

FOREST LABORATORIES INC  
Form 10-K  
June 27, 2002

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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FORM 10-K

(Mark one)

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:

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<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
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  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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TABLE OF CONTENTS  
(Quick Links)

PART I

ITEM 1. BUSINESS

ITEM 2. PROPERTIES

ITEM 3. LEGAL PROCEEDINGS

PART II

PART III

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

AND REPORTS ON FORM 8-K

S-1 REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

S-2 VALUATION AND QUALIFYING ACCOUNTS

EXHIBIT 10.16 CO-PROMOTION AGREEMENT WITH SANKYO PHARMA INC.

EXHIBIT 10.17 S-ENANTIOMER LICENSE AGREEMENT WITH H.LUNDBECK A/S

EXHIBIT 10.18 S-ENANTIOMER SUPPLY AGREEMENT WITH H.LUNDBECK A/S

EXHIBIT 13:

QUARTERLY STOCK MARKET PRICES

SELECTED FINANCIAL DATA

CONDENSED CONSOLIDATED FINANCIAL STATEMENTS:

REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

BALANCE SHEETS

STATEMENTS OF INCOME

STATEMENTS OF COMPREHENSIVE INCOME

STATEMENTS OF SHAREHOLDERS' EQUITY

STATEMENTS OF CASH FLOW

NOTES TO FINANCIAL STATEMENTS

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL

CONDITION AND RESULTS OF OPERATIONS

EXHIBIT 23

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.

**Dexloiglumide:** 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 dexloiglumide 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. Dexloiglumide 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 dexloiglumide 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 hydrofluoroalkane ("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 nitroglycerin 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.

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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:

Report of Independent Certified Public Accountants		S-1
Schedule II	Valuation and qualifying accounts	S-2

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 10-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

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- 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.



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- 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:

<u>/s/ Howard Solomon</u>	Chairman of the Board, Chief Executive Officer and Director	June 27, 2002
Howard Solomon		
<u>/s/ Kenneth E. Goodman</u>	President, Chief Operating Officer and Director	June 27, 2002
Kenneth E. Goodman		

PRINCIPLE FINANCIAL AND ACCOUNTING OFFICER:

<u>/s/ John E. Eggers</u>	Vice President - Finance and Chief Financial Officer	June 27, 2002
John E. Eggers		

DIRECTORS:

<u>/s/ William J. Candee, III</u>	Director	June 27, 2002
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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

S-1

SCHEDULE  
II

## FOREST LABORATORIES, INC. AND SUBSIDIARIES

## VALUATION AND QUALIFYING ACCOUNTS

<u>Column A</u>	<u>Column B</u>	<u>Column C</u>	<u>Column D</u>	<u>Column E</u>
<u>Description</u>	<u>Balance at beginning of period</u>	<u>Additions</u>	<u>Deductions</u>	<u>Balance at end of period</u>
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.

S-2

## 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").

RECITALS:

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 would affect Product labeling, (b) indicates a potential material liability for either party arising in connection with the Product, or (c) is reasonably likely to lead to a recall or market withdrawal of the Product. Information that shall be disclosed pursuant to this Section shall include, but not be limited to:

- (1) Action of any Governmental or Regulatory Authority relating to:
  - (i) inspections of manufacturing, distribution or other related facilities;
  - (ii) inquiries concerning clinical investigation activities (including inquiries of investigators, clinical monitoring organizations and other related parties); and
  - (iii) any communication specifically involving the manufacture, sale, promotion, distribution of the Product or any other material reviews or inquiries relating to the Product;
- (2) receipt of a "Warning Letter" relating to the Product from the FDA; and
- (3) an initiation of any Governmental or Regulatory Authority investigation, detention, seizure or injunction concerning the Product.

**2.6 Product Management; Trademark.** Sankyo shall have sole responsibility for the distribution, sale and invoicing of the Product. All orders for the Product shall be subject to acceptance by Sankyo. Sankyo shall have sole discretion to make pricing and discounting decisions with respect to the Product; provided that material pricing and discount strategies will be reviewed and discussed by the Marketing Committee and Sankyo will provide Forest fifteen (15) days notice prior to implementing any material changes to such prices or discounts. Subject to Forest 's rights to perform co-promotion activities in accordance herewith, Sankyo shall have the sole rights in the Territory to use the trademark in connection with the marketing of the Product.

**2.7 Promotional Materials.** All advertising, promotional, educational, training and communication materials for marketing, advertising and promotion of the Product for distribution to independent third parties (including medical professionals) and to Sankyo 's and Forest 's respective sales forces (the "Promotional Materials"), shall be subject to the review and approval by Sankyo 's Advertising Review Committee (ARC). Forest shall have the right to have representation on the ARC during the Co-Promotion Period. In the event that Sankyo 's and Forest 's representatives on the ARC cannot reach agreement on any issue, the parties agree that the issue shall be referred to the senior marketing executives 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. Notwithstanding the foregoing, neither party will use Promotional Materials or make promotional claims as to which the other party has objected in good faith on the ground that such materials or claims violate applicable laws or regulations. Sankyo shall provide Forest, on a timely basis, with sales and Promotional Materials (including samples and stock bottles of the Product) in quantity and quality reasonably sufficient to allow Forest to make sales calls in accordance with the Marketing Plan then in effect and proportionate to the percentage of Details to be undertaken by Forest. Furthermore, the Marketing Plan will state that Sankyo 's and Forest 's salesforces will be provided funds for "Sales Promotion Expenses" in the same proportion as the number of Weighted Details to be undertaken by such salesforces. Allocation of sales and Promotional Materials, and Sales Promotional Expenses, shall be reviewed Quarterly and adjusted to reflect the relative actual Weighted Details performed by each party. Such "Sales Promotion

Expenses" are included as "Promotional Amounts" hereunder. The parties agree that, as soon as practical and subject to regulatory approval, Sankyo and Forest shall be given equal exposure and prominence on all Product advertisements and Promotional Materials (including display packaging for samples) used or distributed in connection with the Product under this Agreement beginning on the date hereof and through the Co-Promotion Period. Sankyo will utilize Forest logos and trademarks approved by Forest, under conditions reasonably required by Forest, and will cease all use thereof as soon as practicable following termination of the Co-Promotion Period, and in any event shall cease such use within 6 (six) months of such termination. Sankyo shall promptly remove all Forest logos and trademarks from any item in the event of Forest' objection to their use thereon. Neither Forest nor Sankyo shall make claims or statements with respect to the Product unless such claims or statements are strictly consistent with sales and Promotional Materials being used pursuant to a Marketing Plan. Forest shall be responsible for accounting for samples distributed by the Forest salesforces and shall maintain all records with respect to sample distribution by its salesforces as required by applicable laws and regulations. Within 45 days after the end of each calendar month, Forest shall provide to Sankyo a written report summarizing samples distributed by the Forest salesforce for such calendar month. In addition, Forest shall ensure, through appropriate routine monitoring and auditing standards which conform with current good industry practices, that sampling of the Product is carried out by Forest in a manner which is compliant with all applicable laws and regulations. Forest shall immediately advise Sankyo of its discovery of any act or omission of Forest that could violate or require reporting under applicable law. Sankyo shall be solely responsible for the filing of any necessary reports to FDA in connection with sampling. Within thirty (30) days after the expiration or termination of the Co-Promotion Period, Forest shall return, or otherwise dispose of in accordance with written instructions from Sankyo, all remaining samples and will provide Sankyo with a certified statement that all remaining samples have been returned or otherwise properly disposed of in accordance with Sankyo 's instructions and that Forest is no longer in possession or control of any samples in any form or fashion.

**2.8 Training Materials.** Sankyo shall provide Forest with training materials sufficient in quantity and quality to allow Forest to train its salesforce for detailing the Product consistent with the applicable Marketing Plan. Sankyo will, where practicable, permit Forest sales representatives to participate in training sessions of the Sankyo salesforce with respect to the Product and will provide reasonable advance notice to Forest of scheduled training events. Without limiting the generality of the foregoing, the Forest salesforces will participate in the initial Product launch meeting. Each party will have at least 75% of their sales force representatives intended to promote Product during the first Co-Promotion Year at such initial Product launch meeting and such launch meeting shall occur no sooner than two months following FDA approval of the NDA and no sooner than FDA approval of launch Promotional Materials, unless agreed by Forest and Sankyo. Forest 's documented out-of-pocket costs and expenses (excluding labor costs) incurred in connection therewith will either be, at the option of Sankyo, borne by Sankyo as a "Promotional Amount", or will be borne by Forest and reimbursed to it pursuant to Section 3.2.5.

**2.9 Adverse Experience Reporting.** For purposes of this Article 2.9, Adverse Drug Experiences ("ADE 's") shall mean any adverse medical occurrence in a patient to whom the Product has been administered and which does not necessarily have to have a causal relationship with the treatment (as defined by 21 C.F.R. 312.32, 314.80 and any other applicable definitions in regulations promulgated by the FDA or ICH) which require reporting by Sankyo to the FDA or other international regulatory agencies. Forest shall report all suspected ADE 's to Sankyo 's Drug Safety and Surveillance Department or its designee, via telephone at 1-877-4SANKYO (1-877-472-6596), as soon as possible within two calendar days of receipt of such information by any employee or subcontractor of Forest. If requested, Forest will make reasonable efforts to assist Sankyo, or its designee, in obtaining ADE follow-up information from reporters initially identified by Forest. As owner of the NDA, Sankyo shall retain responsibility for all FDA reporting requirements, and Forest shall have no responsibility to report any ADE to the FDA. Sankyo will copy Forest on U.S. Periodic Reports, expedited reports and Periodic Safety Update Reports, within 3 business days of their submission to the appropriate agency.

**2.10 Recalls or Other Corrective Action.** Sankyo shall have sole responsibility and shall make all decisions in its sole discretion with respect to any recall, market withdrawals or any other corrective action related to the Product including the right to cease all sales of Product in the Territory or the promotion and detailing of the

Product in the Territory. Sankyo shall promptly notify Forest of all recalls and all other decisions or notifications (including, without limitation, notifications to or from the FDA) relating to market withdrawals or other such corrective action. At Sankyo 's request, Forest shall use commercially reasonable efforts to assist Sankyo in conducting such recall, market withdrawal or other corrective action, and any documented out-of-pocket costs incurred by Forest with respect to participating in such recall, market withdrawal or other corrective action shall be reimbursed by Sankyo. Forest shall have the right, upon reasonable advance notice, at Forest 's own cost, and not more than once per Contract Year, to inspect facilities, during normal business hours, where Product is manufactured, stored, tested or shipped, and to verify compliance with all applicable legal and regulatory standards so long as such inspection and verification does not unreasonably interfere with such operations.

**2.11 Supply.** Sankyo shall use commercially reasonable efforts to supply Product (both for trade purposes and samples) during the term of this Agreement in sufficient quantities to meet forecasted amounts of demand set forth in the applicable Marketing Plan. Sankyo will, from time to time, at Forest 's written request, promptly inform Forest of all material problems relating to Sankyo 's inventory levels and ability to continue supply of the Product to meet forecasted amounts of demand set forth in the applicable Marketing Plan. Sankyo represents that as of the date of this Agreement, it is not aware of any facts that reasonably could call into question Sankyo 's ability to supply sufficient quantities of the Product (including samples) to meet forecasted amounts of demand set forth in the Marketing Plan.

**2.12 Failure of Supply.** In the event that for any reason (other than reasons such as labor disputes, governmental actions, acts of God and similar events commonly referred to as acts of *force majeure*) Sankyo shall be unable to supply on a timely basis at least eighty five percent (85%) of the volume of all ordered Product during a Quarter, and provided that such orders are not materially greater than the forecasted Product requirements included in the Marketing Plan for such Co-Promotion Year, then the Product prescription volumes will be analyzed. If the failure of Product supply is found to have resulted in lower prescription volumes for such Quarter (with due regard to the prescription volume trends and the promotional activities being conducted by both parties), then the Co-Promotion Fee payable by Sankyo to Forest for such Quarter, shall be increased to the amount of Co-Promotion Fee which Forest would reasonably have been expected to earn during such Quarter but for the failure of Product supply which resulted in lower prescription demand. In the event that Sankyo is unable to supply as described in this Section due to an event of force majeure, and if Sankyo collects damages or insurance proceeds in connection with such event, then such damages or insurance proceeds (less the costs of collection thereof, including attorneys ' fees) will be considered "Net Revenues" received during the time that Sankyo was unable to supply hereunder. From time to time, Sankyo will provide information relating to orders, inventory levels and backlog as reasonably requested by Forest.

**2.13 Contract and Other Salesforces.** During the Co-Promotion period, neither party will utilize the services of non-employee, contract salesforces without the consent of the other party hereto. The costs of any such contract salesforce will not be included as "Promotional Amounts" unless otherwise agreed by the parties hereto. Sankyo agrees that no third party other than Forest will be authorized to Detail or otherwise promote the Product during the Co-Promotion Period.

**2.14 Product Returns.** If any quantities of the Product are returned to Forest, Forest shall notify Sankyo in writing and ship them to the facility designated by Sankyo, with any reasonable or authorized shipping or other cost to be paid by Sankyo. Forest, at its option, may advise the customer who made the return that the Product has been returned to Sankyo, but shall take no other steps in respect of any such return without the written consent of Sankyo. The obligations contained in this Section shall survive the expiration or termination of this Agreement.

**2.15 Infringement.** Sankyo and Forest shall each advise the other in writing promptly upon its becoming aware of any infringement by a third party of the trademark utilized in marketing the Product or of any patent or copyright used in connection with the Product. Sankyo shall have sole discretion to decide what, if any, action should be taken in relation to such infringement. Forest shall cooperate as reasonably requested by Sankyo, at Sankyo 's expense, in any investigation or action taken by Sankyo in respect of such infringement. Any sums obtained

as a result of any such suit or proceeding, whether by judgment, award, decree or settlement, shall be the property of Sankyo and shall first be applied to reimburse Sankyo for its out-of-pocket costs incurred in connection therewith, and then shall be treated as Net Revenues during the period of such infringement.

**2.16 Orders and Distribution.** Sankyo will have the exclusive right and responsibility at its cost to (a) receive and fill orders for the Product, (b) warehouse and distribute the Product, (c) control invoicing, order processing and collection of accounts receivable for the Product, and (d) engage in all other activities relating to the ordering and distribution of Product.

**2.17 Medical Inquiries.** Sankyo shall be responsible at its cost for formulating responses and answering medical questions and inquiries from members of the medical and paramedical professions and consumers regarding the Product. Forest shall comply with the reasonable directions and policies established by Sankyo in connection therewith, including, but not limited to, that all requests for written responses to medical inquiries shall be routed to and answered by Sankyo. Forest shall be entitled in its discretion to have members of its Scientific and Medical Affairs Departments provide in-person, telephonic or written responses to unsolicited medical questions and inquiries from physicians and other healthcare professionals in a manner which complies with Sankyo's directions and policies.

