Jeffrey Tucker, MD, MBA

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CHIEF MEDICAL OFFICER | CHIEF DEVELOPMENT OFFICER

Global Clinical R&D ■ Portfolio Management – Pharmaceutical and Biotechnology Industries

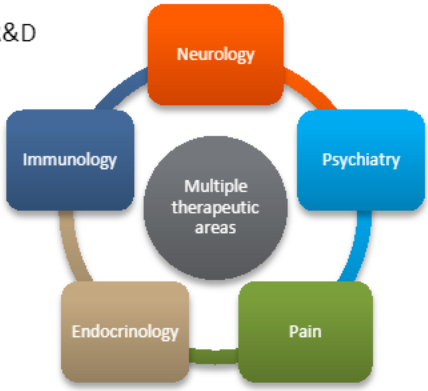
Leading global clinical development and regulatory submissions with an intense, unwavering focus on producing the best possible results in terms of value, quality, timeliness, risk, cost, safety, ethics, and deliverables.

GLOBAL LEADERSHIP EXPERIENCE

- Led R&D, clinical lines, and corporate projects and portfolios in locations throughout North America (U.S., Canada), Europe (Switzerland, United Kingdom, France, Germany), and Asia (Japan, China).
- Managed cross-continental teams of up to 350 professionals in global drug development and regulatory affairs for pharma and biotech companies of all sizes, including 3 startups.
- Well-traveled, global citizen fluent in English, German, Dutch, and French, including technical and medical vocabulary; highly informed on topics of international politics, economics, and health.

BROAD & DEEP TECHNICAL EXPERTISE

- More than 20 years of international pharma/biotech clinical R&D executive leadership for development strategy, planning, execution, clinical trial design, and reporting:
  - Translational medicine through Phase 1, 2, and 3 trials and Phase 4 medical affairs and drug safety/pharmacovigilance; special interest in innovative trial design, including adaptive and SPCD
  - Numerous successful global drug development submissions for combination products as well as small molecule and large biologic drugs in oral, nasal, and injectable formulations



DIVERSE EDUCATION

- Differentiated by intellectual passion for scientific innovation and systematic engineering supported by extensive education spanning medical/clinical therapeutic and business disciplines:
  - MD (infectious disease specialty and Doctor of Tropical Medicine) and EMBA degrees
  - graduate degrees in biostatistics (MS), public health (MPH), pharmaceutical medicine (MS)
  - postgraduate education in epidemiology, decision sciences, and project/portfolio management

CAREER SUMMARY

Sansone Inc. – Trenton, NJ ***2010 – Present***

VICE PRESIDENT, CLINICAL DEVELOPMENT / SENIOR FELLOW

SCOPE: 4 direct reports (VP/directors of translational medicine, clinical science, clinical operations, medical affairs) ■ up to 60 indirect reports ■ budget up to $70 million annually ■ executive leadership and management for all:

- Strategy, design, and direction of global projects in North America, Europe, and Asia
- Comprehensive oversight for execution work completed by multiple internationally located outsourcing CROs
- Processes, systems, technologies, and tools for study design, statistical analysis, and reporting
- Subject/patient and clinical investigation site selection; care and data quality control
- Contractual issues and financial management/budgeting

CONTRIBUTIONS SNAPSHOT: Grew clinical development project portfolio from 1 to 6 projects and led R&D that significantly increased company valuation, ultimately quadrupling stock prices from initial $10/share to $50/share. Lowered risks, decreased costs, and improved efficiency while ensuring that the highest standards of compliance and quality were met. Developed the team, processes, and systems required to enable development of multiple clinical development projects.

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SELECTED LEADERSHIP ACCOMPLISHMENTS

- **Transformed a small (<20), inexperienced clinical development team into a talented team of 60 highly capable professionals**, enabling acquisition of 5 new clinical development projects and creation/execution of a strong translational medicine and early development program.

