



Clinical Network Services (CNS) establishes US operations

Brisbane, Australia- 8 January 2015 - Clinical Network Services (CNS), an integrated product development company based in Australia, New Zealand and the UK providing comprehensive services in the planning, implementation and delivery of preclinical, Phase 1 and 2 trials, today announced that it has established a new office in the USA under the name "Clinical Network Services USA Inc". At the same time CNS appointed Megan Hill as the Business Development Manager in the USA.

Initially based out of San Francisco, California, CNS US will complement BioDesk's established regulatory/product development consultancy services in Australia and Europe and will enable Biodesk to better support its clients seeking to engage with the FDA. This initiative means that CNS is also able to act as US Agent in support of interactions with the FDA.

Mark Reid Director of BioDesk and Regulatory Affairs commented: "It is a very exciting time at CNS currently, and particularly for our BioDesk services. In the last 12 months, we have responded to client requests to provide a broader and deeper international scope to our established BioDesk brand. Last year we launched in Europe and have successfully grown a strong team in Europe. Establishing CNS US Inc now provides BioDesk with a new platform from which it can continue to respond to that demand and provide integrated access to the FDA. It is incredibly important that we provide genuine expertise in the major regulatory environments."

Commenting on Megan Hill's appointment as Business Development Manager US, Paul Cronin Director of CNS UK & Business Development said "We are particularly delighted to have attracted Megan to the team as it is important to CNS that the market understands what we are doing and how this expansion of our service offering might be of benefit to our client's plans."

Ms. Hill has degrees in both Chemistry and Business and brings with her several years of regulatory experience, specifically in orphan products. Her former roles as a regulatory consultant and business development associate give her a great insight into the needs of the US regulatory environment and better positioning on how the international BioDesk team can provide operational and consulting support to our clients.

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About Clinical Network Services

Clinical Network Services (CNS) is an integrated service group focused on product development headquartered in Australia with offices in New Zealand, the UK and the USA, who create value for small-medium sized biotechnology companies by progressing early stage products through phase 1 & 2 clinical trials or the marketplace sooner. CNS offers a unique service where it integrates BioDesk, an intelligent global product development and regulatory affairs consultancy, with our committed, highly experienced

Australian/New Zealand clinical services and biometrics team. CNS' regional clinical advantage is driven by the extremely pragmatic regulatory environment in Australia and New Zealand that makes it possible for clients to enter the clinic quickly, without prior regulatory approval.

CNS offers a uniquely differentiated, customer-orientated, suite of services to clients which enables CNS to guide products efficiently through critical post-discovery development and into initial human trials. Throughout, CNS takes a global development/ regulatory strategic approach to ensure that value is added at every stage of the product development life cycle.

Further information about CNS and its intelligent development services can be found at **www.clinical.net.au**

About Biodesk:

CNS's BioDesk is an expert consulting team offering CMC/manufacturing, toxicology, clinical and regulatory affairs consulting services for readying products to enter clinical trials or marketing approval.

The BioDesk team consists of experienced chemists, toxicologists, medical writers, regulatory affairs specialists and experienced clinicians based in Australia, Europe and the USA. BioDesk works closely with clients to design and implement manufacturing operations and non-clinical plans, mindful of commercial timelines and budgets. BioDesk further adds value by ensuring that a global regulatory standard is inherent within client development programs.

BioDesk core services include:

- Developing clinical development plans and drug development plans - starting with the end in mind.
- Getting client GMP-compliant clinical trial material ready for the clinic.
- Completing client GLP- compliant toxicology studies before human studies start.
- Arranging meetings with the regulators and helping clients ask optimal questions in order to elicit helpful responses.
- Writing up all applications for the regulators including big or small projects: orphan applications, paediatric investigational plans, to New Drug Applications and everything in between.
- Providing medical writers to write up protocols, investigator brochures and all modules in the Common Technical Dossier required for a marketing application.