**2.18 Product Complaints.** Forest shall refer all Product complaints (e.g., tampering, contamination, mix-up, discoloration, incorrect quantities) to Sankyo's Product call center promptly after notice thereof (but in any event within two business days), and except as specifically set forth in this Agreement, or as required by applicable laws, statute, rules, regulations, ordinances, orders, rulings or other pronouncements, investigations or proceedings of any Governmental or Regulatory Authority, Forest shall have no other obligations in respect thereof.

### **3. Reporting; Compensation to Forest; Accounting.**

#### **3.1 Reporting.**

**3.1.1 Detail Reporting.** Within 45 days after each month during a Co-Promotion Year, each party shall provide to the other a report summarizing Details by such party during such month. Such reports shall be based on internal call reporting data prepared and maintained in the ordinary course of business. In addition, within 45 days of the end of each Quarter, each party shall provide the other with a report, in form as specified by the Marketing Committee, which will contain specific information as to the types of physicians called on and frequency of Detailing. The reports required by this Section are referred to collectively as "Detail Reports."

**3.1.2 Promotional Amount Reporting.** Within 45 days after each Quarter during a Co-Promotion Year, each party shall provide to the other a report summarizing (i) in the case of Sankyo, Promotional Amounts incurred by Sankyo during the Quarter and (ii) in the case of Forest, costs that would be considered "Promotional Amounts" had they been incurred by Sankyo during the Quarter. Such reports shall be in a form specified by the Marketing Committee. Such reports required by this Section are referred to collectively as "Promotional Amount Reports."

#### **3.2 Compensation to Forest.**

**3.2.1 Co-Promotion Fee.** Subject to adjustment in accordance with subsection 3.2.4, Sankyo shall pay to Forest a fee (the "Co-Promotion Fee") for each Co-Promotion Year which shall equal the Forest Percentage multiplied by the Product Profit. Sankyo shall pay the Co-Promotion Fee Quarterly in accordance with subsection 3.2.2, subject to annual adjustment in accordance with subsection 3.2.3.

**3.2.2 Payment.** Within sixty (60) days of each Quarter during the Co-Promotion Period Sankyo shall pay Forest an amount equal to the Co-Promotion Fee earned by Forest for such Quarter unless Sankyo

shall provide to Forest a written notice of Sankyo 's objection to such Payment, in which case, Sankyo shall pay the undisputed portion of such Payment in accordance herewith.

**3.2.3 Annual Adjustment.** With respect to the payment of the Co-Promotion Fee for the fourth Quarter of a Co-Promotion Year, Sankyo shall calculate the actual Co-Promotion Fee payable for the entire such Co-Promotion Year and Sankyo shall make payment (or receive a credit), as appropriate, to adjust for any overpayment or underpayment of Co-Promotion Fee to Forest with respect to such completed Co-Promotion Year.

**3.2.4 Adjustments for Detail Deficiency.** In addition to any adjustment for a Co-Promotion Year required by the terms of subsection 3.2.3, in the event that in the third or any subsequent Co-Promotion Year, if either:

a) The total actual Weighted Details performed by both parties do not exceed the total Weighted Details provided by the Marketing Plan, as amended from time to time, (the "Plan Detail Amount") for such Co-Promotion Year and the total number of Weighted Details performed by either party is less than **[Confidential Treatment]** of the total actual Weighted Details for such Co-Promotion Year, then the Forest percentage shall be calculated by (i) dividing (x) the actual number of Weighted Details performed by Forest by (y) the total number of Weighted Details performed by both parties and (ii) reducing the resulting percentage by **[Confidential Treatment]**, or

b) The total actual Weighted Details performed by both parties exceed the Plan Detail Amount for such Co-Promotion Year and the Weighted Details performed by either party is less than 45% of the Plan Detail Amount for such Co-Promotion Year then the Forest percentage shall be calculated by (i) dividing (x) the actual number of Weighted Details performed by the party which is under plan by (y) the Plan Detail Amount and if the party which is under plan is Forest, reducing the resulting percentage by **[Confidential Treatment]** or if the party which is under plan is Sankyo, subtracting the resulting percentage from one and then reducing by **[Confidential Treatment]** (to obtain the Forest Percentage).

Sankyo shall be credited with or shall be obligated to pay, as the case may be, the amount by which the actual Co-Promotion Fee paid to Forest for such Co-Promotion Year varies from the Co-Promotion Fee for such Co-Promotion Year as determined pursuant to this sub-paragraph.

**3.2.5 Reimbursement of Promotional Amount.** Within sixty (60) days after the end of each Co-Promotion Quarter, Sankyo shall pay Forest an amount equal to the costs incurred by Forest during such Quarter that would be considered "Promotional Amounts" had they been incurred by Sankyo unless Sankyo provides to Forest a notice that it disputes such Promotional Amount Report, in which case, Sankyo shall pay the undisputed portion in accordance herewith. In addition, together with the reimbursement of Promotional Amount, the parties shall pay each other (by a payment by Sankyo or the issuance by Forest of a credit to Sankyo, as appropriate) any amounts due by either party to the other for the performance of Additional Details or Hospital Details during the first or second Co-Promotion Years as required by Section 2.5.1, or for Managed Care efforts as required by Section 2.5.4.

**3.2.6 Records.** Each party shall maintain accurate records relating to its obligations hereunder (including, without limitation, records relating to the performance of Details (including records of physicians called on, frequency of calls and other data which underlies the Detail Reports required by Section 3.1), the calculation of Product Profit and guidelines for incentive compensation programs in sufficient detail to permit review of compliance with the standards set forth herein) which shall be kept available for three years following the Co-Promotion Year or Residual Year to which such records relate unless a longer period is otherwise required by any laws, statutes, rules, regulations, ordinances or orders by any Governmental or Regulatory Authority. For such period, each party may audit the other party no more than once per Co-Promotion Year or Residual Year, solely for the purpose of verifying the information contained in any of the reports or statements provided by the other party pursuant hereto or to otherwise verify the calculation of any payment required to be made hereunder or compliance with any

other material obligation hereunder. Such audits are to be performed only by an independent firm to which the other party has no reasonable objection, which firm shall agree to maintain the confidentiality of the information reviewed and shall not disclose such information except to the extent reasonably necessary to assist the party engaging such firm in demonstrating compliance with material obligations which are the subject of the audit (including, without limitation, in connection with any legal proceeding brought in respect of any such obligations). In the event any such inspection or audit reflects underpayments or overpayments of more than 5%, the other party shall be responsible to pay the reasonable cost of such inspection or audit. Following such inspection or audit, the parties will rectify any such underpayment or overpayment. The provisions of this paragraph shall survive any termination of this Agreement.

#### **4. Milestone Payments.**

**4.1 Payment for Co-Promotion Rights.** In consideration for the rights granted to Forest hereby, Forest agrees to make the following payments ("Milestone Payments") to Sankyo:

**4.1.1 Agreement Signing. [Confidential Treatment]** within five business days following execution and delivery of this Agreement; and

**4.1.2 Product Approval. [Confidential Treatment]** within the later of (i) twenty five (25) days following FDA approval of the NDA, including FDA approval of Product labeling and package inserts or (ii) five business days following the date Sankyo has notified Forest that launch quantities of Product, as set forth in the Marketing Plan, are ready for shipment to customers. The payment shall be deferred until the satisfaction of the second condition (with such deferral not to be in limitation of Forest 's rights pursuant to Section 7.3.3); and

**4.1.3 Combination Product Approval. [Confidential Treatment]** within five business days following FDA approval of the NDA for the Combination Product, including FDA approval of Product labeling and package inserts.

#### **5. Compliance with Laws.**

Each party shall fully comply in all material respects with all applicable federal, state and local laws, rules, regulations or ordinances with respect to its obligations hereunder and shall obtain and maintain all licenses, permits, approvals and other authorizations applicable to it in order to enable it to perform its obligations hereunder.

#### **6. Representations.**

**6.1 Mutual Representations.** Each party represents and warrants to the other as follows:

**6.1.1 Existence and Authority.** It is a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation and has the corporate power and authority to execute, deliver and perform this Agreement. The execution of this Agreement and the consummation of the transactions contemplated hereby have been duly authorized by all necessary corporate action on its part and do not conflict with the terms or conditions of any contract, agreement, arrangement or understanding to which such party is subject.

**6.1.2 Enforceability.** This Agreement is a valid and binding obligation of said party, enforceable against it in accordance with its terms.

**6.1.3 Litigation.** There is no action, suit, proceeding or investigation pending or, to its knowledge, threatened before any court or administrative agency against said party which could, directly or indirectly, reasonably be expected to materially affect its ability to perform its obligations hereunder or the marketability of the Product.

**6.2 Sankyo 's Representations.** Sankyo hereby represents and warrants to Forest as follows:

**6.2.1 Product Specifications.** All sample Product delivered to Forest or distributed by or for Sankyo and Product manufactured, distributed or sold by or for Sankyo during the term hereof will comply in all material respects with the specifications for the Product set forth in the NDA; will comply in all material respects with all requirements of the FDA and other applicable laws, rules and regulations; will not be adulterated or misbranded under the United States Food, Drug and Cosmetic Act ("Act") and regulations issued thereunder or other applicable laws; and will have been manufactured in all material respects in accordance with current Good Manufacturing Practices as provided in the Act and its regulations. All Promotional Materials provided or distributed by Sankyo shall comply in all material respects with all applicable laws and regulations.

**6.2.2 Intellectual Property.** Sankyo owns or has licenses to all patents, know-how, trademarks, copyrights, trade secrets and all other intellectual property of any nature whatsoever (collectively, the "Intellectual Property Rights") required to supply, market, sell and distribute the Product in the Territory. Sankyo owns or has licenses to the Intellectual Property Rights free and clear of all liens, claims and encumbrances and free of all royalty or similar payment obligations to any third party, except such liens, claims, encumbrances and obligations as will not have a material adverse effect on Forest 's rights to co-promote the Product under this Agreement. To the knowledge of Sankyo, the supply, sale and use of the Product and distribution of any Promotional Materials provided by Sankyo hereunder or distributed by Sankyo during the Co-Promotion Period and the Residual Period will not infringe any patents, trademarks or other intellectual property rights of third parties. Sankyo does not, as of the date herewith, license any material Intellectual Property Rights from any third party other than Affiliates of Sankyo.

**6.2.3 Information Disclosure.** Sankyo has heretofore disclosed to Forest all material information known to Sankyo with respect to the safety and efficacy of the Product or human risk factors relating thereto.

**7. Term; Termination.**

**7.1 Term.** Unless otherwise terminated pursuant to the following subsections hereof, this Agreement shall remain in full force and effect through the Co-Promotion Period and the Residual Period and shall expire on the last day of the Residual Period. Expiration or termination of this Agreement shall not relieve either party of any obligation of payment or performance accrued prior to such expiration or termination.

**7.2 Termination.** This Agreement may be terminated by the non-defaulting party (as hereinafter defined), as follows:

(i) if the other party fails to perform or observe any material covenant or provision contained herein and such failure shall continue unremedied for a period of 90 days after the receipt of written notice thereof and, if such breach cannot be cured within such 90 day period, such party has not taken reasonable steps to commence and proceed diligently thereafter to cure such default and, in fact, does not cure such default within a reasonable period of time;

(ii) if any material representation or warranty made by the other party shall prove to be incorrect in any material respect at the time when made;

(iii) if the other party shall voluntarily enter into any form of bankruptcy or insolvency proceedings; or

(iv) if any form of bankruptcy or insolvency proceedings shall be brought involuntarily against the other party and such proceedings shall remain undismissed, unstayed or unvacated for a period of 90 consecutive days.



As used in this Section, the term "non-defaulting party" shall mean the party with respect to which no default or condition exists under this Section that would permit termination of the Agreement. Termination under this subsection shall be effective upon notice to the defaulting party and expiration of any applicable cure period without the cure of the event or cause giving rise to such notice of default within such cure period.

Notwithstanding the foregoing, termination pursuant to subsections (i) or (ii) above, if contested, shall not be deemed effective unless the existence or occurrence of the circumstance giving rise to such right of termination shall have been determined by the judgment of a court of competent jurisdiction (from which there is no right of appeal or as to which no appeal has been timely taken). In addition, such right of termination shall not apply unless monetary damages calculated in accordance with law would not be an adequate remedy for such breach or the party owing such damages was unable or unwilling to make full payment thereof.

### **7.3 Other Termination Rights.**

**7.3.1 Commencement of Detailing.** Forest shall have the right to terminate this Agreement effective upon 30 days prior written notice to Sankyo in the event the commencement of Detailing has not occurred by April 30, 2002. Such right shall expire if not exercised prior to the commencement of Detailing. In the event of termination by Forest pursuant to this subsection, Sankyo shall promptly refund to Forest the payment made pursuant to Section 4.1.1.

**7.3.2 Forest Termination Right.** Forest shall have the right to terminate the Co-Promotion Period at any time after the expiration of the third Co-Promotion Year, with termination to be effective as of the last day of the first Quarter which is at least six months following Forest 's written notice (which may be furnished prior to the expiration of the third Co-Promotion Year) of termination to Sankyo. In the event of termination by Forest, pursuant to this subsection, the Residual Period (for this purpose, each Contract Year thereof consisting of the period of four consecutive Quarters commencing with the first Quarter of the Residual Period as herein modified) shall commence as of the first day of the first Quarter following such termination. However, in the event of such termination, the Residual Period shall end on April 30, 2014, less twice the number of Quarters by which the Co-Promotion Period was reduced by reason of termination pursuant to this Section. In any event, such Residual Period shall end immediately upon the day that a third party has lawfully commenced the sale of a generic equivalent to the Product in the Territory.

**7.3.3 Package Insert.** Forest shall have the right to terminate this Agreement effective upon 30 days ' written notice to Sankyo in the event the Product 's package insert, as finally approved by the FDA, varies in Forest 's reasonable discretion, in any materially adverse way from the package insert filed with the NDA and previously made available to Forest. Forest may only exercise the right of termination granted by this Section by furnishing the notice described above no later than 20 days following FDA approval of the Product 's package insert. In the event of termination by Forest pursuant to this subsection, Forest 's sole remedy will be that Sankyo shall promptly refund to Forest all payments previously made by Forest pursuant to Section 4.1.

## **8. Residual Period Compensation.**

**8.1 Residual Fee.** Sankyo agrees to pay Forest a fee (the "Residual Fee") for each Residual Year in an amount to be determined by multiplying (i) the Residual Percentage for such Residual Year by (ii) the Product Profit for such Residual Year by (iii) the Forest Percentage applicable to the Residual Period.

