Elysium Therapeutics, Inc.

3rd Quarter 2018 Update

Highlights

We had an extraordinarily busy summer that involved:

- O2P (Oral Overdose Protection) Program
  - Completing the initial process evaluation (i.e. "route-scouting") and initiating the scale-up of requisite raw materials for O2P leads, ETR028 and ETR029.
  - Assisting CiventiChem, our CMO (Carey, NC) for the O2P program, with the successful acquisition of a DEA manufacturing license.
  - Initiating early evaluation of the GMP manufacturing processes for ETR028 and ETR029.
- XpiRx (Forced Expiry) Program
  - Completing process and method development activities for the GMP manufacturing of ETR019, our XpiRx lead.
  - Expanding formulation development for our XpiRx program to include an elixir formulation.
- Financing and Administration
  - Receiving a $6M NIDA grant award, which, coupled with the $3M Ohio Third Frontier Grant, will allow us to advance our O2P Immediate-Release Hydrocodone product candidate through the pivotal human proof-of-concept study;
  - Establishing our Ohio presence by opening our Ohio office in Akron which enabled the execution of the Ohio Third Frontier Grant Agreement;
  - Closing the Preferred Series Seed II Financing Round, and converted the December 2017 bridge notes to the Preferred Series Seed I shares;
  - Negotiating and executing the Camargo Pharmaceutical Services agreement, which not only filled critical regulatory, study oversight and project management roles on our virtual project team, but also could provide additional financing as we achieve project milestones.
  - Completed the intensive NIH I-Corps Program which provided us the opportunity to conduct over 100 stakeholder interviews with individuals on the front lines of the opioid crisis that validated the importance of our technologies.

4th Quarter 2018 Plans

In the 4th quarter, we will focus most of our attention on regulatory and CMC activities:

- Regulatory – Preparation for Pre-IND FDA Interactions
  - O2P: Our objective is to be granted a pre-IND meeting with the Agency before the end of the year, which could be a challenge given recent feedback regarding the FDA backlog.
  - XpiRx: Our objective is to be granted a pre-IND meeting with the Agency in 1Q2019.

- CMC
  - O2P:
    - Complete synthesis of GxP material for the initiation of IND-enabling studies
    - Initiate the manufacturing of GMP material to support human studies to be conducted in 2019.
  - XpiRx:
    - Identify and engage a CRO for the GMP synthesis of ETR019
    - Complete formulation feasibility studies
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Looking forward to 2019

We plan on conducting IND-enabling studies for the O2P program in 1H2019 and expect to initiate the human proof-of-concept study in 2H2019. For the XpiRx program, we expect to initiate and complete IND-enabling studies.

Financing

We achieved our highest priority goal by raising sufficient funds to allow us to advance our O2P program through first-in-human proof-of-concept (hPOC) studies. An existing SBIR Phase 2B grant is providing funding for our XpiRx program through IND-enabling studies.