

# Q1 2022 REPORT

May 18, 2022

# Disclaimers

## Important information

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# Q1 Highlights

December 15<sup>th</sup> 2021: TARPEYO was granted accelerated approval by FDA in IgA nephropathy, indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR)  $\geq 1.5\text{g/g}$ .

TARPEYO became the first and only approved treatment in the US for this orphan indication and is specifically designed to address the presumed origin of this rare disease.

On January 28, 2022, Calliditas announced that TARPEYO was commercially available in the US, and that same week the company launched its commercial effort in the US, based on 40 sales people backed by an experienced fully integrated medical affairs and commercial leadership team.

Net revenues for TARPEYO in Q1 amounted to \$1.9M (SEK 18.0M) and we continue to see significant interest from all participants.

# Q1 Highlights – cont'd

- First ever approved medication in IgA nephropathy, as rare disease; estimated core target market of 65-75,000 patients in total
- Extremely well-established supportive care paradigm; over 50% of patients prescribed RAS blockade by GPs<sup>1</sup>, titrated by nephrologists to optimized / highest tolerated dose
- Generally slowly progressing disease, with the exception of patients with higher levels of UPCR
- No CD-10 code available

# Q1 Highlights cont'd

Expansion of Everest Medicine's in-licensing agreement of Nefecon for Greater China to also include South Korea. Upfront payment of \$3m.

Dosing of the first patient in the pivotal TRANSFORM study in PBC (primary biliary cholangitis) took place in February of 2022.

# Post period events

Calliditas is on the agenda for the May CHMP meeting; May 16 – 19. Subject to a positive opinion, issuance of a Marketing Authorisation by the EC is expected in Q3, which will be transferred to Stada Arzneimittel AG

We continue to see a very positive development trend in both enrolments and prescriptions for TARPEYO as well as a continuation of P&T committee meetings relating to the coverage of TARPEYO and we remain very encouraged with regards to inbound interest from all relevant market participants

First patient randomised on May 17<sup>th</sup> in the Head and Neck cancer study with setanaxib

Best of AACR Journals - Most cited research articles in 2021 and 2022; “NOX4 Inhibition Potentiates Immunotherapy by Overcoming Cancer-Associated-Fibroblast-Mediated CD8 T-cell Exclusion from Tumors”  
Gareth J. Thomas



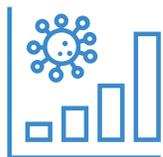
# TARPEYO: Defining the market with the first and only FDA approved drug in IgAN

TARPEYO™ (budesonide) delayed release capsules is a corticosteroid indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR)  $\geq 1.5$  g/g. This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether TARPEYO slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

calliditas  
THERAPEUTICS

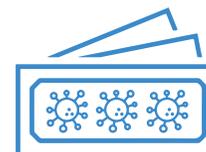
 **TARPEYO**™  
(budesonide) delayed release capsules

# The US IgAN market: Substantial unmet need



## High disease prevalence

- US prevalence: between 130,000 and 150,000
- ~50% of patients are at risk of progressing to end-stage renal disease
- 65% of patients with IgAN likely to progress to dialysis



## Costs associated with disease progression are high

- Costs of dialysis can be significant, at >\$200,000 a year (commercial payers)
- Kidney transplants can cost >\$400,000 and do not always prevent disease recurrence\*



## Leaving an unsatisfied nephrologist market

**52%** of nephrologists believe few or no effective treatment options are available prior to TARPEYO approval

Source: Spherix Global Insights, RealWorld Dynamix IgA Nephropathy 2021 with 188 nephrologists (note 'Nefecon' was the product name used in the research)

\*Cost of dialysis: Childers CP, Dworsky JQ, Kominski G, Maggard-Gibbons M. A Comparison of Payments to a For-profit Dialysis Firm From Government and Commercial Insurers. JAMA Intern Med. 2019;179(8):1136–1138. doi:10.1001/jamainternmed.2019.0431. Cost of transplant: <https://www.statista.com/statistics/808471/organ-transplantation-costs-us/>.

# Our US Commercial Launch leadership team of industry experts



Extensive launch expertise: commercial experience at top-tier pharma (eg, Pfizer, Bayer, BMS, Regeneron)



