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2017 Annual Report of Accomplishments

Most Recent News

SciTech closed a very productive 2017 with word from the FDA that the application seeking *Orphan Drug Designation* for SciTech's lead product, ST-001, was approved for the treatment of T-cell lymphoma. This means that when ST-001 is approved for commercial use SciTech will be able to avail itself of the development tax credits for drugs targeting rare diseases, as well as benefit from seven years of market exclusivity.

This accomplishment is emblematic of other major milestones achieved during the calendar year described below.

ST-001 is Clinic Ready

The major achievement of the year is the status to now claim ST-001 *clinic ready*, meaning it is poised to commence a clinical trial upon the completion of a relatively few, straight-forward, risk-free operational tasks. This status is based upon having achieved the following in 2017

- The drafting, assembly, submission and negotiation of an Investigational New Drug (IND) application and resulting agreement with the FDA leading to
  - A clear path to approval subject to the manufacture of a clinical batch
  - Removal of regulatory risk associated with seeking such approval
  - Acceptance of the clinical trial protocol
  - FDA advice on how to achieve NDA approval at the conclusion of the Phase I clinical trial (such advice and validation is rarely provided)
- The recruitment of the Principal Investigator (PI) and lead clinical trial site for conducting the initial portion of the Phase I trial
- The completion of a "qualifying" production run at the contract manufacturing site yielding
  - The realization of product standards and product stability results required by the clinical trial protocol and the FDA
  - The creation of a clear set of standard operating procedures (SOPs) and product testing methods required by the FDA
  - A plan for manufacturing the clinical batch now required by the FDA

- The completion of a regulatory compliance audit of the manufacturing site to assure readiness to proceed with the manufacture of a clinical grade batch
- The receipt of a proposal to manage clinical trials and conduct all laboratory testing and data collection from a publicly traded, well-established Contract Research Organization (CRO) whose medical employees have past experience with the clinical testing of fenretinide (ST-001 active drug ingredient.)
- The drafting of a ***Fast Track*** application that will be submitted to the FDA upon receipt of IND approval to expedite the drug review process (this is an FDA *Expedited Review Program* for which approval is anticipated, as with the *Orphan Drug Designation*)
- Agreement by the ***National Cancer Institute to provide active drug, gratis***

ST-001 Drug Product Validation Completed

The company also completed a series of additional tasks that add further validation to the potential of ST-001 in the treatment of a cross section of cancers. Here is sampling of some of those accomplishments:

- Met with numerous clinicians from Nationally acclaimed cancer centers, regulatory affairs consulting firms and CRO's to validate
    - The design of the clinical trial protocol
    - The existence of unmet needs in the target markets
    - The unique nature of ST-001 both from a practical and therapeutic perspective
    - The potential size of the initial market
    - The interest of clinicians to put the clinical testing of ST-001 ahead of other products under development or consideration
    - The anticipated short time to market approval
    - The platform technology potential of ST-001 for use
        - In a broad cross section other cancers such pancreatic, ovarian, breast and neuroblastoma
        - As a combination versus a mono therapy
        - As a drug to mop up emerging resistant cell populations following the use of other therapeutic approaches in the treatment of various cancer indications
        - As a therapeutic for the treatment of diseases other than cancer
        - As a therapeutic approach to compliment immune therapy

New Facility Established

- Joined the Sinai Hospital Bioincubator Program in Baltimore, MD
    - Opened a research laboratory
    - Availed the company of the resources provided by
        - Sinai's LifeBridge Health Program
        - Access to the Alvin and Lois Lapidus Cancer Institute
        - The Bioincubator

- Commenced collaborative research activity in support of Sinai and SciTech's mutual development activity with topical diseases

Fund Raising Activity

- Filed with the SEC to conduct a $1.0 M Convertible Note Round (CNR) capital raise
  - Created all the term sheets, agreements and documentation required to conduct such a raise
  - Raised $165,000 to fund the 2017 activity defined in this document
  - Created plans to complete the CNR capital raise upon receipt of IND approval from the FDA
    - The timing and initial amount of the CNR raise was defined by the anticipated impact on corporate valuation from achieving the major clinical, regulatory and manufacturing milestones described above
- Introduced SciTech to the fund raising community by being selected to participate in and present at the following events
  - Biotech Showcase Conference held concurrently with the JP Morgan Healthcare Conference in San Francisco
  - National Investment Banking Association (NIBA) conference in New York City
  - New York Bio conference, New York City
  - Renaissance Undemo Day, Michigan Venture Capital Association, Ann Arbor
  - Redefining Early Stage Investments (RESI) Innovation Challenge in New York City
  - University Startups Conference and Demo Day sponsored by the National Council of Entrepreneurial Tech Transfer (invited for the May 2018 event)
- Spent considerable time familiarizing management with the potential of engaging Investment Bankers to complete the majority of the capital raise
  - Retained Hanover International to provide guidance in working with investment bankers and make introductions
  - Interviewed several dozen investment banking firms
  - Considered engagement letters
  - Evaluated the concept of also raising funds from foundations, private equity firms schooled in the biotech space, angels and venture capital firms that would complement the use of investment bankers by these parties providing market knowledge
- Negotiated the receipt of a second, more specific letter of support from Janssen Pharmaceuticals (Johnson & Johnson) to further validate the commercial potential of ST-001
- Reached agreement with Ferndale Pharma Group to collaborate in the filing of an IND application for a fenretinide based topical drug product (ST-002) for the treatment of skin cancer
  - The parties had previously completed all preclinical studies.