CEL-SCI's Manufacturing of Cancer Killer Multikine Marks a World-Class Facility

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CEL-SCI conducts the largest head and neck cancer clinical trial, a multi-billion dollar industry; Unique cancer treatments earmark CEL-SCI's future success in a clear opportunity for investors

NEW YORK, NY / ACCESSWIRE / April 14, 2016 / Deep in the state of Maryland, home of the coveted blue crab and picturesque Chesapeake Bay, stands CEL-SCI's (CVM) 75,000 square foot manufacturing facility for Multikine, its exceptional immune-boosting drug geared toward head and neck cancer, an aggressive disease comprising a $386 million market expected to top $1.5 billion by 2024 where CEL-SCI stands an excellent chance of grabbing market share from harmful chemotherapy.

CEL-SCI's facility, producing drugs for the largest clinical trial of its primary indication, has been endorsed by FDA and other regulatory bodies. Its 'build it ourselves' attitude reminds me of early immunotherapy hopefuls like Cambridge Antibody Technologies whose drug was eventually bought by Abbott Laboratories for $1.3 billion. CEL-SCI, like Cambridge, has a vertical manufacturing structure bringing it from lab bench to quality control to packaging, to the clinic and finally, to the patient. Such potential rapid roll-out of Multikine, when commercialized, will be highly beneficial to owners of the stock.

Commercializing cell therapies is challenging because biological product needs to be reliable. CEL-SCI's manufacturing uniformity will be critical to success of Multikine, up to standards similar to those of Merck & Co. (MRK), and Bristol-Myers Squibb (BMY), two leaders of approved immunotherapies. One big difference between CEL-SCI and these global giants - producing Multikine is much simpler and cost-effective, and manufacturing economies of scale are easier to attain.

Officer Eyal Talor, Ph.D., also an adjunct professor at nearby Johns Hopkins University and long-time champion of Multikine. Bonding from our mutual association with Hopkins (I received a graduate degree there), Dr. Talor was candid about the pitfalls of making biologic-based drugs: high cost, uncertain replication of results, and huge lab space required because almost all immunotherapies are an autologous mixture of individual patient cells. Multikine, as an allogenic (off-the-shelf) drug, is special and CEL-SCI will not encounter such problems.

Dr. Talor explained that being allogenic, Multikine's batch-to-batch replication, overseen scrupulously with quality control scientists, is tight. Manufacturing costs are conservative enough to produce a fat gross profit margin and large-scale production is highly feasible, a feat economically unavailable to makers of autologous drugs and a huge advantage to CEL-SCI over immunotherapy drug makers. Plant capacity is plentiful to support not only product to numerous clinical trials now done in 24 countries, but also to provide the world with Multikine after approval, an important value proposition for investors who often suffer through product backlogs not able to be turned into cash when manufacturing capacity is compromised by bad forward planning.

The facility was remarkable to my eye, conditioned to viewing countless labs on their way to product approval that often falter due to suboptimal environments that can be detrimental to quality control; not good for gaining investor confidence. Most striking was the enormous effort to comply with strict manufacturing guidelines imposed by regulatory bodies, FDA included. Cleanliness is paramount (floors, walls and even ceilings are scrubbed), and temperatures must be chill enough to prevent bacterial formation that would risk Multikine's integrity. CEL-SCI's manufacturing acumen looks to avoid glitches so often seen with biopharm firms upon FDA approval of their drugs, and once Multikine gets the nod, this company can hit the ground running on its way to providing fast positive returns to shareholders.

Dr. Talor pointed out that Merck and Bristol-Myers need large amounts of laboratory space to process individual cells often varying with age and medical condition. Cost of goods sold can be astronomical for immunotherapy drugs made on commercial scale. Evidence - Dendreon Corp. (DNDNQ), first to attempt making an immunotherapy in big quantities, eventually went bankrupt when production expenses outweighed revenue. CEL-SCI does not run this risk.

