FOREST LABORATORIES INC
Form 10-K
June 27, 2002

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, 2002

[ ] TRANSITION 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	11-1798614
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification Number)*
909 Third Avenue New York, New York	10022
(Address of principal executive offices)	*(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
Rights, as adjusted, to purchase one quarter of one-hundredth share of Series A Junior Participating Preferred Stock, par value $1.00 per share	New York Stock Exchange

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

None

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 ___ .

The aggregate market value of the voting stock held by non-affiliates of the registrant as of June 21, 2002 is $12,138,515,967.

Number of shares outstanding of the registrant's Common Stock as of June 21, 2002: 179,543,109.

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 2002 Annual Meeting of Stockholders of registrant.

Portions of the registrant's Annual Report to Stockholders for the fiscal year ended March 31, 2002.

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PART I

ITEM 1. BUSINESS

General

Forest Laboratories, Inc. and its subsidiaries (collectively, "Forest" or the "Company") develop, manufacture and sell both branded and generic forms of ethical drug products which require a physician's prescription, as well as non-prescription pharmaceutical products sold over-the-counter. Forest's most important United States products consist of branded ethical drug specialties marketed directly, or "detailed," to physicians by the Company's Forest Pharmaceuticals, Forest Therapeutics, Forest Healthcare and Forest Specialty Sales salesforces. The Company emphasizes detailing to physicians of those branded ethical drugs it believes have the most potential for growth, and the development and introduction of new products, including products developed in collaboration with licensing partners.

Forest's products include those developed by Forest and those acquired from other pharmaceutical companies and integrated into Forest's marketing and distribution systems. See "Recent Developments."

Forest is a Delaware corporation organized in 1956, and its principal executive offices are located at 909 Third Avenue, New York, New York 10022 (telephone number 212-421-7850).

Recent Developments

Lexapro™: In January 2002, Forest received an "approvable letter" from the United States Food and Drug Administration ("FDA") for Lexapro (escitalopram oxalate), a single isomer version of Forest's Celexa™ (citalopram HBr) for the treatment of depression. An approvable letter represents the final stage in the FDA approval process to market a pharmaceutical product in the United States. Forest anticipates receiving final FDA approval early in fiscal 2003. 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 ("SSRI") than its parent compound and confirm the antidepressant activity of Lexapro in all clinical measures of depression. Lexapro was developed by H. Lundbeck A/S, a Danish pharmaceutical firm which licenses this compound, as well as Celexa, to Forest. Lexapro has already been approved for sale in 10 European countries.

Celexa: Sales of Celexa, Forest's selective serotonin reuptake inhibitor for the treatment of depression were $1,087,794,000 for the fiscal year ended March 31, 2002. According to data published by IMS, an independent prescription audit firm, as of June 7, 2002 Celexa has achieved a 17.2% share of total prescriptions for antidepressants in the SSRI/SNRI category. Citalopram is currently marketed in most European countries and is the leading antidepressant in several European markets. Forest licenses the United States rights to Celexa from H. Lundbeck A/S.

Benicar™ Co-Promotion with Sankyo Pharma: In December 2001, Forest entered into a co-promotion agreement with Sankyo Pharma for the co-promotion in the United States of Benicar (olmesartan medoxomil) an angiotensin receptor blocker discovered and developed by Sankyo Pharma for the treatment of hypertension. The New Drug Application ("NDA") for Benicar was approved by the FDA in April 2002 and the product was commercially launched in the United States in May 2002.

Pursuant to the co-promotion agreement with Sankyo, Forest and Sankyo will share in the detailing of the product to physicians, hospitals, managed care organizations and other institutional users of pharmaceutical products over a six-year period. Forest will receive co-promotion income based upon the relative contribution of the two companies to the co-promotion effort, and will receive residual payments following the end of the co-promotion period based on sales levels achieved.

Lercanidipine: In November 2000, Forest entered into a license agreement with Recordati S.p.A., a privately-held pharmaceutical company based in Milan, Italy, for the exclusive rights to develop and market lercanidipine in the United States for the treatment of hypertension. Forest submitted an NDA for lercanidipine to the FDA in October 2001. Lercanidipine, currently marketed in twenty-five countries, belongs to the dihydropyridine

calcium channel blocker class of anti-hypertensives, one of the most widely used classes of anti-hypertensives. Lercanidipine has been widely studied in clinical trials and was found to have an excellent safety profile and comparable blood pressure lowering effects to other drugs in this class.

Hypertension is increasingly treated with the use of various drugs with different and complementary modes of action, which are prescribed together to obtain the desired level of blood pressure control. Forest anticipates that, following FDA approval, Forest will be able to market lercanidipine as a stand alone antihypertensive product, as well as a complementary product to other treatments, including Benicar (see "Recent Developments - Benicar Co-Promotion"), for the control of hypertension.

Acamprosate: In October 2001, Forest entered into a Distribution, Marketing, Trademark License and Supply Agreement with Lipha, S.A., pursuant to which Forest licensed exclusive rights to market acamprosate in the United States for the treatment of alcohol addiction. Acamprosate, developed by Lipha, a subsidiary of Merck KGaA of Darmstadt, Germany, has been marketed in most European countries for several years under the brand name "Campral®." Lipha submitted the NDA for acamprosate to the FDA in December 2001, and was informed that the NDA will be reviewed by the FDA on an expedited basis. In May, an advisory committee to the FDA concluded that clinical trial data for acamprosate demonstrates efficacy in the maintenance of abstinence for patients with chronic alcohol dependence when the medication is used in conjunction with psychosocial or behavioral counseling. The FDA will now take the committee's vote into consideration as it completes its review of the NDA for acamprosate, although the FDA is not bound by the recommendation of its advisory committee.

Memantine: In June 2000, Forest entered into a license agreement with Merz + Co. for the exclusive rights to develop and market memantine in the United States. Memantine is the leading prescription product sold for dementia in Germany and has recently been approved for marketing in most European countries. Several large scale studies in Alzheimer's Disease and dementia have been completed, including one in the United States, which demonstrate that the compound is well tolerated and capable of treating the symptoms of Alzheimer's Disease. In addition, a clinical study has demonstrated that memantine is helpful in relieving nighttime neuropathic pain in diabetic patients. Forest intends to prepare an NDA submission for the treatment of moderate to severe Alzheimer's Disease based upon the studies performed to date for submission in fiscal 2003. There is uncertainty about the FDA's acceptance of the NDA as one of the two pivotal studies included does not contain all the endpoints which the Company believes the FDA may require. The Company is performing four additional clinical studies in Alzheimer's Disease to supplement the completed trials. It is anticipated that the results of the first of these studies should be available by the end of 2002. Forest has begun an additional study in neuropathic pain.

Neramexane: In March 2001 Forest entered into a second agreement with Merz to jointly develop neramexane, a newly patented NMDA antagonist which is being developed for several central nervous system disorders.