**8.2 Quarterly Payments.** The Residual Fee shall be calculated and paid on a Quarterly basis 60 days after the end of each Quarter during the Residual Period. Quarterly payments shall be reconciled on an annual basis in accordance with the reconciliation procedures applicable to Co-Promotion Fees set forth in Section 3.2.3.

**8.3 Residual Period Diligence.** During the Residual Period, Sankyo agrees to use commercially reasonable efforts to market the Product in a commercially reasonable manner in light of competitive conditions in the relevant therapeutic categories, including marketing of the Product through other co-promotion partners or licensees.

**8.4 Residual Period Reports.** Together with each payment of Residual Fees, Sankyo shall furnish to Forest a statement which sets forth the calculation of the Residual Fee paid (including, without limitation, setting forth Net Revenues, Promotional Amount and Product Profit) with reasonable specificity.

**9. Exclusivity; Restriction on Hiring; Sale of Product Rights; Change of Control.**

**9.1 Exclusivity.** During the Co-Promotion Period, neither party shall market, promote, distribute or sell in the Territory any pharmaceutical product indicated for the treatment of hypertension and which contains an angiotensin receptor blocker, other than the Product pursuant to this Agreement, ("ARB") or an ACE inhibitor (a "Competitive Product"). Notwithstanding the preceding, Forest may market, promote, distribute and sell a Competitive Product in the Territory after the third Co-Promotion Year if (i) such Competitive Product is a combination product comprised of lercanidipine and an ARB or an ACE inhibitor or (ii) Forest has offered co-promotion rights in such Competitive Product to Sankyo on commercially reasonable terms and Sankyo has declined to copromote such product, provided that Forest may only market and promote any such Competitive Product through separate, dedicated sales forces (including sales representatives and management for primary care, specialty, hospital and managed care sales forces) and separate, dedicated marketing groups. Forest will use reasonable efforts to apply the confidentiality requirements of Section 13.3 to maintain confidentiality of information relating to Product from the above groups involved with sales and marketing of such Competitive Product. Notwithstanding the preceding, Sankyo may market, promote, distribute and sell a Competitive Product in the Territory after the third Co-Promotion Year if i) such Competitive Product is a combination product comprised of olmesartan and another active ingredient provided that if such other active ingredient is subject to an exclusive marketing agreement between Sankyo and a third party, Sankyo shall use commercially reasonable efforts to include Forest, on terms and conditions which consider as nearly as practicable the relative economic interests of Forest and Sankyo hereunder, in any such arrangements with third parties where a combination product including olmesartan is being contemplated at the time of negotiations with any such third party or, in the event no such arrangement is accomplished, Sankyo agrees to provide payments to Forest (for example, by means of a royalty) with respect to sales of such Competitive Product in an amount sufficient to compensate Forest for the loss of Co-Promotion Fee directly related to the sales of such Competitive Product or ii) Sankyo has offered co-promotion rights in such Competitive Product to Forest on commercially reasonable terms and Forest has declined to copromote such product, provided that Sankyo may only market and promote any such Competitive Product through separate, dedicated sales forces (including sales representatives and management for primary care, specialty, hospital and managed care sales forces) and separate, dedicated marketing groups.

The foregoing shall not be deemed to preclude the acquisition by either party of a company, business or assets which includes such a Competitive Product or the merger or other business combination with (or acquisition of a party by) another entity which markets such a pharmaceutical product, provided that such party (or the party surviving any merger or other business combination with a party hereto) publicly announces its intention to divest such Competitive Product contemporaneously with the announcement of the transaction and divests the portion of such business which would violate the prohibition set forth in the first sentence of this Section within 12 months following the consummation of such transaction; provided further that a breach of the obligations of this Section caused by a Change in Control shall not be deemed a breach of this Agreement but shall only give rise to the rights set forth in Section 9.3 . The provisions of this Section shall not be in limitation of either party ' s right to terminate the Co-Promotion Period pursuant to, and in accordance with the terms and conditions, of Section 9.3 or of Forest ' s right to terminate the Co-Promotion Period pursuant to Section 7.3.2.

**9.2 Restrictions on Hiring.** During the Co-Promotion Period and for a period of twelve months thereafter, neither party shall hire any sales representative, sales force manager or employee principally having

marketing responsibilities (including, without limitation, managed care, governmental and other institutional marketing personnel) employed by the other party or who had been employed by such other party within the previous six months. Isolated violations of this provision shall not be deemed a material breach of this Agreement for purposes of Section 7.2 hereof.

### **9.3 Sale or License of Product Rights; Change in Control.**

**9.3.1 Sale or License of Product Rights.** In the event Sankyo determines to sell or license the Intellectual Property Rights to any third party during the Co-Promotion Period or the Residual Period (other than to an Affiliate or indirectly by way of merger, reorganization or other comparable corporate transaction), Sankyo shall provide notice, including identification of the third party, to Forest and, upon Forest 's request furnished to Sankyo within 20 days of such notice, shall negotiate in good faith to sell or license such Intellectual Property Rights to Forest. In any such negotiation, due regard shall be given to Forest 's economic interest in the Intellectual Property Rights deriving from this Agreement. In the event Forest and Sankyo do not enter into a binding written agreement as to such purchase and sale or license following 90 days (the "Negotiation Period") of notice to Forest of such proposed sale or license, Sankyo shall be free to sell or license the Intellectual Property Rights to a third party provided that the purchase price and payment terms of such sale or license offered to such third party are no less favorable to Sankyo than the purchase or license price for the Intellectual Property Rights offered to Forest during the Negotiation Period. In the event no sale of the Intellectual Property Rights occurs within 12 months from the end of the Negotiation Period, Sankyo shall be required to again comply with the provisions of this Section prior to any subsequent sale of the Intellectual Property Rights. In addition to the foregoing, Sankyo shall not make any sale of the Intellectual Property Rights (either directly or indirectly by way of merger, reorganization or comparable corporate transaction) without adequately providing, to Forest 's reasonable satisfaction, for the assumption by the purchaser of all of Sankyo 's obligations of performance and payment required hereby.

**9.3.2 Definition of Change of Control.** For purposes of this Section 9.3, a "Change of Control" shall mean an event where: a) any Person(s), meaning any natural person(s), corporation(s), general partnership(s), limited partnership(s), joint venture(s), proprietorship(s) or other business organization(s), acquire beneficial ownership of capital stock of a party entitling the holder(s) thereof to at least fifty-one percent (51%) of the voting power of the then outstanding capital stock of such party with respect to the election of directors of such party, or b) a party enters into a merger, consolidation or similar transaction with another Person (the "Acquiring Corporation") in which (i) such party is not the surviving corporation in such transaction, (ii) the members of the Board of Directors of such party prior to such transaction constitute less than one half of the members of the Board of Directors of the Acquiring Corporation following such transaction, and (iii) at least fifty-one percent (51%) of the voting power of the outstanding capital stock of the Acquiring Corporation with respect to the election of directors following such transaction is held by Persons who were shareholders of the Acquiring Corporation prior to such transaction, or c) a party sells to any Person(s) in one or more related transactions, properties or assets representing at least fifty-one percent (51%) of (i) such party's consolidated total assets as reflected on its most recent Annual Report on Form 10-K or Quarterly Report on Form 10-Q, provided that all or substantially all of the properties and assets used in connection with such party's pharmaceutical business are included in such transaction(s) and (ii) such party's consolidated operating income for the most recent fiscal year as reflected on its most recent Annual Report on Form 10-K.

**9.3.3 Definition of Impairment.** For purposes of this Section, an "Impairment" shall be deemed to occur if the entity to result from the Change of Control is reasonably likely to have sales and marketing policies or capabilities substantially different from those of the party in respect of which such Change in Control occurs, which differences are reasonably likely to lead to a reduction in marketing efforts (or the efficacy thereof) with respect to the Product from those contemplated by the then current Marketing Plan. Without limiting the generality of the foregoing, such standard shall be deemed to have been met if the entity to result from the Change in Control markets a Competitive Product in the Territory within 6 months from the Change in Control, or if the majority of sales representatives, sales management or marketing personnel responsible for Product co-promotion changes as a result of

such Change in Control.

**9.3.4 Definition of Hostile Change.** For purposes of this Section, a "Hostile Change" shall mean a Change in Control which has not been approved by a majority of the members of the Board of Directors who (together with any other individuals whose election was approved by a two-thirds vote of the directors then in office) constituted a majority of the Board of Directors for a period of at least two consecutive years prior to such Change in Control.

**9.3.5 Sankyo Rights Under Forest Change of Control.** In the event that a Change of Control affecting Forest takes place, Sankyo shall have the right, but not the obligation, to terminate the Co-Promotion Period by furnishing notice of such election to terminate within 30 days of the event permitting such termination, such termination to be effective upon the last day of the Quarter in which notice of such termination is furnished. In the event that Sankyo exercise its rights of termination, the following conditions shall apply:

**9.3.5.1** Subject to the provisions of Sections 9.3.5.3 and 9.3.3, in the event such Change in Control does not lead to, or is not reasonably likely to lead to, an Impairment, Sankyo shall purchase from Forest and Forest shall sell to Sankyo Forest's remaining rights under this Agreement as if no termination of the Co-Promotion Period had been affected by Sankyo. The purchase price for such sale shall be the Fair Market Value of the rights as of the date of termination of the Co-Promotion Period. The parties agree to negotiate the Fair Market Value in good faith promptly following a termination pursuant to this Section. In the event no agreement upon Fair Market Value has been reached within 90 days of such termination, the parties agree that Fair Market Value shall be determined by a Valuation Expert whose determination shall be binding and conclusive on the parties. Payment of Fair Market Value shall be made within 30 business days of its determination.

**9.3.5.2** In the event such Change in Control occurs during the first three Co-Promotion Years and (i) leads to, or is reasonably likely to lead to, an Impairment, or (ii) is a Hostile Change, the Residual Period shall be deemed to commence on the first day of the first Quarter following the termination of the Co-Promotion Period, provided the Residual Period shall only extend for a number of Quarters equal to the number of Quarters for which the Co-Promotion Period extended; provided further that, in the event the aggregate Residual Fee payable to Forest during such Residual Period is less than [Confidential Treatment], Sankyo shall pay Forest the difference between such aggregate Residual Fee and [Confidential Treatment] together with the final payment Residual Fee due hereunder.

**9.3.5.3** In the event such Change in Control occurs following the expiration of the third Co-Promotion Year and (i) leads to, or is reasonably likely to lead to, an Impairment, or (ii) is a Hostile Change, Forest shall be deemed to have exercised its right of termination of the Co-Promotion Period pursuant to, and in accordance with the terms and conditions of Section 7.3.2.

**9.3.6 Forest Rights Under Sankyo Change of Control.** In the event that a Change of Control affecting Sankyo takes place which leads to, or is reasonably likely to lead to, an Impairment, Forest shall have the right, but not the obligation, to terminate the Co-Promotion Period by furnishing notice of such election to terminate within 30 days of the event permitting such termination, such termination to be effective upon the last day of the Quarter in which notice of such termination is furnished. In the event that Forest exercise its rights of termination, the following conditions shall apply:

**9.3.6.1** In the event such Change in Control occurs during the first two Co-Promotion Years the Residual Period shall be deemed to commence on the first day of the first Quarter following the termination of the Co-Promotion Period, provided the Residual Period shall only extend for a number of Quarters equal to the number of Quarters for which the Co-Promotion Period extended; provided further that, in the event the aggregate Residual Fee payable to Forest during such Residual Period is less than [Confidential Treatment], Sankyo shall pay Forest the difference between such aggregate Residual Fee and [Confidential Treatment] together with the final

payment Residual Fee due hereunder.

**9.3.6.2** In the event such Change in Control occurs following the expiration of the second Co-Promotion Year Sankyo shall purchase from Forest and Forest shall sell to Sankyo Forest 's remaining rights under this Agreement as if no termination of the Co-Promotion Period had been affected by Forest. The purchase price for such sale shall be a) 67% of the Fair Market Value of the rights as of the date of termination of the Co-Promotion Period if the Change of Control occurs in the third Co-Promotion Year or b) the Fair Market Value of the rights as of the date of termination of the Co-Promotion Period if the Change of Control occurs after the third Co-Promotion Year. The parties agree to negotiate the Fair Market Value in good faith promptly following a termination pursuant to this Section. In the event no agreement upon Fair Market Value has been reached within 90 days of such termination, the parties agree that Fair Market Value shall be determined by a Valuation Expert whose determination shall be binding and conclusive on the parties. Payment of Fair Market Value shall be made within 30 business days of its determination.

## **10. Indemnification.**

### **10.1 Indemnification.**

**10.1.1 Indemnification by Sankyo.** Sankyo shall indemnify, hold harmless and defend Forest and its Affiliates from and against any and all liabilities, losses, suits, claims, damages and expenses (including, without limitation, attorneys ' fees, expert fees and other disbursements) (collectively, "Liabilities") asserted against or incurred by Forest arising out of or relating to (i) the manufacture, use, distribution, promotion or sale of Product (including, without limitation, Losses relating to product liability and/or personal injury) by Sankyo; (ii) the breach by Sankyo of any of its representations, warranties or other obligations under this Agreement; or (iii) a claim by a third party that the sale of the Product or use of Promotional Material related thereto prepared by Sankyo infringes any patent, trademark or other intellectual property rights of such third party; except to the extent any such Liabilities result from the breach by Forest of its representations, warranties or obligations hereunder, or its negligence or willful misconduct, or its sale of Product or use of such Promotional Materials in a manner inconsistent with the terms of this Agreement. The indemnification provided hereby shall not be deemed to include indemnification for lost profits or indirect or consequential damages, nor shall the parties otherwise be liable to each other for lost profits or indirect or consequential damages.

**10.1.2 Indemnification by Forest.** Forest agrees to indemnify, hold harmless and defend Sankyo and its Affiliates from and against any Liabilities asserted against or incurred by Sankyo, arising out of or relating to (i) performance or breach by Forest of its representations, warranties or obligations under this Agreement; or (ii) any negligence or willful misconduct of Forest, except to the extent such Liabilities result from the breach by Sankyo of its representations, warranties or obligations hereunder or any other actions that would be indemnified against by Sankyo under Section 10.1.1 or its negligence or willful misconduct. The indemnification provided hereby shall not be deemed to include indemnification for lost profits or indirect or consequential damages nor shall the parties otherwise be liable to each other for lost profits or indirect or consequential damages.

**10.2 Cooperation in Connection with Indemnification.** Any party entitled to indemnification pursuant to Section 10.1 shall notify the indemnifying party promptly of any claim that might give rise to a claim of indemnification, shall allow the indemnifying party to handle the defense of the claim (provided the indemnifying party acknowledges its obligation to indemnify hereunder), shall cooperate in the defense of such claim and shall not settle such claim without the indemnifying party 's written consent (which shall not be unreasonably withheld), delayed or conditioned). An indemnified party shall have the right to participate in the defense of any matter as to which indemnification is being provided with its own counsel and at its own expense. Where any indemnity is claimed under this Agreement, the party claiming such indemnity shall take all reasonable action (the reasonable cost of which shall be borne by the indemnifying party) to mitigate such Liabilities.

