UBC LIFE SCIENCES STARTUP COMPETITION 2017

TheraTrix

TheraTrix is a new company that creates medical solutions for pathological tissue regeneration to improve patients' health worldwide

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Executive Summary

The mission of TheraTrix is to develop innovative technologies to control pathological tissue repair. Heart failure is a major chronic disease worldwide that lacks treatment. Our disease modifying drug for heart failure offers a solution to reduce the incidence of heart failure, and drastically impact this $24 billion dollar market. By targeting a critical disease mechanism, this product is one of the most specific and efficacious compared to current therapies in the market and under development. With comprehensive IP, corporate, and financing plans, we aim to advance our product to commercialization, and offer three major exit strategies for early investors.

Market Analysis

2.1. Problem

Heart failure is a leading cause of death in the United States, which is a condition that develops from a damaged heart that is unable to pump sufficient blood to meet the body's needs. 80% of heart failure cases start with a heart attack. The damaged heart triggers cardiac fibrosis, which over time, is the main contributor to end stage heart failure and death. Currently, there is no specific and effective treatment for post-heart attack fibrosis.

2.2. Market Need

Our major customers are patients who suffered at least one heart attack. This group of patients usually comprises men and women over the age of 45, who have either a family history of heart disease, or one or more associated risk factors: smoking, high blood pressure, high blood cholesterol, diabetes, obesity, unhealthy diet, and lack of physical activity.

In addition, as our population ages, the prevalence of heart failure is estimated to increase in the US by 46% over the next 18 years, resulting in more than 8 million people coping with heart failure by 2030.

2.3. Market Size

In the US , about 735,000 people suffer a heart attack every year, comprising our target patient group. In these patients, heart failure develops over subsequent years and requires substantial management, making it one of the costliest diseases. In fact, American insurers spend about $24 billion dollars per year on post-infarction heart failure, which is an enormous financial burden on the health care system.

TheraTrix has generated a drug to target post-heart attack fibrosis, thereby preventing heart failure and greatly reducing the cost of cardiac disease to the health care system.

Competition

3.1. How are Customer Needs Addressed Today

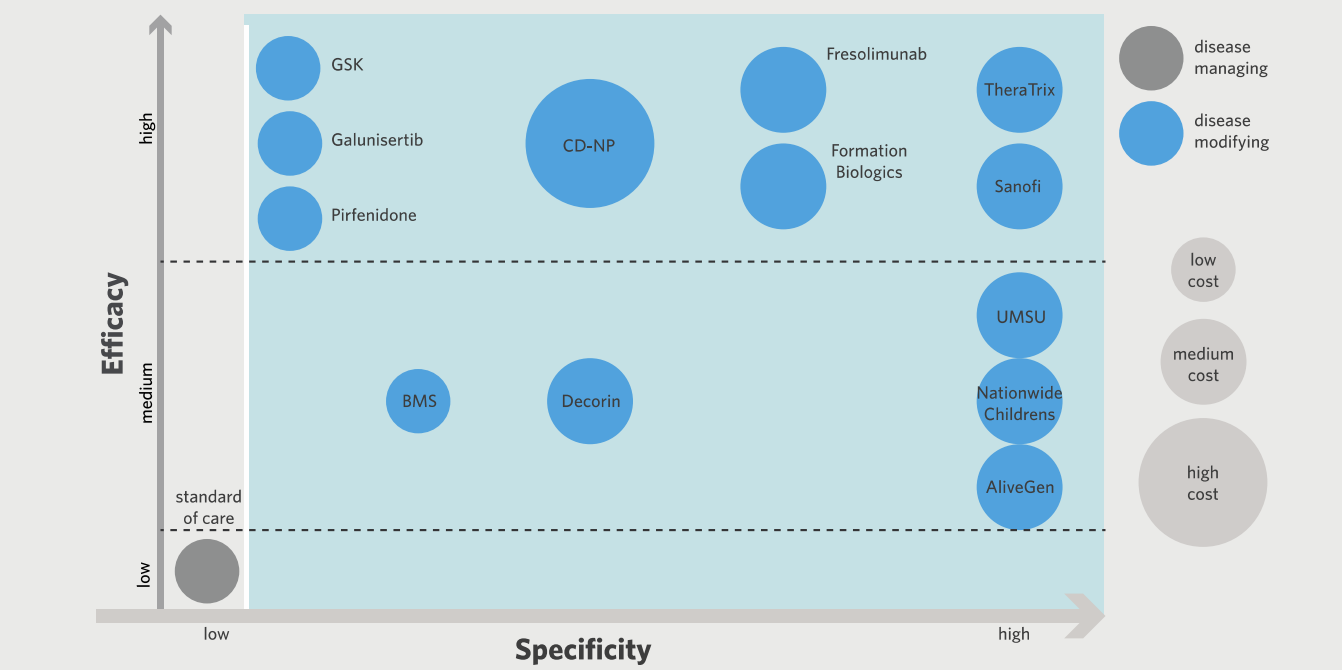
Currently, the standard of care following a heart attack is a group of disease managing drugs that collectively work to reduce levels of cholesterol, lower blood pressure, reduce the strain on the heart and slow down further weakening of the heart muscle to help prevent another heart attack. Examples of these medications are: anticlotting (Aspirin), anticoagulants (Clopidogrel), beta-blockers (Carvedilol), statins (Fluvastatin) and ACE inhibitors (Benazepril). The market is in desperate need for a disease modifying drug that can change the course of disease progression and, ultimately, prevent heart failure.

