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Our ambition is not short-term success but to build a sustainable innovation platform across medical aesthetics and metabolic diseases

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Taiwanese biotech Caliway is trying to redefine fat reduction as measurable medicine. Founded in 2012, Caliway has advanced its first-in-class candidate CBL-514 into pivotal Phase III development in the US, following ten completed clinical studies. President Antony Hsu outlines the science behind selective adipocyte apoptosis, the regulatory strategy behind the programme, and how Caliway is positioning CBL-514 across aesthetics, metabolic care, and rare diseases.

What led you and your team to establish Caliway, and how did the company's strategic direction evolve as you advanced its core scientific focus?

Caliway was founded in 2012 with a clear vision: to develop first-in-class small-molecule drugs that deliver measurable medical value. From the outset, our goal was not incremental improvement but to pursue biological mechanisms capable of delivering transformative innovation.

Our CEO, Vivian Ling, first approached me with a novel scientific concept. We quickly agreed that many therapeutic areas had become increasingly crowded, leaving limited room for truly differentiated innovation. Rather than pursuing conventional targets, we decided to explore adipocyte biology.

We questioned whether adipocytes could be selectively reduced by triggering programmed cell death (apoptosis) through natural cellular pathways, moving away from non-selective approaches. At the time, this strategy had not been applied therapeutically, so we proceeded cautiously and systematically, supported by extensive literature review and multi-year compound screening.

This effort ultimately led to the identification of CBL-514, a compound that demonstrates high cellular specificity by inducing apoptosis in adipocytes without clinically meaningful off-target effects observed to date. We validated these findings stepwise, from cellular models to animal studies, before entering clinical development.

CBL-514 has now completed ten clinical studies and has met all the primary endpoints. In July 2025, both the FDA and Health Canada authorized the pivotal Phase III SUPREME-01 study for the reduction of abdominal subcutaneous fat. This makes CBL-514 one of the first novel 505(b)(1) drug candidates to reach Phase III for this indication. If approved, it would transcend traditional aesthetic claims and establish genuine medical value in fat-mass reduction.

You chose from the outset to conduct all clinical development in the United States. What informed that decision?

Early in our development, we evaluated multiple programs targeting metabolic and obesity-related pathways. As GLP-1-based therapies advanced rapidly, we strategically decided to focus our resources on programs with the strongest differentiation and long-term potential, including CBL-514.

When we presented early CBL-514 clinical data to major U.S. pharmaceutical companies, the mechanism and results generated clear interest. We consistently received feedback that advancing clinical development in the United States would be critical to meeting global regulatory expectations and facilitating future partnerships.

This feedback was highly influential. Conducting clinical trials in the U.S. allowed us to generate data aligned with international standards, thereby positioning the program more effectively for global development and collaboration.

The 2019 period appears to have been financially and operationally difficult. What triggered the capital constraints you faced at that time?

Clinical development requires sustained investment. Around that period, investor sentiment toward early-stage biotechnology became particularly cautious, making fundraising challenging across the sector.

Instead of lowering our standards, we chose to focus on strengthening the company's fundamentals. We continued to invest in talent, intellectual property, and disciplined clinical and regulatory planning. Our internal principle was straightforward: a program would only advance if it had the potential to be a top-tier solution in its field.

During this time, we systematically strengthened our R&D platform, spanning formulation development, pharmacology and toxicology, clinical strategy, and regulatory execution. As data accumulated and consistently met predefined endpoints, confidence gradually returned.

This execution-focused approach laid the foundation for the company's subsequent clinical progress and long-term trajectory.

Aesthetic medicine lacks the clear-cut endpoints seen in oncology. How did you establish objective, FDA-acceptable measures of efficacy?

The FDA emphasized the importance of rigorous and validated assessment methodologies, particularly for aesthetic products. We worked closely with the Agency to align on both study design and the proposed indication.

Our pivotal Phase III studies are designed around a multicomponent primary estimand, comprising both objective and patient-reported measures.

First, reductions in abdominal subcutaneous fat volume are quantitatively assessed using MRI, providing an objective and reproducible physiological measurement.

Second, changes in abdominal fat level are assessed using the Patient-Reported Abdominal Fat Rating Scale (PR-AFRS), a five-grade scale developed by Caliway and validated in accordance with U.S. FDA guidance, including principles from Patient-Focused Drug Development.

Importantly, the FDA agreed with the proposed indication of "reduction of abdominal subcutaneous fat," which moves beyond a purely appearance-based claim to reflect a measurable change in fat volume. This alignment reinforces our confidence in CBL-514's differentiated clinical value.

