FOREST LABORATORIES INC
Form 10-K
May 29, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

_____

FORM 10-K

(Mark one)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended March 31, 2009

oTRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File No. 1-5438

FOREST LABORATORIES, INC.
(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	11-1798614 (I.R.S. Employer Identification Number)
909 Third Avenue New York, New York (Address of principal executive offices)	10022-4731 (Zip code)

(212) 421-7850
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, $.10 par value	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the act:

None

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Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes X No .

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No X .

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes X No .

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in the Proxy Statement incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ..

Indicate by a check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer”, “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer x	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No X .

The aggregate market value of the voting stock held by non-affiliates of the registrant as of September 30, 2008 was $8,460,949,990.

Number of shares outstanding of the registrant's Common Stock as of May 28, 2009: 301,616,739.

The following documents are incorporated by reference herein:

Portions of the definitive proxy statement to be filed pursuant to Regulation 14A promulgated under the Securities Exchange Act of 1934 in connection with the 2009 Annual Meeting of Stockholders of registrant have been incorporated by reference into Part III of this Form 10-K.

Portions of the registrant's Annual Report to Stockholders for the fiscal year ended March 31, 2009 have been incorporated by reference into Parts II and IV of this Form 10-K.

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PART I

ITEM 1. BUSINESS

General

Forest Laboratories, Inc. and its subsidiaries develop, manufacture and sell both branded and generic forms of ethical drug products which require a physician's prescription. Our most important United States products consist of branded ethical drug specialties marketed directly, or "detailed," to physicians by our Forest Pharmaceuticals, Forest Therapeutics, Forest Healthcare, Forest Ethicare and Forest Specialty Sales salesforces. We emphasize detailing to physicians of those branded ethical drugs which we believe have the most potential for growth and benefit to patients, and the development and introduction of new products, including products developed in collaboration with licensing partners.

Our products include those developed by us and those acquired from other pharmaceutical companies and integrated into our marketing and distribution systems.

We are a Delaware corporation organized in 1956, and our principal executive offices are located at 909 Third Avenue, New York, New York 10022 (telephone number 212-421-7850). Our corporate website address is http://www.frx.com. We make all electronic filings with the Securities and Exchange Commission (or SEC), including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those Reports available on our corporate website free of charge as soon as practicable after filing with or furnishing to the SEC.

Cautionary Statement Regarding Forward-Looking Statements

Except for the historical information contained herein, this report contains forward looking statements that involve a number of risks and uncertainties, including the difficulty of predicting FDA approvals, acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, the impact of legislative and regulatory developments on the manufacture and marketing of pharmaceutical products and the uncertainty and timing of the development and launch of new pharmaceutical products. This report contains forward-looking statements that are based on Management's current expectations, estimates, and projections. Words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “seeks,” “estimates,” “forecasts,” variations of these words and similar expressions are intended to identify these forward-looking statements. Certain factors, including but not limited to those identified under “Item 1A. Risk Factors” of this report, may cause actual results to differ materially from current expectations, estimates, projections, forecasts and from past results. No assurance can be made that any expectation, estimate or projection contained in a forward-looking statement will be achieved or will not be affected by the factors cited above or other future events. Forest undertakes no obligation to release publicly any revisions to forward-looking statements as the result of subsequent events or developments. We disclaim any obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. This discussion is provided as permitted by the Private Securities Litigation Reform Act of 1995.

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Recent Developments

The following is a summary of selected key developments affecting our business during the fiscal year ended March 31, 2009, including developments regarding our marketed products and products in various stages of development.

Savella™: In January 2009 we received approval for the marketing of Savella (milnacipran HCl), a selective serotonin and norepinephrine reuptake inhibitor (or SNRI), for the management of fibromyalgia. Fibromyalgia is a chronic condition characterized by widespread pain and decreased physical function and affects as many as six million people in the United States. The safety and efficacy of Savella was established in two Phase III trials conducted in the United States and submitted with the New Drug Application (or NDA) involving more than 2,000 patients with fibromyalgia. We license the United States and Canadian rights to develop and commercialize Savella from Cypress Bioscience, Inc. (or Cypress). Pursuant to our collaboration agreement with Cypress, we made approximately $50 million in upfront and development milestone payments, as well as a $25 million milestone payment upon approval by the United States Food and Drug Administration (or FDA). We will also pay Cypress royalties based on net sales of Savella. We are responsible for sales and marketing activities, and Cypress will also perform a portion of details to specialty physicians on a fee-for-service basis. Our license agreement includes two patents covering the use of Savella as a treatment for fibromyalgia. These patents expire in 2021 and we filed for a patent term extension until 2023. In addition, as a new chemical entity not previously approved by the FDA, Savella will qualify for five years of marketing exclusivity under the Drug Price Competition and Patent Restoration Act of 1984, commonly known as the Hatch-Waxman Act. Savella became available to trade channels in April 2009 at which time we began detailing to physicians.