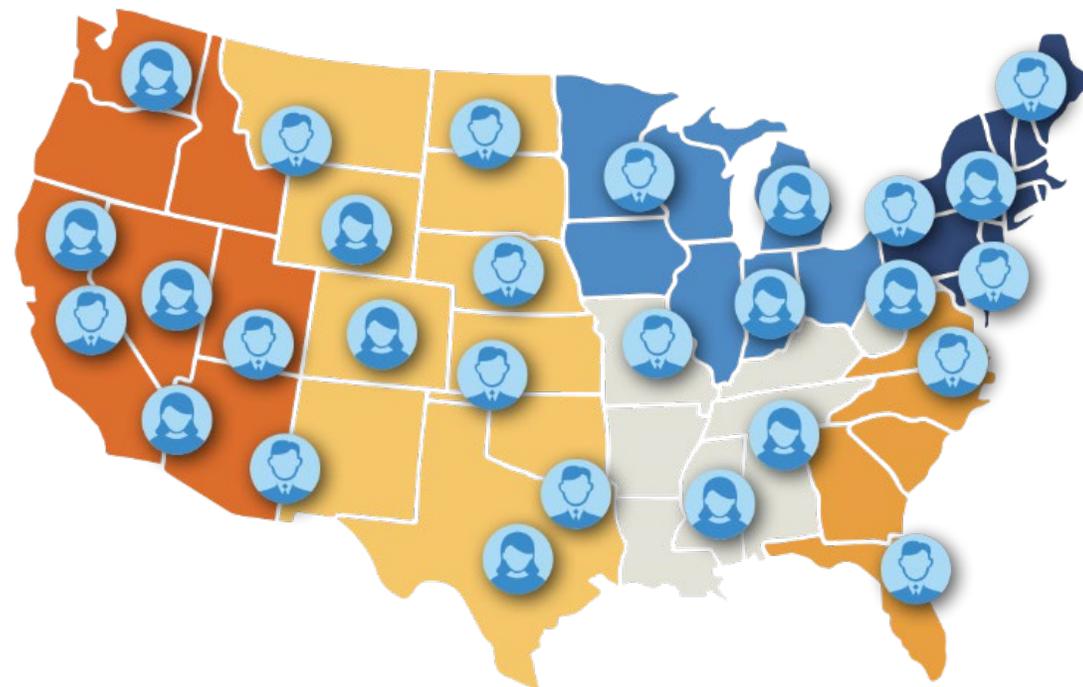
Adept sales force: 40 sales reps with knowledge and experience in rare disease, specialty pharmacy, and nephrology market (70%)



Hands-on managers: 6 national account managers in the field and engaging targeted payers



Expert partners: AmerisourceBergen (ICS), McKesson (Biologics), and CDM and LifeSci (healthcare communications)



# Established highly successful support service for frictionless access

- TARPEYO Touchpoints™: full-service patient and provider support program. Fully operational on day 1 of TARPEYO approval
- Utilizes Biologics by McKesson's PharmacyElite™ model; integrated HUB\* and exclusive Specialty Pharmacy
- Staffed by Care Navigators: dedicated case managers + designated Rare Pod Team (nurses, pharmacists, fulfillment and distribution team)
- Integrated with a financial assistance (commercial co-pay) program provided by CoverMyMeds® from McKesson

\*HUB: Allows a manufacturer to have a singular point of contact with patients. Services generally entail benefits investigation, prior authorization processing, drug delivery and administration support, financial and co-pay assistance, education, compliance with risk evaluation and mitigation strategies (REMS), data reporting, bridge supplies, and prescription triaging.

# A successful foundation that's led to key milestones and results

## Data through Q1, 2022

1

Approved  
Dec 15

2

First sale and  
prescription  
Jan 2022

3

4k+ nephrologists  
calls (including  
virtual)

4

134 enrollments  
111 unique prescribers  
\$1.9M (SEK 18.0M)  
net sales

Q2 (to date):  
Enrollments and  
unique prescribers  
growing at an  
accelerated rate

# Pivotal progress made with market access (as of end of April)



- On average health plans take 6-9 months to review a newly launched product for coverage and formulary placement.
  - Key targeted accounts, including Cigna, Express Script, and Humana, began covering TARPEYO on their predominant formularies
  - TARPEYO is covered by Medicare Part D at launch as it is the only FDA approved treatment in IgAN. For Medicaid patients, the mandatory coverage date is April 1st
- Over 50% of US lives have coverage for TARPEYO (commercial, Medicare, and Medicaid)
- Prior to coverage policies, medical exceptions allow patients in need to gain access.
- To date only one enrolled patient has cancelled due to payer coverage

# Serving a significant number of patients who have eagerly awaited advancements in care

shared a link.

Insurance approved Tarpeyo, hopeful it will decrease my moderate proteinuria which seems to be my primary risk factor for disease progression.

I went through Tarpeyo Touchpoints <https://www.tarpeyotouchpoints.com> for the prescription and it couldn't have been smoother. They assigned a care navigator (I've had them for my Crohn's biologic and they can be super helpful). They took care of the prior authorization and offer a card that brought my \$60 copay down to zero.

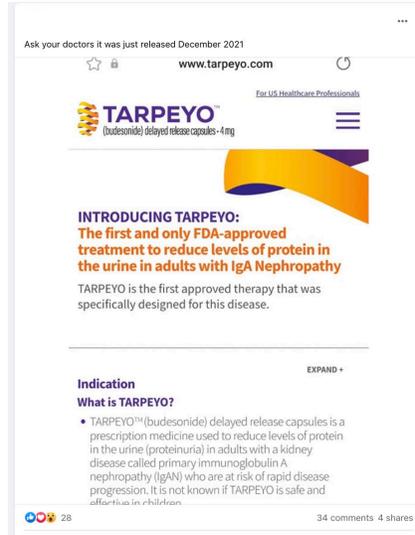
Apparently they use a single specialty pharmacy in North Carolina and the medication will be shipped from there.

