

FOREST LABORATORIES INC
Form DEFA14A
July 12, 2011

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
SCHEDULE 14A
Proxy Statement Pursuant to Section 14(a) of the Securities
Exchange Act of 1934
(Amendment No.)**

- Filed by the Registrant
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 Preliminary Proxy Statement
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Forest Laboratories, Inc.

(Name of Registrant as Specified In Its Charter)

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Letter to our Shareholders

This year may be the most remarkable year in Forest's history, or maybe in the history of any pharmaceutical company, because we will have launched three products within a six month period: Teflaro, which was launched in March of this year, and Daliresp and Viibryd, which will be launched in August, this year. And within the last three years we will have launched a total of five products - Bystolic, Savella, and then Teflaro, Daliresp and Viibryd plus Namenda XR which has been approved, but not yet launched. And, in addition, we are filing NDAs with the FDA this year for aclidinium and linaclotide, which brings the total of new products we will be marketing by next year, assuming approval of this year's submissions, to eight products, including Namenda XR.

Each product has its own virtues that distinguishes it from other products that treat the same indications. We are as different on the inside as we are on the outside - our internal organs and systems, our body's chemistry is as varied, from one person to another, as much as our physical appearance is different. Because of those differences, patients can respond differently to the same medication. What cures one can be harmful to another. And so when we evaluate a new product opportunity, we have to determine, as best we can, based on the data available, what distinguishes the product even if it treats a condition for which there are other, sometimes many other, products available. And then we have to determine how many patients are likely to benefit from the product's distinguishing features.

And so Bystolic is an effective cardio-selective vasodilating beta-blocker that effectively reduces blood pressure with a low incidence of side effects such as fatigue. Sales were \$264 million in fiscal 2011. After three years on the market Bystolic is still growing at the rate of over thirty percent. Savella, for fibromyalgia, had sales of \$90 million in fiscal 2011 and is also growing at the rate of thirty percent.

Teflaro, a novel IV cephalosporin antibiotic for hospital use with a broad spectrum of activity against Gram-positive pathogens, including MRSA, and common Gram-negative pathogens, has had a very successful launch. Over 1,000 hospitals have already tried Teflaro. We expect it to be a widely used successful hospital antibiotic.

Daliresp is the first oral PDE4 enzyme inhibitor that has been shown to reduce the risk of exacerbations in patients with severe

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chronic obstructive pulmonary disease (COPD), which are debilitating events that can lead to hospitalizations and other serious complications.

Viibryd is the only SSRI and 5-HT_{1A} receptor partial agonist for the treatment of depression in adults which is associated with low incidence of spontaneously reported sexual dysfunction and weight gain, two common side effects associated with antidepressant therapy. The clinical effect of the partial agonism of the 5-HT_{1A} receptor has not been specifically determined.

Acidinium is a long-acting muscarinic antagonist for the treatment of COPD, and linaclotide is for the treatment of the multiple symptoms associated with constipation predominant irritable bowel syndrome and chronic constipation. Obviously, all this didn't just suddenly happen. Except for Viibryd, which we purchased in April this year, these launches represent years of searching and selecting and developing and preparing FDA submissions and presenting at Advisory Committee meetings and obtaining regulatory approval for marketing and for labeling and promotional materials. Having completed all the clinical and preclinical work necessary to file an NDA and to obtain approval after the FDA's review, which is always a lengthy and detailed process often involving various FDA groups with differing expertise, is an extraordinary accomplishment. To achieve it with seven products, including acidinium and linaclotide in four years would be a still more impressive achievement.

Launching of course is only the beginning. Then we have to effectively market each product. To handle all these launches we have to increase the size of our sales forces, an unusual necessity in today's pharmaceutical environment in which most companies are reducing their sales forces. It is true that it is increasingly difficult to achieve access to prescribers, but we believe it is still the most effective way of communicating our products' virtues.