Dutogliptin: In October 2008, we entered into a collaboration agreement with Phenomix Corporation (or Phenomix) to develop and commercialize dutogliptin in North America. Dutogliptin is a proprietary orally administered, small molecule dipeptidyl-peptidase-4 (or DPP-4) inhibitor currently undergoing Phase III studies for the treatment of Type II diabetes mellitus. Under the terms of our collaboration agreement, we made an upfront payment to Phenomix of $75 million. Phenomix and Forest will jointly fund the development of dutogliptin in the United States and we will share profits and losses with Phenomix. Phenomix will be responsible for the promotion of dutogliptin to certain specialists, with Forest promoting to both primary care and specialty physicians. In Canada and Mexico, Forest has exclusive development and marketing rights and Phenomix will receive a royalty based upon net sales in these countries. Phenomix retains development and commercialization rights to the product outside of North America and Mexico and will pay Forest a royalty on net sales in these territories.

Dutogliptin inhibits DPP-4 enzymes from breaking down the incretin hormone glucagon-like peptide 1 (or GLP-1), thereby increasing the levels of this hormone in the digestive tract and the blood. The increased levels of GLP-1 stimulate insulin production by the pancreatic beta cells and reduce glucagon production by the pancreas, both of which result in reduced blood glucose levels.

In a double-blind, randomized 12-week, 422 patient, placebo-controlled Phase II(b) clinical trial, dutogliptin met all primary and secondary endpoints, including statistically significant reductions in HbA1c when administered once-daily in combination with metformin, a glitazone, or metformin and a glitazone for the treatment of Type II diabetes. Dutogliptin was also well tolerated. In addition to five years of Hatch-Waxman exclusivity that would be granted upon approval, dutogliptin is covered by a U.S. composition of matter patent that expires in 2024, subject to possible patent term extension.

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F2695: In December 2008, we entered into a collaboration agreement with Pierre Fabre Medicament (or Pierre Fabre) for the development and commercialization of F2695 in the United States and Canada. F2695 is a proprietary selective norepinephrine and serotonin reuptake inhibitor, two neurotransmitters known to play an essential role in regulating mood, and is being developed for the treatment of depression. Under the terms of our agreement, we made an upfront payment to Pierre Fabre of $75 million and are obligated to pay future development milestones. We have assumed responsibility for the clinical development and commercialization of F2695 in the United States and Canada, while Pierre Fabre will fund all pre-clinical development and drug substance manufacturing activities.

In a recently completed European placebo-controlled, double-blind Phase II study of F2695 in over 550 patients with major depressive disorder, the compound demonstrated statistically significant improvement compared to placebo ($p<0.0001$) on the primary endpoint, the change from baseline in total score on the Montgomery-Asberg Depression Rating Scale (or MADRS) and for a secondary endpoint, the Hamilton Depression Scale (or HAMD-17) as well as in response and remission rates using both the MADRS and HAMD-17. F2695 demonstrated symptom improvement compared to placebo within two weeks after treatment initiation. F2695 is an isomer of milnacipran and is protected by a method of use patent that extends through June 2023, subject to patent term extension. We also anticipate that under the Food and Drug Administration Amendments Acts of 2007, F2695 will qualify for five years of Hatch-Waxman exclusivity upon approval.

