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“Biotech sector in Taiwan moves fast, making it easier to pivot and innovate”

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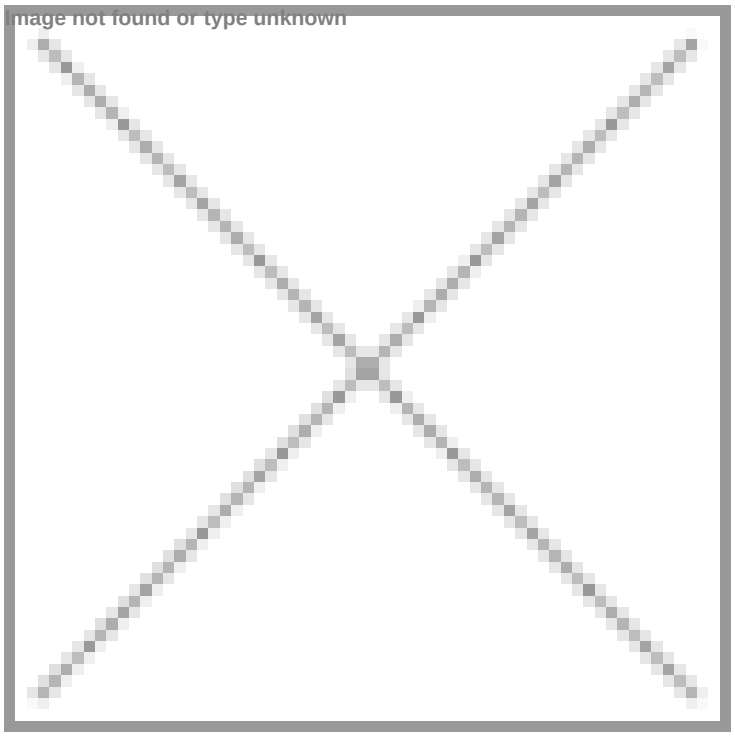
Caliway Biopharmaceuticals has recently announced the completion of its initial public offering (IPO) and up-listing from the Emerging Stock Market to the Taipei Exchange (TWSE-6919). The round raised approximately $206 million (NT$6.4 billion), marking it the largest IPO in Taiwan's biotech industry history and valuing the company at nearly $3 billion. The company is poised for a transformation in 2025, advancing its groundbreaking clinical programmes and strengthening its global market presence. Following its recent record-breaking IPO, BioSpectrum Asia took an opportunity to speak with Vivian Ling, Chief Executive Officer & Chief R&D Officer, Caliway Biopharmaceuticals to explore their innovative contributions in biopharmaceuticals.



Which products are currently under development?

2025 will be a defining year for Caliway as we push ahead with key clinical advancements and corporate milestones, bringing CBL-514 closer to market. CBL-514, a first-in-class small-molecule drug designed to selectively induce adipocyte apoptosis, provides a non-invasive alternative to liposuction for non-surgical fat reduction in medical aesthetics. We are preparing to secure IND approvals for two pivotal Phase 3 studies from the US FDA and Health Canada, a critical step in advancing CBL-514 as the world’s first investigational drug for large-area localised fat reduction. Beyond fat reduction, we’re also submitting a Phase 2 IND application for a new indication focused on improving body weight rebound, expanding CBL-514’s potential applications.

In Q1, Caliway announced positive Phase 2b study results for CBL-514 (0205 Study), the second and final Phase 2b before moving into Phase 3. In Q2, we are preparing for regulatory discussions with the FDA (EOP2) and EMA to align on the next steps for CBL-514's late-stage development.

A key focus in Q4 will be completing patient enrollment for the Phase 2b study of CBL-514 in Dercum's Disease (CBL-514 0202DD). CBL-0202DD is being developed as a potential first-in-class therapy for Dercum's Disease, a rare and painful condition, and has already been granted Fast Track Designation by the FDA and Orphan Drug Designation by both the FDA and EMA. In the early-stage pipeline, CBA-539 offers a novel approach to hyperpigmentation and skin ageing by inhibiting melanin production and transmission, reducing dark spots and evening skin tone, while also stimulating collagen production to improve skin elasticity and firmness for natural, long-lasting results. Expanding into therapeutic applications, CBL-0201OB targets post-weight loss fat accumulation in combination with GLP-1, with a Phase 2 IND submission planned for Q4 2025.

