Cellular Engineering Technologies

Executive Summary

The Company & Technology

CET is a biopharmaceutical company co-founded by Dr. Alan Moy and Mr. Anant Kamath whose mission is to discover, develop and license, well vetted IND-ready, pre-clinical drug assets for rare diseases and niche unmet medical needs. The value of pre-clinical assets has increased dramatically over the past decade with upfront payments by the pharmaceutical industry ranging from $15-40 million per asset. CET has developed a proprietary and differentiated induced pluripotent stem cell (iPSC) platform for rare diseases characterized by a single gene mutation. CET uses its proprietary discovery platform to screen small molecules, sourced internally and externally by CET, in reprogrammed patient-specific IPS cell models. This "disease in a dish" model is very capital efficient and represents a major industry innovation and achievement. CET's business model focuses on developing "early in/early out" strategies to minimize the regulatory and clinical risk commonly associated with drug development. The biopharmaceutical industry is increasingly moving away from a traditional blockbuster drug model in which drug development and clinical trials are extremely lengthy and expensive with low probability for success in getting final regulatory approval. Because it costs >$1B and over 10 years to bring a drug to market the biopharmaceutical industry is increasingly moving towards drug development for rare diseases because development and clinical trial costs are less expensive and more predictable. The FDA also provides attractive patent protections, extended periods of exclusivity and accelerated approval paths for rare diseases representing a shorter path to market. CET is focused on rare diseases because adult stem cells from patients contain all of the disease traits necessary for identifying promising lead compounds with much higher probability of clinical success than for common diseases.

Proof of Concept Established

CET was first to demonstrate that curing a disease in patients with a rare disease containing a single gene mutation can be predicted using the patient's diseased stem cells to discover new therapeutics. CET developed proof of concept with a terminal neurodegenerative disease, called Niemann-Pick Type C (NPC). This rare, fatal neural degenerative disorder, caused by a genetic defect, leads to impairment of cholesterol metabolism in neural cells, causing fat accumulation and ultimately neural cell death. NPC is the most common cause of juvenile dementia and mimics the pathology observed in familial Alzheimer's disease. CET documented that a repositioned drug was able to cure the cellular cholesterol disturbance in NPC stem cells and predicted the successful clinical outcomes in two children utilizing an FDA approved Compassionate Use IND. This proof of concept provides the rationale to develop a pipeline of preclinical drug assets for licensing and clinical development to the pharmaceutical industry for rare diseases and certain cancers utilizing CET's proprietary technology on patient derived diseased stem cells.

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The Team

CET has assembled an outstanding scientific and management team in regenerative medicine; a leading and experienced CEO in regenerative medicine; broad, differentiating intellectual property; and strong strategic non-profit and academic partnerships.

Lyle A. Hohnke, PhD, MBA. CEO: Over 35 years of healthcare industry experience including venture capital investing, biotechnology company management and large pharma drug discovery and development.

Alan Moy, MD. President: CET founder with over 20 years' of experience as a clinician, tenured University of Iowa academician, entrepreneur and accomplished scientist.

Anant Kamath, JD, MS. CSO: CET co-founder, accomplished scientist and IP attorney

Use of Funds

The company seeks to expand its business with a Series A round of funding of $3.0 million that includes $0.5 million of non-dilutive capital from the State of Iowa and $0.4 million of local economic development funding. The investment will permit CET to validate further its proprietary screening platform with NPC, initiate new drug screening in two related Niemann-Pick diseases along with familial Alzheimer's disease, prosecute intellectual property filings and hire key personnel. It is anticipated that results obtained with the Series A financing will significantly increase CET's valuation and facilitate raising a Series B round of $12 million in year 3 from sources that include strategic partnerships, SBIR grants, disease specific foundation grants, product sales and other traditional funding sources. Series B funding will be used to expand screening of drug libraries to identify new leads/hits and perform preclinical studies leading to IND ready assets that will allow CET to license and/or sell these assets beginning in year 5. The CET business model is capital efficient and provides investors with multiple exit opportunities without assuming the clinical and regulatory risks of prolonged clinical trials. The company is also exploiting a profound pharmaceutical need for accessing innovation in the form of new disease targets as a result of huge transformational changes occurring in the industry.

With the Series A financing, CET will accelerate its goal to be a market leader in personalized medicine for rare diseases, create a revenue-generating business model, achieve outstanding growth and valuation in a huge market and become a very attractive acquisition target. The terms of the investment are designed to offer a very attractive return on investment and exit strategy for investors. For further information, contact Dr. Lyle Hohnke (lyle.hohnke@celleng-tech.com, (205) -441-4433 mobile

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