

Insider Insights: **Celerion**

CWWeekly's semi-monthly company profile feature, *Insider Insights*, interviews executives of companies and organizations in the clinical trials space. Writer Ronald Rosenberg sat down with Susan Thornton, president and CEO of Celerion.

Q Celerion is essentially the early-stage clinical trial business acquired from MDS Pharma Services nearly 18 months ago. How has the recent recruiting shift to target patient populations in phase I trials, the use of adaptive designs and other changes helped you grow to become a specialist at a time when other CROs seem to be moving away from early-stage trials?

A Many CROs have been challenged recently to grow their early-stage business. Our exclusive focus in this space strongly positions Celerion to respond to the increasing need of the biopharmaceutical industry to generate as much drug development information as early as possible to make informed go/no-go decisions.

With projections of modest spending growth on clinical trials over the next decade, robust and comprehensive data early in development reduces the risk of costly failures in phase III clinical trials. Furthermore, reaching clinical proof-of-concept is a key milestone for the justification of continued investment to progress a drug in development. These factors have increasingly

driven a desire by companies to incorporate patients into phase I safety and PK studies.

Celerion routinely recruits for a wide range of special patient populations, as well as healthy volunteers, through our four clinics and relationships with three hospitals. In many of these trials, our bio-analytical laboratories also analyze biological markers for early indications of efficacy and mechanism of action. As for targeted populations, we focus on diabetes, obesity, CNS disorders, respiratory indications, ophthalmology and renally and hepatically impaired patients.

With regard to adaptive designs in phase I research, we've been doing that for years. All first-in-human dose-escalation studies involve evaluating data during the course of a trial to determine whether to progress to higher doses or adjust the dose regimen.

What changed recently is the request for more creative or fusion type studies in which you are looking at multiple factors in one trial, such as maximum tolerated dose, food effects and age/gender differences. Again, the data is reviewed as the study progresses to adjust subsequent study strategy. We are seeing more than 50% of our first-in-human studies following adaptive design. The openness of regulators to allow these types of studies in recent years has been a key driver.

We are seeing increasing requests to include more patient populations earlier to

Celerion

Headquarters: Lincoln, Neb.

Year founded: 2010 (from the acquisition of MDS Pharma Services' early-stage development operations and the Development and Regulatory Services consultancy).

Description: An early-stage clinical trials company, providing advanced scientific and technological expertise, NDA-enabling clinical pharmacology, clinical pharmacology sciences, bio-analytical services (discovery through late stage) and drug development services. Its network of U.S., Canadian and Western European facilities includes more than 730 beds, including 24 in a hospital, and resources to meet both the biopharmaceutical and the generic industry's needs for innovative phase 0 through IIa proof-of-concept studies.

Officers: Susan Thornton, Ph.D., President and Chief Executive Officer

JoAnne Rosal, Chief Financial Officer

Philip Bach, Vice President, Global Clinical Research

Michelle Combs, Ph.D., Vice President, Clinical Pharmacology Sciences

Operations: Lincoln, Neb.; Neptune, N.J.; Philadelphia, Penn.; Richmond, Va.; Phoenix, Ariz.; Montreal, Canada; Belfast, Northern Ireland; and Zurich, Switzerland

Offices: Lincoln, Neb.

Clinical trials: Undisclosed

Employees: 850

Web site: www.celerion.com

get to go/no-go decisions sooner. Still, we see a strong need and demand for young, healthy volunteers in early clinical research. There is no faster way to understand a new drug's pharmacokinetics and get a clear idea of drug-related safety issues than by performing studies in healthy volunteers.

Q The company screens, on average, 2,300 clinical trial participants per month using print, radio and television ads, along with health fairs and seminars. What non-traditional approaches, such as social media, do you foresee using to reach a potentially wider and younger audience?



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A With the increased complexity of identifying qualified study participants, we have had to get more creative, particularly around digital recruitment. We use various e-recruitment tactics such as Facebook, Twitter and YouTube. Social media networks provide a great way to get through to the younger population in a more cost-effective way.

Perhaps more challenging is building our database of elderly volunteers. With an increasing focus on healthcare for our aging population, we are seeing a rise in demand for elderly subjects who are not reachable through digital media. For these individuals, we need to take a more hands-on approach, such as community outreach programs.