Bystolic®: In December 2007 we received approval from the FDA for the marketing of Bystolic for the treatment of hypertension. We commenced the sale and marketing of Bystolic in January 2008. Bystolic is a beta-1 selective beta-blocker with vasodilating properties. In its Phase III study program, Bystolic demonstrated significant reductions in sitting diastolic and systolic blood pressure in a general hypertension population. The studies also found that Bystolic was well tolerated, with a low incidence of side effects traditionally associated with beta-blockers. Bystolic has received five years of marketing exclusivity under the Hatch-Waxman Act and is also covered by a U.S. pharmaceutical composition of matter patent set to expire in 2020. We have filed for patent term extension until 2021. See “Business – Patents and Trademarks.” Hypertension affects approximately 72 million adults in the United States and a substantial number of patients diagnosed with hypertension have not reduced their blood pressure to an acceptable range.

In fiscal 2009, Bystolic achieved net sales of $69,238,000.

We recently filed a supplemental New Drug Application (or sNDA) for a congestive heart failure indication based on a single large Phase III study.

We license exclusive U.S. and Canadian rights to Bystolic from Mylan Inc. (or Mylan). In February 2008, we amended our license agreement with Mylan to terminate Mylan’s further commercial rights for Bystolic in the U.S. and Canada and to reduce future payment obligations to Mylan. Pursuant to the amendment, we made a one-time cash payment of $370 million to Mylan. Following such payment, we remain obligated to pay Mylan its original contractual royalties for a period of three years, after which our royalty rate will be reduced.

Cerexa, Inc.: On January 10, 2007, we acquired Cerexa, Inc. (or Cerexa), a biopharmaceutical company based in Oakland, California, in a cash merger pursuant to which Cerexa became a wholly-owned subsidiary of Forest.

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Pursuant to the merger, we acquired worldwide development and marketing rights (excluding Japan) to ceftaroline acetate (or ceftaroline), a next generation, broad-spectrum, hospital-based injectable cephalosporin antibiotic that exhibits bactericidal activity against the most resistant strains of gram-positive bacteria, including MRSA (methicillin resistant Staphylococcus aureus) in patients with complicated skin and skin structure infections (or cSSSI). Ceftaroline has also demonstrated bactericidal activity against penicillin resistant Streptococcus pneumonia and common gram-negative bacteria. Ceftaroline is being developed initially for the cSSSI indication and for the treatment of community acquired pneumonia (or CAP). In June 2008, we announced positive results from two globally conducted multi-center Phase III studies in the treatment of cSSSI. In both studies, ceftaroline as a monotherapy achieved the primary endpoint of non-inferiority versus a combination of vancomycin plus aztreonam. The studies also indicated that ceftaroline was generally well-tolerated. Additionally, two Phase III studies in CAP are on-going and we anticipate the CAP results in calendar 2009. Based on positive results from both indications, we anticipate submitting a New Drug Application to the FDA around the end of calendar 2009.

The rights to ceftaroline are in-licensed by Cerexa on an exclusive basis from Takeda Pharmaceutical Company. In addition to five years of Hatch-Waxman exclusivity that would be granted upon approval, ceftaroline is covered by a U.S. composition of matter patent that expires in 2018, subject to possible patent term extension. Ceftaroline is also covered by two U.S. patents that relate to the ceftaroline formulation that expire in 2021 and that may provide additional exclusivity.

We paid cash consideration of approximately $494 million in connection with the merger and certain related expenses. We are obligated to pay an additional $100 million in the event that annual United States sales of ceftaroline exceed $500 million during the five year period following product launch. The merger consideration paid at closing was expensed in fiscal 2007 as in-process research and development.

NXL104: In January 2008, we entered into an agreement with Novexel, S.A. (or Novexel) for the development, manufacture and commercialization of Novexel's novel intravenous beta-lactamase inhibitor, NXL104, in combination with our ceftaroline compound. NXL104 is designed to be co-administered with select antibiotics to enhance their spectrum of activity. Under the terms of the license, we received the exclusive rights to administer NXL104 with ceftaroline as a combination product in North America. We intend to initiate Phase I studies of the ceftaroline/NXL104 combination during the second half of calendar 2009. We also received a first negotiation right in North America to an additional NXL104 combination with ceftazidime, a cephalosporin antibiotic having a different spectrum of activity compared to ceftaroline. This combination is currently being studied in Phase II clinical trials conducted by Novexel.

NXL104 inhibits bacterial enzymes called beta-lactamases that break down beta-lactam antibiotics (in particular penicillins and cephalosporins). Beta-lactamase inhibition represents a mechanism for counteracting resistance and enhancing the broad-spectrum activity of beta-lactam antibiotics. A composition of matter patent which claims NXL104 would provide protection for the ceftaroline/NXL104 combination product until 2022, subject to possible patent term extension.

