## WHY A REVOLUTION?

## The pharmaceutical industry is not sustainable in its current state

Over the last several decades, the discovery and development of therapeutics has focused on the "average" patient to create "blockbuster" drugs that could treat everyone with the "same" disease. In the past, this traditional drug development approach has been successful, although the efficiency has been very low due to high development costs, long development times, and low clinical success rates despite promising preclinical model data.

A report using 2013 data calculated that the cost of developing an approved therapeutic is about \$2.6 billion, up 145 percent from the cost in 2003. Adding to these financial challenges, patent protections for many blockbuster drugs are maturing, and revenue has decreased relative to the launch of new therapeutics. Consequently, analysts have reported that the pharmaceutical industry is not sustainable without radical changes.

In recent years, the industry has used mergers and acquisitions to concentrate the pipeline of new drugs in a smaller number of companies. They've moved from primarily in-house preclinical research to licensing of potential therapeutics from academia and small biotechnology companies. The next critical phase of gained efficiency will require innovation in developing novel therapeutics specifically developed with population diversity in mind – along with the companion diagnostics that match treatments with patients.

The University of Pittsburgh Drug Discovery Institute is leading a revolution in developing therapeutics, leveraging its strength in the evolving field of quantitative systems pharmacology (QSP). QSP determines the mechanisms of disease progression and drug reactions through iterative and integrated experimental and computational methods.

Our current QSP-driven programs are in metastatic breast cancer, neurodegenerative diseases (including traumatic brain injury), hepatocarcinoma, and non-alcoholic fatty liver disease. We are launching programs in other therapeutic areas jointly proposed by teams of clinical, computational, and experimental investigators to ensure the targeted problems and their solutions are clinically important, practical, and translatable.

## **Questions?**

For more information on these and other QSP programs currently in development at the University of Pittsburgh, please contact:

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