**10.3 Survival.** The foregoing indemnity provisions, together with (i) the representations and warranties of the parties, (ii) payment obligations, (iii) insurance requirements and audit provisions shall survive any termination or expiration hereof.

**10.4 Insurance.** Each of the parties shall maintain product liability insurance (including contractual indemnity coverage) in an amounts of at least \$100,000,000 on a "per occurrence" basis with an insurance company rated at least A+3 by Best 's rating guide. Each of the parties shall be added as an additional insured of the other party 's insurance policy. Any indemnification hereunder shall be net of any insurance proceeds recovered by the indemnified party.

**11. Assignment.**

This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective assigns and successors in interest. Neither party shall assign its rights hereunder to any party without the prior written consent of the other party hereto.

**12. Notices.**

Any notice, request or other communication required or permitted by this Agreement to be given by either party to the other shall be in writing and either mailed by nationally recognized overnight courier; registered or certified mail, return receipt requested, by express delivery service; or by facsimile transmission, addressed to such party, Attention: The President (in the case of Sankyo) and the Chairman (in the case of Forest) at its address indicated above or to such other address as such party may previously have designated by like written notice. Notice shall be deemed to have been given upon receipt. Facsimile transmission numbers for the respective parties are as follows:

If to Sankyo: (973) 630-2808

If to Forest: (212) 224-6740

**13. Miscellaneous.**

**13.1 Relationship.** Neither party shall have or hold itself out to third parties as possessing any power or authority to enter into any contract or make any commitment on behalf of the other party. It is not intended that this Agreement create a partnership, agency, joint venture or joint employer relationship.

**13.2 Entire Agreement.** This Agreement constitutes the entire agreement between the parties relating to the subject matter hereof and supersedes any previous written or oral agreement in connection therewith. Any amendment hereto must be in writing and signed by Forest and Sankyo.

**13.3 Confidentiality.** Each party agrees to maintain in strict confidence all proprietary or confidential business or technical information it may learn about the other party as a result of this Agreement or the transactions contemplated hereby and not to use such information for any purpose unrelated to the performance of its obligations hereunder. This obligation shall survive the termination or expiration of this Agreement for a period of 5 years. The obligations set forth in this Section shall not apply to any information that (i) is in the public domain at the time of disclosure, (ii) enters the public domain after disclosure hereunder other than as a breach of this Section, (iii) the receiving party can demonstrate was in its possession prior to disclosure hereunder, (iv) is received from a third party without violation of any obligation to the disclosing party hereunder or (v) must be disclosed pursuant to law or regulation of any competent legal or regulatory authority (including courts and administrative authorities), in which event the party making such disclosure shall, if permissible, notify the other party sufficiently prior to making such disclosure so as to allow the nondisclosing party adequate time to take whatever action it may deem to be appropriate

to protect the confidentiality of the information.

**13.4 Severability.** If any term, provision, covenant or condition of this Agreement is held by a court of competent jurisdiction to be invalid, void or enforceable, the parties shall in good faith reformulate the same and the other provisions shall remain in full force and effect and shall in no way be effected, impaired or invalidated, unless any such invalidated provisions cannot be reformulated without materially altering the intent of this Agreement and they are so vital to the Agreement as to render impractical the Agreement 's continued implementation, in which case the Agreement shall terminate with immediate effect.

**13.5 Public Disclosure.** Each party shall grant the other the prior opportunity to review and furnish comments with respect to any press release or public announcement concerning this Agreement or the activities contemplated hereby. The foregoing shall not be deemed to limit either party 's right to make any disclosure required by applicable law or regulation.

**13.6 Headings.** The headings in this Agreement are for convenience of reference only and shall not limit or otherwise affect the meaning thereof.

**13.7 Applicable Law.** This Agreement is made pursuant to, and shall be governed by, the laws of the State of New York without giving effect to its principles of conflicts of law. Each of the parties hereby irrevocably and unconditionally submits, for itself and its property, to the jurisdiction of any state or federal court sitting in New York, and any appellate court from any such court, in any suit or proceeding relating to this Agreement. It shall be a condition precedent to each party 's right to bring any such suit or proceeding that such suit or proceeding, in the first instance, be brought in such state or federal court in New York. No party may move to transfer, consolidate, or dismiss any such suit or proceeding for the purpose of bringing the same in another jurisdiction. Each party agrees that a final judgment in any such suit or proceeding shall be conclusive and may be enforced in any other competent jurisdiction by suit on the judgment or in any other manner provided by law. Each party irrevocably consents to service of process on it in the manner provided for notices in Section 12 with respect to any suit or proceeding in a state or federal court sitting in New York. Nothing in this Agreement shall affect the right of either party to serve process in any other manner permitted by law.

**13.8 Waiver.** No waiver or consent of any provision of this Agreement shall in any event be effective, unless the same shall be in writing and signed by the parties hereto, and then such waiver or consent shall be effective only in the specific instance and for the specific purpose for which given.

**13.9 No Implied License.** Except as may be expressly provided in this Agreement, no license to make, use, sell or otherwise exploit the Product in the Territory and its related assets is being conferred on Forest.

**13.10 Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original, but in all of which shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date first written above.

SANKYO PHARMA INC.

By: /s/Joseph Pieroni  
Joseph Pieroni  
President

FOREST LABORATORIES, INC.

By: /s/Mary Prehn  
Mary Prehn  
Vice President - Licensing  
& Corporate Development

EXHIBIT 10.17

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]."

S-ENANTIOMER LICENSE AGREEMENT

S-ENANTIOMER LICENSE AGREEMENT dated this May 29, 2002 by and between Forest Laboratories (Ireland) Limited, a corporation organized and existing under the laws of the Republic of Ireland and having its principal executive offices at Clonshaugh Industrial Estate, Clonshaugh, Dublin 17 Republic of Ireland ("Forest Ireland") and H. LUNDBECK A/S, a corporation organized under the laws of Denmark and having its principal executive offices at 9 Ottiliavej, DK-2500, Copenhagen-Valby, Denmark ("Lundbeck").

R E C I T A L S:

A. The Parties hereto and Forest Laboratories, Inc. ("**Forest Inc.**") have agreed to novate, effective as of March 27, 1998, the License Agreement by and between Forest Inc. and Lundbeck dated the 27<sup>th</sup> day of March, 1998, as supplemented and amended to date (the "**1998 License**") in accordance with the terms hereunder.

B. Lundbeck develops and markets pharmaceutical products. Lundbeck owns all rights in and to certain patents and technology (as hereinafter more fully defined, the "Patents" and the "Technology") relating to the S-Enantiomer which may be potentially useful for the treatment of depression, panic disorder, obsessive-compulsive disorder and related indications.

C. Forest Ireland develops, markets and distributes pharmaceutical products and has evaluated certain pre-clinical data developed by Lundbeck with respect to the S-Enantiomer.

D. Lundbeck desires to grant Forest Ireland, and Forest Ireland desires to receive from Lundbeck, an exclusive license to use the Patents and the Technology for the purpose of marketing, selling and distributing in the Territory (as hereinafter defined) finished pharmaceutical products incorporating the S-Enantiomer as their active ingredients, all as provided and subject to the terms and conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the foregoing and of the terms and conditions hereafter set forth, the parties hereto hereby agree, effective as of March 27, 1998, as follows:



## 1. Definitions.

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

### 1.1

"Act" shall mean the United States Federal Food and Drug Act and regulations promulgated thereunder, including current Good Manufacturing Practice regulations.

**1.2 "Affiliate"** shall mean any person or legal entity controlling, controlled by or under common control with the person or entity with respect to whom such status is at issue.

**1.3 "Commencement Date"** shall mean the date of the commercial launch of any Product in the Territory.

**1.4 "Compound" or "S-Enantiomer"** shall mean the S-Enantiomer form of the compound known as citalopram and shall be deemed to include all analogs, salts, derivatives and enantiomer forms thereof developed using Technology and Non-Program Technology during the term hereof (provided that the racemate form of S-Enantiomer shall not be deemed included in the term Compound).

**1.5 "Cost of Goods"** shall mean Forest Ireland's or Lundbeck's (i) direct cost of raw materials and labor incurred in manufacturing Products, together with allocated applicable manufacturing overheads (but excluding corporate general or administrative overheads) and (ii) Forest Ireland's or Lundbeck's out-of-pocket costs of acquiring inventories of finished Products from the other party or a third party supplier, together with allocated applicable manufacturing overheads (but excluding corporate general or administrative overheads). Cost of Goods shall be determined in accordance with United States generally accepted accounting principles and the standard cost accounting policies of each party as applied to the manufacture or acquisition of finished pharmaceutical product inventories generally.

**1.6 "Development Costs"** shall mean the costs of either party in performing development work (including formulation development, toxicology, bioavailability and pre-clinical and clinical tests and studies and NDA regulatory work, preparation and filing) required or appropriate to obtain an approved NDA to market a Product in the Territory, including both internal and out-of-pocket costs and allocations of research and development overheads (but excluding corporate general or administrative overheads). Development Costs shall be determined in accordance with United States generally accepted accounting principles and in a manner consistent with such party's standard accounting for research and development costs generally.

**1.7 "exclusive"** shall mean, where used in connection with a specific grant of rights in respect of the Patents or the Technology, that the granting party (i) shall retain for itself no ability to use such property and (ii) shall have no ability to authorize its Affiliates or third parties (other than the grantee of such specific rights) to use such property, in the geographic areas and field of use covered by, and for the term of, such grant.

**1.8 "Fair Market Value"** shall mean the price which a willing buyer would pay, on an arm's length basis, for all rights and related intellectual property assets to a Compound or Product for distribution in the Territory, in light of the status of development and reasonably anticipated costs of further development of such Compound or Product and the market potential thereof in the Territory, all as determined based upon objective data possessed and disclosed by both parties hereto.

**1.9 "Forest Ireland Technology"** shall mean all data or information described by the defined term Technology but possessed, developed or acquired by Forest Ireland during the term of this Agreement; provided that Forest Ireland Technology shall not be deemed to include Non-Program Technology.

**1.10 "FDA"** shall mean the United States Food and Drug Administration or any successor agency having comparable jurisdiction.

**1.11 "Marketing and Selling Costs"** shall mean all costs related to selling and promoting a Product in the Territory, including, but not limited to, both internal and out-of-pocket allocated salesforce costs including compensation, bonuses, travel costs, meeting costs and training and management, clinical studies intended for marketing purposes, promotional meetings and seminars, market research, advertising and sample acquisition and distribution costs, and the costs of shipping, billing, product liability insurance and contract administration, together with all directly allocable departmental overheads (but excluding corporate general or administrative overheads). Marketing and Selling Costs shall be calculated in accordance with United States generally accepted accounting principles and in accordance with Forest Ireland's standard cost accounting practices for selling, marketing and promotional expenses generally.

**1.12 "Marketing Year"** shall mean each 12 consecutive month period beginning with the Commencement Date.

**1.13 "NDA"** shall mean a New Drug Application filed with the FDA with respect to a Product for the indications set forth in the Development Plan (as defined and provided in Section 3.1.2) for such Product.

**1.14 "Net Revenues"** for any period shall mean sales of a Product by Forest Ireland, its Affiliates or sub-licensees in the Territory for such period less amounts actually allowed as trade credits, discounts, rebates, returns or, rejections of Product, transportation charges or other allowances or discounts actually given with respect to such sales including, without limitation, rebates or charges required to be paid in connection with such sales by the Prescription Drug Rebate and Improved Access to Medicines requirements of the Omnibus Budget Reconciliation Act of 1990 and comparable United States 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 Forest Ireland's revenue recognition policies from the sale of pharmaceutical products generally.

**1.15 "Non-Program Product Costs"** shall mean costs of either party accounted for in the manner provided by the definitions of Development Costs or Marketing and Selling Costs but undertaken by such party independently of, and not pursuant to the requirements of, a Development Plan or Marketing Plan effect at the time of accrual of such costs.

**1.16 "Non-Program Technology"** shall mean any technology or know-how which would constitute Technology or Forest Ireland Technology, as the case may be, but is developed by or acquired through research and development which is accounted for as Non-Program Product Costs.

**1.17 "Patents"** shall refer to S-citalopram US RE34712, S-citalopram Patent, expiration date 8 June 2009 (reissue of US 4,943,590), together with all extensions, continuations, continuations-in-part, reissues and divisions thereof.

**1.18 "Phase I-III Clinical Trials"** shall mean clinical trials of a Product undertaken to obtain an approved NDA and a "Phase III Clinical Trial" shall mean a well-controlled clinical study meeting FDA requirements for a primary efficacy study required for NDA approval.

**1.19 "Product"** shall mean any finished pharmaceutical product for human use in which the active ingredient is the Compound.

**1.20 "Quarter"** shall mean a three calendar month period ending March 31, June 30, September 30 and December 31.

**1.21 "Technology"** shall mean all methods, processes, techniques, technology, information, data, studies, analyses or expertise, whether patented or unpatented, now in the possession of or hereafter acquired by Lundbeck which are useful in and specifically related to the manufacture, testing, analysis, sale or distribution of Compound or Product, including, without limitation, pharmacology, toxicology, stability, formulation methodologies and techniques, analytical methodologies and techniques, bioavailability data and clinical and non-clinical safety and efficacy studies; provided that Technology shall not be deemed to include Non-Program Technology.

**1.22 "Territory"** shall mean the United States of America, including its territories and possessions.

**1.23 "Trademark"** shall mean a trademark registered pursuant to Section 6 of the S-Enantiomer Supply Agreement and used specifically in connection with the marketing and distribution of a Product in the Territory.

**1.24 "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 60 days of good faith negotiations, such decision shall be submitted to arbitration in accordance with the terms hereof and the individual so selected shall be deemed a Valuation Expert.

## **2. Grant of License; License Fee.**

**2.1** In consideration for the payment of the license fee provided in Section 2.2 and the additional compensation provided or contemplated by Section 5.1 hereof and subject to the terms and conditions hereof, Lundbeck hereby grants to Forest Ireland the exclusive right and license (together with the right to sublicense, subject to Lundbeck's prior written consent, which shall not be unreasonably withheld, the "License") under the Patents and Technology to develop or have developed, manufacture or have manufactured, use, distribute, market or sell the Product in the Territory for the Term of this Agreement and for any additional period provided by Sections 9 or 11 hereof.

