calliditas
THERAPEUTICS

Q4 2021 REPORT

February 24 2022

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Q4 Highlights

- December 15th 2021: TARPEYO 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) ≥1.5g/g.

- TARPEYO is the first and only approved treatment for this orphan indication and has a locally targeted approach, specifically designed to address this disease.

- In Q4, Calliditas finalised its acquisition of the remaining outstanding share capital of Genkyotex SA, which became a wholly owned subsidiary of Calliditas and was delisted from the Euronext stock exchanges.

- Calliditas initiated a pivotal Phase 2b/3 clinical trial, TRANSFORM, in PBC in Q4; the first patient was randomised in February 2022. Callidias is presently also initiating a Phase 2 proof-of-concept trial in head and neck cancer.

Post period events

- On January 28th Calliditas announced the commercial availability of TARPEYO in the US. Shipping of product to patients initiated immediately thereafter.

- Significant inbound interest from nephrologists following the approval. Medical affairs team actively engaged in scientific exchange with large number of healthcare professionals.

- Regulatory process with EMA ongoing. Answers related to the Day 180 questions submitted to EMA.

  Target for opinion from CHMP remains on track for Q1, 2022, with potential conditional approval in Q2.

Commercial Launch

TARPEYO™ (budesonide) delayed release capsules is 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] ≥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.*

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TARPEYO™ (budesonide) delayed release capsules

*Please see full Prescribing Information, available at TARPEYOHCP.com

Unmet medical need, unsatisfied substantial market size

U.S. prevalence is estimated between 130,000 – 150,000, with more than 50% of patients potentially progress to ESRD

Unsatisfied Nephrologist market:

52% Believe there are few/no effective treatment options available (prior to Tarpeyo approval)

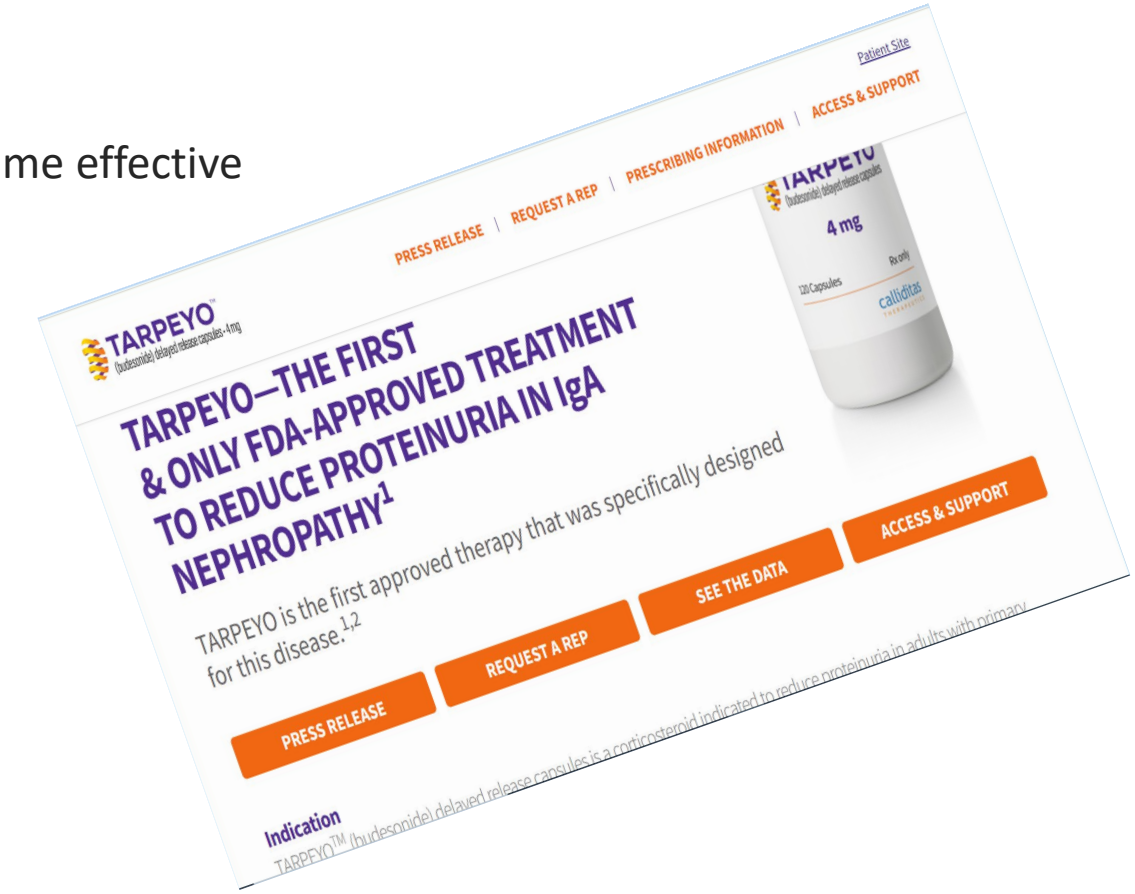
65% Anticipation of IgAN patients they treat who will progress to dialysis