Under the terms of the agreement, we made an upfront license payment of approximately $110 million to Novexel. We will fund development and commercialization of the ceftaroline/NXL104 combination. Following the product's regulatory marketing approval, we will pay Novexel a low double digit royalty on net sales throughout North America.

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Linaclotide: In September 2007, we entered into a 50/50 partnership in the United States with Ironwood Pharmaceuticals, Inc. (or Ironwood) to co-develop and co-market Ironwood's first-in-class compound linaclotide. Linaclotide is currently being investigated for the treatment of constipation-predominant irritable bowel syndrome (or IBS-C) and chronic constipation (or CC).

Under the terms of the agreement, we initially paid Ironwood $70 million in licensing fees. Ironwood and Forest will jointly and equally fund development and commercialization of linaclotide in the United States, sharing profits equally. Additionally, we will have exclusive rights in Canada and Mexico and will pay Ironwood a royalty on net sales in these countries.

Linaclotide is an agonist of the guanylate cyclase type-C receptor found in the intestine and acts by a mechanism distinct from previously developed products for IBS-C and CC. Linaclotide is administered orally but acts locally in the intestine with no measurable systemic exposure.

One out of six adults in developed countries suffers from IBS, a chronic condition marked by abdominal pain and disturbed bowel function. IBS accounts for 12% of adult visits to primary care physicians and is the most common disorder diagnosed by gastroenterologists. Health care costs associated with IBS exceed $25 billion annually. IBS patients fall into three subgroups; constipation-predominant IBS-C, diarrhea-predominant (or IBS-D), and alternating (or IBS-A), and 30% to 40% of these patients suffer from IBS-C. There are currently few available therapies to treat the nine million U.S. patients diagnosed with IBS-C.

As many as 26 million Americans suffer from CC. The discomfort of CC significantly affects patients' quality of life by impairing their ability to work and participate in typical daily activities.

In March 2008, we announced positive top-line results from two Phase II(b) randomized, double-blind, placebo-controlled studies assessing the safety, therapeutic effect and dose response of four different once-daily doses of linaclotide: 75 mcg, 150 mcg, 300 mcg and 600 mcg. The first study examined the effects of linaclotide in patients with CC, while the second study examined its effects in patients with IBS-C. The analyses of the CC study data and the IBS-C study data indicate that each study met its primary endpoint in favor of linaclotide. Based on this data, we and Ironwood have initiated a comprehensive Phase III study program to evaluate linaclotide's safety and efficacy in patients with either IBS-C or CC. The program involves two Phase III double-blind studies in each condition.

In addition to five years of Hatch-Waxman exclusivity that would be granted upon approval, linaclotide is covered by a U.S. composition of matter patent that expires in 2025, subject to possible patent term extension.

Aclidinium: In April 2006, we entered into a collaboration and license agreement with Laboratorios Almirall, S.A. (or Almirall), a pharmaceutical company headquartered in Barcelona, Spain, for the development and exclusive United States marketing rights to aclidinium, Almirall's novel long-acting muscarinic antagonist. Aclidinium is being developed as an inhaled therapy for chronic obstructive pulmonary disease (or COPD). Aclidinium is designed to have specific action in the lungs and is believed to be rapidly metabolized in the lungs with limited systemic exposure. Studies to date support a favorable tolerability profile. The product is being developed in a Multi-Dose Dry Powder Inhaler (or MDPI) which we believe represents an improvement in drug delivery over currently available devices.

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COPD is a debilitating respiratory condition that includes two related lung diseases: chronic bronchitis and emphysema. It affects approximately 24 million Americans, a population even larger than the 20 million who suffer from asthma. However, COPD frequently goes undiagnosed and untreated because it is difficult to identify in its early stages. The primary cause of COPD is prolonged cigarette smoking. It is the fourth leading cause of death in the United States after heart disease, cancer and stroke. According to the National Heart, Lung and Blood Institute, COPD's prevalence and associated death rate are rising. In 2020, COPD is projected to become the third leading cause of death in the United States. Today, the economic burden of COPD on the U.S. healthcare system is substantial, estimated at over $30 billion annually.