Dexloxiglumide: In August 2000, Forest concluded a license arrangement with Rotta Research Laboratorium, S.p.A. of Monza, Italy, for the exclusive rights to develop and market in the United States dexloxiglumide for the treatment of patients with constipation-prone irritable bowel syndrome. Irritable bowel syndrome is a chronic intestinal disorder characterized by recurrent abdominal pain and bloating, accompanied by constipation or diarrhea. Current treatments include diet, laxatives and antispasmodic drugs. Dexloxiglumide is a cholecystokinin-1 ("CCK-1") receptor antagonist. CCK-1 antagonists increase gastric emptying and intestinal motility and may reduce moderate intestinal sensitivity to distension. A successful Phase II study has already been completed. Forest has commenced Phase III studies for dexloxiglumide in the United States.

Aerospan®: On December 3, 1999, Forest and the 3M Pharmaceuticals Division of the Minnesota Mining and Manufacturing Company ("3M") entered into a Supply and Distribution Agreement for the long-term supply and manufacture by 3M on an exclusive basis of a hydrofluroalkane ("HFA") formulation of flunisolide, the active ingredient in Aerobid®, Forest's metered dose inhaled steroid for the treatment of asthma. The HFA formulation, to be

marketed under the brand name Aerospan, does not contain chlorofluorocarbons, which are being phased out of commercial use due to environmental concerns. In addition, Aerospan incorporates a built-in spacer device which Forest believes will enhance use of the product. Forest filed an NDA with the FDA for Aerospan on April 27, 2000, and has received an approvable letter from the FDA. Subject to final FDA approval, the Company expects to begin marketing Aerospan in early fiscal 2004.

Tiazac®: Tiazac, licensed from Biovail Corporation and launched in 1996, is Forest's once-daily formulation of diltiazem, used in the treatment of hypertension and angina. While no generic equivalent to Tiazac has been approved by the FDA, a generic manufacturer has filed an Abbreviated New Drug Application with the FDA for a generic formulation. This formulation has not yet received all necessary regulatory approvals and, accordingly, it is uncertain at this time whether or when approval of such generic product might occur.

Research and Development Facility: In fiscal 2000, Forest acquired a 100,000 square foot and a 20,000 square foot facility in Commack, New York. Forest is developing these locations as a research and development complex which is expected to become operational in fiscal 2003.

Termination of Research and Development Programs: During the 2002 fiscal year, Forest terminated development programs for ALX-0646, a compound being investigated for the treatment of migraine headaches, and ML-3000, a compound being investigated for use as an anti-inflammatory. In each case, Forest terminated the research and development agreements with its corporate partners in the development programs as a result of product development or efficacy problems encountered in the drug development process. In addition, Forest terminated research and development with respect to siramesine, a compound being investigated for the treatment of anxiety and previously included in a 1998 joint venture with H. Lundbeck A/S.

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 and the uncertainty and timing of the development and launch of new pharmaceutical products.

Principal Products

The Company actively promotes in the United States those of its branded products which the Company's management believes have the most potential for growth and which enable its salesforces to concentrate on groups of physicians who are high prescribers of its products. Such products include Celexa, Forest's SSRI for the treatment of depression; the respiratory products Aerobid and Aerochamber®, Tiazac, Forest's once-daily diltiazem for the treatment of hypertension and angina; and Infasurf®, a lung surfactant for the treatment and prevention of respiratory distress syndrome in premature infants.

Sales of Celexa, launched in September 1998, accounted for 69.4% of Forest's sales for the fiscal year ended March 31, 2002 and 60.8% and 49.0%, respectively, of Forest's sales for the fiscal years ended March 31, 2001 and 2000.

Aerobid is a metered dose inhaled steroid used in the treatment of asthma. Aerochamber is a spacer device used to improve the delivery of products administered by aerosol delivery, including Aerobid.

Sales of Tiazac, launched in 1996, accounted for 12.1%, 15.1% and 18.1% of sales for the fiscal years ended March 31, 2002, 2001 and 2000, respectively.

Forest's generic line, marketed by the Company's Inwood Laboratories, Inc. subsidiary, includes generic equivalents to certain of the Company's branded products, as well as difficult to formulate controlled release products.

The Company's United Kingdom and Ireland subsidiaries sell both ethical products requiring a doctor's prescription 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; Suscard® and Sustac®, sustained action nitroglyerin tablets in both buccal and oral form used in the treatment of angina pectoris, an ailment characterized by insufficient oxygenation of the heart muscle and Exorex®, used in the treatment of eczema and psoriasis.

Marketing

In the United States, Forest directly markets its products through its domestic salesforces, Forest Pharmaceuticals, Forest Therapeutics, Forest Healthcare and Forest Specialty Sales, currently numbering approximately 2,100 persons, which detail products directly to physicians, pharmacies, hospitals, managed care and other healthcare organizations. In the United Kingdom, the Company's Forest Laboratories U.K. subsidiary's salesforce, currently 31 persons, markets its products directly. Forest's 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 controlled release and other 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 sold by Forest and drugs utilizing controlled release technologies. Many of these companies have substantially greater financial resources than Forest. The Company also faces competition for the acquisition or licensing of new product opportunities from other companies. In addition, the marketing of pharmaceutical products is increasingly affected by the growing role of managed care organizations, including pharmaceutical benefit management companies, in the provision of health services. Such organizations negotiate with pharmaceutical manufacturers for highly competitive prices for pharmaceutical products in equivalent therapeutic categories, including certain of the Company's principal promoted products. Failure to be included or to have a preferred position in a managed care organization's drug formulary could result in decreased prescriptions of a manufacturer's products.

Government Regulation

The pharmaceutical industry is subject to comprehensive government regulation which substantially increases the difficulty and cost incurred in obtaining the approval to market newly proposed drug products and maintaining the approval to market existing drugs. In the United States, products developed, manufactured or sold by Forest are subject to regulation by the FDA, principally under the Federal Food, Drug and Cosmetic Act, as well as by other federal and state agencies. The FDA regulates all aspects of the testing, manufacture, safety, labeling, storage, record keeping, advertising and promotion of new and old drugs, including the monitoring of compliance with good manufacturing practice regulations. Non-compliance with applicable requirements can result in fines and other sanctions, including the initiation of product seizures, injunction actions and criminal prosecutions based on practices that violate statutory requirements. In addition, administrative remedies can involve voluntary recall of products as well as the withdrawal of approval of products in accordance with due process procedures. Similar regulations exist in most foreign countries in which Forest's products are manufactured or sold. In many foreign countries, such as the United Kingdom, reimbursement under national health insurance programs frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and increases if the ultimate consumer is to be eligible for reimbursement for the cost of such products.

During the past several years the FDA, in accordance with its standard practice, has conducted a number of inspections of the Company's manufacturing facilities. Following these inspections the FDA called the Company's attention to certain "Good Manufacturing Practices" compliance and record keeping deficiencies. Forest has

responded to the FDA's comments and has modified procedures to comply with the requests made by the FDA.