3.2. Environmental Scan & Competitive Advantage

The following graph illustrates the competitive landscape, in which we categorized products based on our predictions of:

- Efficacy: ability to stop cardiac fibrosis.
- Specificity: ability to affect a single molecular target important to cardiac fibrosis and avoid unwanted effects

As shown in the graph:



- Marketed products: products within the standard of care (eg. beta-blockers and ACE inhibitors) have the lowest efficacy because they are not disease-modifying drugs
- Products in development: disease modifying drugs, products targeting the molecular mechanisms directly responsible for fibrosis are considered the most efficacious
- products are ranked in increasing specificity: small molecules, peptides, recombinant proteins, multi-target antibodies, single-target antibodies
- estimated cost of the drugs is represented by the size of the circles; as represented in the graph, the most competitive products are within the same price range than TheraTrix's drug.

Based on our technology (refer to section 4.1) and the current competitive scan, we predict our product to be one of the most cost-effective options under development. Nevertheless, this analysis has identified our main competitor to be a product under development by Sanofi, which is in IP stage. Currently, there is no data available to compare the efficacy of Sanofi's product with ours.

Commercialization Plan

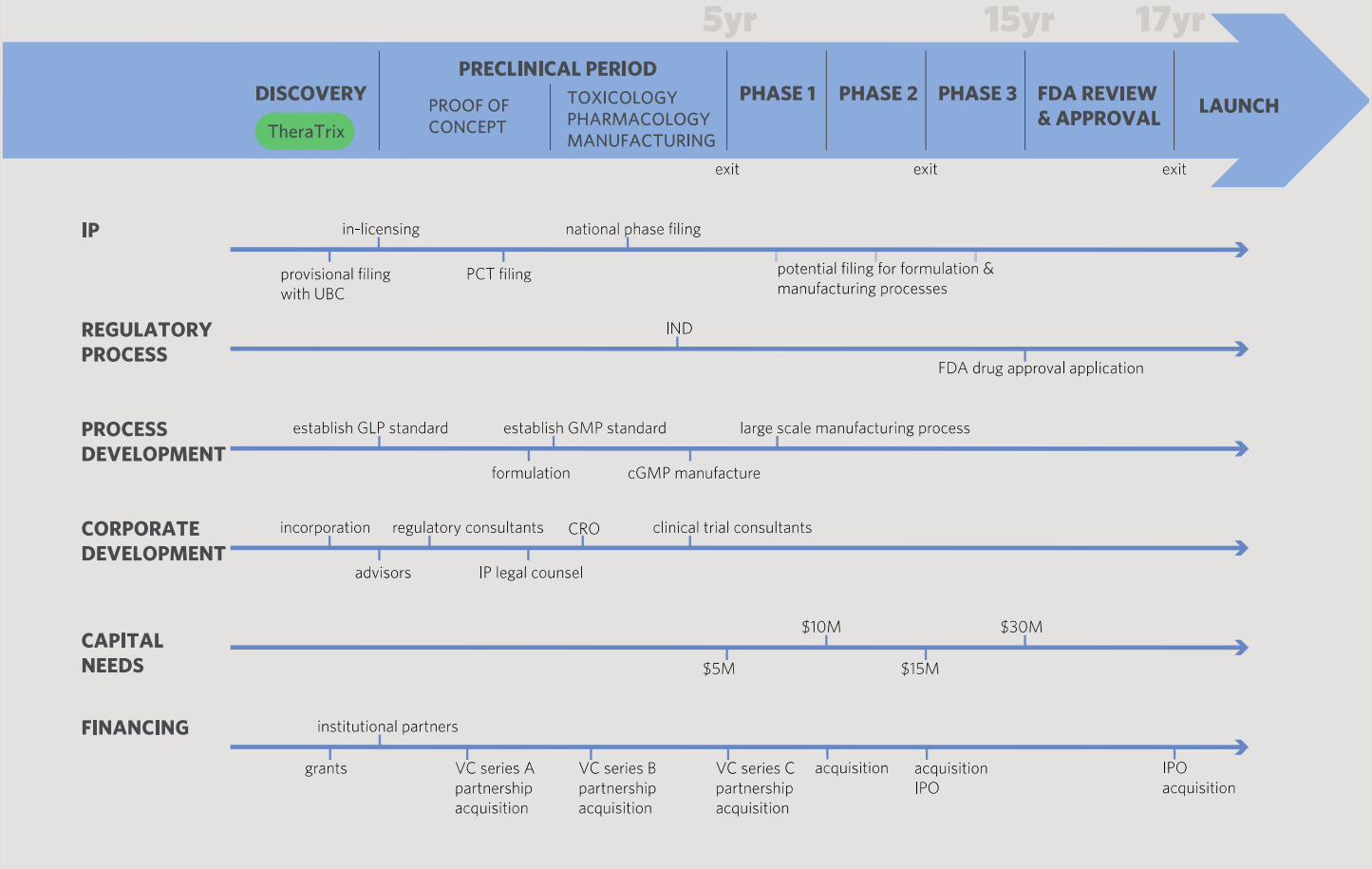
4.1. Science / Technology Overview

In brief, our product is a monoclonal antibody that blocks the main molecular pathway that activates fibrosis-generating cells. As a result, fibrosis is inhibited and no unwanted scar tissue is deposited in the heart, thus stopping heart remodeling and the development of heart failure.

4.2. Growth Strategy and Milestones

The graph below represents TheraTrix proposed growth development plan:
In summary, TheraTrix is currently in the discovery period. In order to reach FDA approval we need to achieve the following milestones:

- Incorporate TheraTrix Company and establish shareholder agreement and capital structure.
- File a provisional patent with UBC, and establish an in-licensing agreement with the aid of IP legal counsel.
- Recruit advisors and regulatory consultants to establish pre-clinical requirements according to good laboratory practices (GLP) and good manufacturing practices (GMP) standards.
