

## Letter to our Shareholders



We had two major management changes this year. Ken Goodman retired as President and Chief Operating Officer. He joined Forest 25 years ago, as Chief Financial Officer and on November 30, 1998 he became President and Chief Operating Officer. He has been a great and inspiring leader and a close friend to many at Forest and particularly to me. He is unquestionably a principle reason for Forest's success. Happily, he has agreed to continue to serve as a Director of Forest.

We were fortunate that Lawrence S. Olanoff, M.D., Ph.D., who just the year before had left Forest where he had been Executive Vice President of Scientific Affairs for ten years, agreed to return to Forest as President and Chief Operating Officer. During his ten years in his previous position he demonstrated the intelligence, the management skills and the invariably sound judgment and leadership that enabled him to build our excellent scientific capacity. We are already benefiting from those skills in his new position.

Also this year we acquired a new board member, Dr. Nesli Basgoz, who is Associate Chief for Clinical Affairs at Massachusetts General Hospital in its Division of Infectious Disease, and also Associate Professor of Medicine at Harvard Medical School. She is already a valuable Board member whose knowledge was so very helpful in the Cerexa acquisition.

“... all of us have differences in our biological chemistry; if we didn't we would all look alike, love alike, and die at the same time. And so it is perfectly natural that we react differently to various medications.”

Given our relatively stable business model, it is interesting that recently several big pharma companies have been describing to investors what purport to be novel management technologies for obtaining new products - technologies that sometimes sound more different than they really are. We do not claim new technologies to increase our product opportunities. How Forest acquires products is easy enough to state, but like everything else it all depends on execution, just as research itself depends on creativity, persistence, infinite attention to details and patience.

Forest continues to obtain products the way we have in the past, but more broadly and on a significantly expanded scale. We still principally enter into partnerships with companies that have products that interest us, as well as expanding our relationships and explore further product opportunities with our existing partners. But we are now more skilled, truly more desirable as a partner in many cases as compared to Big Pharma. We have a much larger group engaged in product development activity, and we have many more opportunities each year to evaluate. We seldom fail to achieve the transaction that we really want.

This year we also broadened our methodology for product acquisition in two respects. First, in lieu of acquiring a license, we acquired an entire company – Cerexa, Inc. – which means that we acquired two additional products and a distinguished group of executives and employees in an area – infectious disease in hospitalized patients - that is entirely new for us. And second, we entered into several relationships which take us to the very beginning of the development of new drugs. These are partnerships with companies that have drug discovery capability with whom we have contracted for the development of compounds for targets which we have identified and which we believe are involved in serious illnesses. Of course, these programs are the most risky and the most long term, but we believe we should have a modest participation in cutting edge areas in which our scientists believe there are medical needs and our marketers believe there are business opportunities.

Every year I point out that our modest size is often a significant advantage, in the rapidity and quality of decision making and in our appeal and accessibility to our existing partners and to potential partners. Of course it can be a disadvantage to be too small, even with brilliant science, like so many of the startup biotech companies. I wrote in our annual Report in 2000 that “We think in fact that smaller is often better as long as smaller is big enough”. We are almost unique in our industry in meeting that standard and it is a fact that some of our most desirable partnerships have happened or been facilitated by our size.

## Letter to our Shareholders

Our three current major promoted products, Lexapro, Namenda and Benicar, are all growing quarter by quarter, and year by year, and we believe will continue to do so. The most important patent expiry we face is Lexapro in 2012. As of this writing, there are several products sufficiently advanced in development that we expect will be approved before or around 2012, which together could ultimately produce several billions of dollars in sales. And we work assiduously to augment that prospect with additional products already in our portfolio, some in later and some in earlier stages of development. And we expect to develop or obtain additional products, and maybe even companies, in the years ahead.

Nebivolol, for hypertension, received an approvable letter from the FDA to which we recently responded. We anticipate Nebivolol to be approved this year. Ceftaroline, one of the hospital intravenous antibiotics we obtained in our acquisition of Cerexa, is in Phase III.

Aclidinium bromide, an inhaled muscarinic antagonist for the treatment of chronic obstructive pulmonary disease, which we licensed from Almirall, in Spain, is also in Phase III, and several combination products with aclidinium are in earlier development. We expect Almirall, the largest Spanish pharmaceutical company, with an impressive history and current pipeline, to become an important partner for us.

The second Phase III trial for milnacipran, our product for fibromyalgia which we licensed from Cypress Bioscience, Inc., was completed in May. The results showed significant differences from placebo for fibromyalgia syndrome, a very significant achievement. We expect to file the NDA before the end of this calendar year and believe the product could be a significant addition to our product line. Together with nebivolol we will have two new exciting products for our salesforce in the near future.

On the other hand, the Phase II study of desmoteplase, for stroke, which we licensed from Paion, was not successful. The conception of the drug was quite brilliant and it could have been very valuable for severe stroke patients, but the drug failed to separate from placebo in the Phase II study even though there were encouraging signals in earlier smaller studies.