For the period described in the above paragraph, Forest Ireland hereby grants to Lundbeck the exclusive right and license in respect of all countries in the world other than the Territory, with the right to grant sub-licenses, subject to Forest Ireland's prior written consent, which shall not be unreasonably withheld, to all Forest Ireland Technology developed or acquired by Forest Ireland with respect to the Compound or the Product solely in connection with the formulation, manufacture, sale, use, distribution, marketing and sale of the Product in countries outside of the Territory.

**2.2** In consideration of the License granted to Forest Ireland pursuant to Section 2.1, Forest Ireland agrees to pay Lundbeck a license fee of [**Confidential Treatment**] by wire transfer to a bank account previously designated by Lundbeck within 30 days from the date hereof. Such license fee shall be deemed fully earned and nonrefundable.

## **3. Development Program**

**3.1** The parties agree to cooperate in the development of the Product in accordance with the following:

**3.1.1** The parties shall establish a joint development committee (the "Development Committee") of four members, two of whom shall be designated by Forest Ireland and two of whom shall be designated by Lundbeck. Each party shall designate its or an Affiliate's President and senior executive officer in charge of research and development as members of the Development Committee. Decisions or actions of the Development Committee shall require a majority vote or consent. The Development Committee shall meet in person

and by telephonic communication as needed to review and monitor the Development Program and the progress of development thereunder for each Product. Each party shall make appropriate executive and research and development personnel reasonably available from time to time for consultation with, and assistance in the accomplishment of the objectives of, the Development Committee. Each party shall disclose, on a continuing basis, all material Technology or Forest Ireland Technology, as the case may be, as requested or directed by the Development Committee.

**3.1.2** Lundbeck agrees to use its commercially reasonable efforts to undertake, subject to the terms and conditions hereof, a program of research and development (including formulation and pre-clinical and clinical tests and studies) which includes all such research and development required to obtain an approved NDA for the marketing of Product formulated from the Compound in the Territory. Each such program shall be undertaken pursuant to the terms of a development plan (a "Development Plan") submitted by Lundbeck and approved by the Development Committee. Each Development Plan will set forth the principal steps, allocation of responsibilities and related budget for those pre-clinical and clinical studies and related regulatory work necessary to obtain approvals for such indications as approved by the Development Committee. Each Development Plan shall be subject to revision with the approval of the Development Committee, in light of the progress of the development work from time to time.

**3.1.3** Lundbeck shall be responsible for Development Costs up to a maximum of [Confidential Treatment] with respect to S-Enantiomer (the "Maximum Costs"). To the extent the Development Costs for the development of the Compound exceed the respective Maximum Costs applicable to Compound, Forest Ireland shall be responsible for the entire amount of such excess to the extent related to the development of the S-Enantiomer.

**3.1.4** In light of the progress of the Development Work, the Development Committee shall review and recommend sources, and terms and conditions, of supplies of Compound and Product, both for developmental and for commercial and marketing supply requirements in the Territory. It is contemplated that (i) Compound may be supplied to Forest Ireland by Lundbeck for formulation into Product, (ii) Lundbeck may supply finished Product or (iii) Product or Compound may be acquired from third party contractors.

**3.1.5** In the event the Development Committee is unable to agree upon the approval of a material component of the Development Plan or any modification thereof, Lundbeck shall have the final decision making authority with respect to such issue. However, Forest Ireland shall have the final authority as to whether an element of the Development Plan is required for NDA approval or useful in connection with the marketing of a Product in the Territory. To the extent an element of a Development Plan has been determined by Forest Ireland to be so inapplicable, the costs associated therewith, if undertaken by Lundbeck, shall be deemed Non-Program Product Costs.

**3.1.6** The Development Plan shall require Forest Ireland to be responsible for all regulatory work required to prepare and file the NDA and may require Forest Ireland to undertake formulation work to develop appropriate dosage forms or to oversee development activities, such as the performance or monitoring of clinical studies, taking place primarily in the Territory. Forest Ireland will involve Lundbeck in the preparation of the regulatory strategy and, upon Lundbeck's request, Lundbeck may participate in meetings with the FDA or third parties provided such participation does not adversely affect a meeting.

**3.1.7** Nothing set forth herein shall be deemed to prevent either party from performing formulation or development work not required by the terms of the Development Plan with respect to the Compound or Product, provided that no such development work is inconsistent with the objectives of a Marketing Plan or Development Plan and does not pose a risk to the overall development of such Compound or Product. Costs associated with any such work shall be for the account of the party performing such work and shall be deemed Non-Program Product Costs. The other party shall be obligated to provide such technical cooperation, including the supply of Compound or Product, as applicable, to the party undertaking such work as if such other party were an "assigning party" for purposes of Section 9.3 hereof.

**3.1.8** The Development Committee shall have the authority to determine, in light of the progress of the development work, that further development work is unlikely to result in the development of a Product at a commercially reasonable cost or to provide a commercially reasonable return on investment. In the event of such determination, the License with respect to the relevant Patents and Technology shall be deemed terminated in all respects, such Product or Compound shall no longer be deemed Product or Compound for purposes of this Agreement and any subsequent development or marketing thereof in the Territory shall not give rise to obligations of payment or performance hereunder. In the event the parties do not agree upon such determination, the party which does not wish to proceed with development shall promptly assign all rights to the relevant Technology and Patents, or Forest Ireland Technology, as the case may be, to the party wishing to proceed, for purposes of enabling such party to proceed with the development and marketing of such Product in the Territory at its own cost and without obligation or right to or of the other party hereunder.

**4. Marketing.**

**4.1** The parties agree that Forest Ireland shall market the S-Enantiomer in the manner provided or permitted by the terms of that separate S-Enantiomer Supply Agreement between Lundbeck and Forest Ireland of even date herewith (the "S-Enantiomer Supply Agreement").

**5. Additional S-Enantiomer Compensation.**

**5.1** Simultaneously herewith, the parties have executed the S-Enantiomer Supply Agreement which provides for further compensation arrangements between Forest Ireland and Lundbeck with respect to the supply of Compound and Product and the marketing of such Product.

6.

**Representations and Warranties.**

**6.1** Each party represents and warrants to the other as follows:

6.1.1

**Existence and Authority.** It is a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation and has the corporate power and authority to execute, deliver and perform this Agreement. The execution of this Agreement and the consummation of the transactions contemplated hereby have been duly authorized by all necessary corporate action on its part and do not conflict with the terms and conditions of any contract, agreement, arrangement or understanding to which such party is subject.

**6.1.2 Enforceability.** This Agreement is a valid and binding obligation of said party, enforceable against it in accordance with its terms.

**6.1.3 Litigation.** There is no action, suit, proceeding or investigation pending or, to its knowledge, threatened before any court or administrative agency against said party which could, directly or indirectly, reasonably be expected to affect its ability to perform its obligations hereunder.

**6.2** Lundbeck hereby represents and warrants to Forest Ireland that:

**6.2.1** Lundbeck is the sole owner of the Patents and the Technology and is not subject to any license, restriction, royalty obligation, encumbrance or claim of any nature whatsoever with respect thereto. Lundbeck has the right to grant Forest Ireland the License in accordance with the terms and conditions hereof.

**6.2.2** Lundbeck has disclosed or made available for review by Forest Ireland sufficient information and data possessed by Lundbeck with respect to the Patents and Technology and the Compound to enable Forest Ireland to evaluate its interest in entering into this S-Enantiomer License Agreement.

**6.2.3** No claim of ownership, invalidity or patent infringement has been asserted by any third party (including, without limitation, by employees, consultants or other personnel of Lundbeck) against Lundbeck or any Affiliate with respect to the Patents or the Technology nor is Lundbeck aware of any reasonable basis for the assertion of any such claim.

**6.3** Each of Forest Ireland and Lundbeck hereby covenant to the other as follows:

**6.3.1** Each party shall perform its obligations hereunder in compliance with all applicable requirements of law or governmental regulations, including the Act.

**6.3.2** Forest Ireland shall disclose to Lundbeck and Lundbeck shall disclose to Forest Ireland, in each case within ten (10) calendar days and in writing, all reports or other knowledge ("Safety Data") they may from time to time obtain or otherwise receive with respect to "serious adverse experiences", whether or not considered fatal or life threatening (as defined in 21 CFR ' 312.32 and ' 314.80) without regard to casualty assessment, with respect to Product (whether occurring within or outside of the Territory). With respect to "fatal or life-threatening experiences" (as defined in 21 CFR ' 312.32 and ' 314.80) without regard to casualty assessment, each party shall disclose to the other such Safety Data within five (5) calendar days after they obtain or otherwise receive such Safety Data. Transmission of Safety Data will be by facsimile transmission or electronic transfer, followed by confirmation mail. Each party shall cause its other sublicensees to disclose to it any Safety Data which they may from time to time obtain or otherwise receive, within the same time limits as are provided in this Section, and each party hereto shall disclose to the other party hereto such Safety Data received from its sublicensees within the time limits provided herein after receipt thereof. Each party shall promptly deliver to the other all correspondence which such party may receive from regulatory authorities in jurisdictions where such party has rights to market Product, except for procedural, nonsubstantive communications which do not relate to the safety of the Product. Each party shall deliver to the other party in an annual report the "other safety information" (as referred to in 21 CFR ' 312.32 (d)(4)) which it obtains or possesses from time to time.

**6.4** Forest Ireland hereby represents and warrants to Lundbeck that Forest Ireland has had an opportunity to review all data furnished or made available to Forest Ireland by Lundbeck with respect to the Patents, Technology and Compound and has had an opportunity to make such inquiries with respect to such data as Forest Ireland deemed appropriate to determine to enter into this S-Enantiomer License Agreement.

## **7. Confidentiality Exclusivity.**

**7.1** Each party recognizes the proprietary interest of the other party in the technical information, know-how, technology, process, data, results of testing and clinical development acquired or possessed by the other party relating to the development, formulation, manufacture, testing, marketing or distribution of Compound or Product and which may be disclosed by the other party to such party from time to time under this Agreement (the "Confidential Information"). Each party hereto agrees to maintain Confidential Information of the other party in strict confidence and not to disclose, without the prior written consent of the other party, directly or indirectly, such information to third parties except for:

- (a) information which was generally available to the public at the time of disclosure;
- (b) information which becomes generally available to the public by disclosure by a third party having a legal right to make such disclosure and without fault on the part of either party hereto, subsequent to the disclosure under this Agreement;

- (c) information which was received by the disclosing party from a third party having a legal right to disclose such information;
- (d) information which was possessed by the disclosing party at the time of disclosure hereunder, as established by written evidence, and which was not subject to any obligation of confidentiality on the part of the disclosing party; and
- (e) except as otherwise contemplated by this Agreement or as may otherwise be required by applicable laws.

**7.2** The obligations of confidentiality set forth in this Section 7 shall survive any termination of this Agreement however caused or the expiration of this Agreement.

**7.3** Neither party shall market or sell, or participate (including by means of license or distributorship arrangements) in the marketing or sale of, pharmaceutical products for sale or distribution in the Territory during the first three Marketing Years of a Product which are indicated primarily for the indications for such Product and which utilize substantially the same mode of pharmacologic action (each such product a "Directly Competitive Product"), except for the Product. The foregoing shall not be deemed to apply to the product known as Citalopram which is anticipated to be marketed in the Territory by Forest Ireland pursuant to a separate license agreement with Lundbeck.

**7.4** In the event that either party is developing, acquiring or licensing (or commences to do so) products or compounds which are reasonably anticipated to become Directly Competitive Products within the first three Marketing Years of a Product, such party shall be obligated to offer the other party to include the development and marketing of such product under terms consistent with the terms of the Joint Venture Agreement between Forest Inc. and Lundbeck dated the 27th day of March, 1998 on terms and conditions hereof applicable to Compound or Product, or such other terms and conditions as may be mutually agreed.

## 8. Indemnification.

**8.1** Lundbeck shall indemnify and hold Forest Ireland harmless from and against any direct costs, expenses (including, without limitation, reasonable attorneys' fees) or direct damages which directly arise from breach by Lundbeck of any of its representations, covenants, warranties or obligations set forth herein, except to the extent arising from any matter as to which Forest Ireland has agreed to indemnify Lundbeck hereunder. Forest Ireland shall indemnify and hold Lundbeck harmless from and against any direct costs, expenses (including, without limitation, reasonable attorneys' fees) or direct damages which directly arise from breach by Forest Ireland of any of its representations, covenants, warranties or obligations set forth herein, except to the extent arising from any matter as to which Lundbeck has agreed to indemnify Forest Ireland hereunder. In the event a third party claim is asserted against either party in connection with Product or Compound which does not arise from the breach by either party of a representation, warranty, covenant or obligation hereunder, such party shall be indemnified by the other to the extent of 50% of the direct costs and losses incurred. The party obligated to provide indemnity pursuant to this Section 8.1 is hereinafter referred to as the "Indemnifying Party."

**8.2** Promptly after the receipt by any party hereto of notice of (a) any claim or (b) the commencement of any action or proceeding, such party will, if a claim with respect thereto is to be made against any party obligated to provide indemnification pursuant to Section 8.1 hereof, give such Indemnifying Party written notice of such claim or the commencement of such action or proceeding. Such Indemnifying Party shall have the right, at its option, to compromise or defend, at its own expense and by its counsel, any such matter involving the asserted liability of the party seeking such indemnification. Such notice, and the opportunity to compromise or defend, shall be a condition precedent to any liability of the Indemnifying Party under the indemnification agreement contained in said Section 8.1. In the event that any Indemnifying Party shall undertake to compromise or defend any such asserted liability, it shall promptly notify the party seeking indemnification of its intention to do so, and the party seeking indemnification agrees to cooperate fully with the Indemnifying Party and its counsel in the compromise of, or

defense against, any such asserted liability. In any event, the indemnified party shall have the right, at its own expense, to participate in the defense of such asserted liability, provided that the Indemnifying Party's counsel shall make all final decisions concerning the defense or compromise or settlement of such litigation.

**8.3** Each of the parties hereto shall be entitled to be represented at any proceeding brought by the other party under this Section 8 by its own counsel, at its own cost and expense, and shall fully cooperate with the other party in any such proceeding.

**9. Term.**

**9.1** Unless otherwise sooner terminated in accordance with the terms hereof, this Agreement shall expire on December 31, 2010 (the period from March 27, 1998 through such date being referred to as the "Initial Term"). The term of this Agreement shall automatically be deemed to extend after the Initial Term for successive five year periods (each a "Renewal Term") unless either party shall have notified the other in writing, no later than 12 months prior to the expiration of the Initial Term or any Renewal Term of its intention not to renew the term hereof. The Initial Term together with all Renewal Terms are referred to collectively as the "Term".

**9.2** Following the expiration of the Term, Forest Ireland shall continue to have an exclusive License under the Patents and Technology to develop, manufacture, market, sell and distribute Products in the Territory, provided that the terms and conditions of the S-Enantiomer Supply Agreement or any successor agreement or arrangement continue to apply.

