

## Speed Advancing Lead Drug Candidate

### SUMMARY

Integrated preclinical IND-enabling program developed on tight timelines.

### APPROACH

A biotechnology company was referred to Ricerca to fill the need for an integrated drug development program to advance a lead candidate.

Ricerca replied on the same day, executed a CDA, and within two weeks delivered a comprehensive chemical synthesis and development proposal. The client visited Ricerca's site and met with the biology team and Ricerca developed an IND-enabling study proposal.

The program is moving ahead rapidly and from a single site Ricerca has now provided:

- process chemistry development of five-step route
- preclinical supply of API
- cGMP API scale-up for Phase I trials
- analytical methods development
- multiple toxicity studies (mouse IP/rats/swine)
- bioanalytical method development and testing

The client has elected to focus on its core development activities and entrusted Ricerca to deliver on chemistry and biology studies. Through Project Management and expert consultations, a strong relationship has been built between the client and Ricerca.

### RESULTS

Process chemistry development, GLP toxicology, analytical support for CMC, and bioanalytical completed in eight months.

For detailed comments from the client, please contact Ricerca's Business Development Team at 440-357-3300.