Notable Highlights

- ✓ *Built a 60 person clinical development team*
- ✓ *Acquired 5 new clinical development projects*
- ✓ *Increased company valuation; raised stock prices 400%*
- ✓ *Brought 4 promising drug candidates into development*
- ✓ *Cultivated excellent FDA and EMA relationships*

- **Strengthened credibility with FDA and EMA regulatory authorities** as result of assembling a solid mix of medical, statistical, and operational talent; gained approval to pursue innovative development strategies, trial designs, statistical analysis, and missing data handling methods.
- **Built robust, high-value, diversified portfolio of clinical development projects**, bringing 4 promising drug candidates into development for indications that included antipsychotic weight gain, pain, multiple sclerosis, and inflammation. Led the team to many successes, including pre-IND and IND submissions and NDA regulatory dossier submissions.
- **Developed medical affairs teams** and implemented clinical research registry and Phase 4 studies. Additionally built a strong drug safety and pharmacovigilance team, process, and system.

SELECTED CLINICAL DEVELOPMENT ACCOMPLISHMENTS

- *Challenge* – With scarce available internal resources and a goal of maximizing compliance and quality while minimizing risks, efficiently develop a novel long-acting schizophrenia treatment.

  Actions – Devised aggressive, carefully vetted Phase 1-3 global development program that beat competitors 50% in terms of time, costs, and subjects. Negotiated and obtained FDA approval.

  Results –Executed entire program in just 3 years to NDA submission preparation. Performed extensive modeling and simulation of pharmacokinetics and pharmacodynamics to complement empirical data, saving additional time, costs, resources, and subjects.

- *Challenge* – Reduce risks, time, and costs in the development of a new, first-class therapeutic for the notoriously difficult indication of adjunctive treatment in major depressive disorder.

  Actions – Validated drug candidate through accelerated program of integrated Phase 1 and proof-of-concept study. Capitalized on innovative, efficient clinical trial designs (SPCD, Maurizio Fava) to reduce risks, time, and costs up to 50% while greatly improving true signal detection.

  Results – Obtained support from European regulators and won acceptance of FDA for SPCD study design and for the first time as a Phase 3 pivotal trial design. Set a record in depression drug development for efficiency; completed Phase 1 and 2, including final meeting with the FDA, in less than 2 years. In just 6 months, prepared for initiation of Phase 3 trials currently underway.

Albano Pharmaceuticals, Inc./Spectrum Pharmaceuticals, Inc. – Philadelphia, PA ..... ***2006 – 2010***

CHIEF MEDICAL OFFICER / EXECUTIVE VICE PRESIDENT, R&D

SCOPE: 4 direct reports (VPs of Pre-clinical R&D, Clinical R&D, Pharmaceutical R&D, Regulatory Affairs) ■ 5 indirect reports and oversight of outsourcing partners for operational execution ■ managed all:

- Selection and due diligence of companies and projects
- Negotiation of licensing deals and funding of R&D projects
- Recruitment and development of the required team, processes, systems, and outsourcing partnerships
- Development of R&D strategy and plans; design of rigorous studies and trials
- Execution of projects, delivering on-time, on-budget, and on-quality

CONTRIBUTIONS SNAPSHOT: Member of founding leadership team for 2 start-up biotech companies (Albano in 2006 and Spectrum in 2009). Obtained $36 million funding from US and EU venture capital firms; identified, evaluated, licensed, and developed neuropathic pain drug candidate (Albano). Licensed and developed clinical Phase 1 and 2 projects in neuropathic pain and Parkinson's disease (Spectrum).

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deRochement Neuropharmaceuticals, Inc. (formerly Bass Therapeutics, Ltd.) – Quebec, Canada ***2003 – 2006***
EXECUTIVE VICE PRESIDENT, R&D

SCOPE: 4 direct reports (VPs of Pre-clinical R&D, Clinical R&D, Pharmaceutical R&D, and Regulatory Affairs) ■ 6 indirect reports and oversight of outsourcing partners for operational execution

CONTRIBUTIONS SNAPSHOT: Recruited to join the leadership team of this start-up biotech, providing executive leadership for R&D through 3 distinct phases. 1) development of existing asset from lead optimization to IND submission in a single year; 2) turnaround and rebranding of the company into Cita Neuropharmaceuticals; 3) implementing successful IPO campaign.

- **Secured $15 million series A funding** and led project to IND submission in less than 1 year, then terminated upon observing safety issues in Phase 1 trial.
- **Turned around and rebranded the company**, reallocating resources to projects with higher potential value and lower risk; identified, evaluated, and licensed novel drug candidates. Secured funding from Canadian, US, and EU VC.
- **Planned and executed IPO campaign**, completing successful M&A transaction that resulted in acquisition of the company for more than $100 million by a French biotech company.