In March 1997, the FDA announced a proposed rule which could result in the withdrawal of approval to market metered dose inhaler formulations of corticosteroids (such as the Company's Aerobid product) containing chlorofluorocarbons ("CFC's") once three distinct non-CFC products are available in that therapeutic category. The Company has developed Aerospan, a non-CFC formulation of flunisolide (the active ingredient in Aerobid) and has filed an NDA with the FDA covering this formulation. (See "Recent Developments - Aerospan.") Forest has received an "approvable" letter from the FDA and expects to receive NDA approval in time to meet the proposed rule.

The cost of human health care products continues to be a subject of investigation and action by governmental agencies, legislative bodies and private organizations in the United States and other countries. In the United States, most states have enacted generic substitution legislation requiring or permitting a dispensing pharmacist to substitute a different manufacturer's version of a drug for the one prescribed. Federal and state governments continue to press efforts to reduce costs of Medicare and Medicaid programs, including restrictions on amounts agencies will reimburse for the use of products. In addition, several states have adopted prescription drug benefit programs which supplement Medicaid programs and are seeking discounts or rebates from pharmaceutical manufacturers to subsidize such programs. Under the Omnibus Budget Reconciliation Act of 1990, manufacturers must pay certain statutorily-prescribed rebates on Medicaid purchases for reimbursement on prescription drugs under state Medicaid plans. Federal Medicaid reimbursement for drug products of original NDA-holders is denied if less expensive generic versions are available from other manufacturers. In addition, the Federal government follows a diagnosis related group ("DRG") payment system for certain institutional services provided under Medicare or Medicaid. The DRG system entitles a health care facility to a fixed reimbursement based on discharge diagnoses rather than actual costs incurred in patient treatment, thereby increasing the incentive for the facility to limit or control expenditures for many health care products.

Under the Prescription Drug User Fee Act of 1992, the FDA has imposed fees on various aspects of the approval, manufacture and sale of prescription drugs. The Company expects that competing healthcare reform proposals will continue to be introduced and debated. The adoption of any such proposal may entail new regulatory requirements and may affect the marketing of prescription drugs. The Company cannot predict the outcome or effect on the marketing of prescription drug products of the legislative and political process.

Principal Customers

For the years ended March 31, 2002, 2001 and 2000, McKesson Drug Company, Cardinal Distributors, Inc. and AmerisourceBergen Corporation accounted for 23%, 19% and 23%, 22%, 17% and 23%, and 19%, 13% and 26%, respectively, of the Company's net sales. No other customer accounted for 10% or more of Forest's net sales for those fiscal years.

Environmental Standards

Forest anticipates that the effects of compliance with federal, state and local laws and regulations relating to the discharge of materials into the environment will not have any material effect on capital expenditures, earnings or the competitive position of Forest.

Raw Materials

The principal raw materials used by Forest for its various products are purchased in the open market. Most of these materials are obtainable and available from several sources in the United States and elsewhere in the world, although the Company's most important products, including Celexa, contain patented or other exclusively manufactured materials available from only a single source. Forest has not experienced any significant shortages in supplies of such raw materials.

Product Liability Insurance

Forest currently maintains $150 million of product liability coverage per "occurrence" and in the aggregate. Although in the past there have been product liability claims asserted against Forest, none for which Forest has been found liable, there can be no assurance that all potential claims which may be asserted against Forest in the future would be covered by Forest's present insurance.

Research and Development

During the year ended March 31, 2002, Forest spent $157,794,000 for research and development, as compared to $105,706,000 and $70,292,000 in the fiscal years ended March 31, 2001 and 2000, respectively. Included in research and development expense are payments made pursuant to licensing agreements for new product opportunities where safety and efficacy have not yet been demonstrated and accordingly payments made in connection with acquiring the product rights are charged to research and development. Forest's research and development expenditures consist primarily of the conduct of preclinical and clinical studies required to obtain approval of new products, as well as phase IV clinical studies designed to further differentiate Forest's products from those of its competitors or to obtain additional labeling indications for its products.

Employees

At March 31, 2002, Forest had a total of 3,731 employees.

Patents and Trademarks

Forest owns or licenses certain U.S. and foreign patents on many of its branded products and products in development, including, but not limited to, Aerobid, Aerospan, Lexapro, Tiazac, Cervidil®, Monurol®, Forest's licensed oxycodone/ ibuprofen analgesic, and memantine, lercandipine, dexloxiglumide, neramexane and other compounds under development pursuant to license arrangements (see "Recent Developments"), which patents expire through 2014. While no longer subject to patent protection, Celexa enjoys legal marketing exclusivity in the United States under the Waxman-Hatch Act until 2003. Lexapro is covered by a United States patent which expires in 2009 and may be subject to a patent term extension of approximately two years. Forest believes these patents and other rights are or may become of significant benefit to its business. Additionally, Forest owns and licenses certain U.S. patents, and has pending U.S. and foreign patent applications, relating to various aspects of its Synchron® technology and to other controlled release technology, which patents expire through 2008. Forest believes that these patents are useful in its business, however, there are numerous patents and unpatented technologies owned by others covering other controlled release processes.

Forest owns various trademarks and trade names which it believes are of significant benefit to its business.

Backlog -- Seasonality

Backlog of orders is not considered material to Forest's business prospects. Forest's business is not seasonal in nature.

ITEM 2. PROPERTIES

Forest owns a 150,000 square foot building on 28 acres in Commack, New York. This facility is used for packaging, warehousing, administration and sales training. In addition, Forest owns additional buildings of 100,000 and 20,000 square feet in Commack, New York and is developing these locations as a research and development complex which is expected to become operational in fiscal 2003.

Forest also owns five buildings and leases two buildings in and around Inwood, Long Island, New York, containing a total of approximately 125,000 square feet. The buildings are used for manufacturing, research and development, warehousing and administration. In addition, Forest leases approximately 44,000 square feet in Farmingdale, New York for use as a clinical laboratory testing facility and leases an additional 105,000 square foot warehouse and administrative office facility in Hauppauge, New York. Forest recently leased an additional 57,000 square foot facility in Hauppauge which will be available for occupancy in July 2002 and will be used for Forest's information technology departments.

Forest also leases approximately 69,000 square feet of office space in Jersey City, New Jersey, which is used by certain of its scientific and regulatory personnel. Forest has also leased additional space in a building which will be operational in 2002, and will bring the total leased square footage in Jersey City to approximately 145,000. This space will be used for Forest's scientific affairs department.

Forest Pharmaceuticals, Inc. ("FPI"), a wholly owned subsidiary of the Company, owns two facilities in Cincinnati, Ohio aggregating approximately 108,000 square feet. In St. Louis, Missouri, FPI owns a 330,000 square foot facility on 26 acres of land. This facility is being used for warehousing, distribution and administration. In addition, FPI owns a facility of 22,000 square feet in St. Louis, Missouri. This facility is used for manufacturing and production.

Forest Laboratories UK owns an approximately 95,000 square foot complex in the London suburb of Bexley, England, which houses its plant and administrative and central marketing offices.

