BioTherapeutics Inc.
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EXECUTIVE SUMMARY

Company Background: BioTherapeutics, Inc (BTI) is a science-based biotechnology company that integrates nutraceuticals, pharmaceuticals, and informatics to advance precision medicine intervention to prevent and treat autoimmune and metabolic diseases. BTI Pharmaceuticals is a preclinical stage biotech company developing novel first-in-class therapeutics for inflammation and diabetes. Current medications have limited efficacy and significant side effects. There is an unmet clinical need for more effective and safer therapeutics. BTI's products are orally active, safer and more effective than current therapies, plus target a novel MoA.

Technologies: BTI has identified *Lanthionine Synthetase C-Like 2* (*LANCL2*) as a novel therapeutic target for inflammatory diseases and diabetes. Based on extensive pre-clinical studies, BTI has demonstrated a unique mechanism of action (MOA) that exerts potent anti-inflammatory effects with an encouraging early safety profile. BTI's lead candidate for inflammatory bowel disease (IBD), BT-11, is supported by strong animal pharmacology proof of concept in three validated animal models of gut inflammation, a promising safety profile, and human translational data. BT-11 is a transformative LANCL2-based therapy that addresses a significant unmet clinical need in autoimmune diseases and diabetes.

Market Problem/Opportunity: Immune-mediated chronic inflammatory diseases are widespread and debilitating conditions that occur when the immune system mistakenly attacks and destroys healthy tissue. There is currently a global pandemic of autoimmune related disorders and there are more than 80 different types of autoimmune disorders without a cure. Examples include IBD, systemic lupus, rheumatoid arthritis, psoriasis, multiple sclerosis and type 1 diabetes. An overriding goal of treatment is to reduce the inflammation and tissue damage. Current oral therapies are limited by efficacy (5-ASAs) or side effects (steroids and immunosuppressants), while biologic anti-TNF therapies have to be injected and are associated with serious adverse side effects including cancer and increased risk for infections.

The initial focus of BTI is to address a sub-set of this market - IBD; an autoimmune disease without a cure. It encompasses two clinical manifestations: Ulcerative colitis (UC) and Crohn's disease (CD). IBD afflicts over 1.4M people in the US and over 4M people worldwide. As described the current therapies for IBD are modestly successful with significant adverse side effects, and so there is a significant and unmet market need to better manage IBD with oral therapies in this growing with a global market of $5B.

Value Proposition/Competition: The most effective chronic treatments currently available for IBD are injectable anti-TNF monoclonal antibodies. Treatment is expensive, ~$20,000/yr, and as well as having serious side effects. The route of administration is via IV or subcutaneous injection, requiring visits to clinics/surgeries and frequent monitoring. Therefore, the use of anti-TNF antibodies is generally reserved for patients who have failed to respond to other medications such as 5-ASAs and rescue steroids. BTI's unique LANCL2-based therapy is orally bioactive and is expected to be more effective than 5 ASAs, and as effective as anti-TNF monoclonal antibodies without their side effects, with a much lower cost of good (COG). BTIs lead compound for CD, BT-11, is supported by strong animal pharmacology in three validated animal models of gut inflammation, an excellent safety profile in animal studies to date, and human translational data, suggesting that it could be suitable for induction and maintenance of remission for the majority of stages of the disease. Similar oral products for CD such as Celgene's GED-0301 (mongersen) have been acquired for upfront payments of $710M and are anticipated to total over $1B in global annual net sales. Additionally, this pharmacology provides a path for developing an expansible therapeutic pipeline for other inflammatory conditions including various autoimmune diseases and type 2 diabetes.

Management Team: BTI has assembled a committed leadership team to advance the product pipeline

into clinical development, late-phase development and commercialization partnerships.

Josep Bassaganya-Riera, President and CEO
20 years of business development and fundraising experience leading biotech companies.

Simon J. Tulloch, Drug Development & Operations
25 years of pharmaceutical and biotech experience in strategic business development, clinical development and R&D management.

Raquel Hontecillas, Chief Scientific Officer
20 years of translational research experience in the biotech industry and managing a $12M translational research program in mucosal immunology.

Adria Carbo, Director of Business Development
Extensive experience in outreach and business development and promotion of series A fundraising campaign from pharmaceutical companies, VCs, and angels

Janine Penman, Pharma Partnerships and Capital Acquisition
18 years of clinical and medical affairs experience. Managed R&D and commercial budgets totaling over $250M for leading pharmaceutical companies including Novartis, Pfizer, Shire, and AstraZeneca.

Lee Sandstead, Marketing and Communications Manager
Over 20 years experience in collaborating with cross-functional teams to produce effective promotional materials.

Noah Philipson, Operations Manager
Experience in managing cross-functional teams and coordinating efforts to ensure development of clinical leads.

Intellectual Properties: Innovative proprietary technology with strong IP protection (therapeutics and the LANCL2 pathway). BTI has an exclusive license from Virginia Tech to 11 patent applications that have been developed; 5 patents have issued. In addition, BTI has filed new composition of matter USPT and PCT applications covering broad classes of new chemical entities, including the lead compounds.

Product Development: BTI has a broad therapeutic pipeline for development with an initial focus on treating IBD with the potential to expand into additional autoimmune related inflammatory indications and type 2 diabetes. The development plan for BTI's lead compound, BT-11, is anchored on a pre-IND meeting scheduled in January 2016. BTI will complete the CMC package and IND-enabling pre-clinical safety testing by Q3 2016. BT-11 will be in Phase I clinical studies in Q4 2016. Phase IIa clinical studies in CD patients will be initiated in the second half of 2017.

Competition: The current treatment paradigm for CD includes using 5-ASAs, corticosteroids, immunosuppressant 6-mercaptopurine and anti-TNF biologics. However, current therapies fail to induce remission and have significant side effects. Celgene's oral GED-0301 is currently in clinical testing for CD and BT-11 is likely going to be the next wave of oral CD therapeutics. BTI's has developed new disruptive small molecule drugs with the oral route of administration, suitable for all stages of disease. BTI anticipates they will be more efficacious than 5 ASA and biologics, and safer than biologics, with easy and inexpensive production with low COG. This will give BTI's oral products a distinct clinical and market advantage.

Funding: BTI is seeking $5M in Series A funding to complete IND-enabling CMC, and GLP toxicology studies to initiate human clinical trials by 2016. Series A is divided in three tranches: $2.5M to fund IND enabling studies and file the IND, $2.5M for Phase I clinical trials.