How does your therapeutic approach compare with existing modalities for fat reduction, particularly surgical liposuction and injectable treatments such as deoxycholic acid?

The key differences lie in safety, selectivity, and invasiveness.

Surgical liposuction is effective but invasive and carries well-documented procedural risks. In contrast, CBL-514 is an injection-based therapy that avoids surgery altogether. The procedure is minimally invasive, comparable to routine aesthetic injections, and typically takes 30 to 40 minutes. In clinical studies, more than 52% of participants achieved at least a 1-grade improvement on the Clinician-Reported Abdominal Fat Rating Scale (CR-AFRS) after just a single CBL-514 treatment, highlighting the consistency and rapid onset of effect.

Across a clinical program involving more than 500 subjects, CBL-514 has demonstrated a favorable safety profile. To date, we have not observed serious treatment-related adverse events beyond transient injection-site reactions such as mild pain or swelling. Notably, patients have been willing to return for subsequent treatments based on the clinical benefits experienced.

While some existing injectables rely on non-selective chemical mechanisms to disrupt fat tissue, CBL-514 operates through a fundamentally different biological pathway. It selectively induces apoptosis in adipocytes through natural cellular processes. This selectivity helps minimize inflammation and supports a more controlled, physiological reduction of fat tissue.

We are currently advancing CBL-514 through late-stage clinical development, with the pivotal Phase III program ongoing.

Commercial success in aesthetics requires surgeon engagement and procedural training. Have you defined your go-to-market model, and do you plan to commercialise independently or through partners?

Our commercialization strategy is partnership-oriented rather than focused on standalone execution.

CBL-514 sits at the intersection of medical aesthetics and metabolic medicine, attracting strong strategic interest from a broad range of potential partners, including global pharmaceutical companies.

Our approach is designed to be complementary, not competitive. CBL-514 selectively reduces localized adipose tissue through adipocyte apoptosis, whereas systemic therapies like GLP-1

receptor agonists primarily address overall body weight or appetite regulation. Together, they have the potential to deliver more comprehensive and clinically meaningful outcomes.

Practically, CBL-514 is administered via a familiar injection-based procedure easily adopted by trained physicians. This ease of integration into existing clinical workflows further supports a partnership-led go-to-market model, especially for global commercialisation.

Given that obesity has been reframed as a reimbursable disease area, could partnering with an aesthetics-focused company complicate the narrative established by GLP-1 manufacturers?

We do not view aesthetics and disease-focused development as mutually exclusive; in practice, they often reinforce each other.

A significant portion of today's weight-management market remains self-pay, reflecting strong demand beyond reimbursed indications. Simultaneously, regulatory and clinical focus is shifting toward long-term outcomes, body composition improvement, and post-treatment weight maintenance—areas where current therapies still face limitations.

In this context, CBL-514 is being developed across multiple indications. Beyond localized fat reduction, we recently submitted a Phase 2 IND to the U.S. FDA for weight management, evaluating CBL-514 in combination with GLP-1 receptor agonists. This program is designed to address body composition and the weight rebound that can follow treatment discontinuation.

In parallel, we are advancing rare-disease programs where adipocyte dysfunction is central, such as Dercum's disease. These indications clearly fall within a reimbursable medical framework and demonstrate the broader therapeutic relevance of our platform.

This multi-indication strategy allows us to engage different partners across aesthetics, metabolic medicine, and rare diseases while maintaining a consistent scientific foundation.

What is the current development status of your rare-disease programme, and how are you approaching partnership discussions as it advances?

Our rare-disease program is built on a dedicated formulation of CBL-514 for conditions including Dercum's disease, a rare disorder characterized by painful lipomas with no approved and effective

treatment options.

CBL-514 has completed a Phase 2 study in Dercum’s disease, meeting all primary and secondary endpoints with meaningful reductions in lipoma size and clinically significant pain relief. The program has since advanced into an FDA-approved Phase 2b study in the United States, which is currently ongoing. In parallel, CBL-514 has received Orphan Drug Designation from both the U.S. FDA and the European Medicines Agency, as well as Fast Track designation from the FDA, reflecting the significant unmet need and strength of the clinical data.

From a partnering perspective, we are taking a disciplined, data-driven approach. Our focus is on advancing the program to a point where a robust dataset can support high-quality, long-term partnerships while preserving strategic flexibility.

Amongst your current pipeline, which programme do you consider most strategically valuable?

Our most strategically valuable program remains CBL-514 for localized fat reduction. It represents a differentiated and scalable opportunity supported by clear clinical validation and a well-defined regulatory pathway.

