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The Most Powerful Name in Corporate News

DavosPharma
A Davos Chemical Company
DISCOVERY ▪ CHEMISTRY ▪ FORMULATION

Discovery, Chemistry and Formulation Services for the Pharma Industry

Barry Robins
President

"Davos is completely virtual, utilizing the tremendous technical capabilities of manufacturers world-wide. Our capital is the knowledge, skills and experience of the talented group of staff we have assembled." - Barry Robins

Davos Pharma

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CEOCFO: ***Mr. Robins, what is the idea behind Davos?***
Mr. Robins: Our goal is to help clients efficiently move their discoveries through the drug development process. DavosPharma was originally launched as Davos Chemical Corporation back in 1972. 1972 was a very different time; the world was in the midst of the first major oil crisis, the availability of commodities based on oil suddenly became unpredictable, and prices and delivery times skyrocketed. Outsourcing, especially for pharmaceuticals, was unknown. For the first decade, Davos engaged in the oil based commodity and specialty chemicals market, gradually moving into made to order custom manufacturing which emerged in the 1980s. During the 80s, the market for custom manufactured raw materials and intermediates for specialty chemicals, agricultural and pharmaceutical products matured. By the 90s, most of the industries were outsourcing more and more of the early processes, with pharma lagging the others. By the late 90s, even pharma had fully endorsed the outsourcing model for custom starting materials and advanced intermediates. Davos continued to evolve in this market place. By the turn of the millennium, the start-up or biotech sector emerged based on the availability of risk capital. This model emphasized the role of virtual development and manufacturing. Davos' unique experience positioned us to offer our custom manufacturing services through GMP

manufacturing of both the API and dosage form. By this time, Davos had almost exclusively targeted the pharmaceutical sector prompted by the enormous growth in risk capital investing in meeting unmet medical needs.

Davos is completely virtual, utilizing the tremendous technical capabilities of manufacturers worldwide. Our capital is the knowledge, skills and experience of the talented group of staff assembled at Davos. The majority of employees have both advanced technical degrees and prior experience working in pharmaceutical development.

CEOCFO: ***What are you doing for them?***
Mr. Robins: What we do for top management is to offer them a source for the services they need to bring new pharmaceutical products to market in a style that is as if we were employees answering to the board. We take the work off their desk, and deliver the goods allowing the top management to focus on the more critical aspects of pharmaceutical development such as establishing clinical safety and efficacy in a product and treatment competitive marketplace.

Davos' competences range from preclinical activities such as chemistry in support of lead generation, screening of candidates in model screens, preclinical toxicology and preformulation work. Once a decision is ready to advance or lead to an IND (a critical milestone for funding), Davos will supply the toxicology, chemistry from optimization to manufacturing of CTM under GMP, dosage form, from development of a phase I appropriate dosage form to CTM manufacture under GMP, as well as analytical development, stability studies and regulatory submissions (CMC and tox sections). Therefore, Davos can move our clients into the clinic to meet their milestones.

CEOCFO: ***You are not the only company in this space. What do you understand fundamentally at Davos about the process of working in these areas that perhaps other companies do not know quite as well?***
Mr. Robins: Davos managed over 150 separate projects in 2014, ranging from discovery to commercial supply, from mg to tons, from screening studies to full blown tox studies, from APIs to dosage forms to excipients. Davos has the infrastructure to accept purchase orders from vetted clients exceeding 6 figures and guarantee delivery. Davos has unmatched coverage of the drug development process with the scope of expertise to successfully bring pharmaceutical projects from discovery to IND and commercial approval in the CMC and toxicology areas. Davos has invested heavily in well educated and experienced staff whose credentials in these areas of pharmaceutical development are unrivaled. The staff at Davos continues to push the technology envelope in working with our partner CROs to provide cutting edge solutions to contemporary drug development. Our staff has long histories and diverse experience in the pharmaceutical industry.

