DR REDDY'S LABORATORIES

Trials by Fire

▶CHAIRMAN: **K. Anji Reddy**

NCES IN THE PIPELINE: Five

THERAPEUTIC AREAS OF FOCUS: Metabolic disorders, cardiovascular indications and cancer

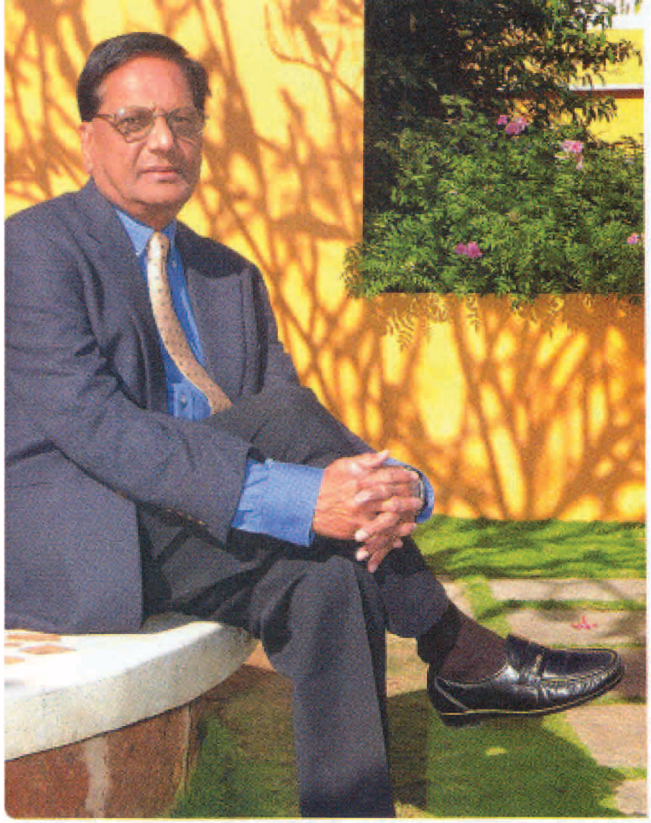
PROGRESS MADE: One in Phase III, two in Phase II, one has completed Phase I and one is in Phase I

INVESTMENTS SO FAR IN NCE RESEARCH: N.A. Currently, investment is Rs 80-100 crore annually

ANNUAL INVESTMENT IN R&D: 7-8 per cent of revenue

LIKELY TARGET DATE FOR NEW DRUG LAUNCH: 2011- 2012

CEO (G.V. PRASAD) -SPEAK: "In five years, we need to get a drug to market"



A. PRABHAKAR RAO

WHEN THE DRUG MOLECULE CARRYING his name let him down, Kallam Anji Reddy, the scientist Founder-Chairman of Dr Reddy's Laboratories, hinged all his hopes on the Lord. The next compound, Balaglitazone (Bala there referring to the Lord), has apparently retained his faith and kept his hopes alive. Unlike the earlier Ragaglitazar (Raga stood for Reddy), where further developments had to be suspended following some unacceptable side-effects. On August 1, 2007, Rheoscience A/S and Dr Reddy's announced that the first patient has been dosed in a Phase III study with Balaglitazone (DRF2593-307), which is an insulin sensitiser that acts as a partial PPAR (peroxisome proliferator-activated receptor) gamma agonist. "It is difficult to predict here, but the earliest we hope to hit the market with a drug is 2011-2012," says G.V.Prasad, VC and CEO.

What is perhaps important is that he says this despite possible additional tests/ experiments the company may have to carry out in the light of developments in the case of GlaxoSmithKline's Avandia, where the US Food & Drug Administration (USFDA) issued a safety alert last year on the blockbuster diabetes pill which, in 2006, posted worldwide sales of £1.6 billion ($3.2 billion). This came in the wake of reports that the drug may raise the risk of heart attack (the data on this remains inconclusive) and the company has revised its labelling in the US.

Balaglitazone also comes in the class of glitazones and there are only two major drugs in this class for diabetes. Other than Avandia, there is Japan's Takeda Pharmaceutical's Actos. Both have a combined market worth around $7 billion annually. "We have a 60 to 70 per cent chance of making it to the market by 2011," is what Anji Reddy told a few journalists on the sidelines of a meet in Hyderabad recently. The company is not willing to discuss the nature of additional experiments to be performed or the additional costs and time involved. All that Prasad says is: "Increasingly, drug regulators worldwide are becoming more conscious of safety concerns. This is making it tougher for companies to come out with compounds that are highly safe (as the data indicates) and efficacious at the same time."

In Dr Reddy's pipeline are five molecules in various phases of development. Three of these (one of which has completed Phase I, one is in Phase I, and another has completed Phase IIA) are in co-development with Perlecan, promoted jointly by Dr Reddy's and private equity investors ICICI Venture Funds and Citigroup Venture Capital. The industry is rife with speculation that the investors in Perlecan want to pull out. Neither is the company willing to talk about this nor are the officials at ICICI Venture available for comment. "I have nothing to report on Perlecan and we will not comment on anything that is speculative in nature," is all that Prasad is willing to say at the moment. Whatever the situation, it would be foolish to write off the pioneer of drug discovery in India.

E. KUMAR SHARMA