**9.3** None of the expiration of the Term, termination of this Agreement or termination of the License or assignment of assets contemplated by this Section or by Sections 3.1.8, 10 or 11 shall be deemed to relieve either party of any obligation of payment or performance accrued prior to such event. In addition, in connection with any expiration, termination or other event where one party is to assign Technology or Patents, or Forest Ireland Technology, to the other, the assigning party shall be obligated to cooperate with the party receiving such rights in order to complete such technology transfer in a complete and efficient manner, including the disclosure of all necessary data and the reasonable availability of appropriate personnel for technical cooperation. In addition, both parties shall furnish ongoing cooperation, including, as applicable, a continuing supply of Compound or Product and continuing disclosure of information and technical cooperation as reasonably required to assure that the party acquiring or continuing to own Technology, Patents or Forest Ireland Technology is able to proceed with the development and commercialization of the Compound or Product in question.

**10. Termination.**

**10.1** A party which is not then subject to an event of default (the "non-defaulting party") may terminate this Agreement in the event of a default by the other party (the "defaulting party"), defined as follows:

- (i) the failure by the defaulting party to perform or observe any material obligation or covenant of payment or performance, which failure shall remain unremedied for a period of 90 days after the receipt of written notice thereof or, if such breach is not susceptible of cure within such period, such party has not taken reasonable steps to commence and thereafter diligently proceed to cure such default, and, in fact, does not cure such default within a reasonable period of time thereafter.
- (ii) if the defaulting party shall voluntarily enter into bankruptcy, insolvency, dissolution or similar proceedings or any form of bankruptcy or insolvency proceeding shall be brought against the defaulting party, which proceedings are not dismissed or vacated within 60 days.



In the event of a disagreement of the parties as to the occurrence or persistence of a default, no termination shall be effective pursuant to this Section unless the occurrence of such default has been established pursuant to arbitration in accordance with Section 13 hereof and the defaulting party shall not have thereafter promptly paid any amount or performed any action required to cure the default so established.

**10.2** In the event this Agreement is terminated pursuant to Section 10.1, the effect of such termination on rights to the S-Enantiomer are set forth in the S-Enantiomer Supply Agreement. Termination of this Agreement shall not be in limitation of any rights or remedies to which either party may be entitled hereunder or at law.

## **11. Change of Control.**

**11.1** For purposes of this Section 11, a "Change of Control" shall mean (i) the acquisition, directly or indirectly, of beneficial ownership of a percentage of the voting power of a party or its ultimate corporate parent (as applicable) sufficient to exercise de facto control over the policies and business decisions of a party or of all or substantially all of the business or assets of such party (whether by way of merger, sale of stock, sale of assets or otherwise) by any person or entity (including a "group" as defined in Section 13(d)-3 of the Securities Exchange Act of 1934 (the "Exchange Act")) (provided that the acquisition of less than 50% of such voting power shall not be deemed to constitute a "Change of Control" for as long as the acquiror or "group" qualifies to report, and does in fact report, its beneficial ownership on Schedule 13G in accordance with Rule 13(d)-1 promulgated under the Exchange Act) or (ii) individuals who, for a period of at least two consecutive years prior to such determination (together with any other individuals whose election was approved by a two-thirds vote of the directors then in office) shall cease to constitute at any time a majority of the members of the Board of Directors of its ultimate corporate parent.

### 11.2

In the event either party is subject to a Change of Control which was not approved or recommended by the Board of Directors of such party or its ultimate corporate parent (as applicable) as constituted immediately prior to such Change of Control, the following provisions shall apply:

**11.2.1** The party which has not undergone such Change of Control (the "Unaffected Party") shall retain or reacquire, as the case may be, all rights to the Patents, Technology and Trademarks in connection with marketing Products in the Territory (i.e., if such Unaffected Party is Forest Ireland, Forest Ireland shall continue to own the Trademarks and shall be deemed to have a perpetual License to such other assets and if such Unaffected Party is Lundbeck, Forest Ireland shall assign to Lundbeck all of the assets contemplated by Section 10.2 and the License shall be deemed to have expired), subject to the payments contemplated by Section 11.2.2.

**11.2.2** The Unaffected Party shall be obligated to pay the party which has undergone such Change of Control if the S-Enantiomer has completed a Phase III Clinical Study (the "Phase III Condition"), 100% of the Fair Market Value of such Product, or if the S-Enantiomer has not completed the Phase III Condition, a royalty of five percent of Net Revenues. The payment obligation of any such additional compensation and royalty obligations shall extend through any period in which Product is being sold by either party in the Territory.

**11.3** In the event either party is subject to a Change of Control which is approved or recommended by the Board of Directors of such party or its ultimate corporate parent (as applicable) as constituted immediately prior to such Change of Control, the following provisions shall apply:

**11.3.1** With respect to the S-Enantiomer, if it has not completed the Phase III Condition, the Unaffected Party shall have the Development Option, as defined and in accordance with the terms and conditions of Section 11.3.3.

**11.3.2** With respect to Compound or Product which has completed the Phase III Condition but only as to which there has been an "Impairment" (as defined in the next sentence), the Unaffected Party shall have the option (to be exercised by the furnishing of written notice of such exercise to the other party within 90 days of the Change of Control), but not the obligation, to reacquire or retain rights to such Compound or Product, as the case may be, in accordance with Section 11.2.1 and, upon the exercise of such option, shall pay in the case of the S-Enantiomer, a lump-sum payment equal to 100% of Fair Market Value within sixty (60) days of the furnishing of the notice of option exercise, or, if Fair Market Value is to be determined by a Valuation Expert, promptly following such determination. For purposes of this Section, an Impairment shall be deemed to have occurred in respect of a Product only if:

- (a) Such Product has not been marketed in the Territory for more than three years;
- (b) The product line of the party which has undergone the Change of Control and its Affiliates includes a Directly Competitive Product; and
- (c) The party which has undergone such Change of Control does not undertake and implement structures, procedures or practices (for example, commitments to specific marketing programs or the marketing of Products through a separate dedicated salesforce) which assure the anticipated value of such Product in light of such party's obligations hereunder notwithstanding the marketing of a competitive product.

**11.3.3** With respect to Compound or Product which has completed the Phase III Condition and as to which there has been no Impairment, the Unaffected Party shall not have rights to reacquire or retain rights to Patents or Technology; provided that (but only in the event there is then no approved NDA for such Products), the Unaffected Party shall have the option (the "Development Option"), but not the obligation, to assume full authority for the continued development of such Compound or Product without the participation of the Development Committee or the other party as may reasonably be required to obtain an approved NDA to market such Product in the Territory in light of the objectives of this S-Enantiomer License Agreement. In the event the Unaffected Party has exercised the Development Option (i) if such Unaffected Party is Lundbeck, Forest Ireland shall be obligated to pay Lundbeck in connection with the marketing of such Products, in addition to the compensation provided by Section 5.1 hereof, an amount equal to the amount of Sole Development Costs incurred by Lundbeck with respect to such Product and (ii) if such Unaffected Party is Forest Ireland, Forest Ireland shall receive a credit against compensation payable to Lundbeck pursuant to Section 5.1 hereof for the amount of Sole Development Costs incurred by Forest Ireland with respect to such Product.

## **12. Payments; Accounting Formats; Records; Currency Translation and Adjustments.**

**12.1** All payments by one party to the other hereunder (whether of additional license fees pursuant to Section 5.1, reimbursement of Development Costs, the purchase price for Compound or inventories of Product, or, unless otherwise agreed by the parties, any other payment) shall be made quarterly by the 30th day following the end of each Quarter. All payments hereunder shall be made in United States Dollars. To the extent the basis for any such payment is calculated in a currency (including any currency which may be subsequently introduced by the European Union) other than United States Dollars, such amount shall be converted into United States Dollars based upon the prevailing rate of exchange during the Quarter to which such payment relates.

**12.2** The chief financial officers of each of Forest Ireland and Lundbeck shall cooperate to develop a system of reporting and payments which will provide for the netting of payments between the parties for any Quarter as well as a reporting format which identifies with reasonable specificity the basis and calculation hereunder for any payment, currency or other adjustment or netting made or required to be made hereunder.

**12.3** Each party agrees to maintain accurate books and records in accordance with all applicable accounting standards and law and regulations and consistent with the books and records of such party generally, which accurately reflect all costs, expenses and revenues relevant to the determination and payment obligations of this Agreement. Each party, together with its independent representatives and accountants to which the other shall have no reasonable objection (and subject to appropriate safeguards of confidentiality), shall be entitled to audit such books and records of the other party solely for purposes of verifying any such determination or payment obligation. The costs of such audit shall be borne by the party undertaking such audit; provided that if such audit discloses an underpayment to or overpayment by such party of 10% or more, the cost of such audit shall be borne by the other party, as well as prompt rectification of the underpayment or overpayment so made.

### **13. Arbitration**

**13.1** Any disputes arising with respect to the interpretation or enforcement of, or claims with respect to, any provision hereof, and any determination required to be made pursuant to Section 1.24 or any decision of a Valuation Expert, shall be submitted to arbitration in London, England in accordance with the rules of the London Court of International Arbitration, as amended from time to time. In any arbitration pursuant to this Agreement, the award or decision shall be rendered by a majority of the members of an arbitration panel consisting of three members, one of whom shall be chosen by each of the parties hereto and the third of whom, who shall be the chairman of the panel, shall be appointed by mutual agreement of the two arbitrators so appointed by the parties. Each arbitrator shall have pharmaceutical executive or relevant legal experience. Arbitration proceedings shall be conducted in the English language. Each party shall bear 50% of the costs of such arbitration proceeding; provided that the arbitration panel shall have the authority to award such costs to a party as it determines to be equitable. This is an arbitration for the purposes of the Arbitration Act, 1996 and will be final, binding and conclusive upon the parties. Enforcement of such award or decision may be obtained in any court having jurisdiction over the party against whom such enforcement is sought.

### **14. Relationship of the Parties.**

**14.1** The relationship of Forest Ireland and Lundbeck shall be that of independent contractors. This Agreement shall not be construed to constitute Forest Ireland and Lundbeck as partners or joint venturers, or to establish any relationship in the nature of agency. Neither party shall hold itself out as having the authority to bind the other party hereto.

### **15. Events of Force Majeure.**

**15.1** Neither Forest Ireland nor Lundbeck shall be held liable or in default for failure of performance for any cause beyond its reasonable control including, for example, Acts of God, declared or undeclared war, fire, flood, interruption of transportation, embargo, insurrections, accident, explosion, governmental laws, orders, regulations, or restrictions, any strike, lockout or other labor troubles or similar events commonly known as events of *force majeure*.

### **16. Miscellaneous**

**16.1** Subject only to Sections 7.3 and 7.4, nothing set forth herein shall be deemed to limit, restrict or preclude Forest Ireland and its Affiliates or Lundbeck and its Affiliates from performing other research or development projects, independently or in collaboration with others, or from developing, launching or marketing other pharmaceutical products, whether for their own account or for the account of third parties.

**16.2** This Agreement shall be governed by and construed in accordance with the laws of England; provided that such choice of law shall not be deemed to include provisions of the Treaty of Rome applicable to the licensing of intellectual property to the extent such provisions do not apply by their terms to the licensing of

technology for exploitation in the Territory.

**16.3** Each of the parties shall, from time to time during the term of this Agreement, upon request by the other, execute and deliver all such further documents or instruments as may be required in order to give effect to the purpose and intent of this Agreement.

**16.4** This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective assigns and successors in interest. Neither party may assign its rights or duties hereunder, except to a wholly-owned subsidiary, without the prior written consent of the other party.

**16.5** Any notice, request or other communication required or permitted by this Agreement to be given by either party to the other shall be in writing and either mailed by registered or certified mail, return receipt requested, by express delivery service or by facsimile transmission, addressed to such party, Attention: The President at its address indicated above or to such other address as such party may previously have designated by like written notice. Notice shall be deemed to have been given upon receipt. Facsimile transmission numbers for the separate parties are as follows:

If to Forest Ireland: 353 1 8672226

If to Lundbeck

(Legal Department): 45 36 30 27 32

**16.6** This S-Enantiomer License Agreement; the Umbrella Agreement of even date herewith by and among Forest Inc., Forest Ireland, and Lundbeck; and the S-Enantiomer Supply Agreement by and between Forest Ireland and Lundbeck of even date herewith (collectively, the "**Agreements**") contain the entire agreements between Forest Inc. or Forest Ireland and Lundbeck with respect to the subject matter thereof. The Agreements supercede any and all other agreements, written or oral, between Forest Inc. or Forest Ireland and Lundbeck with respect to the subject matter thereof or in conflict with their terms.

**16.7** No modification or waiver of any of the terms of this Agreement shall be deemed valid unless it is in writing and signed by the party to whom such modification is sought to be enforced. The failure of either party to insist upon the strict performance of any term of this Agreement or the waiver by either party of any breach under this Agreement shall not prevent the subsequent strict enforcement of such term and shall not be deemed a waiver of any other or subsequent breach.

**16.8** In the event any court declares illegal or unenforceable, as written or applied, any provision of this Agreement, the balance of such provision and this Agreement shall continue in full force and effect as if such provision had been deleted or inapplicable to the situations to which such provision cannot be legally applied.

**16.9** Neither party shall issue any press release or make any public announcement covering this Agreement or the transactions contemplated hereby without affording the other party the prior opportunity to review and comment upon such release or announcement. The foregoing shall not be deemed to limit either party's right to make disclosures required by applicable provisions of law.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

FOREST LABORATORIES (IRELAND) LIMITED

By: /s/Raymond Stafford  
Name: Raymond Stafford  
Title: Chief Executive

H. LUNDBECK, A/S

By: /s/Erik Sprunk-Jansen  
Name: Erik Sprunk-Jansen  
Title: Chairman and President

EXHIBIT 10.18

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]."

S-ENANTIOMER SUPPLY AGREEMENT

S-ENANTIOMER SUPPLY AGREEMENT dated this May 29, 2002 by and between Forest Laboratories (Ireland) Limited, a corporation organized and existing under the laws of the Republic of Ireland and having its principal executive offices at Clonshaugh Industrial Estate, Clonshaugh, Dublin 17 Republic of Ireland ("Forest Ireland") and H. LUNDBECK A/S, a corporation organized under the laws of Denmark and having its principal executive offices at 9 Ottiliavej, DK-2500, Copenhagen-Valby, Denmark ("Lundbeck").

R E C I T A L S:

A. The Parties hereto and Forest Laboratories, Inc. ("**Forest Inc.**") have agreed to novate, effective as of March 27, 1998 (except as otherwise provided herein), the Supply Agreement by and between Forest Inc. and Lundbeck dated the 27th day of March, 1998, as amended to date (the "**1998 Supply Agreement**") in accordance with the terms hereunder.