- Expand the R&D department in order to provide the proof of concept data.
- Out-source to a contract research organization (CRO) in order to achieve the required toxicology and pharmacology studies.
- Submit the Investigational New Drug (IND) Application after the preclinical studies are completed.
- Recruit a clinical trial consultant in order to proceed with clinical studies.



5. Financial Plan: Financial needs, justification and funding strategy.

As shown in the diagram above, we need about $5 million to complete the preclinical period, which will be financed in the following order:

- Apply for grants, such as NSERC industry development grant, CIHR translational medicine grant, StemCell Network industrial partnership grant, and SRED program.
- Recruit institutional partners, such as UBC, which may contribute additional tangible assets
- One to three rounds of venture capital financing
- Establish partnerships with pharmaceutical corporations

We will issue convertible notes, series equity, and other instruments to achieve financing goals. To finance the required funding for each phase of the clinical trial, we aim to seek opportunities in corporate partnerships, out-licensing, acquisitions, or initial public offering.

Exit

We have highlighted three potential exit points for our early investors. Each exit points may involve different opportunities for a liquidity event, such as subsequent financing, partial or full corporate acquisitions, or IPO.

Team

The co-founders of TheraTrix are Diana Canals (B.Sc., Ph.D Candidate in Medical Genetics), Elena Groppa (B.Sc., M.Sc., Ph.D), and Regan Zhang (HBSc, PhD). We intend to recruit in our advisory board Dr. Fabio Rossi (UBC) and Dr. Carl Hansen (AbCellera Inc.,) as scientific experts in the field of tissue regeneration and antibody development, respectively.

Plans for expansion: as mentioned earlier, during the pre-clinical stage we plan to expand our R&D department and out-source to a CRO in order to meet IND requirements. Close to the beginning of the clinical phase, in order to meet the drug demand, we will expand our manufacturing capabilities likely through use of a CMO and out-source to a clinical trial management group. During these stages of development, we will also grow the financial and quality assurance department.