

Mission

Therapeutic Systems Research Laboratories (TSRL), Inc. is a privately owned oral drug delivery specialty firm focused on R&D efforts to enhance the oral absorption of investigational and marketed compounds currently not suitable for this most convenient route of drug administration. We have developed a variety of patented technologies for improving oral absorption of drug candidates, including prodrug and carrier technologies as well as time and rate controlled delivery systems. Through customized problem-solving strategies and tailored delivery solutions, TSRL is able to provide patentable oral drug delivery technologies for drug candidates with low solubility, low intestinal permeability and those which are highly metabolized.

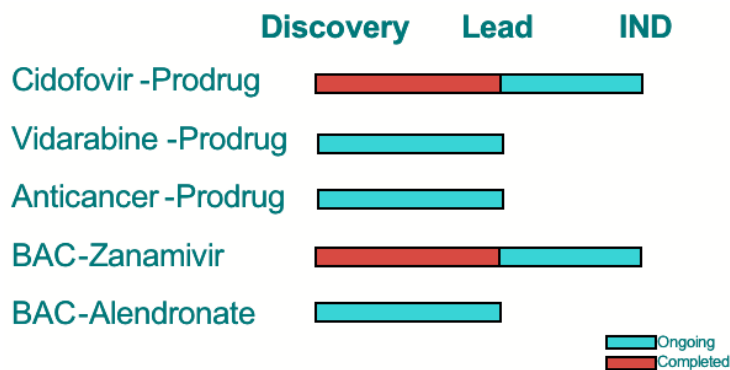
Highlights

- Management team with extensive research and drug development experience in academia, large pharma and biotech.
- Internationally recognized experts in the field of solubility, transport phenomena, prodrugs, and drug absorption.
- Co-authors of regulatory guidance documents for the Biopharmaceutics Classification System (BCS).
- Multiple patented oral drug delivery technologies provide an increased opportunity for success.
- Promising product pipeline with oral candidates for treatment of infectious diseases and cancer.
- Result-oriented, disciplined project execution



Overview

Therapeutic Systems Research Laboratories (TSRL), Inc. is a privately owned oral drug delivery specialty firm focused on R&D efforts to enhance the oral absorption of investigational and marketed compounds currently not suitable for this most convenient route of drug administration. TSRL has developed an oral drug delivery technology portfolio which addresses the three most common barriers to adequate systemic exposure of drug candidates when given orally: low aqueous solubility, poor intestinal permeability and high presystemic metabolism. Our patented technologies encompass formulation approaches that consist of GRAS materials, which may improve solubility of drug candidates up to 5000-fold, and significantly increase in vivo drug product dissolution rate. Furthermore, we have developed prodrug and carrier technologies that address poor intestinal permeability of drugs by formulating those candidates in such a fashion that enables utilization of intestinal transporters to increase absorption. Exploratory preclinical studies have demonstrated increases in absorption of low permeability compounds up to 20-fold. The third product concept of TSRL's technology portfolio is a rate and time controlled release drug delivery formulation. This technology allows for delivery of drug candidates to either specific intestinal sites or releases drug at predetermined time points in a pulsatile or controlled release fashion. Both our solubility and permeability enhancing formulations can be combined with this modified release formulation.



Our technologies have reached a level of developmental maturity such that we are seeking to partner with interested pharmaceutical or chemical organizations to jointly work on the scale-up and manufacturing processes for a specific therapeutic candidate.

Management Team

Gordon L. Amidon, PhD
President and Chief Scientific Officer

John M. Hilfinger, PhD
Executive Vice President

Elke Lipka, PhD, MBA
VP Business Development

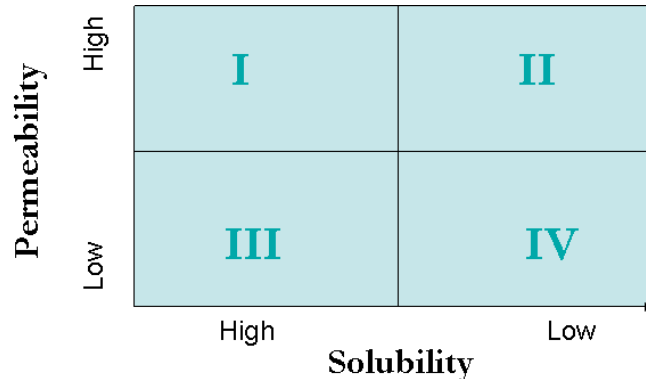
Funding History

19 Phase I SBIR grants, six of which were funded through the Phase 2 level, one R21 grant, one Cooperative (U01) Grant and a Michigan 21st Century Job Fund grant.

Contact Info

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In addition, TSRL provides consulting and problem solving services to clients who seek to identify the mechanism of the poor oral bioavailability of a drug candidate. Within this scope, TSRL has carved out a niche service by classifying client drugs according to the Biopharmaceutics Classification System (BCS), which is an international drug regulation that allows for waiving of clinical bioequivalence trials for drugs in certain BCS classes after drug product manufacturing changes. This may translate into substantial development cost savings for clients.



TSRL has been a valued partner to pharmaceutical companies for over 20 years. Our founder and president, Gordon L. Amidon, is internationally recognized as a world leader in oral drug delivery research. In fact, the BCS classification system was conceived as a consequence of Gordon's sabbatical research at the FDA. Researchers at TSRL are experts of biopharmaceutical strategies for oral drug delivery with over 100 years of combined experience. Our 5,300 sq.ft. integrated research facility combines *in vitro* drug product research, tissue culture research, *in vivo* preclinical ADME/BCS testing and state-of-the-art analytical capabilities to provide our partners with highest quality data and expert consulting on oral drug delivery issues. It is our mission to be a virtual extension of your drug discovery or development team to aid you in the development of scientifically sound and commercially viable oral drug delivery strategies.