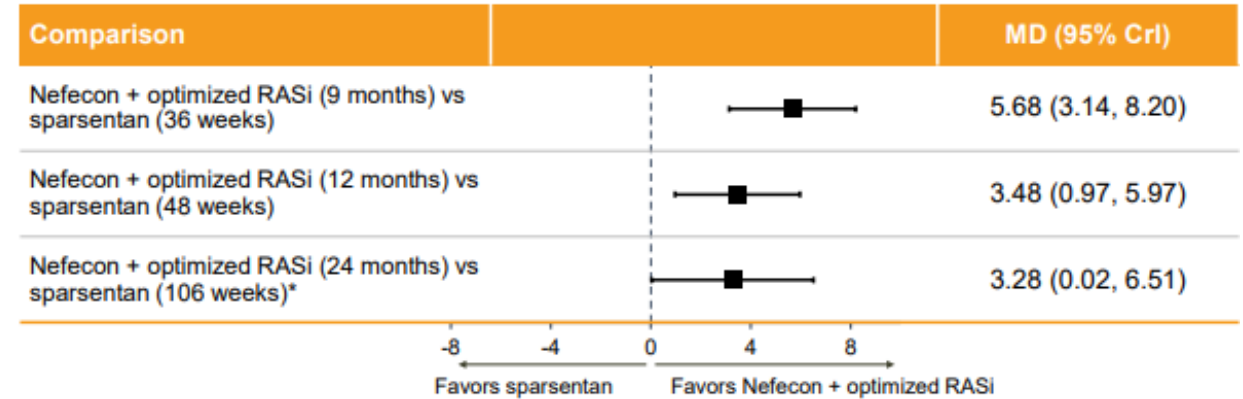
- The primary endpoint was met; statistically significant reductions in ALP in both setanaxib arms versus placebo were observed from week 8 onwards (from week 4 onwards for combined dose comparison)
- Favourable improvements in liver stiffness observed at 24 weeks in patients treated with setanaxib, compared to placebo
- Setanaxib was generally well-tolerated

Nefecon Update

Scientific Communications

Calliditas at ERA-EDTA

- Two oral/ poster presentations:
 - Real-world challenges associated with the use of systemic glucocorticoids in a US IgA nephropathy cohort
 - Matching-adjusted indirect comparison of eGFR in patients with IgA nephropathy treated with Nefecon or sparsentan
- Industry-sponsored symposium
 - “Clinical markers in IgA nephropathy: Is all proteinuria the same?”



President, North America Maria Törnsén

Q2 2024 US Financial Metrics



750

New Patients enrolled in Q2
6% QoQ growth



343

New Prescribers in Q2
LTD Prescribers: 2,336



\$46M

Net sales of TARPEYO® in
Q2 2024

- Record quarter sales since launch; TARPEYO® net sales \$73M YTD
- Strong underlying demand for TARPEYO®, with record number of enrollments and continued growth of new prescribers

Q2 Highlights

Full Approval Promotional Campaign Launch

First and only product FDA-approved to reduce the loss of kidney function



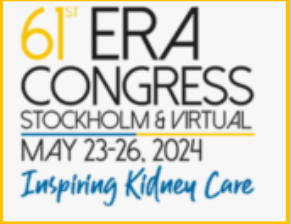
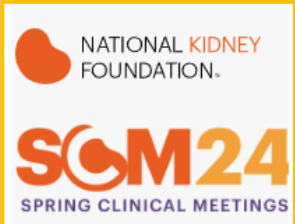
Payor Policies

>80% of lives covered by commercial plans have policies reflecting the new label

>80% have no UPCR criteria or UPCR >0.8



Scientific Congresses



Exciting Journey Ahead



Continue US promotional efforts to drive TARPEYO®'s positioning as a disease-modifying cornerstone therapy in IgAN



Participating in ASN annual congress and driving scientific exchange and data dissemination

