Over the last three decades therapeutic peptides have emerged as a therapeutically and commercially important class of drugs, with growth driven in part by advances in synthetic, delivery, and formulation technologies. Forty-eight therapeutic peptides are now on the market worldwide, with four reaching global sales of more than $500 million each in 2007. The pharmaceutical industry has steadily increased its investment in the development of these products through internal development programs as well as by acquisition, in-licensing, and joint development programs. New therapeutic peptide product development is expected to continue at a strong pace.

To better understand clinical development and approval trends for these products, Tufts CSDD assessed data on 318 therapeutic products that entered clinical development sponsored by commercial firms worldwide. Key findings are presented in this Tufts CSDD Impact Report and will serve as a baseline against which future growth will be measured.

Of 318 therapeutic peptides included in the analysis, 42% are currently in clinical development, with the remainder either in regulatory review, approved in at least one country, or terminated.

68% of products that entered clinical study during 2000-07 are in Phase I or Phase II studies.

The average annual number of therapeutic peptides entering clinical study in the 2000-07 period nearly doubled, to 16.9 from 9.7 during the 1990s.

During 2000-07, new peptides entering clinical development were most frequently studied as treatments for metabolic (26%) indications, one of 15 therapeutic areas in which peptides were being developed.

Average total clinical study and FDA approval time for new therapeutic peptides was 10.8 years.

Efficacy issues and commercial considerations were most often cited as reasons for discontinuing clinical studies of new therapeutic peptides.

Approval success rates have remained steady – in the 21%-24% range

Therapeutic peptides in clinical study in 2000-07 nearly doubled 1990s rate