CECOFO: ***Are people coming to you these days? Do you still need to advertise?***
Mr. Robins: Occasionally, clients will come to us "out of the blue". However, the majority of this business is more hard work and less glamour; we reach out to new and old clients on a daily basis to best serve their needs when required. Most of the technical staff are out of the office and reaching out to clients daily. We work in an open environment,

so considerable time is spent with clients visiting the sites of our supplier partners to promote the close connection between the clients and the people doing the actual work.

CEOCFO: ***Your site indicates you are expanding and evolving. How so?***
Mr. Robins: We are evolving with many new chemistries, biologies and delivery technologies, such as monoclonal antibodies, gene therapy, vaccines, antibody drug conjugates, amorphous and nanoparticular drug delivery to name a few. There is a trend in personalized medicines, including gene therapy, where they take out blood, modify it, and return it to the patient. There are unheard of novel treatments with also unheard of price tags, yet providing novel therapies for unmet medical needs. This raises enormous ethical and financial issues in the delivery of medical care. These discoveries are hot priorities for acquisitions by multinationals with weak pipelines. We have multiple gene therapy and vaccine projects. The drug discovery is no longer guessing at chemistry, the genes and their pathways are identified and now the drug design is dictated by the biology, not the chemical synthesis. This expansion in expertise is supported by having two Ph.D. level biologists on staff, both with well recognized credentials and expertise in the field.

The Davos staff and offices cover the United States with the head office in Upper Saddle River, New Jersey and local offices in Research Triangle Park in NC, Boston/Cambridge, Philadelphia, San Diego and San Francisco. We try to closely match the client base.

CEOCFO: ***Are there particular types of projects you prefer to work on, given a choice?***
Mr. Robins: Sure, we would like to see a project which comes from an institute like NIH or NCI, or from an early project at a multinational where Davos can apply our talents to all aspects of the project to bring it to the clinic. We find if we can do everything for the CMC and toxicology packages, we find them most efficient and rewarding. But we do not limit the technology we will look at (as long as we are confident in our technical expertise), not that we try to pick winners and losers. We are not so arrogant to believe we know what therapies will work and what won't. We will advise on the technical feasibilities of the processes involved.

CEOCFO: ***When someone comes to you, are there times when you look at the project and do not think it is going to work?***
Mr. Robins: There are two aspects to this question: first, if not going to work refers to the clinical safety or efficacy, as mentioned above, we don't pick winners or losers. This is the client's area of expertise. Second, if it refers to the technical experiments or manufacturing techniques, we will advise the client where we find that there is or isn't a lot of precedent for the technology employed. Davos almost always provides quotations for deliverables, which are only possible if the literature and industry expertise supports the risk. So we work very hard to collaborate with CROs who lead the industry in novel technologies. Occasionally, the therapy is so novel that there is no industry precedent for the process or product. In these cases, we will use a staged approach with an initial phase of proof of principle (usually time and materials) and move expediently to the next phase where we provide a firm quote for the deliverables. Davos prides ourselves on always delivering and not blowing a batch.

CEOCFO: ***How do you keep on top of all the technology and new equipment?***
Mr. Robins: It would be presumptuous to say we can stay on top of everything. We have smart and bright people at Davos and when they recognize a new technology that is emerging, they become informed on its science and engineering. We often learn from both our customers and collaborators. We attend shows and symposia. But the critical piece is Davos' ability collectively to learn from what each other is doing and the novel solutions they are working on. We have deep contacts within NIH and NCI and other institutes and centers. It is the cross fertilization of ideas, knowledge and technologies within Davos that provides the novel solutions for our clients.

CEOCFO: ***Why are people choosing Davos?***
Mr. Robins: Word-of- mouth, reputation and recommendations. Really the foundation we all use to build and innovate. Davos has an excellent track record for deliverables, which is critical in meeting project and ultimately funding milestones. Right product on time and within specification has always been our motto. We have flexibly morphed from custom starting materials to complex project deliverables targeting IND submissions and approvals. Moving from multinationals to start-ups. The driving forces in the pharmaceutical industry are constantly changing and getting more sophisticated. Davos has morphed and changed to meet this new challenge and will continue to do so.

Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

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