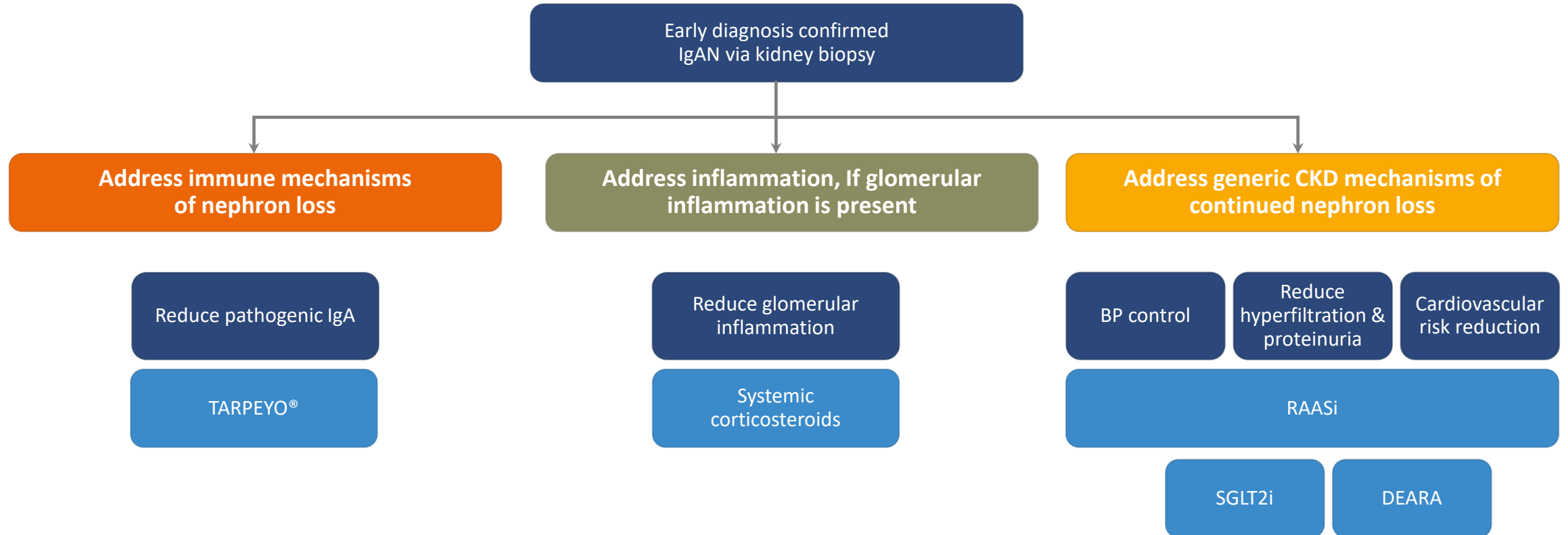


Leverage KDIGO guidelines expected in 2H 2024



Continue to educate and inform US payors on the full approval to ensure TARPEYO® payor policies are reflecting the new label

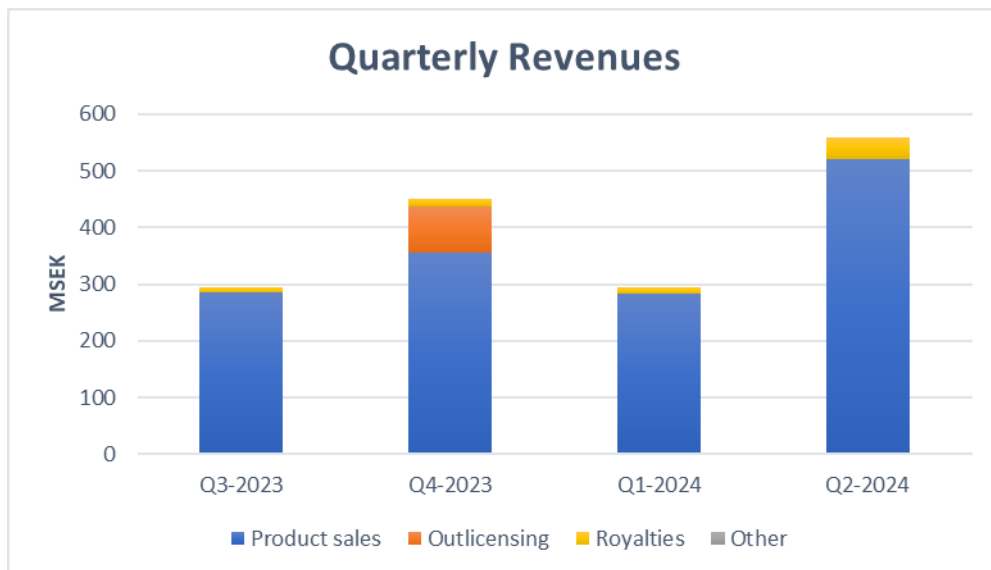
The IgAN Treatment Paradigm is Evolving Reinforcing TAREPYO®'s Position as a Cornerstone Treatment in IgAN