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Susan Thornton, president and CEO, Celerion

Q Often, small drug companies initially strive to capture a return on investment when the product demonstrates clinical proof-of-concept. This involves “fast-to-patient” testing in a target population and is among the new clinical strategies to determine whether to proceed with further drug development. How is the company developing this strategy?

A Smaller and emerging pharmaceutical companies are an important segment of our customer base because we have the expertise to get them to clinical proof-of-concept quickly. Our name, Celerion, is derived from the Latin “celeritas” meaning swiftness and speed, and that is what we focus on every day.

We spend a lot of time thinking about new technologies to enrich the information about a drug collected in early development, to reach proof-of-concept as quickly as possible. For example, we are the first CRO to deploy Bluetooth wireless Holter

monitoring with high-definition signaling and highly automated data analysis to provide better ECG data more quickly and at a lower cost.

Celerion also has a relationship with the accelerator mass spectrometry company Xceleron to perform microtracer studies. Microtracers can be added to dose-

escalation studies to provide information about absolute bioavailability and metabolic profiles that are faster and earlier than more traditional approaches.

Another way we facilitate fast-to-patient strategies is by providing biomarker panels and novel biomarkers through our bioanalytical laboratories in Lincoln (Nebraska) and Zurich. We also have developed external relationships to expedite recruitment of patients into studies. We have a 24-bed clinical research unit at Bryan LGH Hospital, located two miles from our clinic in Lincoln, for more complex patient trials and for studies requiring hospital services such as advanced imaging.

Overseas, we have collaborated with Queens Hospital in Belfast and have been recognized as a member of the U.K. Respiratory Therapeutic Capability Cluster, which acknowledges our combined expertise in early clinical research in respiratory diseases.

At our Phoenix facility, we have a highly specialized ophthalmology suite for early studies on new ocular medicines. We bring our PK statistics and bioanalytical expertise into collaborations with specialty clinics that

conduct studies in renal and hepatically impaired patients and in patients with serious CNS diseases.

Finally, we recently obtained ANVISA certification for our Lincoln and Belfast sites that enables us to support drug approvals for the Brazilian market.

Q Since generic drug makers are among the company’s customers, are you participating in early-stage development of biosimilars? Do you see this as a major expansion area for the company?

A We are well-positioned to provide services for the emerging opportunities in biosimilar development in

Europe, where a regulatory pathway to approval exists. We view biosimilars as a major expansion area and are already working with clients on development strategies for these follow-on drugs, as well as supporting their development with bio-analytical assays, PK analyses and early clinical protocols.

Our Zurich laboratory is the biggest large-molecule, bio-analysis facility in Europe, having been in operation for 25 years. We have assayed many of the current large molecule drugs on the market and have already supported pre-clinical assay work for new biosimilar products.

Our Belfast clinic has operated since 1990 with 78 beds, an appropriate size to perform the initial comparative PK studies required in a biosimilar development program. We’ve been active in the development of large molecule drugs for many years through pharmacokinetic analysis, medical writing and regulatory needs. And we continue to build in that space.

Q As trials become more global, sponsors seek speed, lower costs and treatment-naïve patients. What will you do

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to preserve and grow your U.S. clinical trials business—not just the number of trials but new ways to recruit patient volunteers?


A The need to find treatment-naïve patients is greatest in large multi-center, late-stage clinical trials, which is not our area of focus. The majority of our trials still depend on filling study panels with healthy volunteers.

With regard to cost, some of our sponsors have sent trials to India. However, these are primarily generic studies in which price is the driving factor in picking a vendor.

Recently, increased regulatory scrutiny in India has resulted in some quality issues and some sponsors have come back to us.

The majority of our business is first-in-human and NDA-enabling studies for innovator drugs. Our sponsors are more comfortable conducting these studies at our U.S. and European sites.

With regard to Asia, one area of potential interest among our sponsor companies is ethnic bridging studies. Other compelling reasons also may influence a drug company to go to one geography and not another.

We are in discussions and anticipate making a decision later this year as to our expansion strategy in Asia. 

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