B. Forest Ireland and Lundbeck are parties to a S-Enantiomer License Agreement of even date herewith (the "**S-Enantiomer License Agreement**") pursuant to which, among other things, Lundbeck has granted Forest Ireland the exclusive right and license under the Patents and Technology (as therein defined) to manufacture or have manufactured, market, sell and distribute finished pharmaceutical products in which the active ingredient is the chemical known as S-(+)-Citalopram (as more fully defined herein, the "Compound") and pursuant to which Lundbeck will undertake a program of research and development to obtain regulatory approval to market such

finished pharmaceutical products in the Territory.

C. Forest Ireland and Lundbeck wish to set forth their agreement pursuant to which Lundbeck shall supply to Forest Ireland, and Forest Ireland will purchase from Lundbeck, Forest Ireland's requirements of the Compound or Finished Product to the extent such purchase and sale is contemplated, or may subsequently be required, by the terms, conditions and procedures of the S-Enantiomer License Agreement.

NOW, THEREFORE, in consideration of the foregoing and of the terms and conditions hereof, the parties hereto hereby agree, effective as of March 27, 1998 (except as otherwise provided herein), as follows:

**1. Definitions.**

Except as otherwise defined herein, capitalized terms shall have the respective meanings assigned to them in the S-Enantiomer License Agreement. In addition, the following terms shall have the respective meanings assigned to them below:

**1.1 "Average Daily Dose"** for any period shall mean the average number of milligrams of Original Product and Finished Product, respectively, used by consumers using the respective product in the Territory.

**1.2 "Compound" or "S-Enantiomer"** shall mean the Compound (S)-1-[3-(dimethylamino)propyl]-1(4-fluorophenyl)-1, 3-dihydro-5-isobenzofurancarbo-nitrile.

**1.3 "Equivalent Quantity"** shall refer to the quantity of Original Compound required to formulate a number of Average Daily Doses of Original Product which equals the number of Average Daily Doses of Finished Product formulated from one kilogram of Finished Product.

**1.4 "Finished Product"** shall mean pharmaceutically formulated finished products having the Compound as their only active ingredient in form for sale and distribution pursuant to an approved NDA.

**1.5 "Formulate"** shall mean to formulate Compound into Finished Product.

**1.6 "Marketing Year"** shall mean each 12 consecutive month period beginning with the commercial launch of Finished Product in the Territory.

**1.7 "Minimum Price"** shall mean a price, expressed in Danish Kroner, for a kilogram of Compound, which is calculated so as to produce the same profit or loss to Lundbeck as the Minimum Supply Price (as defined in the License and Supply Agreement between Forest Ireland and Lundbeck dated October 3, 1995 (the "**1995 Agreement**")) for the amount of Original Compound needed to produce the number of tablets of Original Product which corresponds to the Equivalent Quantity. **"Sample Price"** shall mean a price, expressed in Danish Kroner, for a kilogram of Compound, which is calculated so as to produce the same profit or loss to Lundbeck as the price for samples set forth in Article 10(f) of the 1995 Agreement for the amount of Original Compound needed to produce the number of tablets of Original Product which corresponds to the Equivalent Quantity.

**1.8 "Net Selling Price"** for any dosage form of Finished Product for any period shall mean the price obtained by dividing (i) Net Revenues of such Finished Product for such period by (ii) the number of units of such Finished Product with respect to which Net Revenues were determined.

**1.9 "Original Compound"** shall mean the chemical entity known as Citalopram as more fully described in the 1995 Agreement.

**1.10 "Original Product"** shall mean finished pharmaceutical products formulated from Original Compound.

**1.11 "Quarter"** shall mean each three calendar month period ending March 31, June 30, September 30 and December 31, and the first Quarter shall be deemed to include the period from the commencement of the first Marketing Year through the end of the first calendar quarter in which the first Marketing Year commenced.

**1.12 "Specifications"** shall mean the specifications for Compound set forth on Schedule 1.8 hereto, as such Specifications may be amended by the Development Committee in light of requirements for FDA approval of the NDA.

## **2. License Grant And Development.**

**2.1** The parties acknowledge that, pursuant to the S-Enantiomer License Agreement, Lundbeck has granted to Forest Ireland, and Forest Ireland has acquired from Lundbeck, the License as defined in, and subject to the terms therein set forth. The parties further acknowledge that the License shall not be deemed to apply to uses of the Patent for cerebrovascular disorders and inhibition of platelet aggregation (the "Use Patent") from and after August 6, 2005, from and after which date Zeria Pharmaceutical Co. Ltd. ("Zeria") will regain all rights to such use in the Territory, unless and to the extent the license arrangements between Lundbeck and Zeria have been amended or modified at such time. If Forest Ireland wishes to continue utilization of the Use Patent after such date, Forest Ireland shall inform Lundbeck no later than January 1, 1999 whereupon Lundbeck undertakes to negotiate an extension of the agreement with Zeria in order to permit Forest Ireland's continued exploitation of the Use Patent. Lundbeck does not warrant that Lundbeck will be able to achieve any such extension. In the event Lundbeck has not achieved any such extension by August 6, 2004, Forest Ireland shall have the right to negotiate for such rights directly with Zeria.

**2.2** In accordance with the terms of the S-Enantiomer License Agreement, the Development Committee may determine that (i) Lundbeck shall supply all of Forest Ireland's requirements of Compound or Finished Product and Forest Ireland shall purchase such requirements from Lundbeck or (ii) Lundbeck or Forest Ireland may acquire Compound or Finished Product from a third party vendor. The parties hereby agree that purchases of Compound or Finished Product by Forest Ireland from Lundbeck for purposes contemplated by the S-Enantiomer License Agreement shall be pursuant to the terms and conditions hereof and that, in the event Compound or Finished Product is supplied by a third party vendor for purposes of the S-Enantiomer License Agreement, Lundbeck shall purchase such product for delivery to Forest Ireland as approved by the Development Committee and shall remain entitled to the payments of purchase Price and Royalty to be paid by Forest Ireland hereunder.

**2.3** Lundbeck agrees to continue performing development work with respect to the Compound pursuant to the terms of the Development Plan for the Compound to be approved pursuant to the S-Enantiomer License Agreement. The costs of such development work through the completion of a Phase I Clinical Study shall be for the account of Lundbeck and shall not be deemed "Development Costs" for purposes of the S-Enantiomer License Agreement. Lundbeck shall supply an adequate quantity of citalopram dicarbinol racemate without charge to Forest Ireland so as to yield **[Confidential Treatment]** of Compound. The costs of conversion of such citalopram dicarbinol racemate into Compound, together with the costs of development work incurred following the completion of such Phase I Clinical Study, shall be deemed Development Costs for purposes, and subject to the terms and conditions, of the S-Enantiomer License Agreement.

**2.4** The parties acknowledge that, as part of the development work contemplated hereby, Lundbeck may, either directly or through contractual arrangements with independent third parties, undertake the development or acquisition of manufacturing capability to formulate and manufacture Compound from Original Compound or an intermediate thereof and, in connection therewith, may incur capital expenditures to build or acquire such manufacturing capacity. In the event that the Development Committee, pursuant to the terms of the S-Enantiomer License Agreement, determines not to proceed with further development of Compound or the Compound is not

commercially launched in the Territory for any reason, Forest Ireland agrees to reimburse to Lundbeck Lundbeck's direct, out-of-pocket capital expenditures and directly allocable internal overheads (but not corporate general or administrative overheads), together with the costs of noncancelable contractual obligations ("Reimbursable Expense") in developing or acquiring such manufacturing capacity to the extent such Reimbursable Expenses exceed the value of such capacity for other viable or available uses. Before incurring any Reimbursable Expenses or obligations therefor, Lundbeck will consult with Forest Ireland and will not incur such expenses or obligations unless Forest Ireland has agreed to the programs pursuant to which such expenses are to be incurred. Lundbeck agrees to maintain true and complete records of Reimbursable Expenses in accordance with Section 3.5 hereof.

**2.5** Lundbeck hereby grants to Forest Ireland a right of first refusal to receive from Lundbeck a right to co-market Finished Product in Canada, pursuant to a separate co-marketing agreement to be negotiated and entered into, provided that Lundbeck determines to market Finished Product in Canada and provided further that Forest Ireland then has, directly or indirectly (i.e., through distributors or other third party arrangements reasonably satisfactory to Lundbeck) adequate sales capability in Canada. "Co-marketing" shall mean the marketing, use, distribution and sale of Finished Product by the parties hereto under different trademarks. In the event Forest Ireland is granted co-marketing rights for Canada, Forest Ireland may have Finished Product co-promoted in Canada, provided that Forest Ireland shall be responsible for acts or omissions of Forest Ireland's co-promotion partner.

### **3. Purchase Price; Royalties.**

**3.1** The purchase price (the "Purchase Price") for Compound purchased by Forest Ireland hereunder shall be [**Confidential Treatment**] of Net Revenues. In addition, Forest Ireland shall pay a royalty (the "Royalty") in respect of the use of the Trademark of [**Confidential Treatment**] of Net Revenues. In no event shall the sum of the Purchase Price and Royalty for a Quarter be less than the Minimum Price for the quantity of Compound purchased during that Quarter.

**3.2** Lundbeck shall provide Forest Ireland with Compound for Formulation by Forest Ireland and distribution as free samples during the first three Marketing Years at no charge to Forest Ireland; provided that, to the extent the value of the quantity of such free Compound exceeds [**Confidential Treatment**] of Net Revenues during any such marketing Year (such value determined by calculating the number of units of Finished Product represented by such Compound and assuming such amount was sold at the Net Selling Price for the Marketing Year in question) Forest Ireland shall pay to Lundbeck a Purchase Price equal to the Sample Price per kilogram of Compound in excess of such quantity to the extent used for sampling purposes. Forest Ireland shall be entitled to purchase Compound for the formulation of Product to be distributed as samples following the expiration of the third Marketing Year at the Sample Price.

**3.3** Payments of Purchase Price and Royalty shall be made by Forest Ireland on an "on account" basis within 30 days of each shipment of Compound to Forest Ireland, and settled following the end of each Quarter pursuant to Section 12 of the S-Enantiomer License Agreement. The "on account" payment shall be equal to [**Confidential Treatment**] of the weighted value of such order. The weighted value of an order shall mean the sum of (a) the amount determined by multiplying (i) the number of individual doses represented by such quantity of Compound after deducting the number of such doses reasonably anticipated by Forest Ireland to be distributed as samples by (ii) the Net Selling Price in effect as of the last day of the preceding Quarter (or, with respect to any Quarter prior to the first commercial sale of Finished Product, a reasonably estimated Net Selling Price) and (b) the total Sample Price, if any, which would be applicable to the anticipated distribution of samples, after allowing for the number of samples as to which there is no charge to Forest Ireland pursuant to Section 3.2. Following the end of each Quarter, the actual Purchase Price and Royalty shall be determined based upon the actual Net Revenues and sample distribution for such Quarter and the parties shall adjust payments, in accordance with Section 12 of the S-Enantiomer License Agreement, so that Lundbeck shall have received the Purchase Price and Royalty provided hereby.



**3.4** It is the intention of the parties that the profit earned by Lundbeck from selling Compound to Forest Ireland, including Purchase Price and Royalty, shall not be less, on an absolute basis, than the profit which Lundbeck would have earned from selling Original Compound to Forest Ireland, after allowing for the different quantities resulting from differences in formulation of finished dosage forms and different Average Daily Doses between Original Product and Finished Product. Accordingly, the parties have agreed as follows:

**3.4.1** At the end of each Marketing Year, Forest Ireland shall calculate, based upon information supplied by Lundbeck (a) Lundbeck's profits from the sale of the Compound ("Compound Profit") by subtracting (i) Lundbeck's direct manufacturing costs, including allocated manufacturing overheads but excluding corporate general or administrative overheads ("Costs") for manufacturing the quantity of Compound purchased by Forest Ireland during such Marketing Year from (ii) the total Purchase Price and Royalty payable by Forest Ireland with respect to purchases of Compound during such Marketing year, and (b) the assumed profit to Lundbeck from the sale of the Equivalent Quantity of Original Compound ("Original Compound Profit") by subtracting (i) Lundbeck's Costs of manufacture of the Equivalent Quantity from (ii) the total compensation which Forest Ireland would have had to pay Lundbeck for such Equivalent Quantity pursuant to the terms of the 1995 Agreement, based upon the Net Selling Price for Original Product in effect during such Marketing Year. To the extent the Original Compound Profit exceeds the Compound Profit for a Marketing Year, Forest Ireland shall pay the amount of such excess to Lundbeck as additional Purchase Price for such previous Marketing Year. In calculating Costs, only costs applicable to an efficient manufacturing operation within customary industry standards and in light of alternate sources of supply, or sources which could reasonably be expected to become available, shall be taken into account.

**3.4.2** Following the end of the first Marketing Year, the parties shall discuss in good faith an adjustment to the aggregate Purchase Price and Royalty so as to achieve the purpose of Section 3.4.1 without the need for the annual adjustments contemplated by that Section, taking into account the profit being earned by Lundbeck for the equivalent Average Daily Dose of original Product and the marketing conditions and expenses applicable to Forest Ireland's marketing of the Finished Product. In the event the parties are unable to agree upon such adjustment, the provisions of Section 3.4.1 shall continue to apply in accordance with their terms.

**3.5** Each of Forest Ireland and Lundbeck shall maintain true and complete books and records of all data necessary for the calculation of Net Revenues, sample distribution, Compound Profit, Original Compound Profit and Reimbursable Expenses, as the case may be, to enable the calculation, confirmation and audit of any determination of Purchase Price, Royalty or Reimbursable Expenses required to be made hereunder. Such books and records shall be subject to audit by the other party and its representatives in accordance with the terms and conditions of Section 12.3 of the S-Enantiomer License Agreement.

**3.6** All payments to be made hereunder shall be made net in United States Dollars by bank transfer remittance to Lundbeck's account 3016-57321-3 held at Den Danske Bank A/S, Holmes Kanal 2, Copenhagen, Denmark, or any other account designated by Lundbeck. Payments shall be subject to netting, recalculation and currency adjusted in accordance with Section 12 of the License Agreement.

**3.7** To the extent required by law, Forest Ireland is entitled to withhold from amounts payable to Lundbeck under this Agreement all income related taxes levied or assessed thereon. As Lundbeck may receive for such tax payments a credit on the taxes payable by it in the Kingdom of Denmark or elsewhere, Forest Ireland shall without undue delay provide Lundbeck with certified tax receipts or other evidence of payment required by the relevant tax authorities for the taxes legally deducted from payments hereunder.

