novapeutics

SECTOR

- Diabetes Curative
- Beta Cell Regeneration
- Orally Delivered
- Small Molecule

STATUS

- Proof of concept for first-in-class using small molecules
- Developed of several lead drug candidates
- Target has been shown to be effective in reversing diabetes using Type 1 and Type 2 diabetes murine models.

INTELLECTUAL PROPERTY

- IP from the University of Pennsylvania
- Novapeutics filed IP for the new drug lead candidates

EXTERNAL SUPPORT

- Legal: Fox Rothschild LLP
- Accounting: Stephano Slack
- Strategic: RSM US

FINANCING TO DATE

- $10 million for academic R&D prior to company formation in 2011 and continuing, such as supported by American Diabetes Association, Juvenile Diabetes Research Foundation, National Institute of Diabetes and Digestive and Kidney Diseases.
- Technology ongoing support from the Harrington innovation discovery and development project.
- $252K SBIR Phase I award to Novapeutics from the NIH in 2013 (non-dilutive).

COMPANY OVERVIEW

Novapeutics LLC is a biopharmaceutical company spun-out from the University of Pennsylvania that aims to develop a first-in-class, oral therapeutic to reverse the course of diabetes by regenerating insulin-producing beta cells.

MARKET OVERVIEW

According to the CDC, 10% of Americans currently suffer from Type 2 Diabetes (T2D), and if the current trend continues, one in three Americans that is born after 2000 will be a diabetes sufferer. The American Diabetes Association estimates that total healthcare expenditures associated with diabetes is $245 billion yearly, with greater than $34 billion spent on therapeutics in 2012. IMARC Group reported that the US market for diabetes drugs has grown at a CAGR of around 11.8% during 2011-2018, reaching a value of US$ 45.4 Billion in 2018. World Health Organization estimated that in 2014 there were 422 million people world-wide suffer from diabetes.

PROBLEM: NO DIBETES REVERSAL FOR TYPE 2 DIABETES

Conventional T2D treatments utilize mechanisms of action that all aim to maintain normal blood glucose levels by tweaking insulin or blood glucose levels. However, no treatment addresses the major underlying cause of this disease, which is a decrease in the pancreatic beta cells. Therefore, despite these therapeutic options, many patients are unable to curb beta cell depletion and disease progression, and ultimately requires exogenous insulin injection at its advance stage. These patients that are in need of beta cells regeneration to restore pancreas and boost endogenous production of insulin.

SOLUTION: AN ORAL CURE VIA BETA CELL RESTORATION

We are developing a first-in-class, small molecule (iMen, ~ 500 Dalton), orally delivered regenerative therapy to interrupt menin and Mixed-Lineage Leukemia (MLL) binding. Such interruption has been shown to restore the number of functional pancreatic beta cells and achieve effective endogenous insulin production in response to blood glucose. Our drug candidate has the potential to reverse advanced T2D, and prevent patients from needing exogenous insulin injections to maintain normal blood glucose levels.

COMPETITIVE ADVANTAGE

A fundamental issue in diabetics is inadequate beta cells to normalize the blood glucose level. As the T2D disease advances, the number of beta cells die dramatically due to constant stress. Regenerating the depleted beta cells in a diseased pancreas provides the opportunity to restore its function, and allowing patients to reestablish their own ability to normalize blood glucose level. iMen can potentially replenish beta cells in the diabetic patients. These therapies can be delivered orally rather than through an injection and do not require constant self-monitoring of glucose levels and / or using an insulin pump.

PROOF OF CONCEPT AND MILESTONES ACHIEVED

1) We have identified novel menin – MLL disruptor small molecule leads via structure-based rational drug design coupled with high throughput screening.
2) iMen class of small molecules have been used and demonstrated that it could reverse diabetes in two different murine models: Non-Obese Diabetes (NOB) Type 1 and Diet Induced Obese (DIO) Type 2 diabetic mouse models.