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

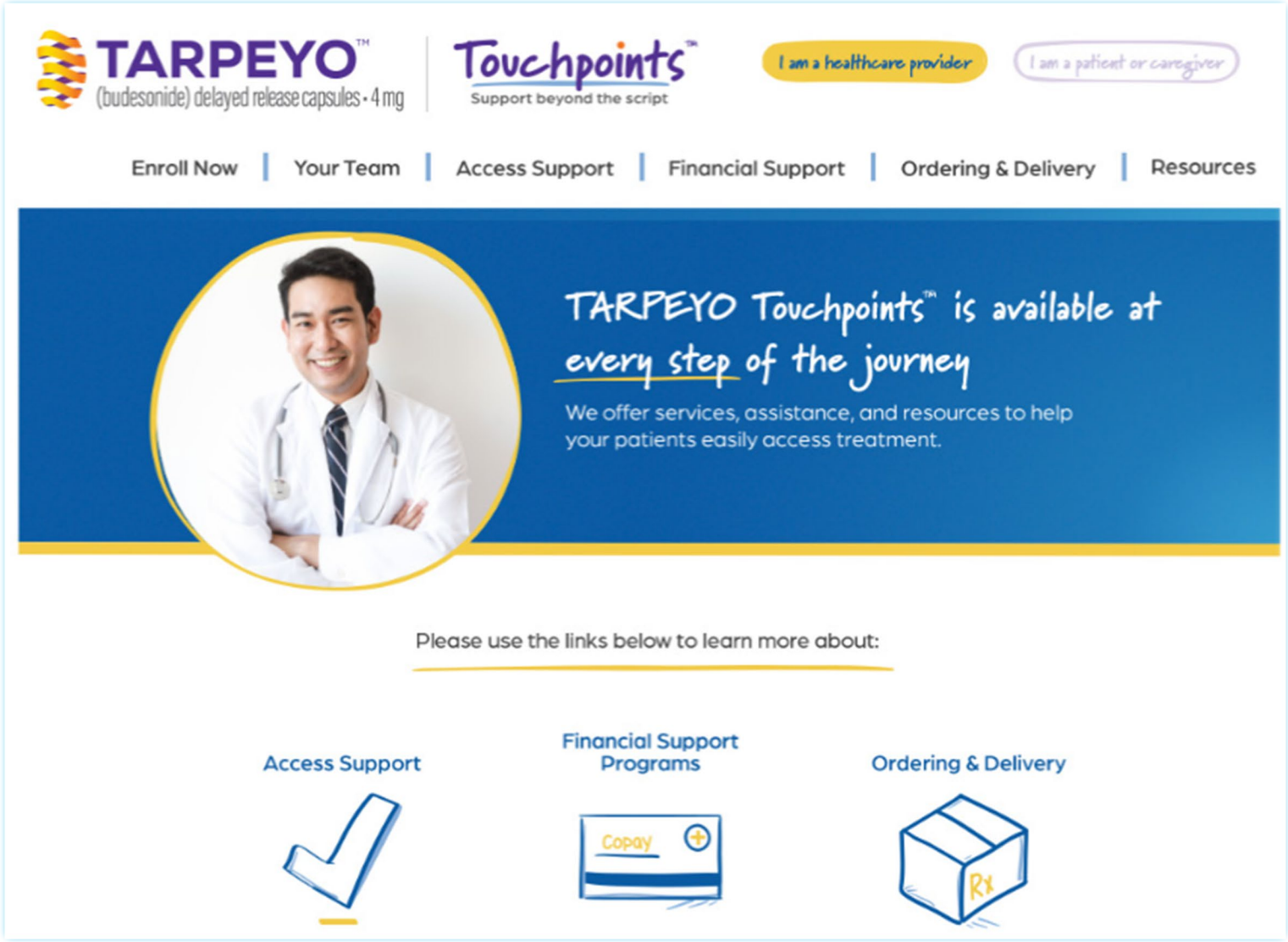
*Cost of dialysis: Childers CP, Dworsky JQ, Kominski G, Maggard-Gibbons M. A Comparison of Payments to a For-profit Dialysis Firm From Government and Commercial Insurers. JAMA Intern Med. 2019;179(8):1136–1138. doi:10.1001/jamainternmed.2019.0431. Cost of transplant: https://www.statista.com/statistics/808471/organ-transplantation-costs-us/).