Forest's Tosara subsidiary owns an 18,000 square foot manufacturing and distribution facility located in an industrial park in Dublin, Ireland. Forest Ireland, a subsidiary of Forest, owns an approximately 130,000 square foot manufacturing and distribution facility located in Dublin, Ireland. The facility is currently used principally for the manufacture of and distribution to the United States of Celexa and Lexapro tablets.

Forest presently leases approximately 120,000 square feet of executive office space at 909 Third Avenue, New York, New York. The lease expires in 2010, subject to 2 five year renewal options.

Management believes that further purchases or leases of property are likely in order to meet the present and anticipated increases in Forest's overall operations.

Net rentals for leased space for the fiscal year ended March 31, 2002 aggregated approximately $7,732,396 and for the fiscal year ended March 31, 2001 aggregated approximately $5,714,000.

ITEM 3. LEGAL PROCEEDINGS

The Company remains a defendant in actions filed in various federal district courts alleging certain violations of the federal anti-trust laws in the marketing of pharmaceutical products. In each case, the actions were filed against many pharmaceutical manufacturers and suppliers and allege price discrimination and conspiracy to fix prices in the sale of pharmaceutical products. The actions were brought by various pharmacies (both individually and, with respect to certain claims, as a class action) and seek injunctive relief and monetary damages. The Judicial Panel on Multi-District Litigation has ordered these actions coordinated (and, with respect to those actions brought as class actions, consolidated) in the Federal District Court for the Northern District of Illinois (Chicago) under the caption "In re Brand Name Prescription Drugs Antitrust Litigation."

On November 30, 1998, the defendants remaining in the consolidated federal class action (which proceeded to trial beginning in September 1998), including the Company, were granted a directed verdict by the trial court after the plaintiffs had concluded their case. In ruling in favor of the defendants, the trial Judge held that no reasonable jury could reach a verdict in favor of the plaintiffs and stated "the evidence of conspiracy is meager, and the evidence as to

individual defendants paltry or non-existent." The Court of Appeals for the Seventh Circuit subsequently affirmed the granting of the directed verdict in the federal class case in favor of the Company.

Following the Seventh Circuit's affirmance of the directed verdict in favor of the Company, the Company has secured the voluntary dismissal of the conspiracy allegations contained in all of the federal cases brought by individual plaintiffs who elected to "opt-out" of the federal class action, which cases were included in the coordinated proceedings, as well as the dismissal of similar conspiracy and price discrimination claims pending in various state courts. The Company, together with other manufacturers, remains a defendant in many of the federal opt-out cases included in the coordinated proceedings to the extent of claims alleging price discrimination in violation of the Robinson-Patman Act. While no discovery or other significant proceedings have been taken to date in respect of such claims, there can be no assurance that the Company will not be required to actively defend such claims or to pay substantial amounts to dispose of such claims.

The Company is not subject to any other pending legal proceedings, other than ordinary routine claims incidental to its business.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE

OF SECURITY HOLDERS

Not Applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON

EQUITY AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to page 36 of the Annual Report.

Forest has never paid cash dividends on its Common Stock and does not expect to pay such dividends in the foreseeable future. Management presently intends to retain all available funds for the development of its business and for use as working capital. Future dividend policy will depend upon Forest's earnings, capital requirements, financial condition and other relevant factors.

ITEM 6. SELECTED FINANCIAL DATA

The information required by this item is incorporated by reference to page 22 of the Annual Report.

ITEM 7. MANAGEMENT'S DISCUSSION AND

ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The information required by this item is incorporated by reference to pages 19 through 21 of the Annual Report.

ITEM 7A. QUANTITATIVE AND QUALITATIVE

DISCLOSURES ABOUT MARKET RISK

The information required by this item is incorporated by reference to page 21 of the Annual Report.

ITEM 8. FINANCIAL STATEMENTS AND

SUPPLEMENTARY DATA

The information required by this item is incorporated by reference to pages 23 through 35 of the Annual Report.

ITEM 9. CHANGES IN AND DISAGREEMENTS

WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not Applicable.

PART III

In accordance with General Instruction G(3), and except for certain of the information called for by Item 12 which is set forth below, the information called for by Part III (Items 10 through 13) is incorporated by reference from Forest's definitive proxy statement to be filed pursuant to Regulation 14A promulgated under the Securities Exchange Act of 1934 in connection with Forest's 2002 Annual Meeting of Shareholders.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following sets forth certain information as of March 31, 2002 with respect to compensation plans of the Company under which securities of the Company may be issued:

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in first column)

Equity compensation plans approved by security holders	16,335,867	$36.35	5,726,022
Equity compensation plans not approved by security holders	-0-	-0-	-0-
Total	16,335,867	$36.35	5,726,022

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(a) 1. Financial statements. The following consolidated financial statements of Forest Laboratories, Inc. and Subsidiaries included in the Annual Report are incorporated by reference herein in Item 8:

Report of Independent Certified Public Accountants

Consolidated balance sheets -
March 31, 2002 and 2001

Consolidated statements of income -
years ended March 31, 2002, 2001 and 2000

Consolidated statements of comprehensive income -
years ended March 31, 2002, 2001 and 2000

Consolidated statements of shareholders' equity -
years ended March 31, 2002, 2001 and 2000

Consolidated statements of cash flows - years ended March 31, 2002, 2001 and 2000

Notes to consolidated financial statements

2. Financial statement schedules. The following consolidated financial statement schedules of Forest Laboratories, Inc. and Subsidiaries are included herein:

All other schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are not required under the related instructions or are inapplicable, and therefore have been omitted.

3. Exhibits:

(3)(a) Articles of Incorporation of Forest, as amended. Incorporated by reference from the Current Report on Form 8-K dated March 9, 1981 filed by Forest, from Registration Statement on Form S-1 (Registration No. 2-97792) filed by Forest on May 16, 1985, from Forest's definitive proxy statement filed pursuant to Regulation 14A with respect to Forest's 1987, 1988 and 1993 Annual Meetings of Shareholders and from the Current Report on Form 8-K dated March 15, 1988.

(3)(b) By-laws of Forest. Incorporated by reference to Forest's Current Report on Form 8-K dated October 11, 1994.

(10) Material Contracts

10.1 Benefit Continuation Agreement dated as of December 1, 1989 between Forest and Howard Solomon. Incorporated by reference to Forest's Annual Report on Form 10-K for the fiscal year ended March 31, 1990 (the "1990 l0-K").

10.2 Benefit Continuation Agreement dated as of May 27, 1990 between Forest and Kenneth E. Goodman. Incorporated by reference to the 1990 10-K.

10.3 Benefit Continuation Agreement dated as of April 1, 1995 between Forest and Phillip M. Satow. Incorporated by reference to Forest's Annual Report on Form 10-K for the fiscal year ended March 31, 1995 (the "1995 10-K").