TEAM

- **Frank Leu, Ph.D. –** CEO & Co-Founder; 16 years in specialty bio-pharma leadership roles from R&D to executive.
- **XianXin Hua, M.D., Ph.D. –** Discoverer of the MOA, Co-Founder; Professor at University of Pennsylvania; Full member of Institute of Diabetes Obesity and Metabolism; Full member of Penn's Diabetes Research Center; World renowned menin and diabetes expert.
- **Thais Sielecki, PhD –** VP Drug Development; BMS, Merck, DuPont, and Cytokine Pharmasciences; over 25 years in drug development.
- The UPStart Program at PCI Ventures, University of Pennsylvania. Represented by the business advisor **Michael Poisel, Director of PCI Ventures** and former Principal at New Spring Ventures.

CONTACT

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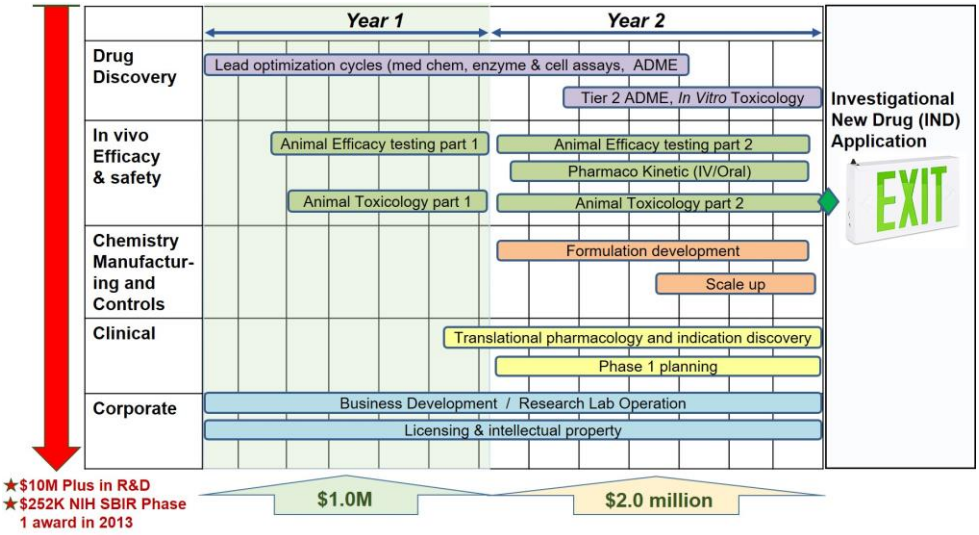
DEVELOPMENTAL TIMELINE



CURRENT RAISE UP TO $3M

We are currently raising up to $3M to achieve the following milestones:

1) Optimizing pharmacokinetics for our potential leads.
2) Continue non-GLP *in vivo* animal studies to assess the efficacy and toxicology of our drug leads.
3) Conduct IND-enabling studies with GLP work in 2 different animal models.
4) Submit IND application and getting ready for human clinical trial phase 1.

EXIT STRATEGY

As the prevalence of diabetes and the corresponding market opportunity continue to grow, there has been significant interest among pharmaceutical companies to invest, partnering or acquire and to co-develop treatments with novel mechanisms of action with the potential to cure diabetes. In 2010, a company developing a therapy that targets beta cells with a peptide therapeutic was acquired by Sanofi for $335 million at the preclinical stage. Our small molecule provides a superior approach to this, as it acts through an independent mechanism of action that is critical for beta cell regeneration and has the potential for a more convenient oral delivery than a peptide therapeutic, which is delivered via injection. Based on this demonstrated interest in beta cell regenerative therapeutics, we anticipate that an exit could occur as early as completion of IND-enabling studies, prior to the start of a Phase I clinical trial, which is scheduled to occur two years upon funding.

FUTURE OPPORTUNITIES: TYPE 1 DIABETES & LEUKEMIA

In addition to be a potential curative for the mid to advanced T2D, patients with Type 1 Diabetes (T1D). Our therapeutic approach utilizes a mechanism of action that could also address inadequate of beta cells in T1D. T1D drug cost in the U.S. is projected to exceed $4 billion dollars by 2016. Another indication is for the leukemia treatment, which had $9.44 billion dollars of global market in 2016, and estimated to be around $11.97 billion by end of 2022.

WHY INVEST IN NOVAPEUTICS

- Strong evidences demonstrating a curative approach to diabetes
- Huge opportunity to disrupt a $45.4 Billion diabetes treatment market
- Potential for exit in two years