Under the terms of the agreement, we made an upfront payment of $60 million to Almirall in May 2006, development milestone payments in May 2007 and September 2008 and may be obligated to pay future milestone payments. In addition, Almirall will receive royalty payments based on aclidinium sales. Forest and Almirall will jointly oversee the development and regulatory approval of aclidinium and share all expenses for current and future development programs. Almirall has granted us certain rights of first negotiation for other Almirall respiratory products that could be combined with aclidinium. Pursuant to such rights, we have commenced the development of a fixed-dose combination of aclidinium and the beta-agonist formoterol, which is currently in Phase II testing.

In September 2008, we and Almirall announced results from two global Phase III studies of aclidinium. In both trials, once-daily aclidinium showed a statistically significant difference versus placebo in the primary endpoint of trough FEV1, a measure of pulmonary function that is decreased in patients with moderate to severe COPD. After consultation with the FDA, we and Almirall have determined to conduct additional clinical trials of aclidinium to provide further support for a range of dosing regimens, including higher and more frequent dosing.

We will be responsible for sales and marketing of aclidinium in the U.S. and Almirall has retained an option to co-promote the product in the U.S. in the future while retaining commercialization rights for the rest of the world. In addition to five years of Hatch-Waxman exclusivity that would be granted upon approval, aclidinium is protected by an issued U.S. composition of matter patent expiring in 2020, subject to possible patent term extension.

Lexapro®: In September 2002, we launched Lexapro (escitalopram oxalate), a single isomer version of citalopram HBr for the treatment of major depression, following approval of the product by the FDA in August 2002. Citalopram is a racemic mixture with two mirror image molecules, the S- and R-isomers. The S-isomer of citalopram is the active isomer in terms of its contribution to citalopram's antidepressant effects, while the R-isomer does not contribute to the antidepressant activity. With Lexapro, the R-isomer has been removed, leaving only the active S-isomer. Clinical trials demonstrate that Lexapro is a more potent selective serotonin reuptake inhibitor (or SSRI) than its parent compound, and confirm the antidepressant activity of Lexapro in all major clinical measures of depression. During fiscal 2009, sales of Lexapro were $2,300,945,000. According to data published by IMS, an independent prescription audit firm, as of April 30, 2009, Lexapro's market share was 16.03% of total prescriptions for antidepressants in the SSRI/SNRI category.

In December 2003, Lexapro received FDA approval for the treatment of generalized anxiety disorder (or GAD), a disorder characterized by excessive anxiety and worry about everyday events or activities for a period of six months or more. The approval was based upon three GAD studies involving Lexapro which demonstrated significantly greater improvement in anxiety symptoms relative to placebo. Forest began marketing Lexapro for the treatment of GAD in January 2004.

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In March 2009, the FDA approved our supplemental NDA for the acute and maintenance treatment of Major Depressive Disorder (or MDD) in adolescents, 12-17 years of age. Lexapro is only the second antidepressant to be approved for the treatment of MDD in adolescents, a condition that affects approximately two million adolescents in the United States. The approval of Lexapro for the treatment of adolescent depression was supported by two placebo-controlled studies, one conducted in adolescent patients taking Lexapro and one conducted in children and adolescents taking citalopram. In an 8-week flexible-dose, placebo-controlled study that compared Lexapro 10-20 mg/day to placebo in 12 to 17 year old patients reported in 2008, Lexapro showed statistically significant greater mean improvement from baseline, compared to placebo, on the Children's Depression Rating Scale-Revised (CDRS-R). In another 8-week, flexible-dose, placebo-controlled study, children and adolescents 7 to 17 years of age treated with citalopram 20-40 mg/day showed statistically significant greater mean improvement from baseline on the CDRS-R compared to patients treated with placebo. The positive results for this trial largely came from the adolescent subgroup. The FDA's determination of the efficacy of Lexapro in the acute treatment of MDD in adolescents was established, in part, on the basis of extrapolation from this study. Two additional flexible-dose, placebo-controlled MDD studies were conducted: one Lexapro study in patients 7 to 17 and one citalopram study in adolescents. Neither study demonstrated statistically significant efficacy on the primary parameter. Although maintenance efficacy in adolescent patients has not been systematically evaluated, the FDA in its review concluded that maintenance efficacy can be extrapolated from adult data along with comparisons of escitalopram pharmacokinetic parameters in adults and adolescent patients.