10.4

	Split Dollar Life Insurance Agreement dated March 29, 1994 between Forest and Howard Solomon. Incorporated by reference to Forest's Annual Report on Form 10-K for the fiscal year ended March 31, 1994 (the "1994 10-K").
10.5	Split Dollar Life Insurance Agreement dated March 29, 1994 between Forest and Phillip M. Satow. Incorporated by reference to the 1994 10-K.
10.6	Split Dollar Life Insurance Agreement dated March 29, 1994 between Forest and Kenneth E. Goodman. Incorporated by reference to the 1994 10-K.
10.7	Employment Agreement dated as of September 30, 1994 by and between Forest and Howard Solomon. Incorporated by reference to 1995 10-K.
10.8	Employment Agreement dated as of September 30, 1994 by and between Forest and Kenneth E. Goodman. Incorporated by reference to the 1995 10-K.
10.9	Employment Agreement dated as of October 24, 1995 by and between Forest and Dr. Lawrence S. Olanoff. Incorporated by reference to Forest's Annual Report on Form 10-K for the fiscal year ended March 31, 1996 (the "1996 10-K").
10.10	Employment Agreement dated June 24, 1998 between Forest and Elaine Hochberg. Incorporated by reference to Forest's Annual Report on Form 10-K for the fiscal year ended March 31, 1998 (the "1998 10-K").
10.11	Employment Agreement dated June 21, 1999 between Forest and John E. Eggers. Incorporated by reference to Forest's Annual Report on Form 10-K for the fiscal year ended March 31, 1999 (the "1999 10-K").
10.12	Employment Agreement dated January 16, 1995 between Forest and Mary Prehn. Incorporated by reference to the 1998 10-K.
10.13	Employment Agreement dated November 22, 2000 between Forest and Charles E. Triano. Incorporated by reference to Forest's Annual Report on Form 10-K for the fiscal year ended March 31, 2001.
10.14	License Agreement dated September 11, 1995 between Biovail Corporation International and Forest. Incorporated by reference to Exhibit No. (C)(2) to Schedule 14D-1 of Forest dated September 18, 1995.
10.15	License and Supply Agreement dated October 3, 1995 between Forest Laboratories (Ireland) Limited and H. Lundbeck A/S. Incorporated by reference to the 1999 10-K.
10.16	Co-Promotion Agreement dated December 10, 2001 by and between Sankyo Pharma Inc. and Forest Laboratories, Inc.
10.17	S-Enantiomer License Agreement dated May 29, 2002 by and between Forest Laboratories (Ireland) Limited and H. Lundbeck A/S.

10.18	S-Enantiomer Supply Agreement dated May 29, 2002 by and between Forest Laboratories (Ireland) Limited and H. Lundbeck A/S.
13	Portions of the Registrant's Annual Report to Stockholders.
22	List of Subsidiaries. Incorporated by reference to Exhibit 22 to the 1988 10-K.
23	Consent of BDO Seidman, LLP.

SIGNATURES

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, Forest has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: June 27, 2002

FOREST LABORATORIES, INC.

By: /s/Howard Solomon
Howard Solomon,
Chairman of the Board,
Chief Executive Officer
and Director

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of Forest and in the capacities and on the dates indicated.

PRINCIPAL EXECUTIVE OFFICERS:		
/s/ Howard Solomon Howard Solomon	Chairman of the Board, Chief Executive Officer and Director	June 27, 2002
/s/ Kenneth E. Goodman Kenneth E. Goodman	President, Chief Operating Officer and Director	June 27, 2002
PRINCIPLE FINANCIAL AND ACCOUNTING OFFICER:		
/s/ John E. Eggers John E. Eggers	Vice President - Finance and Chief Financial Officer	June 27, 2002
DIRECTORS:		
/s/ William J. Candee, III	Director	June 27, 2002

William J. Candee, III		
/s/ George S. Cohan	Director	June 27, 2002
George S. Cohan		
/s/ Dan L. Goldwasser	Director	June 27, 2002
Dan L. Goldwasser		
/s/ Lester B. Salans	Director	June 27, 2002
Lester B. Salans		
/s/ Phillip M. Satow	Director	June 27, 2002
Phillip M. Satow		

REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

Board of Directors and Shareholders
Forest Laboratories, Inc.

The audits referred to in our report dated April 19, 2002 relating to the consolidated financial statements of Forest Laboratories Inc. and Subsidiaries, which is referred to in Item 8 of this Form 10-K, include the audits of the accompanying financial statement schedule. This financial statement schedule is the responsibility of the Company's management. Our responsibility is to express an opinion of this financial statement schedule based on our audits.

In our opinion, such financial statement schedule presents fairly, in all material respects, the information set forth therein.

/s/ BDO Seidman, LLP
BDO Seidman, LLP

New York, New York
April 19, 2002

SCHEDULE
II

FOREST LABORATORIES, INC. AND SUBSIDIARIES

VALUATION AND QUALIFYING ACCOUNTS

Column A	Column B	Column C	Column D	Column E
Description	Balance at beginning of period	Additions	Deductions	Balance at end of period
Year ended March 31, 2002:				
Allowance for doubtful accounts	$11,123,000	$ 2,920,000	$ 402,000 (i)	$13,641,000
Allowance for cash discounts	8,665,000	47,870,000	43,069,000 (ii)	13,466,000
Inventory reserve	12,949,000	7,110,000	4,213,000 (i)	15,846,000
Year ended March 31, 2001:				
Allowance for doubtful accounts	$ 7,936,000	$ 3,623,000	$ 436,000 (i)	$11,123,000
Allowance for cash discounts	6,078,000	34,555,000	31,968,000 (ii)	8,665,000
Inventory reserve	14,001,000	2,145,000	3,197,000 (i)	12,949,000
Year ended March 31, 2000:				
Allowance for doubtful accounts	$10,314,000	$ 3,830,000	$ 6,208,000 (i)	$ 7,936,000
Allowance for cash discounts	6,380,000	22,996,000	23,298,000 (ii)	6,078,000
Inventory reserve	13,911,000	8,273,000	8,183,000 (i)	14,001,000

(i) Represents actual amounts written off.

(ii) Represents cash discounts given.

EXHIBIT 10.16

THIS AGREEMENT HAS CONFIDENTIAL
PORTIONS OMITTED, WHICH PORTIONS
HAVE BEEN FILED SEPARATELY WITH
THE SECURITIES AND EXCHANGE

COMMISSION. OMITTED PORTIONS ARE
INDICATED IN THIS AGREEMENT
WITH "[CONFIDENTIAL TREATMENT]."

CO-PROMOTION AGREEMENT

AGREEMENT dated this 10th day of December 2001 by and between **SANKYO PHARMA INC.**, a Delaware corporation having its principal executive offices at Two Hilton Court, Parsippany, New Jersey 07054 ("Sankyo"), and **FOREST LABORATORIES, INC**., a Delaware corporation having its principal executive offices at 909 Third Avenue, New York, New York 10022 ("Forest").

