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Transdermal's Promising Future

The science & business of drug development in specialty pharma, biotechnology, and drug delivery

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DRUG DELIVERY Executive

PARTICLE SCIENCES
DRUG DEVELOPMENT SERVICES

PARTICLE SCIENCES: PROVIDING FORMULATION & ANALYTIC SERVICES TO MEET DEMANDING DRUG DELIVERY CHALLENGES

Robert Lee, PhD
VP, Drug Development

Particle Sciences, Inc.

"A key aspect of our business strategy is our initial interaction with our clients. Early in our discussions, we strive to understand exactly what our clients' goals are; we want to make sure we hear and understand their needs and design our programs to satisfy those goals."

Particle Sciences, Inc. (PSI) is a leading CRO to the pharmaceutical, biotech, and drug device industries. Building on decades of experience, PSI offers expertise in nano-based approaches to drug delivery and brings this skill-set to bear on its clients' goals, independent of the dosage form, from topical to ocular to intravenous to intrathecal. Through internal development and an active in-licensing program, the company has a broad array of technologies from which to choose. This approach has resulted in an average annualized growth rate of over 25% and a very high rate of new project awards from existing clients. As Vice President of Drug Development, Dr. Robert W. Lee is responsible for overseeing PSI's scientific direction. Drug Delivery Technology recently interviewed Dr. Lee to discuss how his company is managing to thrive in such a tough business environment.

Q: 2009 was very challenging for pharma, with the top 10 lay-offs totaling 66,850. This follows several years of downsizing. How was business for PSI?

A: Particle Sciences (PSI) managed to grow 30% in revenue and increased headcount by 20%. The business model of many pharma companies is changing, and even several large Pharma companies have shifted to an outsourcing paradigm for drug development, which may include formulation development, drug delivery, analytical services, and clinical trial material manufacturing. This reduces fixed costs and helps their bottom line. However, the work still needs to get done, and this is the challenge given the reduction in internal resources. This provides growth opportunities for CROs operating in these areas. PSI is relatively unknown, but we continue to gain exposure and expand our client base. Last year, our services were in demand by both new and existing clients and in fact, we are very proud of that our existing clients continue to place additional work at PSI, a testimony to their satisfaction.

Q: Can you discuss the types of clients who seek your services?

A: Our clientele range from venture-backed start-ups to large pharma to not-for-profit organizations. We take our clients' projects with the utmost seriousness. In the case of our smaller clients, they may only be working on one project, so their success is very much in our hands. In dealing with all of our clients, our objectives are to set reasonable targets with obtainable but aggressive timelines, then delivering on-time and within the agreed to budget. This is one reason the majority of our smaller clients stick with us as their project matures. It is gratifying to see their success and to have contributed to it.

Q: How does your business strategy differ from other CROs?

A: PSI is rare in that we started as a formulation group, and that remains our core. We continue to grow deeper and deeper in our core skill set and are intentionally not trying to be all things to all people. Our goal is to solve our clients problems, and we are not wed to any given drug delivery technology. To that end, we have designed or acquired multiple drug delivery technologies in order to best serve our clients.

As our name implies, our expertise is with particulate-based systems. This encompasses both microparticles and nanoparticles. We are well versed in several technologies, including encapsulation, particle size reduction - both top-down (including high-energy milling and high-pressure homogenizers, such as Microfluidizers®) and bottom-up (solvent/antisolvent precipitation, including Microfluidics Reaction Technologies system) approaches, and particle engineering. As mentioned earlier, these techniques can be called upon when appropriate for a client's goal and have been leveraged for multiple routes of administration including, for example, non-sterile, sterile, oral, vaginal, topical, ophthalmic, inhalation, injectables, etc. It may appear that PSI has capabilities spanning almost too wide a range; however, the common thread is our deep understanding of particulate systems: solid-in-solid, solid-in-liquid, and liquid-in-liquid. We can leverage this knowledge to all routes of administration. This being the case, we opt to grow by expanding our knowledge, expertise, and capabilities in this area and not to grow in areas that are not core to us, such as in vivo or clinical testing.

Some of our service offerings, such as combination drug-eluting devices, flow naturally from our sweet spot in particulates. Our focus on particulate-based drug delivery systems and difficult to formulate API's we believe better serves our clients, and seems to be in sync with their requirements. Of course, we can and do formulate solution-based products, but this constitutes a minority of our projects. There is a tendency in times of solid revenue growth to expand as quickly as possible. This is not always the best tactic and, if there isn't a good strategic plan in place to guide that growth, it is a recipe for disaster. PSI has been and will continue to be disciplined in not over-reaching our core competencies or growing too rapidly without a sound strategy.