Notable Highlights
- ✓ *Masterminded IPO that resulted in lucrative $100 million acquisition of the company*
- ✓ *Solicited and raised $15 million series A funding*

Baraket Ihm-Araby – France, Germany, and US ***2000 – 2003***
Niebles/Iverson Pharma AG – Switzerland, UK and US ***1992 – 2000***
EXECUTIVE DIRECTOR, GLOBAL DEVELOPMENT PROJECT MANAGEMENT (2000 – 2003)
EXECUTIVE DIRECTOR, GLOBAL R&D PORTFOLIO MANAGEMENT (1998 – 2000)
EXECUTIVE DIRECTOR, GLOBAL BIOMEDICAL OPERATIONS (1993 – 1998)
GLOBAL CLINICAL & BIOMEDICAL OPERATIONS PROJECT MANAGER (1992 – 1993)

Advanced through progressive leadership positions on global clinical development projects, line functions, and special global, multi-organization/process/system integration projects. For both companies, reduced drug development risks, time, and costs across the entire R&D project portfolio through the creation of effective global project management organizations, including all standards, processes, and systems.

Notable Highlights
- ✓ *Drove global development of 6 drugs*
- ✓ *Achieved FDA and EMEA/CHMP approval of Wittmer®/Zullo® for Parkinson's disease*
- ✓ *Spearheaded $850 million merger of a global R&D organization*
- ✓ *Created new 250-person U.K. organization and developed/led a 350-person startup global line function with staff spanning 3 continents*

- **Supervised global development**, from IND/CTA to CTD/NDA submission of Spizale (Valivete®) for Acne as well as dermatologic anti-infectives, anti-fungals, anti-inflammatory, anti-psoriatic and oncology drugs.
- **Managed senior Iverson merger integration team i**n charge of the design, selection, standardization, and implementation of global R&D organization, processes, and systems.
- **Spearheaded development and leadership of new global line function** with 350 staff in Switzerland, EU, US, and Japan.
- **Led successful clinical development and submission** of Cyclosporin Neoral in Organ Transplantation [Vinopal® Ziemba] in North America, Europe, and Japan.
- **Built new, UK-based 250-person organization**, processes, and systems, enabling efficient global clinical trials.

EDUCATION

EMBA, Columbia University Business School, New York, NY
MS Pharmaceutical Medicine, and Swiss FMH Pharmaceutical Medicine Specialty, Basel University Medical School, Switzerland
MS Biostatistics, Harvard University, School of Public Health, Boston, MA
Postgraduate Degree Epidemiology, New England Epidemiology Institute (NEEI), Tufts University, Boston, MA
MPH (Master of Public Health), Brussels Free University, School of Public Health, Brussels, Belgium
DTM (Doctor of Tropical Medicine), Institute of Tropical Medicine, Antwerp, Belgium
MD (Medical Doctor), Brussels Free University Medical School, Brussels, Belgium

Addendum available with details of professional and academic affiliations, publications, and presentations

Résumé Strategy

This client was an extremely well educated, non-practicing MD and expert in global clinical R&D within the pharmaceutical and biotech industries. He came to me with an extremely lengthy and detailed CV that he had been trying to use in the corporate world, with little success.

It took some extensive consulting with the client to get him to think about his work in terms of results and benefits—especially results or benefits that we could quantify. He simply wasn't used to thinking about his work in these terms and this was further complicated by the fact that it truly was difficult to quantify many of his accomplishments. Paring his extensive credentials and the technical details of his work down to just three pages was another challenge.

The resulting résumé was well worth it. The structure, formatting, and design of the entire résumé was created to succinctly convey his many technical qualifications and make them as easy-to-read as possible at just a glance. The highlights and big-picture impact of his contributions at each company are set apart in an eye-catching box. Notable highlights for each are called out in a bulleted box. I created an addendum for details of his many additional credentials, and I instructed the client to bring this with him as a leave-behind for interviews.

Conservative design elements and coloring used in the résumé help make it eye-appealing, but appropriate and acceptable to the target industry