R E C I T A L S:

A. Sankyo manufactures and markets pharmaceutical products. Sankyo has filed a New Drug Application (the "NDA") for a pharmaceutical product (as more fully defined herein, the "Product") generically known as olmesartan medoxomil, which NDA is currently pending before the United States Food and Drug Administration ("FDA").

B. Forest manufactures and markets pharmaceutical products. Following approval of the NDA by the FDA, Forest desires to co-promote the Product with Sankyo in the United States and Sankyo desires to enhance the launch and marketing of the Product in the United States through the participation of Forest, all in accordance with the terms and conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the foregoing and of the mutual covenants herein contained, the parties hereto intending to be legally bound hereby agree as follows:

1. Definitions.

As used herein, the following terms shall have the respective meanings set forth below:

1.1 "Affiliate" shall mean a person controlling, controlled by or under common control with the person or entity as to which such status is in question. As used herein, the term "control" means direct or indirect ownership of fifty percent (50%) or more of the voting stock, or other voting interest, of a corporation, partnership or other business organization, or the possession of the power to direct the management and policies of a person, corporation, partnership or other business organization.

1.2 "Commencement Date" shall mean the first day of the first calendar quarter in which Detailing of the Product begins; provided, however, that if such Detailing does not commence before the 15th calendar day of the second month of such quarter, then the Commencement Date shall mean the first day of the calendar quarter immediately succeeding such month.

1.3 "Contract Year" shall mean, with respect to the first Contract Year, the 12 month period commencing on the Commencement Date and, with respect to subsequent Contract Years, each successive 12 month period thereafter.

1.4 "Co-Promotion Fee" and **"Residual Fee"** shall have the meanings assigned to them in Sections 3.2.1 and 8.1, respectively.

1.5 "Co-Promotion Period" shall mean the period beginning on the Commencement Date and ending on the last day of the sixth Contract Year, unless sooner terminated in accordance with the terms of this Agreement. Each Contract Year during the Co-Promotion Period is referred to herein as a "Co-Promotion Year."

1.6 **"Cost of Goods"** for any period shall mean **[Confidential Treatment]** of Net Revenues for such period.

1.7 **"Details"** shall mean in-person sales presentations of the Product made by a party's sales representatives to physicians and to other healthcare professionals legally entitled to prescribe the Product, all of whom shall meet criteria as to type specified in the Marketing Plan. Details shall be deemed to include only presentations of first or second position in a sales presentation and shall not be deemed to include tertiary or "reminder" details, in each case as such terms are generally understood in the pharmaceutical industry.

1.8 **"Detail Reports"** and **"Promotional Amount Reports"** shall have the meanings assigned to them in Sections 3.1.1 and 3.1.2, respectively.

1.9 **"Distribution Costs"** for any period shall mean **[Confidential Treatment]** of Net Revenues.

1.10 **"Fair Market Value"** shall mean the price which a willing buyer would pay, on an arm's length basis, for Forest's rights under this Agreement at the time such value is to be determined, as determined based upon objective data possessed and disclosed by both parties hereto.

1.11 **"Forest Percentage"** shall be **[Confidential Treatment]**; provided that with respect to Contract Years during the Co-Promotion Period following the end of the second Contract Year, the Forest Percentage shall be subject to adjustment as set forth in Section 3.2.4. The Forest Percentage during the Residual Period shall be **[Confidential Treatment]**.

1.12 **"Governmental or Regulatory Authority"** shall mean any court, tribunal, arbitrator, authority, agency, commission, official or other instrumentality of the United States of America, including its territories and possessions, any foreign county or any domestic or foreign state, county, city or other political subdivision.

1.13 **"Marketing Plan"** shall refer to each marketing plan for the Product developed pursuant to Section 2.5 hereof.

1.14 **"Net Revenues"** for any period shall mean the gross invoiced amount of sales of the Product by Sankyo, its Affiliates or licensees to third parties in the Territory for such period (but not including sales between Sankyo and its Affiliates) less amounts actually allowed as trade credits, discounts, rebates (including chargeback rebates), returns (including transportation, freight, insurance charges, customs or excise duties, sales tax and other taxes (except income tax) or duties related to such returns) or rejections of Product, or other allowances or discounts actually given with respect to such sales, including, without limitation, those granted on account of price adjustments, billing errors, bad debt, fees, reimbursements or similar payments granted or given to wholesalers or other distributors, buying groups, health care insurance carriers or other institutions, rebates, or charges required to be paid in connection with such sales to any Governmental or Regulatory Authority including, without limitation, by the Prescription Drug Rebate and Improved Access to Medicines requirements of the Omnibus Budget Reconciliation Act of 1990 and comparable federal or state requirements now or hereafter in effect, all as recorded in accordance with generally accepted accounting principles and in a manner consistent with Sankyo's revenue recognition policies from the sale of pharmaceutical products generally. Net Revenues shall also be reduced by the out-of-pocket costs of transportation and freight charges, and customer refunds related to Product recalls. Net Revenues for the first Quarter shall be deemed to include all sales of the Product by Sankyo prior to the Commencement Date (other than sales to Sankyo's Affiliates) net of all trade credits, discounts, rebates, returns, rejections and other allowances and discounts applicable to such sales as set forth in this definition.

1.15 **"Phase IV Study"** shall mean a clinical study of the Product not undertaken for inclusion in the NDA submission.

1.16 "**Product**" shall mean finished pharmaceutically formulated products containing (5-Methyl-2-oxo-1,3-dioxolen-4-yl)methyl 4-(1-hydroxy-1-methylethyl)-2-propyl-1-[[2`-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl] imidazole-5-carboxylate, known generically as olmesartan medoxomil. In addition, "Product" shall include finished pharmaceutically formulated products that are combinations of olmesartan medoxomil and hydrochlorothiazide (sometimes referred to hereinafter separately as a "Combination Product"). "Products" and "Combination Products" shall not include ophthalmic formulations. Sankyo shall provide Forest with notice of its intention to develop and market in the Territory any product(s) which are i) salts or metabolites of olmesartan medoxomil or ii) combinations of olmesartan and any other active ingredient. Sankyo will negotiate in good faith the terms and conditions for co-promotion of such product(s) in the Territory by Forest if Forest requests such co-promotion and in the case of ii) above, such other active ingredient is not subject to an exclusive marketing agreement between Sankyo and a third party. The marketing of any such other products in the Territory shall be subject to the provisions of Section 9.1.

1.17 "**Product Profit**" with respect to a period shall refer to Net Revenues for such period less the sum of (i) Cost of Goods, (ii) Distribution Costs and (iii) Promotional Amount, in each case as applicable to the period for which Product Profit is to be determined. In the event Product Profit with respect to a period is a negative amount (a "Loss"), the amount of such Loss shall be subtracted from determinations of Product Profit in subsequent periods until so fully applied, provided that any remaining balance of such Loss carryover will be repaid by Forest at the end of the Residual Period. Forest shall not be required to pay any portion of a Loss following the withdrawal of the Product by Sankyo from marketing in the Territory, whether voluntarily or pursuant to applicable regulatory or legal order or decision.