A key aspect of our business strategy is our initial interaction with our clients. Early in our discussions, we strive to understand exactly what our clients' goals are; we want to make sure we hear and understand their needs and design our programs to satisfy those goals. For example, an early question is whether or not our clients are interested in a formulation approach using proprietary intellectual property (IP). In some cases, our clients have strong IP surrounding their new chemical entity or use for their molecule and are interested in a straight line to some value-inflection milestone, such as in vivo evaluation or human proof-of-concept. In these cases, PSI will employ, if possible, a non-proprietary drug delivery approach. We are agnostic when it comes to using our existing proprietary or non-proprietary drug delivery technology; it is based on our clients' requirements, and often a simple emulsion or non-proprietary nanoparticulate approach works fine. In other cases, our clients may be seeking to reposition a marketed drug or may have mediocre or no IP protection for their product concept. For these clients, PSI can draw upon our existing IP or create new IP to better protect their products. It is important to understand our clients' needs, and PSI is uniquely positioned to support their development strategies from a technical as well as business perspective.

Q: What do you believe are some near-future growth areas for PSI?

A: With the current and ongoing trend in downsizing and outsourcing, I believe our clinical trial material (CTM) manufacturing services will continue to grow, especially in the areas of sterile products and drug-eluting devices. We are capable of manufacturing small-scale, aseptically processed CTM and excel at manufacturing challenging, hard-to-make products. We will continue to grow our capabilities to manufacture CTM. As a side note, whenever we work on formulation and process development, we do so with the commercial product in mind; we develop robust, scalable, commercially viable products. However, we do occasionally have a product that is transferred in from another developer that can be challenging to reproduce and may not be commercially viable. In those cases, we can execute the technology transfer and, in parallel, work on a scalable process to meet our client's requirements and stay on time.

Highly potent compounds (HPCs) are an increasing part of our business and we see this as another area for growth. There is a clear need for CRO's that are competent in handling such materials and we have invested heavily in both the needed physical and procedural infrastructure.

Another area of growth is working on challenging APIs or delivery requirements. As you can imagine, we rarely, if ever, get simple APIs to work on; those that are water-soluble, stable, and bioavailable. In most cases, the API is water insoluble. This is not too difficult a challenge, and we have several options to circumvent this issue.

However, in some cases, we are asked to formulate APIs that may or may not have low aqueous solubility, but are hydrolytically or enzymatically labile as well. These cases require work, but the challenges are not insurmountable. Another recent challenge we have been faced with has been to convert a water-soluble API into a nanoparticle formulation that is suitable for intravenous administration.

As mentioned previously, we have proprietary drug delivery technology that we have either invented or in-licensed. Our ultimate goal is a satisfied client, which leads to repeat business and a good reputation. It is in everyone's best interest to use the drug delivery approach that works best for a given API and delivery goal. It is not accurate that one size fits all, so we believe in having a good selection of drug delivery technologies, that we have demonstrated to ourselves as commercially viable, at our disposal for use on our clients' projects.

Q: What other services do you offer clients?

A: PSI has a very accomplished analytic and bioanalytic group. In addition to the traditional separation approaches, PSI offers in vitro release testing using Franz diffusion cells. We can conduct this testing to support R&D or conforming to cGMP requirements for use in regulatory filings.Our physico-chemical characterization capabilities, including optical microscopy coupled with image analysis, several different methods to measure particle size distribution, and a suite of other techniques to characterize semi-solids and particulate systems provide our clients with a one-stop shop for their CMC needs.

Q: What are PSI's future plans?

A: PSI is forming alliances with other service providers and equipment manufacturers that we consider best-in-class in order to provide our clients with seamless access to a host of services. This allows PSI to concentrate on what we do best and leverage the infrastructure of other companies to best serve our clients. An example of such an alliance is with Microfluidics Corporation. We evaluated several high-pressure homogenizers and concluded that Microfluidizers are the best-in-class. They excel at emulsions and can also be used to reduce the particle size of crystallineAPIs. This alliance provides PSI and our clients access to the Microfluidics Reaction Technology system, which is a state-of-the-art solvent/anti-solvent precipitation system. Presently, there are less than a handful of these systems in the field, and we have one. We are working closely with Microfluidics to ensure our scientists are fully up to speed and experts in this technology. Similar arrangements ranging from ADME services to large-scale commercial production will be announced in the coming months, all aimed at providing our clients the most complete set of tools possible while minimizing their administrative burden and allowing PSI to maintain its focus on developing superior drug products. ◆