IB Interview

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A Conversation with Gaston Salinas

Gaston Salinas, CEO, Botanical Solution Inc., Davis, California, USA

any useful compounds can be found in nature, and consumer demand for natural materials is set to skyrocket. The traditional botanical market is expected to exceed \$17.8 billion in value by 2025 across diverse market segments that include pharma, food and beverages, and cosmetics among other relevant industries. However, traditional botanical products are seriously affected by critical issues related to supply and quality of raw materials, often obtained under exploitation of natural resources with a sizeable environmental footprint.

Botanical Solution Inc. (BSI, Davis, CA, USA) has developed a proprietary technology that allows a scalable and sustainable supply of key botanical products with none of the issues related to current production of traditional botanical raw materials and active ingredients. The Biotechnology platform, based on plant tissue culture, allows BSI to discover and develop botanical products that are sustainable, highly consistent, and cost effective.

The company's ABM-01 is an advanced botanical material based on the native Chilean plant *Quillaja saponaria Molina*. ABM-01 is the active ingredient in BSI's broad spectrum biofungicide Quillibrium. The product prevents and controls *Botrytis cinerea*, *Alternaria alternata*, Powdery Mildew, Sour Rot and other harmful fungal diseases in highvalue crops worldwide, diseases which are responsible for hundreds of millions of dollars in losses every year. This biofungicide is commercialized in Chile, Peru and later this year in Mexico through a partnership between BSI and Syngenta since 2019, and will soon be registered in other Latin American countries. Additional regulatory progress has also been achieved in the United States and European Union.

Additionally, the launch of an alternative source for sustainable production of the vaccine adjuvant, QS-21, also based on ABM-01 is expected soon. QS-21, which has been in commercial vaccines since 2017, is currently used in COVID-19 vaccines, as well as shingles, Respiratory syncytial virus (RSV) and Malaria vaccines, and is expected to be in short supply due to high demand and strict deforestation laws in Chile. *Industrial Biotechnology (IB)* recently interviewed CEO G.S. to discuss the outlook for biopesticides and the potential for plant tissue culture to revolutionize the botanicals market.

IB: Can you tell our readers about the Quillibrium and how it solves problems faced by the botanicals market?

G.S.: *B. cinerea* is increasingly impacting high-value crops, such as table grapes, cherries, and blueberries. The fungus manages to develop no matter what the temperature is, and growers have difficulty combatting it—especially close to harvest when they have to think about export markets and residue restrictions. This is where fungicides like Quillibrium come in. They can provide insurance for growers to keep fresh produce free of *B. cinerea* longer.

What makes our products so different from other botanical products is that we have internally developed a platform to produce practically any plant material in our lab to supply key active ingredients. Depending on the plant species, sometimes you can address shortfalls in the supply of those materials or, just as importantly, improve quality. Even if you grow plants in the same area, there will still be variations in how much light or irrigation each plant receives—ultimately changing the chemical composition of the extracted botanicals.

To address this, we're controlling and vertically integrating the process from plant production all the way to final product. We start with growing plants in vitro for 30–60 days. We inoculate in a bioreactor system to achieve two things. The first objective is to grow the biomass really quickly, and at the same time, produce specific chemical compounds. The plants are biofactories; we are able to produce as much as needed of this biomass all year-round. The other objective is really that no matter if you take 1 gram, 1 kilogram, or 1 ton of this fresh material, the technical composition evaluated batch to batch of those materials are almost identical. This consistency cannot be achieved with traditional growing and extracting.

IB: Can you talk about the registration process for Quillibrium and how that might compare with traditional crop protection products?

G.S.: Registration processes vary by country. In the case of Chile, it took us 4 years to get approval back in 2016 because we

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had to follow the traditional chemical pathway. Approval in Peru was way faster, it took about 18 months. By that time, they had created a registration process for biological products to reflect the better safety profile compared with traditional chemicals.

But it can still be difficult. In Mexico, registration has been stuck almost 2 years. In the United States, a market we are very keen to enter, it's been a mixed story. Four to five years ago, it was easier to get a biological registered with Environmental Protection Agency (EPA) and California Department of Pesticide Regulation. But these days, it's more difficult. We don't expect to be registered in the United States any sooner than 2026. Still faster than EU registration, but still a significant length of time.

