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Asahi Kasei Furthers Its US, Health Care Growth With \$1.1bn Calliditas Buy

by Mandy Jackson

Asahi Kasei established a US presence and expertise in renal disease when it bought Veloxis in 2020 and will expand in both areas with Calliditas's Tarpeyo for immunoglobulin A nephropathy (IgAN).

<u>Asahi Kasei Corporation</u> aims to build on the US presence it established and the health care business growth it jumpstarted when it bought <u>Veloxis Pharmaceuticals A/S</u> by paying approximately \$1.1bn for <u>Calliditas Therapeutics AB</u>, maker of Tarpeyo (budesonide extended-release capsules) for immunoglobulin A nephropathy (IgAN), in a deal announced on 28 May.

The Japanese conglomerate said it sees health care as one of its three main pillars for growth and views the US as a prime market for its ambitions in pharmaceuticals and medical devices. Its \$1.3bn acquisition of Veloxis in 2020 gave Asahi Kasei a drug for the prevention of kidney transplant rejection, Envarsus XR (tacrolimus extended release), providing a foundation for building out a renal disease specialty that now includes Tarpeyo for IgAN.

Asahi Kasei said it will continue to grow its health care business through organic growth and business development in the areas of renal disease, immunology, organ transplantation and severe infectious diseases. With Calliditas, the company

Key Takeaways

- Asahi Kasei will pay \$1.1bn to buy Calliditas, gaining Tarpeyo for IgAN and setanaxib in Phase II drug for multiple indications.
- The Japanese conglomerate sees health care as one of three main growth pillars, with its pharma- and medical devicebased business accounting for 34% of its operating income in fiscal year 2023.
- Tarpeyo is expected to exceed \$500m in sales after Asahi Kasei's fiscal year 2030,



also gains the NOX inhibitor setanaxib in Phase II clinical trials for head and neck cancer, primary biliary cholangitis (PBC), idiopathic pulmonary fibrosis (IPF) and Alport syndrome.

and while competition is growing in IgAN, the company is building on its existing renal disease capabilities.

Calliditas "aims to realize the benefits of being part of a larger platform and the potential opportunity to accelerate the company's revenue growth trajectory as well as pipeline development" through the Asahi Kasei transaction, the Swedish firm said in a same-day statement.

"Deal is a good fit for Asahi – builds on existing immunology, renal transplant and rare disease focus," Jefferies analyst Maury Raycroft said in a 28 May note. The deal's valuation makes sense as well, Raycroft said, because of the large IgAN market opportunity, Tarpeyo's first-to-market status in the US, the drug's strong intellectual property position and its good market uptake to date.

Premium Paid For IgAN, Pharma Growth Opportunity

Tokyo-based Asahi Kasei will pay SEK208 (\$19.70) per ordinary share of Calliditas traded on the Nasdaq Stockholm and SEK416 (\$39.41) for each American depository share (ADS) traded on the Nasdaq Global Select Market in the US, with each ADS representing two ordinary shares, for a total purchase price of SEK11.8bn (\$1.1bn).

The offer price is 83% above Calliditas's 27 May closing price on the Nasdaq Stockholm and 74% higher than its 24 May closing price in the US. Asahi Kasei expects to close the all-cash deal by the end of September. The three biggest Calliditas shareholders and others, together accounting for 44.65% of outstanding shares, have indicated that they will accept Asahi Kasei's tender offer.

"We are not surprised by Asahi's decision to acquire Calliditas at a premium, which we believe validates the company's significant growth potential," with both Tarpeyo and setanaxib, H.C. Wainwright & Co. analyst Andrew He said in a 28 May note.

Asahi Kasei anticipates Tarpeyo peak sales to exceed \$500m globally after fiscal year 2030, making it a significant product in the company's pharma and medical device portfolio, for which it aims to

Calliditas Confident Of Setanaxib's Potential Despite Unclear Data

By Kevin Grogan

07 May 2024

The Sweden-headquartered biotech has emphasized the promising survival data in a head and neck cancer study of setanaxib rather than the NOX inhibitor's inability to



achieve JPY1tr (\$6.4bn) in fiscal year 2030 revenue. The company's health care portfolio already is on a fast growth trajectory, with a compound annual growth rate (CAGR) of 13% for its pharma assets and a 16% CAGR for its medical

shrink tumors.

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device business between fiscal years 2011 and 2024.

It said in 2019 when it first announced the Veloxis acquisition that Asahi Kasei's health care business provided 15% of the company's net sales and 19% of its total operating income in fiscal year 2018. Post-Veloxis, Asahi Kasei said in its Calliditas deal announcement that health care provides 20% of the company's net sales and 34% of its operating income. Homes and environmental solutions are its other two growth pillars.