Immediately Upon Approval

- Digital assets go live!
- Peer-to-peer approval outreach program
- Sales representative contingent offers became effective



Patient and Provider services: TARPEYO Touchpoints™



- **TARPEYO Touchpoints™** is a full-service patient and provider support program, fully operational from December 15th when TARPYEO was approved
- Utilizes **Biologics** by McKesson's *PharmacyElite*™ model – integrated Hub and exclusive Specialty Pharmacy
- Staffed by **Care Navigators** (dedicated Case Managers) and a designated Rare Pod Team (Nurses, Pharmacists, fulfillment and distribution team)
- Integrated with co-pay assistance program provided by CoverMyMeds from McKesson

Sales ready…

- Sales force
  - ✓Recruitment based on rare disease, specialty product, and nephrology market experience
  - ✓Contingent offers accepted for all 40 territories, with over 70% having nephrology experience
  - ✓Training initiated for early deployment in January
- Field force designed to optimize reach and frequency of nephrologists treating IgAN patient population

*Note: As per January 28th press release, sales have commenced.

US Access Environment

- Commercial and government-sponsored health insurances offer thousands of health plans[1]
  - 1,162 commercial plans covering ~185 million lives
  - 2,472 Government plans covering ~130 million lives
- Pharmacy and Therapeutics (P&T) committee at each payer makes:
  - “must add”, “may add” or “do not add” formulary recommendation for new treatments, AND
  - utilization management approach such as prior authorization, step edit/therapy, quantity limits, etc.
- Most payers have a medical exception process in place to provide more nuanced coverage of new treatments for 3 to 6 months prior to P&T committee recommendation
- Payers conduct periodic drug utilization reviews that may change a drug’s formulary position and utilization management

Source: 1. Breakaway Partners LLC.

TARPEYO Payer Engagement

- Focus on 49 payers covering over 80% of commercial lives and key federal/state payers
  - In a 2021 syndicated research, a majority of IgAN patients (68%) have commercial insurance[1]
- National account managers have been engaging targeted payers since Q3 2021
- The P&T committee review of TARPEYO will start in late January 2022, aligned to product availability
  - 8 clinical presentations to payers scheduled, including CVS, ESI and Cigna
  - Most commercial plans expected to complete their P&T review in Q2/Q3 of 2022
- Our exclusive specialty pharmacy partner, Biologics, will help patients and prescribers to navigate the medical exception process
  - Leveraging its experience in working with payers on specialty drugs and our copay assistance program for commercially insured patients

