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## Letter from Editor



**Dear friends and colleagues,**

After a busy and eventful year, we are at the stage to say 'goodbye' to year 2009.

This has surely been a memorable year. In the U.S., we witnessed the first African-American president into the White House in January. In Washington, healthcare reform has become its major agenda, and significant progress has been made throughout the year. In the recent Copenhagen UN Climate Summit, hundreds of world leaders met and set up goals and policies to combat the global warming. At the same time, we experienced the worst economic recession since 1930s' Great Depres-

sion, were threatened by the H1N1 flu epidemics, and worried about other global issues such as war in Iraq and Afghanistan and climate change.

In China, despite reduction of the export and other negative influences due to the global economic downturn, the annual GDP growth is expected to reach near 8%. The central government announced an over \$580 billion economic stimulus package in 2008 and, of which, 850 billion RMB was dedicated to healthcare reform in the three-year period from 2008 to 2011. At the same time, both Chinese central and regional governments are strongly promoting life science R&D as well as biopharmaceutical industry in China.

Healthcare reform demands safe, efficacious, and more affordable therapeutic products. While there are numerous approaches in achieving this, the current issue of TBI intends to focus on one of the most controversial topics: development of biosimilars, the class of patent expired protein and antibody-based biological drugs.

Due to the nature of biological drug development and the lack of clear regulation and legislation in the U.S., China, and many other countries in the world, unlike generic small molecule drugs, biosimilars face the challenges of long, expensive, and complicated manufacture and regulatory process, market recognition, and competition from innovated drugs and other generic products. Therefore, how feasible it is to develop biosimilars, what is the real cost saving, and what will be the true benefit to patients and to the entire industry are in the center of the heated debate. In this issue of TBI, we are very fortunate to gather four articles in this area to help the readers to understand the underline issues. The first article, written by Drs. William and Shen from Merck & Co., Inc., will give us a general introduction of the biosimilars. The subsequent three articles then focus on specific areas including manufacturing (by Dr. Chen of Sangamo, Inc.), intellectual property (by Huang, Liu, Fishman, and Dr. Howard of Orrick, Herrington & Sutcliffe, LLP), and venture investment perspectives (by Jonathan Wang of Burrill & Company). From these articles, we hope you will get a more complete view about the challenges and opportunities that lie in biosimilars development in the U.S., China, or the rest of the world.

As a life science professional, I think we are very fortunate to live in such an exciting historical moment. It would be helpful to reflect our experience and thoughts from time to time on how our day-to-day work and life is influenced by and contributing to the global changes.

With that, I wish all of you a happier, healthier, and more prosperous 2010.

Yingfei Wei  
Editor