It will take time—a few years certainly—for the sales of our numerous new products to increase in volume and the ones that are yet to be filed with the FDA, or are in development, in negotiation, or which we will obtain in the future, altogether to surpass the sales of Lexapro which loses its patent protection in 2012, and Namenda which loses its patent protection in 2015. It is always a little difficult to predict the sales levels that each particular product will ultimately obtain. Certainly Lexapro, and Namenda to a lesser degree, surpassed our expectations. Lexapro entered an already crowded field as the seventh antidepressant, but its virtues and our effectiveness in marketing those virtues led to its great success. Lexapro together with its predecessor Celexa (Lexapro is an enantiomer of Celexa), are the most prescribed antidepressants in the United States, accounting for approximately one third of antidepressant use, which attests to the clinical virtues of the products. Celexa was turned down by three major pharmaceutical companies in the United States before Forest was able to persuade its Danish innovator, who was reluctant to waste time with yet another American company, particularly one he had never heard of, to license it to Forest. The products have benefited millions of American patients. We continue to receive accolades from patients who are using Lexapro, which is one of the greatest emoluments we can achieve as a pharmaceutical company.

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We expected Namenda (licensed to us by a privately held German company) to be successful, but we did not anticipate the level of sales it has already achieved. We have also received family testimonies to its benefits. We think all the products in our portfolio of new products will be successful and some may achieve outstanding results. It has been clear to us for years that the more successful Celexa and Lexapro and Namenda became, the larger the problem when their patent protection expired. We have done our best to protect our patents, and in the case of Lexapro, we defended the patent through trial and appeal, even though the faint-hearted thought we should settle. And in the case of Namenda, we defended it successfully in court and made a very modest settlement with thirteen generic companies which had challenged our patent. All patented pharmaceutical products will be challenged by generic companies and therefore as part of our initial evaluation of a product opportunity we have to evaluate the quality of the available patents.

But all good things come to an end and so we anticipated and planned for patent expirations for years. Patent expirations are part of our business, perhaps more so than in many other businesses which do not have a plethora of generic companies ready to pounce the day of patent expiry.

Daliresp and Viibryd will be launched in August at the same national meeting of all of our sales forces. Teflaro was introduced earlier this year at a meeting of our newly organized specialty sales force to market our first exclusively hospital product. Of course, introducing so many new products in so short a time means heavy promotional expense that in the early years will exceed actual product margins until sales reach and then exceed a level that surpasses their expenses.

We still believe our basic corporate strategy is sound and will enable us to grow beyond our present sales levels over the next several years, despite patent expirations. We still do not do discovery research and we are reluctant to take on products at the preclinical stage of development, although we have scientists working at Forest who crave the intellectual challenge of early stage research, which can be so thrilling when it works, on the few occasions when it does. And so we do sometimes wade carefully into those dangerous waters.

Products are the essential ingredient in the pharmaceutical industry, and there are various ways to obtain them. We have established over the years the reputation, the technology and the skilled business development group that is able to be thoroughly informed, identify opportunities and precipitate the essential scientific and marketing evaluations that are indispensable to the success of a licensing strategy. It still works exceedingly well. Of course there is competition for the opportunities that we want, but we have the appeal and the skill and the persistence and the enthusiasm that enables us to obtain most of the opportunities we truly covet. And our more modest size and our partnership culture have often facilitated our product acquisitions.

I thought it might be of interest to include in this letter the results of an analysis recently published by Forbes, of the annualized appreciation in stock value by companies whose Chief Executive Officers were still serving as CEO after twenty years in that position. The results are summarized in the following tabulation:

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Note that Forest was only one percentage point lower than the legendary Berkshire Hathaway. These results are clearly the achievement of all of our employees, so many of whom have been with us during the entire twenty year period or a substantial part of it.

As you may have read, I have received a notice from the Department of Health and Human Services, Office of Inspector General (OIG) that it is considering excluding me from participation in matters involving any payments by the U.S. Government for our products. I believe that this use of the exclusion remedy is unprecedented in that at no time have I been charged with or accused of any wrongdoing in the matters that were the subject of an extensive investigation by the U.S. Government which resulted in a negotiated resolution by a subsidiary of our Company. As I have previously stated, I will challenge the OIG's intention to exclude me through vigorous administrative and legal action.