Lexapro was developed by us and H. Lundbeck A/S (or Lundbeck), a Danish pharmaceutical firm which licenses to us the exclusive United States marketing rights to this compound, as well as Celexa®.

Lexapro is covered by a U.S. composition of matter patent which expires in March 2012, inclusive of additional exclusivity granted as a result of a pediatric study we performed. In September 2007, the United States Court of Appeals for the Federal Circuit affirmed a July 2006 decision by the United States District Court for the District of Delaware which determined that our composition of matter patent for Lexapro is valid and upheld our injunction against Teva Pharmaceuticals (or Teva) preventing Teva from launching a generic equivalent to Lexapro. During fiscal 2007, Caraco Pharmaceutical Laboratories (or Caraco), a generic manufacturer, filed an Abbreviated New Drug Application (or ANDA) seeking approval to market a generic version of Lexapro. We, together with Lundbeck, have commenced patent infringement litigation against Caraco which is pending in the United States District Court for the Eastern District of Michigan. Caraco has stipulated to infringing our patent leaving only Caraco's invalidity defenses to be litigated. A five day bench trial, originally scheduled to begin on April 27, 2009, was adjourned until June 1, 2009. See "Item 3. Legal Proceedings".

Namenda®: In October 2003, Namenda (memantine HC1) was approved for marketing and distribution by the FDA for the treatment of moderate and severe Alzheimer's disease. Namenda is a moderate-affinity, uncompetitive N-methyl-D-aspartate (or NMDA) receptor antagonist that modulates the effects of glutamate - a neurotransmitter found in the brain. Excessive levels of glutamate are hypothesized to contribute to the dysfunction and eventual death of brain cells observed in Alzheimer's disease. We believe that Namenda's mechanism of action is distinct from other drugs currently available to treat Alzheimer's disease. We obtained the exclusive rights to develop and market memantine in the United States by license agreement with Merz Pharma GmbH & Co. KgaA of Germany (or Merz), the originator of the product.

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Namenda achieved sales of $949,289,000 during our 2009 fiscal year and, according to data published by IMS, an independent prescription audit firm, as of April 30, 2009, Namenda achieved a 34.01% share of total prescriptions in the Alzheimer's market. Namenda is covered by a U.S. method of use patent which expires in 2010. In March 2009 the U.S. Patent and Trademark Office issued a Notice of Final Determination that Namenda is entitled to a patent term extension until April 2015. In January 2008, we and Merz commenced patent infringement litigation against several generic manufacturers who had filed ANDAs seeking FDA approval to market generic equivalents of Namenda. The actions are pending in the United States District Court for the District of Delaware. We intend to fully enforce our patent rights for Namenda.

In February 2008, we received preliminary results of a Phase III study of memantine HC1 in a novel once-daily formulation. The study evaluated the efficacy, safety and tolerability of an innovative, proprietary, 28 mg memantine extended-release, once-daily formulation compared to placebo in outpatients with moderate and severe Alzheimer's disease currently treated with an acetyl- cholinesterase inhibitor. The results indicated that patients treated with memantine 28 mg extended-release formulation experienced statistically significant benefits in cognition and clinical global status compared to placebo. Based on the results of this study, we intend to prepare a NDA for this new formulation.

Cariprazine: In November 2004, we entered into a collaboration and license agreement with Gedeon Richter Ltd. (or Richter), based in Budapest, Hungary, for the development of and exclusive United States rights to Richter's cariprazine (RGH 188) and related compounds, being developed as an atypical antipsychotic for the treatment of schizophrenia, bipolar mania and other psychiatric conditions.

In September 2008, we received positive preliminary top-line results from a Phase II study of cariprazine in patients with acute mania associated with bipolar disorder. A review of top-line results of a Phase II study in schizophrenia indicated that cariprazine demonstrated a nominally statistical significant (i.e., not adjusted for multiple comparisons) therapeutic effect compared to placebo in a low-dose arm and a numerical improvement compared to placebo in a high-dose arm that did not reach nominal statistical significance. Based on the review of the results, we and Richter initiated a Phase II(b) dose-ranging study in schizophrenia patients. This study is being performed in order to better determine an optimal dose to take into the planned Phase III program. We expect to report this data in the second half of calendar 2009. In addition, two Phase II studies to explore the safety and efficacy of cariprazine in bipolar depression and as adjunct therapy in major depressive disorder will begin later this year.