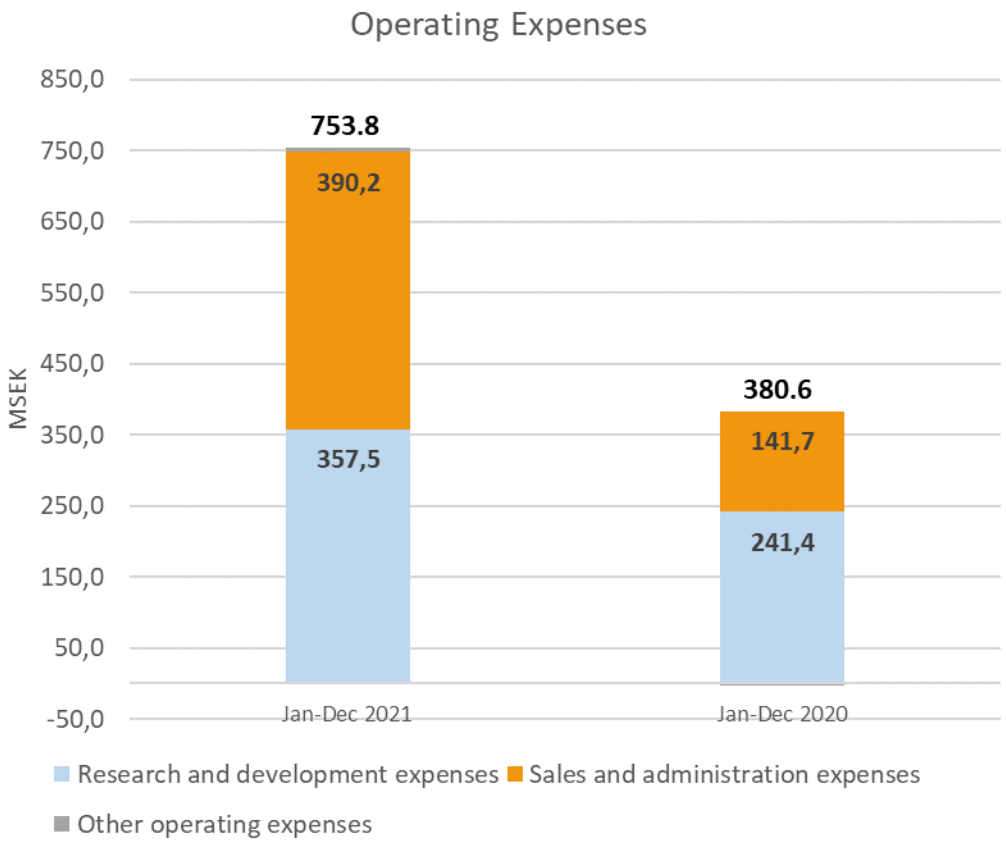
Biologics By McKesson

Source: 1. Spherix RealWorld Dynamix IgAN 2021

Anticipated Payer Management of TARPEYO

- For a specialty drug, such as TARPEYO, it is very common to have a prior authorization (PA) requirement.
- Through payer advisory boards and mock P&T, we anticipate the PA will contain some or all of the following elements:
  - ✓Required renal biopsy for diagnosis
  - ✓Nephrologist involvement in prescribing
  - ✓Requirement for certain level of proteinuria and/or eGFR
  - ✓Maximizing of ACE inhibitors or ARBs for several months
  - ✓Hard documentation needed for meeting some of these requirements
- In alignment with KDIGO clinical practice guideline for IgAN, we expect potential patients for TARPEYO are likely to meet all PA elements.

Financial Overview – Full Year 2021



- Revenues of SEK 229.3 M reported originating from the EUR 20 M upfront fee from the Stada outlicensing and USD 3 M milestone from Everest.
- Operating loss of SEK 524.5 M vs SEK 379.7 M
  - Research and development expenses increased to SEK 357.5 M vs SEK 241.4 M, representing 47% of total operating expenses. Increase primarily due to the setanaxib trials and setanaxib development.
  - Administration and selling expenses increased to SEK 390.2 M vs SEK 141.7 M, mainly due to preparations for the commercialization of Tarpeyo in the US.
- Cash flow used in operating activities was SEK 461.6 M vs SEK 309.2 M.
- Cash flow from financing activities was 435.2 M vs 768.6 M
- The cash position per end of December 2021 was SEK 955.5 M vs SEK 996.3 M.