I do want to make it very clear that the consideration of exclusion is irrelevant to what has always been Forest's and my deep personal conviction that we must all be law abiding in all that we do. That is how I have lived my life. It is how Forest has been administered and it is a message I have often communicated to our employees and shareholders. As a company we and I as CEO, have always maintained compliance policies and systems that are aligned with industry and legal standards. Further, whenever we became aware of lapses, we instituted changes to preclude such events in the future.

We have been committed to compliance with the law and had procedures in place even before the government required procedures to assure compliance. We absolutely believe that drugs should not be marketed without FDA approval or for uses not specifically approved by the FDA, and

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that physicians should not be enticed or rewarded for prescribing our products. They should only prescribe what is best for their patients, and I do believe that in general this is exactly what physicians do. Neither Forest nor I have just joined the choir; we were there at the creation, and we want everyone in the choir to carry the tune as flawlessly as humanly possible.

I have described all the exciting product events that have crowded together in the last few years. I assure you that is not the end of our product opportunities, only the most fully developed and the most recent ones. I do not expect that we will launch three products every year, but I do expect our product acquisition and approval programs to continue to produce new opportunities.

Our recent spurge of product acquisitions and regulatory approvals will not at all diminish our efforts in the future, but on the contrary will only encourage greater efforts. And that is because our operational groups Business Development, Scientific, Marketing and Sales are thirsty to undertake more and more challenges.

There are enormously hard working people at Forest at every step in the process. I say it every year, and it continues to be true, that we owe so much to the employees of Forest who make all of our achievements possible, from the very beginning and until they are fully realized. Their ardor and skill and loyalty are our priceless treasure and it is our responsibility to inspire, encourage, preserve and reward it. And protect it, because it is ultimately fragile. It is unique, and it should not be mishandled. A company's work ethic is not like a factory that can be replaced or moved. It is a culture among a group of people and ultimately it determines our performance as a company and our future. I cannot adequately express how grateful we must be to all of our employees.

Howard Solomon

Chairman, Chief Executive Officer & President

P.S. As you may know, we received a notice from Carl Icahn that while reporting beneficial ownership of 6.5% of our stock, he is seeking the election of four members to our Board of nine. The recommendation of our Board with respect to this matter will be contained in the proxy materials for our 2011 Annual Meeting of Stockholders. Be assured that our Board will act consistently with its fiduciary duties in the best interest of all of our stockholders to ensure the maximization of value, including the effective launch and growth of our new products.

Forward Looking Information

Except for the historical information contained herein, this document contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements involve a number of risks and uncertainties, including the difficulty of predicting FDA approvals, the acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, the timely development and launch of new products, changes in laws and regulations affecting the healthcare industry and the risk factors listed from time to time in Forest Laboratories Annual Reports on Form 10-K (including the Annual Report on form 10-K for the fiscal year ended March 31, 2011), Quarterly Reports on Form 10-Q, and any subsequent SEC filings.

Important Additional Information

Forest Laboratories, its directors and certain of its executive officers may be deemed to be participants in the solicitation of proxies from Forest shareholders in connection with the matters to be considered at Forest Laboratories 2011 Annual Meeting. On June 21, 2011, Forest Laboratories filed a preliminary proxy statement (as amended by Amendment No. 1 to such proxy statement filed on July 8, 2011, the Proxy Statement) with the U.S. Securities and Exchange Commission (the SEC) in connection with such solicitation of proxies from Forest shareholders. **FOREST SHAREHOLDERS ARE STRONGLY ENCOURAGED TO READ THE PROXY STATEMENT AND ACCOMPANYING PROXY CARD AS THEY BECOME AVAILABLE AS THEY CONTAIN IMPORTANT INFORMATION.** Detailed information regarding the identity of potential participants, and their direct or indirect interests, by security holdings or otherwise, is set forth in the Proxy Statement, including in Appendix B thereto. Shareholders will be able to obtain the Proxy Statement, any amendments or supplements to the Proxy Statement and other documents filed by Forest Laboratories with the SEC for no charge at the SEC's website at www.sec.gov. Copies will also be available at no charge at Forest Laboratories' website at www.frx.com or by writing to Forest Laboratories at 909 Third Avenue, New York, New York 10022.