In what amounted to a private tutorial on Multikine, Dr. Talor clarified it's the only drug to attempt treating head and neck cancer patients before standard procedures - surgery, radiation and chemotherapy; astonishingly, nothing new has been developed in fifty years. Therapy must be given within one month of diagnosis

thwart Multikine's ability to "see" tumors and induce a massive infiltration of helpful T-cells to create a healing benefit. We both marveled at the bright future of this impressive drug, targeting a multi-billion dollar market that CEL-SCI will have almost all to itself.

CEL-SCI's manufacturing facility in Maryland

Underground workings –perfectly maintained and always operational

Example of clean hallways at the facility

Climate-controlled around the clock

Multikine ready to be shipped to clinical sites

Dr. Talor authored the first peer-reviewed scientific paper on Multikine's Phase II revealing positive data for long term survival of head and neck cancer. Up to 40% of subjects showed improvement in median survival at 3 ½ years, post-Multikine. More stunning, overall survival with Multikine was 67% after 42 months. No bad side effects were observed. If Multikine, under Orphan Drug status, works in Phase III as well as it did in Phase II, CEL-SCI will submit a Biologics License Application to FDA late next year with approval projected sometime in 2018.

CEL-SCI's Phase III enrollment success, posting an average of 26 patients per month, is due to a smartly-executed switch in contract research organizations. As of March 31st, patient census was up to 756, a strong showing over February that should continue. At this rate, the goal of 880 subjects, I believe, could be realized in four to five months. Most important, CEL-SCI and its CRO act as partners, with financial support of $12 million already granted to the company. I think the market should be paying better attention to CEL-SCI's progress.

Investors should be aware that CEL-SCI does not yet produce revenues. For fiscal 1Q16 (ended December 31), cash stood at $10.4 million although funding of $624,000 occurred in mid-February 2016 and Geert Kersten, CEO, made a purchase of stock worth roughly $1.1 million in January 2016 - a strong testament to his belief in his drug. Research and development costs rose 5.9% year-over-year, a small amount considering the scope of Phase III. General and administrative costs declined significantly, reflect-

soon. In October 2015, the company filed charges of breach of contract and fraud against a former CRO, seeking an award of $50 million in damages. If CEL-SCI wins, it gains a substantial amount of non-dilutive funding on its balance sheet. With a current market cap of $76.6 million, a judgement of this size is meaningful and would prove a large boost to the company's valuation. Further, CEL-SCI has an arrangement with a well-known provider of litigation funding, receiving $5 million to help its case, an obligation that would be paid out of proceeds only if CEL-SCI is successful in court. A hearing is upcoming.

Standard risks for a company with upcoming binary events apply: although actively traded with good news flow, bad clinical trial results can damage shares and regulatory paths, especially in the US, can be tricky. Softening this last risk, CEL-SCI's clinical presence is so geographically diverse that quicker-than-expected approval times may result since rates of drug approval vary widely across the globe (Europe, Israel and Canada can often be much faster than the US), hastening Multikine's entrance in the marketplace on its way to significant sales. Burning funds at an annualized rate of more than $22 million, cash will become tight, requiring CEL-SCI to conduct possibly dilutive financing if it does not prevail in its lawsuit with the CRO.

CEL-SCI's manufacturing power is ready as its Phase III trial nears completion for enrollment and dosing. With Multikine, CEL-SCI is perfectly positioned to gain a strong foothold in cancer immunotherapy. Better drugs are needed for its primary indications, which, in addition to disfiguring head and neck malignancies, include using Multikine in highly prevalent human papillomavirus. With the potential ability to kill certain cancers to keep humans healthy, CEL-SCI embodies the definition of an undervalued biotechnology play and a tremendous opportunity for investors.

About Small Cap Forecasting, Inc.

Sharon di Stefano has spent 20 years as an analyst, beginning her career at Smith Barney, Harris Upham & Co. specializing in medical devices, pharmaceuticals, healthcare information technology, and bio-pharmacology. Ms. di Stefano had also served as Senior Venture Officer for the Edison Innovation Fund, implemented through the New Jersey Economic Development Authority that provided funding for early-stage life sciences companies. Industry experience includes laboratory research for Johns Hopkins Hospital and the Department of Defense. Ms. di Stefano received a Master's of Science degree, in Business, from Johns Hopkins University in 1986, and a Bachelor of Arts from the University of Delaware in 1984 with a minor in biology.

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