Upon execution of the collaboration agreement, we paid Richter an upfront license fee and we will be obligated to pay further milestone payments if development and commercialization are successfully completed. We are also obligated to pay Richter a royalty based on net sales and to purchase our requirements of the active pharmaceutical ingredient from them. Our license grants us exclusive development and commercialization rights in the United States and Canada. We will collaborate with Richter in product development and will jointly fund such development activities.

In addition to five years of Hatch-Waxman exclusivity which would be granted upon approval, Richter owns pending U.S. patent applications covering the cariprazine compound that if issued, will expire in 2024.

Radiprodil (RGH-896) and mGLUR1/5 Compounds: In November 2005, we entered into two new collaboration agreements with Richter with whom we are currently developing cariprazine for the treatment of schizophrenia and bipolar mania.

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The first collaboration will focus upon a group of compounds that target the NR2B receptor that will be developed for the treatment of chronic pain and other central nervous system (or CNS) conditions. Radiprodil is the first of this group and is currently in Phase II in patients with diabetic peripheral neuropathic pain with results expected in calendar year 2010. We paid Richter an upfront payment and will become obligated to pay milestone payments based upon achievement of development objectives. The two companies will jointly fund the development program. Forest has exclusive marketing rights in the United States and Canada and will pay Richter a royalty on net sales. In addition to five years Hatch-Waxman exclusivity that would be granted upon approval, radiprodil is covered by a U.S. composition of matter patent that expires in 2024, subject to possible patent term extension.

The second new collaboration will focus upon a series of novel compounds that target metabotropic glutamate receptors (or mGLUR1/5). mGLUR1/5 antagonists represent novel potential agents for the treatment of anxiety, depression and other CNS conditions. Forest and Richter intend to advance promising leads to clinical trials within the next two to three years. We paid Richter an upfront payment and will pay milestone payments based upon the achievement of development objectives in addition to royalties. We will have exclusive marketing rights in North America while Richter will retain exclusive rights in Europe and countries comprising the former Soviet Union. The two companies will share rights in other countries.

Oglemilast: In September 2004, we entered into a collaboration and license agreement with Glenmark Pharmaceuticals Ltd. (or Glenmark), of Mumbai, India, covering oglemilast (GRC 3886) Glenmark's PDE4 inhibitor. Oglemilast is a novel, orally available phosphodiesterase-IV (or PDE4) inhibitor in development for COPD and asthma, and may also have use in other conditions.

Bronchodilators and anticholinergics are the most commonly prescribed therapies in COPD, but do not address the underlying inflammation. PDE4 inhibitors represent a new class of drugs that are interesting because they have the potential to relax the smooth muscles of the airway resulting in bronchodilation, as well as inhibit inflammatory cell activity, thus providing both short-term relief and control over the progression of the disease.

We have commenced a Phase II study of this compound for the COPD indication with results expected in the second half of calendar 2009. Glenmark is conducting a Phase II study in adult patients with asthma. In addition to five years of Hatch-Waxman exclusivity that would be granted upon approval, oglemilast is covered by a U.S. composition of matter patent that expires in 2024, subject to possible patent term extension.

We will develop, register and commercialize oglemilast for the North American market, while Glenmark will retain commercialization rights for the rest of the world. We paid Glenmark an upfront payment upon initiation of the agreement and additional payments upon the successful completion of other development milestones. We will be required to pay future milestones if the development and commercialization of the product is successfully completed in the North American market. Additionally, after commercial launch, Glenmark will earn a royalty from us on net sales of the product, and will supply all of the active pharmaceutical ingredient required by us.

Co-Promotion of Benicar® with Daiichi Sankyo: In December 2001, we entered into a co-promotion agreement with Daiichi Sankyo (or Sankyo) for the co-promotion in the United States of Benicar (olmesartan medoxomil) an angiotensin receptor blocker (or ARB) discovered and developed by Sankyo for the treatment of hypertension. The NDA for Benicar was approved by the FDA in April 2002. In August 2003, the FDA approved Benicar HCT®, a combination of Benicar and hydrochlorothiazide, which was also jointly promoted by Forest and Sankyo.