In our industry, we never know for sure whether a drug is truly effective until there is testing in a sufficient number of patients, and it is not uncommon that earlier encouraging signals disappear in a larger well controlled study.

We have two products which have successfully completed Phase III, nebivolol with an approvable letter to which we have responded to the FDA, and milnacipran, for which we expect to submit an NDA later this year. And two significant products currently in Phase III, acclidinium for chronic obstructive pulmonary disorder (e.g. emphysema and chronic bronchitis) and ceftaroline, a novel antibiotic for a range of serious infections requiring hospitalization.

And we have a number of earlier stage products, including RGH 188, a novel atypical antipsychotic, from Gedeon Richter, that is in Phase II trials which we expect to be completed this year. And there is an additional antibiotic which was owned by Cerexa prior to our acquisition which will shortly enter Phase I. These are added to a number of other products already in our portfolio which are in earlier stages.

Various federal and state government agencies and certain members of Congress, and the media continue their complaints about the pharmaceutical industry. The current gravamen is the danger of some drugs, even widely used drugs, with the implication that these dangers were deliberately not disclosed or minimized as a result of the greed of the drug's innovators or incompetence at the FDA. This has led to a timorous approach by the FDA to drug approval, which may in fact adversely affect the community's health. The proper balance, always difficult to attain, may have become unbalanced, and not in the patient's favor by exaggerated emphasis on side effects for the few and minimized understating of the benefits for the many.

Of course it is well established that for some patients some drugs will have medically important but relatively rarely occurring adverse effects and that sometimes those effects will not become apparent until after the drugs have been available for some time. The reason for those events and the fundamental insight that these critics disregard is that all of us have differences in our biological chemistry; if we didn't we would all look alike, love alike, and die at the same time. And so it is perfectly natural that we react differently to various medications. And for drugs that are specifically intended to interfere with our chemistry with greater potency, there are bound to be some people who are going to be affected adversely. If even peanuts can be fatal to some people, how can we expect all drugs to be safe for everybody?

**"... the passion to reduce healthcare costs can ultimately only result in reduced quality of healthcare, as in certain European markets."**

## Letter to our Shareholders

Of course pharmaceutical companies and the FDA have to make every effort to determine and evaluate the safety of drugs before they are approved and, in fact, on the whole they do a very good job of doing just that. But sometimes, perhaps due to human error or insufficient experience, a safety risk is not adequately identified. It is almost invariably not the system or the motives or the competence of the innovators or the FDA that are flawed, but the fact that defects will occur which even the most careful testing cannot or does not uncover. All of us who regularly deal with the FDA know how painstakingly the agency attempts to assure the safety of drugs.

And while there are complaints about pharmaceutical profits, there seems to be the same pricing complaints about the non-profit hospitals. Unfortunately, there is a pervasive failure to appreciate the enormous cost of health care, no matter who the provider is. And so the passion to reduce healthcare costs can ultimately only result in reduced quality of healthcare, as in certain European markets.

“... the pharmaceutical industry has transformed the quality and duration of our lives.”

At the same time, there is a parallel propensity to take for granted the astonishing benefits that available healthcare can provide. Pharmaceutical products are a significant portion of our healthcare. Some pharmaceutical products are the difference between life and death. Some vastly improve the quality of life. Overall, the pharmaceutical industry has transformed the quality and duration of our lives. The convenience of getting somewhere faster, or increasing the availability of entertainment, or facilitating virtually instant communication are all trivial benefits compared to what the pharmaceutical industry, through the talent of brilliant researchers and the vast expenditure of resources has achieved. All that is disregarded in the complaints about the industry's profits, as if the profit motive itself were the cause of the problem. But profits are the ubiquitous engine for all parts of our economy and ultimately our prosperity. The irony is that most of the criticism the industry receives from the media and from some political leaders are ultimately derived from the very same human flaws and ambitions that they themselves or their own institutions are subject to. When the criticisms are fair we can all benefit from their being identified; when unjust or out of proportion, they can be destructive, and sometimes very destructive.

# Forest Laboratories, Inc.

And so we take great pride in what we do at Forest. We receive the most moving letters from victims of depression or Alzheimer's or from their family members expressing their wonder and gratitude for the help our products have given them.

Our employees above all are entitled to that pride, because they make it possible for Forest to achieve what we have. I wish I could tell them every time they license a product, or complete a pre-clinical or clinical study, or successfully negotiate a favorable outcome with the FDA, or successfully and personally communicate the patient benefits to the physicians they call on, how much what they have done contributes to the ultimate result, to the patient benefits that all together we have made possible. We too often let those moments pass without recognition. But I want to take at least this occasion to tell them all how very much each of them contributes to the Company's achievements and even more important, how much they help the millions of people who use and benefit from our products.



**Howard Solomon**

Chairman & Chief Executive Officer

**Lawrence S. Olanoff, M.D., Ph.D.**

President and Chief Operating Officer