Asahi Kasei sees itself as a global specialty pharma company, it said in briefing materials distributed to investors to justify the Calliditas transaction. The Japanese firm expects to focus on less competitive areas with modest probability of drug development success in indications that require smaller clinical trials and lower R&D expenditures without a big investment in large commercial teams. The goal is to attain low promotional costs that leave the company with capital to spend on R&D and business development, with BD activity focused on areas too small for big pharma but too big for small biotech companies to handle on their own.

The global IgAN market is \$40bn with an estimated 8% CAGR, while the kidney transplantation market for Envarsus XR is \$7bn with an estimated 5% CAGR, according to Asahi Kasei. The company noted that there are more than 5,000 nephrologists who see IgAN patients and more than 2,500 kidney transplant doctors in the US, the market where Calliditas retains full rights to Tarpeyo.

More Approvals For Tarpeyo, Competitors

Tarpeyo has conditional approval in the EU where <u>STADA Arzneimittel AG</u> markets the drug as Kinpeygo. (Also see "<u>Stada Poised To Launch As Calliditas Finally Wins EU Nod For Kinpeygo</u>" - Scrip, 20 May, 2022.) Partner <u>Everest Medicines Limited</u> launched the drug in China this year and <u>Viatris Inc.</u> has rights to the IgAN therapy in Japan. It won accelerated approval in the US in 2021 and full approval in December 2023, with a standard marketing authorization in the EU expected later this year, according to H.C. Wainwright's He. He noted that China, however, is the drug's largest market, with about 2 million patients.

Tarpeyo's sales have grown from \$22m in 2021 to \$75m in 2022 and \$113m in 2023, meeting reduced full-year 2023 guidance of \$110m-\$120m. (Also see "*Calliditas Confident Despite Cutting Tarpeyo Sales Guidance*" - Scrip, 18 Aug, 2023.) Tarpeyo sales of \$26m in the first quarter of 2024 were down from \$32.1m in Q4 of last year, largely due to payer reimbursement patterns in the



US, but Calliditas maintained its full-year 2024 guidance of \$150m-\$180m.

Jefferies' Raycroft noted Asahi Kasei's confidence that the full approval of Tarpeyo late last year will broaden the drug's potential market and increase uptake of the product, but pointed out that competition in the IgAN market is set to rapidly increase. The only other IgAN drug approved in the US, <u>Travere</u> <u>Therapeutics, Inc.</u>'s Filspari (sparsentan), received accelerated approval in February

First-To-Market Calliditas Picking Up Speed In IgA Nephropathy

By Andrew McConaghie

23 May 2024

A few hiccups aside, Tarpeyo is on track in the US, but major competition from Novartis is just round the corner.

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2023 and is awaiting a decision on full approval by 5 September. (Also see "*Travere's Filspari US Approval Marks First For IgAN*" - Scrip, 20 Feb, 2023.)

<u>Novartis AG</u> also has two drugs in contention for IgAN, including the oral complement factor B inhibitor Fabhalta (iptacopan), with a Food and Drug Administration approval decision expected by October. (Also see "<u>Novartis Draws Out Its APPLAUSE</u>" - Scrip, 16 Apr, 2024.) Novartis plans to file for approval of its oral selective endothelin A antagonist atrasentan by the end of June. (Also see "<u>Novartis Aims To Dominate Rare Renal Disorders</u>" - Scrip, 25 May, 2024.) The Swiss pharma acquired iptacopan in the \$3.2bn acquisition of Chinook Therapeutics last year. (Also see "<u>Novartis Aims To Fly High In Kidney Disease With Chinook Buy</u>" - Scrip, 12 Jun, 2023.)

Growing competition has not scared off Asahi Kasei and other buyers chasing a piece of the IgAN market, which may have room for many players considering the Japanese conglomerate's assertion that the global market size is \$40bn. <u>Biogen, Inc.</u> recently agreed to pay \$1.15bn up front for <u>Human Immunology Biosciences, Inc.</u> (HI-Bio) and its candidate for felzartamab, which is being developed for several indications, including IgAN. (Also see "<u>Biogen Buys Desired Growth In Immunology With \$1.15bn Hi-Bio Deal</u>" - Scrip, 22 May, 2024.)

Also, <u>Vertex Pharmaceuticals Incorporated</u> agreed in April to pay \$4.9bn for <u>Alpine Immune</u> <u>Sciences Inc.</u>, which has a lead drug candidate ready to move into Phase II for IgAN; povetacicept is a dual antagonist of BAFF and APRIL. (Also see "<u>Vertex's \$5bn Alpine Buyout Builds Autoimmune Disease Presence</u>" - Scrip, 11 Apr, 2024.)