Localized fat accumulation is a widespread concern, while existing options are either invasive or limited in delivering consistent results over large areas. CBL-514 addresses this gap by selectively reducing adipose tissue through adipocyte apoptosis, offering a non-surgical approach with strong clinical consistency.

Importantly, CBL-514 has demonstrated a favorable safety and tolerability profile across more than 300 treated subjects. The magnitude and consistency of fat reduction support its potential to deliver clinically meaningful outcomes over large treatment areas—historically difficult without surgery.

In parallel, the global weight-management market continues to expand rapidly, driven by GLP-1RA therapies. While effective at reducing body weight, these treatments do not directly reduce adipocyte number or enable targeted fat reduction. In addition, following treatment discontinuation, weight regain and reversal of certain cardiometabolic improvements may occur in a proportion of patients, highlighting an unmet need in long-term body composition management.

We are advancing CBL-514 along a complementary path. Preclinical evidence suggests that combining CBL-514 with GLP-1 receptor agonists may enhance fat reduction, improve body composition, and help address post-treatment weight regain.

Data from multiple animal studies indicate that CBL-514, alone or in combination with GLP-1RAs, may support more favorable fat distribution, including reductions in both subcutaneous and visceral fat. These findings point to the potential for more sustainable and healthier weight management outcomes.

Rather than competing, CBL-514 is positioned to complement existing therapies. This dual relevance—as a standalone solution for localized fat reduction and as part of a combination approach in weight management—is what makes it our strategic priority.

Despite developing exclusively for the US market, you chose to list in Taiwan. What motivated that choice, and how do you view your future capital-markets strategy?

Our decision to list in Taiwan was driven by pragmatic considerations. The market provides access to long-term capital and a growing base of institutional investors increasingly engaged with innovative healthcare and biotech.

Since listing, we have seen steady growth in foreign institutional participation, supported by greater international visibility following our inclusion in the Taiwan component of the MSCI Global Standard Index in 2025. This has helped broaden our shareholder base and enhance liquidity.

Looking ahead, we remain open to additional capital-market options as the company evolves. Any future decisions regarding broader international market access will depend on pipeline maturity, regulatory progress, and market conditions. For now, our focus remains on disciplined execution and clinical advancement.

As you look ahead over the next two to three years, what do you see as the most significant execution risks or challenges?

Over the next few years, the most critical challenge will be maintaining disciplined focus—advancing our clinical programs efficiently while upholding rigorous scientific and regulatory standards.

As with any global biotech operating today, geopolitical uncertainty and capital-market volatility are external factors we monitor closely. While beyond our control, we have structured our development and partnering strategy to remain flexible and resilient.

Our priority is stepwise execution: progressing clinical milestones, strengthening global partnerships, and preserving strategic optionality as the company grows.

Your organisation is scaling rapidly as a publicly traded company. How is your leadership approach evolving to match the demands of this next phase?

My leadership approach relies on delegating to specialists across every function. Clinical development, in particular, is a core capability at Caliway.

While our organization remains intentionally lean, the clinical team is our largest functional group, working closely with investigators and regulators in North America. Managing studies across time zones often requires late-night or early-morning coordination with U.S.-based principal investigators, but this commitment is essential for global development.

From an early stage, we implemented equity participation programs to ensure employees share meaningfully in the value they create. Today, approximately one-third of our workforce has achieved financial independence through stock options. This long-term alignment has been critical for retaining talent and sustaining motivation through late-stage development complexities.

I see my role as building a platform—a stage where talented individuals can perform at their best. Our people are the actors, our pipeline is the narrative, and leadership’s responsibility is to create the conditions for exceptional execution.

As I approach my sixties, my priority is cultivating the next generation of leaders who will ultimately steer the organization. My goal is not to lead indefinitely but to build an institution that can thrive independently over the long term.

As we conclude, what key message would you like to share with the investors, analysts, and pharmaceutical business-development leaders who will read this interview?

At its core, Caliway’s mission is to develop market-transforming innovations that genuinely improve patients’ lives.

Our ambition is not short-term success but to build a sustainable innovation platform across medical aesthetics and metabolic diseases. We are focused on developing medicines that go beyond existing therapies, supported by rigorous science, disciplined execution, and a long-term commitment to quality.

For investors and partners, we offer a differentiated approach—combining clear clinical rationale, advancing global programs, and a team aligned around execution excellence. Ultimately, our goal is to translate scientific innovation into meaningful medical and societal impact.

This philosophy is encapsulated in our guiding belief: Market-transforming innovations that make lives amazing.

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