1.18 "**Promotional Amount**" for any period shall mean all out-of-pocket costs and expenses incurred (i.e., paid to third parties or accrued therefore) by Sankyo or by Forest (and required to be reimbursed by Sankyo to Forest pursuant to Section 3.2.5) and expressly contemplated by the Marketing Plan with respect to the advertising and promotion of the Product for such period, including, without limitation, costs for advertisements, agency fees, launch salesforce meetings, other meetings scheduled solely for the Product (but not periodic salesforce meetings of a party, which shall remain the sole responsibility of such party), promotional meetings, conventions and seminars, market research, sponsorships, grants including funding of continuing medical education programs which are relevant to the therapeutic area of the Product, and other payments for programs to institutional and managed care purchasers (except to the extent the same are calculated as deductions in the definition of Net Revenues), acquisition and shipping costs of promotional and training materials and the cost of field aids and sales premiums and other tokens, whether distributed by Sankyo or Forest. "Promotional Amount" shall also include costs for samples distributed in each Quarter calculated per unit of samples distributed as (a) **[Confidential Treatment]** of the quotient of (i) Net Revenues in such Quarter over (ii) the total number tablets of Product sold in such Quarter plus, (b) the actual charges for sample packaging. "Promotional Amount" will also include Sankyo's or Forest's direct costs for production of direct mail pieces and the printing of promotional materials, including labor and material (but excluding all manufacturing and other overheads and with such costs not to exceed the price that would be charged by a non-Affiliate party in an arms-length transaction for the same items or by the other party). The Promotional Amount for the first Quarter shall also include all such costs incurred after April 1, 2001 but prior to the Commencement Date. The Promotional Amount shall also include the out of pocket costs (i.e. amounts paid to third parties and not including any allocations of internal costs or overheads) of Phase IV Studies undertaken in accordance with this Agreement but not including studies set forth on Schedule 2.4 (the cost of the latter such Phase IV Studies to be the sole responsibility of Sankyo). Any costs referred to herein that are for the benefit of the Product and one or more other products of a party hereto shall be reasonably apportioned as determined by mutual written agreement of the parties.

1.19 "**Quarter**" shall mean each calendar Quarter during a Contract Year or Residual Year and shall be deemed to include any stub period in a Contract Year or Residual Year, such that the final Quarter shall end on the expiration or termination of this Agreement.

1.20 **"Residual Percentage"** shall mean, subject to the further provisions hereof, (i) **[Confidential Treatment]** with respect to the first Residual Year, (ii) **[Confidential Treatment]** with respect to the second Residual Year, (iii) **[Confidential Treatment]** with respect to the third Residual Year and, (iv) **[Confidential Treatment]** with respect to the fourth and each subsequent Residual Year.

1.21 **"Residual Year"** shall refer, subject to the further provisions hereof, to each of the consecutive 12 month periods commencing with the first day following the expiration of the sixth Contract Year and "Residual Period" shall refer to the period beginning on the first day of the first Residual Year and ending on the sooner of the day that a third party has lawfully commenced the sale of a generic equivalent to the Product in the Territory or on April 30, 2014, unless sooner terminated in accordance herewith.

1.22 **"Territory"** shall mean the United States of America and Puerto Rico, and to the extent Sankyo is granted these rights, other territories and possessions of the United States of America.

1.23 **"Valuation Expert"** shall mean an independent third party having expertise and experience in the valuation of pharmaceutical products for human use appointed by mutual agreement of the parties. In the event the parties are required by the terms hereof to select a Valuation Expert and are unable to do so after 30 days of good faith negotiations, each party will choose one such expert and such experts shall choose a third, who shall serve as a Chairperson. A valuation determination by a majority of such three experts shall be deemed the opinion of a Valuation Expert for purposes hereof.

1.24 **"Weighted Details"** for a party during any period shall mean the number of Details performed by such party during such period, with each Detail of first position weighted as one Detail and each Detail of second position weighted as half of a Detail.

2. Completion of Development; Co-Promotion of the Product.

2.1 **Continued Development.** Sankyo will use commercially reasonable efforts to continue development and regulatory approval activities in the Territory with respect to the Product. Sankyo will keep Forest informed as to the regulatory status of the Product and all developments related thereto. Without limiting the generality of the foregoing, Sankyo will consult with Forest during labeling, package insert and launch Promotional Materials discussions with FDA and allow representatives of Forest to attend such discussions. In addition, Forest will have access, with the right to copy, the NDA and all regulatory files, submissions and correspondence with respect thereto, except for Sankyo`s confidential information concerning the manufacturing methods of the Product.

2.2 **Development of Combination Product.** Sankyo shall continue to use commercially reasonable efforts to develop and obtain FDA approval for the marketing of the Combination Product for the treatment of hypertension. Sankyo will keep Forest informed of the development plan for the Combination Product, the status of all development activities and material developments during the development process. Forest shall be granted a reasonable opportunity to review drafts of the NDA submission for the Combination Product and the final NDA prior to FDA submission.

2.3 **Co-Promotion.** Sankyo and Forest hereby agree to co-promote the Product effective as of the Commencement Date, subject to the terms and conditions hereof.

2.4 **Marketing Committee; Regulatory Affairs.** Sankyo and Forest shall form a Marketing Committee promptly following the date hereof and during the Co-Promotion Period, which shall be composed of an equal number of representatives from each party. The Marketing Committee shall meet from time to time as determined by the participants, but no less than once prior to the Commencement Date and two times during each Co-Promotion Year. Subject to the terms and conditions hereof, the Marketing Committee shall determine all aspects of the marketing of the Product, including (subject to the following provisions of this Section), without limitation, the