BP=blood pressure; CKD=Chronic Kidney Disease; SGLT2i=Sodium-Glucose Transport Protein 2 Inhibitors; DEARA=Dual Endothelin Angiotensin Receptor Antagonist; RAASi=Renin-angiotensin-aldosterone system inhibitors

CFO Fredrik Johansson

Financial Overview – Second Quarter 2024



- Total revenues for Q2 2024 of SEK 559.8 M vs SEK 269.4 M for Q2 2023.
 - Whereof SEK 493.4 M (USD 46.3 M) in Q2 2024 in net sales from TARPEYO vs SEK 259.2 M (USD 24.7 M) for Q2 2023, a growth of 90%.
 - Whereof SEK 66.4 M from partners for Q2 2024 vs SEK 10.1 M for Q2 2023.
- Operating expenses in Q2 2024 amounted to SEK 537.8 M vs SEK 330.3 M for Q2 2023.
- Operating loss in Q2 2024 amounted to SEK 31.5 M vs SEK 75.2 M for Q2 2023.
 - Excluding expenses related to the Asahi Kasei offer and expenses related to provisions for social security contribution for incentive programs in the quarter, totaling SEK 101.7 M, the adjusted operating profit¹ amounted to SEK 70.2 M.
- Cash used in operating activities for Q2 2024 amounted to SEK 7.0 M vs SEK 163.0 M for Q2 2023.
- The cash position per end of June 2024 was SEK 797.3 M vs SEK 866.2 M per end of June 2023.

MSEK	Apr-Jun 2024	Apr-Jun 2023	Jan-Jun 2024	Jan-Jun 2023
Net sales	559,8	269,4	855,3	460,7
Gross profit	506,3	255,2	787,8	437,5
Operating loss	31,5	75,2	235,3	255,2
Loss for the period	47,5	91,9	293,6	279,5
	Jun 30 2024	Jun 30 2023		
Cash Position	797,3	866,2		

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Key Takeaways for the quarter

- Record quarter in terms of net product revenues (\$46.3 m) for TARPEYO as well as for the Nefecon franchise (~\$53 m)
- Achievement of operational profitability¹, excluding advisory costs related to the Offer by Asahi Kasei and incentive program provisions
- Granting of full approval of Kinpeygo in Europe by the European Commission
- New patent issued by USPTO covering setanaxib with expiry in 2039
- Strong cash position and continued strong demand for TARPEYO
- Total revenue guidance for 2024 updated, reflecting TARPEYO growth expectations of USD 165 – 185M
- **IgAN: Category leader – Backbone treatment - Disease modification**

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Non-IFRS Measure

Adjusted operating profit/loss

(SEK in thousands)	Three Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,
	2024	2023	2024	2023	2023
Operating income (loss)	(31,503)	(75,172)	(235,329)	(255,246)	(373,055)
<i>Adjustments in the operating result:</i>					
Provisions social security contribution for incentive programs	70,532	-	70,532	-	-
Advisor fees for Asahi Kasei public offer	31,218	-	31,218	-	-
Adjusted operating profit (loss)	70,247	(75,172)	(133,579)	(255,246)	(373,055)