On the corporate front, we are moving forward with a stock split to enhance market liquidity and investor engagement. Additionally, Caliway is now part of the MSCI World Small Cap Index, originally a Q4 goal further strengthening our global investor presence.

In October 2024, we completed our IPO, raising $206 million, making it the largest IPO in Taiwan's biotech industry history and positioning us among the top biotech IPOs in the US in 2024. This strong financial foundation provides the necessary resources to advance CBL-514 into global pivotal Phase 3 studies, explore additional indications, and further expand our pipeline.

How do you plan to utilise the funds raised from your recent IPO to advance R&D?

We are strategically deploying IPO funds to accelerate clinical development, expand global partnerships, and strengthen commercialisation efforts. Our key areas of investment include CBL-514 Phase 3 Studies. A significant portion of the funds is being directed toward launching pivotal global multi-centre Phase 3 studies for CBL-514, ensuring a smooth regulatory pathway in key markets. Focusing on new indications development, we are expanding CBL-514's applications beyond fat reduction by advancing studies for Dercum's Disease and weight rebound prevention, broadening its potential.

To leverage international licensing and investment experts, we are actively engaging with global investment and licensing professionals to expedite partnership negotiations, increase visibility among potential collaborators, and secure the most favourable commercialisation deals.

For clinical collaboration with KOLs and investigators, we are strengthening relationships with renowned clinical researchers to expand study participation, enhance scientific credibility, and increase visibility in international markets.

We are also expanding global business development and market positioning; and engaging global pharmaceutical companies for licensing and partnerships. We are actively negotiating potential global licensing agreements discussions and strategic partnerships to drive CBL-514's commercial success.

We are further strengthening our presence at key global industry events to connect with strategic partners and investors by participating in global industry conferences.

Most recently, we participated in IMCAS 2025 in Paris, where we presented the advancements in clinical progress. These efforts maximise our growth potential, drive regulatory approvals, and ensure long-term commercial success.

Could you tell us about strategic partnerships or licensing agreements with other pharmaceutical companies, key to accelerating the development and commercialisation of your products?

Strategic partnerships are a key driver of Caliway's growth. We are actively engaging with leading pharmaceutical companies for licensing and co-development opportunities to accelerate CBL-514's commercialisation. We are also deepening industry connections through key industry events, including BIO, IMCAS, AMWC, JP Morgan Healthcare Conference, and the World Orphan Drug Congress, ensuring we stay at the forefront of global biotech and aesthetic medicine collaborations. These partnerships will be crucial in accelerating product commercialisation and maximising CBL-514's global impact.

What are your strategies for expanding the market reach of CBL-514, especially in regions like Taiwan, China, Korea, and Southeast Asia?

We are executing a multi-faceted market entry strategy to ensure a structured and phased approach to regulatory approvals and market commercialisation. CBL-514 is a 505(b)(1) first-in-class small-molecule drug designed to address an unmet need in non-surgical fat reduction. Given its innovative mechanism of action and strong clinical data, our primary entry strategy is to focus first on regulatory approvals in the US, our key reference market. Once established, we will gradually expand into additional key regions, including Asia. We are actively engaging with global pharmaceutical companies for potential licensing and other strategic partnerships to accelerate commercialisation. Our pivotal global Phase 3 studies will further strengthen CBL-514's market valuation and licensing potential, paving the way for successful entry into international markets.

Focusing on the Taiwan biotech market in particular, what are the existing challenges and opportunities?

Biotech development comes with its challenges. Regulatory processes can be complex, which may impact drug development timelines. Another key challenge is the shortage of specialised R&D talent, particularly in pharmaceutical sciences and clinical research. That said, Taiwan has significant advantages that make it an attractive hub for biotech innovation. Taiwan's healthcare system is highly advanced, cost-effective, and well-structured. The high density of hospitals, cutting-edge medical technology, and experienced medical professionals make it an ideal environment for research, especially in niche indications and rare diseases. Taiwan's market agility and adaptability also set it apart. The biotech sector here moves fast, making it easier to pivot and innovate. Additionally, many global pharma companies use Taiwan as a strategic entry point, launching products before expanding into larger markets. With its strong medical ecosystem, advanced infrastructure, and strategic position in the region, Taiwan offers a unique and competitive environment for biotech growth and drug development.

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