Whole process took about one month.

**IgA Nephropathy**

Fed Ex'd overnight after speaking with the pharmacist at their North Carolina specialty pharmacy yesterday afternoon. Whole process couldn't be easier and gratified insurance approved. Of course, being the **ONLY** FDA-indicated med for IgAN probably helps.

Clinical trial showing decrease in proteinuria went for 9 months so that's my commitment 🙌



- Numerous peer-to-peer discussions via social channels creating awareness around launch

**IgA Nephropathy**

Like Comment Send

5

All comments

I also thought that whole process was very easy. Just started my second month. Let's hope it works!

46m Like Reply

Facci sapere per favore See Translation

34m Like Reply

Write a reply...

My new general nephrologist (who just completed his fellowship last year) hadn't even heard of the med when I asked about it. Having lived with autoimmune illnesses for a long time I've learned to be my own advocate.

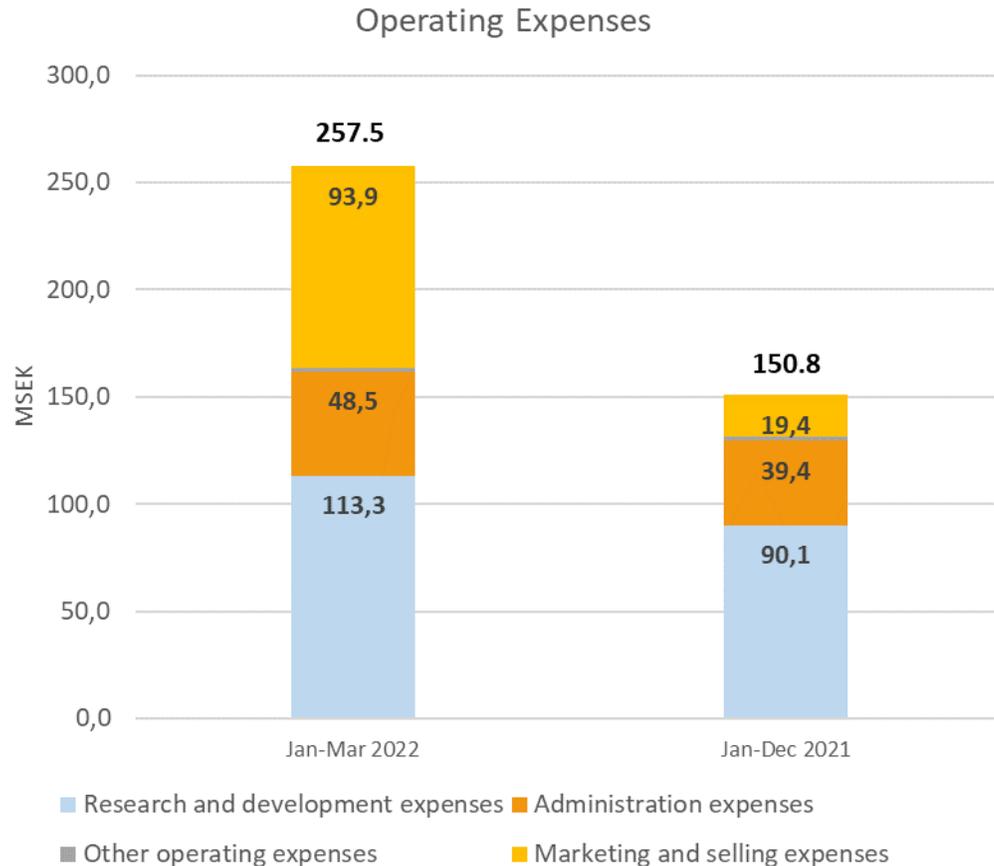


- High engagement and proactivity shown by patients
- Increasing number of inbound inquiries

## Key takeaways

- **Launch excellence:** Expert team leading a strong start to define and establish the market for IgAN following accelerated approval
- **Commercial execution:** Delivered on commercial plan with reach, frequency, and market access (trade distribution, payers, patient services)
- **Strong uptake:** Establishing significant prescribers and sales
- **Promising future:** Encouraging trends

# Financial Overview – Q1 2022



- Revenues of SEK 49.7 M reported in Q1 2022
  - Whereof SEK 18.0 M in net sales from TARPEYO
- Operating loss of SEK 208.4 M vs SEK 150.8 M for Q1 2021
  - Marketing and selling expenses increased by SEK 74.5 M to SEK 93.9 M vs 19.4 M, increase due to full commercial organization in place in Q1 2022, incl sales force.
  - Research and development expenses increased by SEK 23.2 M to SEK 113.3 M vs SEK 90.1 M, Increase primarily due to the setanaxib trials.
- Cash flow used in operating activities was SEK 191.4 M vs SEK 134.2 M.
- Cash flow from financing activities was SEK 60.1 M vs (SEK 9.6 M)
- The cash position per end of March 2022 was SEK 825.4 M vs SEK 867.3 M.