determination of Phase IV Study programs. A schedule of the initial Phase IV Study program agreed upon by the parties is annexed hereto as Schedule 2.4. Sankyo agrees to use commercially reasonable efforts to perform each of the studies identified on Schedule 2.4 and will keep Forest informed of the progress of all material developments arising from or affecting such studies. Forest will have access, upon request, to all study records and documentation relating to such Phase IV Studies and the right to participate, together with representatives of Sankyo, in discussions or interviews of investigators participating in such studies. Additionally, the Marketing Committee will direct efforts to develop and implement strategies of institutional, governmental and managed care marketing. A representative of Sankyo shall serve as the Chairperson of the Marketing Committee. In the event the Marketing Committee cannot reach agreement on any issue, the parties agree that the issue shall be referred to the senior marketing executive of each party for resolution. In the event such executives do not reach agreement within 45 days of such referral, Sankyo shall retain the ultimate decision-making authority; provided, however, that during the Co-Promotion Period the consent of Forest will be required to (i) increase the number of Details required to be performed by Forest, or materially change any criteria regarding the physicians to be called on by Forest, from such number of Details or types of physicians, as the case may be, applicable to Forest during the second Co-Promotion Year, (ii) increase the Promotional Amount (excluding all prelaunch, launch meeting and Phase IV Study amounts) during the first or second Co-Promotion Years to more than **[Confidential Treatment]** and **[Confidential Treatment]**, respectively, (iii) increase the Promotional Amount for the period from April 1, 2001 through the Commencement Date to more than **[Confidential Treatment]**, (iv) approve the inclusion of any Phase IV Study amounts in the Promotional Amount or (v) in the third Co-Promotion Year and, thereafter, establish Promotional Amounts or Detailing efforts at levels which exceed those applicable to the second Co-Promotion Year or otherwise do not correspond to customary industry levels in light of all available objective evidence possessed by either party with respect to the market potential for the Product at such time. In the case where Sankyo desires to conduct a Phase IV Study, and Forest does not agree to include the costs of such study in the Promotional Amount per section (iii) above, the parties agree to the following approach for potential reimbursement of such study costs. Sankyo and Forest will determine specific marketing and/or scientific criteria for study success. If the study is conducted, and meets these criteria, Forest will retroactively pay Sankyo 130% of its share of the study costs. No party shall be required to undertake any activity under this Agreement that it believes, in good faith, may (i) violate any applicable laws or regulations or (ii) establish an ethical problem based on medical or scientific properties of the Product. Each party shall bear its own costs associated with its participation in the Marketing Committee or any other committee jointly formed by the parties under this Agreement. Changes in the Product or in its label or labeling, other than those necessitated by regulatory concerns or new indications, or any significant development, planned or implemented studies, and improvements, that may significantly affect the marketing of the Product in the Territory, shall not be implemented during the Co-Promotion Period without the consent of both parties. Changes in advertising or Promotional Materials shall be determined by the Marketing Committee. Neither party may utilize, publish or disseminate any Promotional Materials that have not been approved by the Marketing Committee or a subcommittee thereof and by Sankyo's Advertising Review Committee, pursuant to section 2.7.

2.5 Marketing Plan.

2.5.1 Marketing Plan. Prior to the commencement of each Co-Promotion Year, the Marketing Committee will develop and finalize a Marketing Plan, including a sales forecast for the upcoming year. Unless otherwise mutually agreed in writing by each of Forest and Sankyo, the Marketing Plans shall specify that i) for the first and second Co-Promotion Years the parties will each perform **[Confidential Treatment]** Weighted Details, of which at least **[Confidential Treatment]** and **[Confidential Treatment]** shall be of first position in the first and second Co-Promotion Years, respectively and ii) for the first two Co-Promotion Years, at least 50% of first position details will be delivered to **[Confidential Treatment]** prescribers.

To the extent either party actually performs more than 50% of the Weighted Details ("Additional Details") in either of the first or second Co-Promotion Years (but only to the extent such Additional Details, together with the Details performed by both parties, do not exceed the total maximum Weighted Details agreed upon by the parties to be performed for either such Co-Promotion Year), the party performing less than 50% of

such Weighted Details shall pay the party performing such Additional Details an amount equal to **[Confidential Treatment]** for each Additional Weighted Detail.

In addition, the Marketing Plan for each Co-Promotion Year shall specify the number of Details to be performed by each party's hospital sales force in hospital settings ("Hospital Details"). To the extent either party performs more than 50% of the Hospital Details provided by a Marketing Plan for the first or second Co-Promotion Years (but only to the extent such Additional Details, together with the Details performed by both parties, do not exceed the total maximum Weighted Hospital Details agreed upon by the parties to be performed for either such Co-Promotion Year), the other party shall reimburse such party's actual direct costs of performing each such additional Hospital Details (with such costs subject to reasonable allocation among all products which are the subject of such Hospital Detail). Hospital Details delivered during the first or second Co-Promotion Years are not to be included in the aggregate Weighted Detail calculations discussed elsewhere in this Agreement. Following the end of the second Co-Promotion Year, Hospital Details shall be included in these calculations; provided that Hospital Details shall not be included to the extent they exceed **[Confidential Treatment]** of a party's Weighted Details.

With respect to the Marketing Plan for the third and each subsequent Co-Promotion Year, each Marketing Plan shall provide that each party shall perform 50% of the aggregate Weighted Details.

2.5.2 **Additional Promotional Efforts.** Neither party shall be prohibited from engaging in promotional activities (including Detailing, advertising and, in the case of Sankyo, the conduct of Phase IV Studies) which exceed the levels for such promotional activities required by the terms of this Agreement or any Marketing Plan, provided that unless the other party agrees to amend the Marketing Plan to so include such activities, such activities shall be undertaken at the sole expense of the party seeking to undertake them and will not be taken into account for purposes of this Agreement. Additional promotional activities shall be consistent in all material respects with the terms and obligations of the then current Marketing Plan, and the design of any programs or materials associated with such additional promotional activities, including any and all items defined as labeling or advertising in Section 201(m) of the FD&C Act or 21 C.F.R. Section 202.1(1)(1) and (2) and other applicable Acts (as such sections may be amended from time to time), are subject to the approval of the Marketing Committee.

2.5.3 **Salesforces.** Each party agrees to market the Product in accordance with the terms of the Marketing Plan during the Co-Promotion Period. Each of Forest and Sankyo will train its salesforces to market the Product pursuant to a training program developed by Sankyo with Forest's participation. During the first and second Co-Promotion Years sales representative and manager target incentive compensation payable by either party to the sales personnel performing promotion of the Product, will be a substantial portion of the incentive compensation payable, taking into account the total number of Details, and the position of such Details, required to be performed.

2.5.4 **Managed Care.** During the Co-Promotion Period, Forest and Sankyo will mutually agree from time to time on sales and marketing activities to be directed to governmental, institutional, long-term care and managed care entities, subject to approval by the Marketing Committee. Such activities will include efforts to gain access to formularies and to optimize utilization of the Product, and shall in all material respects conform to industry standards for products of the same commercial and medical potential as the Product. Forest agrees that it shall use commercially reasonable efforts to cooperate with Sankyo to assure that such levels of activity are achieved during the Co-Promotion Period. All contracts, if any, with governmental, institutional or managed care entities relating to the Product will be entered into by Sankyo. The conduct of the foregoing activities shall be subject to procedures developed by the Marketing Committee based upon the input of both parties. To the extent the Marketing Plan provides for, or the parties agree upon in writing, materially disproportionate marketing activities in such areas, the party providing the greater level of marketing activity shall be entitled to be reimbursed 50% of its direct costs for the additional activities by the other party.

2.5.5 **Expiration of Co-Promotion Period.** Forest shall not be required or authorized to perform Details or other marketing activities with respect to the Product following the expiration of the Co-Promotion

Period.

2.5.6 Regulatory and Other Information. During the Co-Promotion Period, Sankyo will (i) provide Forest with copies of all submissions to the FDA related to manufacture or sale of the Product (other than ministerial submissions which do not involve safety or efficacy issues) and (ii) notify Forest promptly (and in any event within 2 business days) of its receipt of information from the FDA, other Governmental or Regulatory Authority, that (a) raises any material concerns regarding the safety or efficacy of the Product or wou