When it comes to residues, with our product they are all natural molecules, produced by plants. But on the other hand, botanical materials have different challenges when it comes to characterization. The EU requests 80% of the compounds be characterized for registration. The United States is not that strict, and we're focusing more energy on the U.S. market and also defining a strategy for other botanical products we plan on bringing to the marketplace. Extracts obtained with our technology have shown efficacy against *Alternaria alternata*, powdery mildew, *Anthracnose penicillin*, and other opportunistic diseases affecting these crops.

IB: How was the fungicidal potential of Quillaja saponaria Molina first discovered?

G.S.: *Q. saponaria Molina* is part of the indigenous culture of Chile and has been used for multiple purposes. It is also known as the soapbark tree because indigenous people used to use extract to make detergents. The novelty of our work was the discovery that the plant, grown *in vitro* using biotechnology produced a unique biochemical profile was biologically active as a fungicide was never described in literature before. That allowed us to file a patent and protected formulation that combined the method of production of the biomass and the use, benefits, and biological activity.

IB: Can you discuss your current scale?

G.S.: Tissue culture techniques are difficult to scale by definition and that is part of our innovation. We made scale-up cost effective. We can make as much biomass as needed to make our active ingredients and develop our different products. It is a completely vertically integrated manufacturing process. We have 2,000 square meters where we do all our work. It takes about 30–60 days to get the plant from, I would say, the initial state all the way to when it is mature enough to get harvested. This is enough capacity to cover over 100,000 hectares of agricultural land.

We have distribution agreements with Syngenta in Chile and Peru. Syngenta is going to be our distributor in Mexico. This year, we expect to generate about \$1.5 million in revenues. The product is growing, but because of the high entry barriers in some markets, it is taking longer than we expected. Our first application was in 2013, and 11 years later we're in almost three countries. The processes could be better.

IB: What is the state of your funding?

G.S.: We closed a Series A back in early 2022 which was followed by a Series A extension by the middle of 2023, because as we all know, markets were difficult for most of 2023. And we expect that to continue in 2024. We have a very pragmatic base of investors and reached a total of \$13 million. With that, we keep funding our R&D programs and field testing to accelerate the path to market. We're working on getting the proper registrations for the US and at the same time the EU. We knew trying to do both simultaneously would be a bold move but it's been even more challenging than we expected.

In addition to distribution, Syngenta has been actively testing the product in different geographies. But when it comes to registration and efficacy trials, that is all our funding.

There are cycles in ag funding. The biocontrol space is getting overcrowded with products and over 200 companies trying to sell the same story. Fortunately, our unique value proposition is backed by seasoned investor that believe in our technology and our products.

IB: What do you think the future of agriculture will look like?

G.S.: We know that agriculture is facing challenging times. The sector is facing pressure from sustainability macrotrends while at the same time having to figure out how to feed 9 billion people by the year 2050.

In our view, it doesn't make sense to grow and harvest a full hectare of a natural resources to then be used to protect a hectare of table grapes, cherries or any other crop of interest. We are not just one more supplier of natural active ingredients; We are trying to change a broken paradigm of exploitation of natural resources. There are a lot of opportunities ahead to deploy this technology.

IB: Can you talk a little bit about the vaccine adjuvant potential and how that opportunity is evolving?

G.S.: We almost entered the pharmaceutical space by accident. We knew that QS-21—a saponin of *Quillaja Saponaria*—is a gold standard vaccine adjuvant used in popular RSV, Shingles, Malaria, and other vaccines. But we never had an intention to enter the pharmaceutical space, having started out with a narrow focus on agriculture. But it soon became apparent that pharma industry was relying on the wild *Quillaja Saponaria*, which only grow in Chile. The tree takes 25–30 years before it can be harvested. But our biofactories can scale the ingredient much faster.

We'll start sales to this market later this year. We have a publicly announced partnership with Croda, a multibillion dollar UK-based company specialized in vaccine adjuvants, and we have been conducting tests with major Big Pharma companies interested in QS-21. They've been qualifying our materials and after our Series B we expect to allocate more resources to expand production.