Brooklyn Biologics
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Executive Summary:

Brooklyn Biologics specializes in developing protein-based transfection reagents that significantly improve the transportation of DNA and RNA into living cells by up to 3-fold. This technology provides value as a research tool in life sciences – validated by benchmark tests with leading transfection products – but also demonstrates potential as a delivery vehicle platform technology for gene-based therapies.

Company History:

Brooklyn Biologics was founded and currently led by the scientific team at NYU that invented and guides the commercialization of the core technology. Carlo Yuvienco, PhD currently leads the venture, managing the fundraising, IP strategy, and business development efforts in close collaboration with Joseph Frezzo, who upon completion of his doctorate in 2016, will continue to oversee R&D operations, primarily conducted in collaboration with New York University. Together they provide 20+ years of industrial and academic R&D experience. The venture has yet to incorporate, but has secured $200K in non-dilutive NSF funds specifically for prototype optimization pertaining to the transfection reagent tool product. An additional $50K was committed by NYU's Office of Industrial Liaison to sponsor the proof-of-concept of the technology to accelerate diabetic wound healing.

Market Opportunity / Unmet Need:

Research institutions conducting biomedical research make up 60-68% of the market while the remainder of the market share belongs to the industrial biotech sector, totaling a domestic $150M research tool market. The improvement in performance of our technology over currently available products, when applied to difficult-to-transfect cell types, provides a value to end-user customers as well as an opportunity to grow the market. For cell lines that are easier to transfect with existing products, our technology may be integrated with these products, through industrial partnerships, to improve the stability of their performance as well as extend the applicability to harder to transfect cells, thus improving robustness and output of meaningful research results for end-users. In this regard, we estimate capturing 5% of the market value through standalone product sales and integration with existing competing products.

The long-term development of our technology to address the diabetic wound healing market provides an additional $5B therapeutic market opportunity given the current standard of care. The prevalence of type II diabetes is characterized by peripheral neuropathy and peripheral artery disease, which lead to non-healing wounds in lower extremities and limb amputations. Management of these complications is a $200 billion dilemma in the U.S. alone, but current approaches are only palliative, including glycemic control, aggressive debridement, and moist dressings. They do not address the primary underlying dysfunction of the diabetic regenerative niche. This provides the motivation to situate our technology as a novel transdermal vehicle that will allow silencing of genes specific to diabetic wound beds with therapeutic short-interfering RNA (siRNA).

Products/Services – Launched & Pipeline:

The technology is currently being optimized to be marketed as a research tool for U.S. distribution in mid-2016. Discussions with Sigma-Aldrich have commenced to market and distribute the product. Suppliers of reagents, such as Mirus and Polyplus, have expressed additional interest in integration of our technology as an additive to their product lines. R&D and launch of the transfection tool product line will precede and inform its development as a therapeutic platform. Early-stage work is being conducted to validate the technology's potential to deliver DNA/RNA-based therapeutics across a variety of clinical indications, the most immediate of which focuses on diabetic wound healing. The proof-of-concept milestones for these therapeutic use cases are anticipated for late-2015/early-2016. Other clinical indications being investigated include psoriasis, B cell lymphoma-associated wounds, and Huntington's disease.

Commercial / Technical Milestones:

Research reagents based on our core technology will be launched in mid-2016, distributed via mainstream reagent suppliers. Technical benchmarks necessary for launch will be validated by end of 2015, requiring at least 2x-3x fold better performance for a variety of cell lines. Concurrently, proof-of-concept work to validate applications against diabetic wound healing will be completed by end of 2015, marked by an achievement in a 30% reduction in healing time. This milestone segues to a kick-off of early/pre-clinical work in 2016.

Intellectual Property:

The intellectual property is currently owned by New York University, and being prosecuted as a full patent application in the U.S. It is the intention of Brooklyn Biologics to license the technology for therapeutic as well as non-therapeutic applications. License negotiations will commence in mid-2015 and are substantiated by the university's expressed support for a spin-out venture. Opportunities for Brooklyn Biologics to generate additional IP exist with regards to additional protein-based transfection products and therapeutic applications thereof.

Competition:

The major competitors include Life Technologies, Thermo Fisher, Roche, Promega, Qiagen, Lonza, Mirus, and Polyplus, defined by the multitude of liposomal and non-liposomal reagents. However, none of the large competitors develop engineered protein-based solutions.

Financial Projections (Unaudited):

The first three years of operation will yield $1.91M in gross profits from research tool products, the majority of which will feed the R&D costs associated with therapeutic application development. The research tool products are projected to gain traction within the first year of operation, requiring $250K in start-up funds for manufacturing process development. The current strategy to raise these funds focuses on SBIR and foundation funding. We plan to engage ABL, Inc. and Sigma Aldrich as CDMO and distribution partners, respectively, but are actively looking for additional distribution partners for the standalone transfection tool product.

Please indicate primary purpose of Presentation:

- Investments to jumpstart the research tool launch, contributing to the necessary $250K.
- Business development toward partnerships with distributors and upstream supply chain organizations.
- Recruitment of experienced personnel to join the management team and/or management advisory board, augmenting the business experience of the team. We have a specific need for guidance negotiating license and contract agreements, most immediately with New York University in mid-2015, but eventually with our partnering entities.