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Pursuant to the co-promotion agreement with Sankyo, we shared with Sankyo in the detailing of the product to physicians, hospitals, managed care organizations and other institutional users of pharmaceutical products over a six-year period ended March 31, 2008 (we subsequently agreed to perform limited additional detailing through May 2008). We received co-promotion income based upon the relative contribution of the two companies to the co-promotion effort through fiscal year ended March 31, 2008, and will receive residual payments on a reduced basis following the end of the co-promotion period based on sales levels achieved through the fiscal year ending March 31, 2014. During fiscal 2009, we received co-promotion income of $195,563,000. According to market share data published by IMS, an independent prescription audit firm, as of April 30, 2009, Benicar and Benicar HCT achieved a combined 18.33% share of total prescriptions in the ARB market. Benicar and Benicar HCT are covered by a U.S. composition of matter patent that expires in 2016. Sankyo has sued a generic manufacturer for infringing this patent after an ANDA was submitted seeking FDA approval to distribute generic versions of Benicar. A bench trial in this lawsuit was completed in April 2009.

Effective July 1, 2008, we terminated our co-promotion agreement for Azor® (amlodipine and olmesartan medoxomil), Sankyo's fixed-dose combination of two antihypertensives, the calcium channel blocker amlodipine besylate and the angiotensin receptor blocker olmesartan medoxomil. In connection with this termination, we recorded a one-time charge of approximately $44,100,000 which is comprised of a one-time payment to Sankyo of approximately $26,600,000 related to the termination of the agreement and $17,500,000 related to the unamortized portion of the initial upfront payment. We determined that the resources we had allocated to the Azor co-promotion would be better utilized in providing additional support for our other currently marketed products.

Share Repurchase Program: On May 18, 2006 our Board of Directors (or the Board) authorized a share repurchase program for up to 25 million shares of our common stock (or the 2007 Repurchase Program). On August 13, 2007 the Board authorized the purchase of an additional 10 million shares of common stock. The authorizations became effective immediately and have no set expiration dates. We expect to make the repurchases from time to time on the open market, depending on market conditions. As of May 28, 2009, 29,346,700 shares have been repurchased and we continue to have authority to purchase up to an additional 5,653,300 shares under the 2007 Repurchase Program.

Principal Products

We actively promote in the United States those branded products which we believe have the most potential for growth and patient benefit, and which enable our salesforces to concentrate on groups of physicians who are high prescribers of our products. Such products include: Lexapro, our SSRI for the treatment of major depression and GAD; Namenda, our NMDA antagonist for the treatment of moderate and severe Alzheimer's disease; Bystolic, our beta-blocker for the treatment of hypertension; and Savella, our newest product, a dual reuptake inhibitor for the treatment of fibromyalgia.

Sales of Lexapro, launched in September 2002, accounted for 63% of our sales for the fiscal year ended March 31, 2009 and 66% of our sales for our fiscal years 2008 and 2007.

Sales of Namenda, launched in December 2003, accounted for 26% of our sales for the fiscal year ended March 31, 2009 and 24% and 21%, respectively, of our sales for fiscal years 2008 and 2007.

Our generic line, marketed by our Inwood Laboratories, Inc. subsidiary, includes generic equivalents to certain of our branded products, including Tiazac®, as well as products using our controlled release technology.

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Our United Kingdom and Ireland subsidiaries sell both ethical products and over-the-counter preparations. Their most important products include Sudocrem®, a topical preparation for the treatment of diaper rash; Colomycin®, an antibiotic used in the treatment of cystic fibrosis; Infacol®, used to treat infant colic; and Exorex®, used in the treatment of eczema and psoriasis.

Marketing

In the United States, we directly market our products through our domestic salesforces, Forest Pharmaceuticals, Forest Therapeutics, Forest Healthcare, Forest Ethicare and Forest Specialty Sales, currently numbering approximately 2,700 persons, which detail products directly to physicians, pharmacies, hospitals, managed care and other healthcare organizations. In the United Kingdom, our Forest Laboratories U.K. subsidiary's salesforce, currently 41 persons, markets its products directly. Our products are sold elsewhere through independent distributors.

Competition

The pharmaceutical industry is highly competitive as to the sale of products, research for new or improved products and the development and application of competitive drug formulation and delivery technologies. There are numerous companies in the United States and abroad engaged in the manufacture and sale of both proprietary and generic drugs of the kind which we sell. Many of these companies have substantially