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Specialty Contract Manufacturer Microsize, uses Milling and Micronization Technologies to Reduce Particle size of Poorly Soluble APIs and Functional Excipients for the Pharmaceutical Space

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Interview conducted by:
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CEOCFO: ***Mr. Higley, what is Microsize?***
Mr. Higley: Microsize is a specialty contract manufacturing firm, that focuses on particle size reduction of poorly soluble APIs (Active Pharmaceutical Ingredients) and functional excipients used within the pharmaceutical space via milling and micronization technologies.

CEOCFO: ***Why do we want particle reduction? What is the concept of micronization?***
Mr. Higley: There are two main reasons to pursue particle size reduction. First is the functional aspect, which is to improve bioavailability of API particles considered to be poorly soluble (brick dust). By reducing the particle size, the surface area increases exponentially. To put the size reduction that is achievable via micronization into perspective; the API's typically provided to Microsize are often only precipitated or coarse milled to several hundred microns and considered a "fine" powder as defined by the API manufacturer. Our primary technology for micronization is jet milling and it will reduce the same powder to particle sizes in the single digit range, representing a

70-100 fold decrease. In turn, the increased surface areas allow the particles to efficiently dissolve in bio-fluids in the GI tract. A fully dissolved API has a better probability of becoming bioavailable thereby making micronization an enabling technology for poorly soluble API compounds classified as class 2a within the DCS classification system.

The second main advantage is the quality improvement that results in the finished dosage form (FDF) attributed to the very narrow and uniform particle size distribution inherent in post-micronized material. This particle size distribution curve is typically a breath of under 10 microns and the homogeneity of the particles provides improved reproducibility from batch to batch or tablet to tablet. This uniformity becomes even more critical for low dose/high potency FDFs.

CEOCFO: ***Shouldn't everybody be going for Microsize, or shouldn't everybody want better bioavailability / uniformity?***
Mr. Higley: The number of new chemical entities (NCEs) filed with poor solubility attributes increases every year and the number of clients searching for enabling technologies is definitely growing. Speed to market and cost of development continue to be paramount. We would argue that of all the competing BA enhancement technologies, that milling/micronization is the fastest, most affordable, established, scalable, and streamlined approach for solving these challenges. Due to low entry barriers of evaluating the technology quickly, using very little API, we would agree everyone with a poorly soluble API should be aware of micronization. It should be included into their formulation development program especially for dissolution limited chemistries or DCS 2a classified materials.

CEOCFO: ***According to your site, Microsize is recognized for its speed, responsiveness, and high customer touch business model. Would you touch on those three features and how they play out day to day?***
Mr. Higley: The speed is inherent with the technology. Number one, it does not require any novel or elaborate analytical or formulation development methods to characterize the finished product or to prove that the technology is suitable. Laser diffraction is the primary method used, and that is a one-day, low-cost method development. The jet milling technology itself only has two primary variables to control the process which are feed rate and pressure. Developing the design space, scaling up, and validating are all very empirical and straightforward processes.

The responsive, high touch experience is really a function of returning to a small company environment with local decision making and direct customer access which has allowed the site to flourish for over the previous three decades. As Microsize transitions from an integrated, global player to an independent company, we are letting go of any bureaucracy that didn't serve the customers and internal support teams well. We are aggressively investing in systems and headcount to shorten lead times and increase capacity to current and future client needs.

CEOCFO: ***Would you tell us about the spin-out from Lonza? Why now?***

Mr. Higley: Our site was a redundant particle size reduction asset for Lonza. Lonza has micronization capability overseas closer to their API manufacturing assets. A significant and valued portion of our business is working with functional excipients which internally Lonza determined to be non-core following the acquisition of a vertically integrated Capsugel business of which we were a part of from 2015-2016. I believe our investor group of former pharma CDMO executives provided an attractive exit for Lonza to focus on their core business and simultaneously provide a good home for clients and colleagues on a go forward basis which was mutually important for everyone involved.

CEOCFO: ***What has changed for you, if anything, from the spin-out? What might you do differently, or is it really a continuation?***
Mr. Higley: A couple of things. From a business standpoint, we have begun to build out and will continue to build out solid-state analytical characterization services, starting with already acquired or onboarded polarized light microscopy, XRPD (x-ray powder diffractometer), and SEM (scanning electronic microscope). Additional capital is allocated to acquire further analytical instrumentation to have the most commonly used solid-state characterization technologies in house over the near term. As to the historical business, we are building additional production capacity over the next 12 months for key projects and simultaneously will double the production head count to improve service time. It's a step change backed with more commitment, urgency, and passion rather than "a continuation" would imply.

CEOCFO: ***Are you seeking partnerships, investment, or funding at all at this point?***
Mr. Higley: The near term plans are well covered by the current group of owners and they understand the space and needs of the client and what it takes to make a successful and growing enterprise. That said we are always open to exploring partnerships that provide more value to drug developers in the space.

CEOCFO: ***Are there newer technologies, you make it sound pretty simple, from what you said before, so where does the technology stand in what you are doing?***
Mr. Higley: The jet milling technology itself is well established and probably the widest used technology for increasing bioavailability over the last many decades. It has been used since the 1970s in the pharmaceutical space and for the number of approved NDAs using the technology, micronization is the lion share of those. That being said, the need for new advancements in using the jet milling technology safely in conjunction with newer APIs that possess increased potency, lower dose, and higher cyto-toxicity, requires special handling, and containment capabilities, which not everyone has in house. Therefore, it is an ideal capability to search for in the contract marketplace to ensure proper containment technologies and established handling protocols.

CEOCFO: ***Are there any supply chain issues, material, equipment, ingredients, and so on; any issues that many other industries and companies are facing, or are you pretty much above that at Microsize?***

Mr. Higley: I think the entire industry is capacity constrained, primarily due to available space and manpower. This continues to be our focus.

CEOCFO: ***You mentioned building up your staff. How do you attract people to the company? Why would someone want to work at Microsize?***
Mr. Higley: We do a great job of providing a small company atmosphere, where people are empowered. Cross functionality is valued and ultimately rewarded with big company "total reward" compensation and benefits packages. If you're a manufacturing enthusiast, this is your home.

CEOCFO: ***Why pay attention to Microsize?***
Mr. Higley: There are few CDMOs in this space that focus on micronization from the R&D scale to all the way through commercial. This one stop shop with the process and analytical development horsepower is combined with all scales of commercial GMP manufacturing. This is critical to ensuring the speed to market our pharma clients require. Microsize creates an attractive value proposition for the client to lower their manufacturing COGS and shorten supply chains with a higher throughput that could be otherwise achieved in house or elsewhere. This is due to Microsize having the largest mills in the space.