**3.8** It is currently contemplated that Lundbeck will supply Compound pursuant to this Agreement for Formulation into Finished Product by Forest Ireland. In the event the parties may subsequently agree that Lundbeck is to supply Finished Product, the Purchase Price, Minimum Price and Sample Price shall each be increased by Lundbeck's Cost of Goods for the additional manufacturing and packaging procedures required to produce Finished Product from Compound.

**3.9** In addition, in the event Compound is supplied by a third party vendor, Forest Ireland shall make the "on account" and quarterly settlement payments to Lundbeck pursuant to Section 3.3 as if such Compound had been delivered by Lundbeck hereunder.

**4. Forecasts; Orders; Deliveries.**

**4.1** No later than 18 months prior to the date on which Forest Ireland reasonably anticipates requiring the first delivery of Compound to take place, Forest Ireland shall supply Lundbeck with a non-binding forecast from the anticipated date of such first delivery through December 31 of such year and for the period of three years thereafter. In addition, Forest Ireland will update the three year forecast at least once per year so that Lundbeck is always in possession of a forecast for the succeeding three years. These forecasts shall not be binding on Forest Ireland or Lundbeck except to the extent of the provisions of Sections 4.2 and 4.3.

**4.2** No later than 10 months prior to the first requested delivery date for Compound, Forest Ireland shall furnish Lundbeck with a binding order covering Forest Ireland's requirements of Compound through the period from such first requested delivery and ending on the next December 31. Lundbeck shall be obligated to fill such binding order, provided that such binding order does not exceed by more than 20% the quantity forecast for such period pursuant to the forecast delivered pursuant to Section 4.1 hereof. To the extent such order exceeds such forecast, Lundbeck shall use its commercially reasonable efforts to supply such excess quantities.

**4.3** For each four Quarter period following the end of the period referred to in Section 4.2, Forest Ireland shall furnish Lundbeck with binding forecasts for each such four Quarter period no later than 6 months prior to the beginning of each such four Quarter period. Such forecast shall be submitted on a rolling quarterly basis so that Lundbeck will always be in possession of forecasts pursuant to this Section 4.3 representing four consecutive Quarters commencing 6 months from the date of such forecast. The forecast for the first Quarter shall be deemed a binding order for such Quarter; the forecasts for the next three subsequent Quarters shall be deemed a commitment by Forest Ireland to order an amount of Compound equal to at least 80% of the amount of the forecasts for such Quarters. Such commitment shall become firm orders in subsequent rolling forecasts pursuant to this Section 4.3. Each binding order of Forest Ireland pursuant to this Section 4.3 shall constitute Forest Ireland's agreement to purchase and, but only to the extent such binding orders do not exceed the applicable forecast for such Quarter pursuant to this Section 4.3 by more than 20%, Lundbeck's agreement to sell the quantity of Compound covered by such firm order for the Quarter in question. Lundbeck will use its commercially reasonable efforts to supply quantities of Compound requested by Forest Ireland in excess of amounts forecast pursuant to this Section.

**4.4** All deliveries of Compound shall be made by Lundbeck CIP Forest Ireland's Dublin facilities (Incoterms 1990), and title and risk of loss shall pass to Forest Ireland in accordance therewith.

**5. Marketing; Minimum Purchase Requirements.**

**5.1** Forest Ireland shall market Finished Product in the Territory as if Finished Product were a pharmaceutical product resulting from Forest Ireland's own research and development activities, in light of the commercial potential for the Finished Product in the Territory.

**5.2 Minimum Purchase Requirements.**

**5.2.1** Forest Ireland shall be obligated to achieve minimum Net Revenues (the "Minimum Net Revenues") for each of the first three Marketing Years as follows:

Marketing Year	Minimum Net Revenues
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1	[Confidential Treatment]
2	[Confidential Treatment]
3	[Confidential Treatment]

**5.2.2** Subject to the following provisions of this Section 5.2.2, if the Minimum Net Revenues are not achieved for a Marketing Year, Lundbeck shall be entitled to convert the License granted by the S-Enantiomer License Agreement, but solely in respect of the Compound and Finished Product, into a non-exclusive license upon three months prior written notice by Lundbeck to Forest Ireland. Notwithstanding the preceding sentence, the License shall not become non-exclusive if Forest Ireland shall, following such notice by Lundbeck, (a) pay to Lundbeck an amount equal to **[Confidential Treatment]** of the Net Revenues not achieved, less Lundbeck's Cost of Goods corresponding to such quantity, (b) purchase the quantity of Compound corresponding to the Net Revenues not achieved at a purchase price of **[Confidential Treatment]** of such Net Revenues or (c) agree to carry forward the amount of such Net Revenues not achieved to the Minimum Net Revenue requirement for the succeeding Marketing Year (which Minimum Net Revenue requirements shall be satisfied by the end of the third Marketing Year). In addition, the parties agree that Forest Ireland shall have met the Minimum Net Revenues required for a Marketing Year if Forest Ireland shall have purchased the quantity of Compound during such year, which, if formulated into Finished Product and sold at the Net Selling Price for such Marketing Year, would equal or exceed the Minimum Net Revenue requirement for such Marketing Year.

## **6. Trademark.**

**6.1 Selection/Filing/Prosecution Maintenance.** Lundbeck will suggest a Trademark to be used by Forest Ireland hereunder. Lundbeck's suggestion shall be adopted by Forest Ireland unless Forest Ireland has reasons which, in Lundbeck's judgment, reasonably justifies that Lundbeck's suggestions can not be applied. In such case, Forest Ireland may freely select a Trademark for use in conjunction with the marketing of Finished Products in the Territory hereunder. Forest Ireland's choice shall be subject to Lundbeck's approval, which approval shall not be unreasonably withheld. However Lundbeck is not obliged to accept registration and use of an already registered Lundbeck trademark if such registration does not comply with Lundbeck's strategy in the Territory. Lundbeck shall file applications for registrations for the Trademark agreed upon. Forest Ireland shall have the right to market a generic version of the Finished Product in the event it appears reasonably likely that a generic version of the compound has been or will be introduced in the Territory by an independent third party. Any name, including a generic name as e.g., "Citalopram Enantiomer," under which such Finished Product is sold shall be deemed a "Trademark" for purposes of Sections 3.1 and this Section 6.1 and the marketing of such Finished Product shall be governed by the financial terms and conditions provided by Section 3.1. Forest Ireland will notify Lundbeck promptly of its decision to introduce a generic version of the Finished Product in accordance with this Section 6.1. Lundbeck will prosecute such applications and maintain the registration and keep Forest Ireland advised of the status of each application and registration. If Lundbeck has difficulties or is unable to register a selected Trademark, Lundbeck shall advise Forest Ireland and Forest Ireland shall either request Lundbeck to then continue prosecution of the application and/or Forest Ireland shall select another Trademark. All out-of-pocket costs and expenses (including attorneys' fees) associated with the filing of applications, prosecution of applications, registration and maintenance of registrations shall be paid by Lundbeck. Forest Ireland shall assist and cooperate with Lundbeck in its filing and prosecuting all Trademark applications and maintaining Trademark registrations as well as sign all documents necessary to carry out filing and prosecuting such applications and maintaining such registrations. All uses of any Trademark by Forest Ireland anywhere in the Territory shall inure to the benefit of Lundbeck. Forest Ireland is not entitled to market Finished Product without using Trademark.

**6.2 Ownership.** Subject to the terms of the License Agreement, Trademark selected and registered in accordance with Section 6.1 shall be and remain the sole exclusive property of Lundbeck and Lundbeck may freely register and use any Trademark outside the Territory.

**6.3 Enforcement.** Forest Ireland will inform Lundbeck of any known trademarks, applications, registrations, or use of trademarks in the Territory, known or which ought to be known by Forest Ireland, which may cause confusion with Forest Ireland's selected Trademark. Lundbeck may initiate action to enforce its Trademark rights at Lundbeck's cost. In the event Lundbeck elects not to initiate action to enforce its Trademark rights or fails or refuses to do so within sixty days after written request therefore by Forest Ireland, Forest Ireland shall have the right at its option to initiate such action in Lundbeck's name with Lundbeck's full cooperation, provided that Lundbeck is entitled to enforce the Trademark rights in question. In such action by Forest Ireland, Forest Ireland shall pay all costs and expenses. Any award for damages collected through infringement suit in the Territory shall be divided between the parties according to the share of loss or potential loss each party would suffer from the infringement. If a Trademark, identified and chosen by Lundbeck, must be substituted by a new trademark after launch of Finished Product, due to an infringement suit brought against Forest Ireland or Lundbeck, the Trademark royalty rate as provided for in Section 3.1, shall be reduced to **[Confidential Treatment]** for a period of two (2) years from the date on which substitution has taken place in the market. No further compensation shall be paid by Lundbeck to Forest Ireland in this respect.

**6.4 Quality Control.** Forest Ireland will provide Lundbeck with samples of Finished Product bearing the Trademark at Lundbeck's request. All Finished Products sold by Forest Ireland bearing the Trademark shall meet the standard, specifications and instructions laid down or approved by the FDA or the equivalent authority in any state of the Territory. Forest Ireland agrees and undertakes to use the Trademark only on or in connection with the Finished Products under this Agreement. All Finished Products must bear the Trademark.

**6.5 Infringement.** If the Trademark has been identified and chosen by Forest Ireland, Forest Ireland shall be responsible for claims or damages awarded as a result of Trademark infringements. Forest Ireland shall indemnify Lundbeck for claims of Trademark infringement made by an independent third party.

## **7. Patents.**

**7.1 Alleged Infringement.** If a claim of infringement is brought against Forest Ireland alleging infringement of any patent owned by an independent third party by reason of Forest Ireland exploiting Finished Product commercially under the Patents or Technology, Forest Ireland shall promptly give notice to Lundbeck of such claim and provide to Lundbeck all information in Forest Ireland's possession regarding such claim or suit. Not more than ninety (90) days from such notice, Lundbeck shall advise Forest Ireland of Lundbeck's decision as to whether it will or will not defend such suit or claim. If such claim constitutes a suit for infringement, Lundbeck, at its expense, may conduct the defense of such suit and Forest Ireland shall furnish to Lundbeck such reasonable assistance as Lundbeck needs and from time to time reasonably requests, and, at its option and expense, may participate. If Lundbeck elects not to defend such suit in the Territory and has not otherwise disposed of such claim, Forest Ireland may defend or dispose of such suit or claim, and Lundbeck shall furnish to Forest Ireland such reasonable assistance as Forest Ireland needs and from time to time reasonably requests.

**7.2 Damages.** If damages or costs of defense or liability are incurred or awarded against Forest Ireland, Lundbeck shall indemnify Forest Ireland for such damages or costs up to the amount of Purchase Price and Royalties previously paid by Forest Ireland to Lundbeck with respect to Finished Product sold by Forest Ireland in the Territory.

**7.3 Royalties.** If Forest Ireland becomes obligated to pay royalties to any independent third party in order to exploit Finished Product commercially, said royalties shall be creditable against Purchase Price and Royalties otherwise payable to Lundbeck hereunder. If Lundbeck elects not to defend such suit and has not otherwise disposed of such claim, and if Forest Ireland elects to dispose of such claim, any amounts paid or payable to the independent third party by Forest Ireland in disposing of such suit or claim shall at the time of payment be creditable against Purchase Price and Royalties otherwise payable to Lundbeck hereunder.

**8. Indemnification.**

**8.1** Lundbeck shall defend, indemnify and hold harmless Forest Ireland and its officers, directors, agents and employees from and against any and all liability, demands, damages, costs, expenses (including attorneys' fees), and losses for death, personal injury, illness or property damage arising (a) out of the manufacture or supply of Compound or Finished Product by or behalf of Lundbeck to Forest Ireland to the extent such manufacture or supply is not in accordance with any representation or warranty of Lundbeck hereunder or (b) as a result of using any or all of the Patents or Technology licensed by Lundbeck to Forest Ireland under the S-Enantiomer License Agreement and related to Compound or Finished Product in connection with the manufacture, sale or distribution of Compound or Finished Product in countries outside of the Territory or (c) the breach by Lundbeck of any representations or warranties of Lundbeck made herein. Such indemnification shall neither apply to liability resulting from the gross negligence or intentional wrongful acts of Forest Ireland; nor from Forest Ireland's failure to observe express warranties made to Lundbeck with respect to Compound or Finished Product.

**8.2** Forest Ireland shall defend, indemnify and hold harmless Lundbeck and its officers, directors, agents and employees from and against any and all liability, demands, damages, costs, expenses (including attorneys' fees), and losses for death, personal injury, illness or property damage arising out of (a) the manufacture, distribution, use, testing, sale, or other disposition, by Forest Ireland, or any distributor, customer, or representative of Forest Ireland or anyone in privity therewith, of Finished Product in the Territory, except to the extent arising in connection with a matter as to which Lundbeck is required to indemnify Forest Ireland pursuant to Section 8.1 or (b) the breach by Forest Ireland of any representations or warranties of Forest Ireland made herein. Such indemnification shall neither apply to liability resulting from the gross negligence or intentional wrongful acts of Lundbeck, nor from Lundbeck's failure to observe express warranties made to Forest Ireland with respect to the Compound.

**8.3** The provisions of Section 8.2 of the S-Enantiomer License Agreement shall apply to the obligations of indemnification set forth in this Section.

**9. Term; Termination.**

**9.1** The term of this Agreement (the "Supply Term") shall be for a period equal to the Term of the S-Enantiomer License Agreement, including any Renewal Term.

**9.2** Following the expiration of the Supply Term, and subject only to the payment obligations of Section 9.4, Forest Ireland shall continue to possess the License in accordance with the terms of the S-Enantiomer License Agreement and shall continue to have an exclusive license to use the Trademark in connection with the marketing of Finished Product in the Territory and Lundbeck shall be obligated to continue supplying Compound and to furnish the technical cooperation contemplated by Section 9.3 of the S-Enantiomer License Agreement as reasonably required, and for as long as reasonably necessary, to permit Forest Ireland to develop or acquire an alternate supply of Compound so as to permit the continued and uninterrupted marketing of the Finished Product in the Territory.

**9.3** Lundbeck may terminate the Supply Term upon written notice to Forest Ireland providing for a termination date no earlier than three years from the date of such notice. Following any such expiration, the provisions of Section 9.2 shall apply.

**9.4** Following the expiration or termination of the Supply Term, Forest Ireland shall continue paying Lundbeck the Royalty for as long as Forest Ireland continues to market Finished Product in the Territory.

**9.5** If force majeure conditions as set forth in Section 11, persist for a time period of more than six (6) months from the date when the notice in which a party has pleaded force majeure was sent, the other party will be entitled to terminate the Supply Term with immediate effect.

**9.6** Termination of the Supply Term shall not relieve either party of any obligation of payment or performance accrued prior to such termination.

**10. Termination For Cause.**

**10.1** This Agreement, together with the S-Enantiomer License Agreement, shall be construed and interpreted as a single agreement. Accordingly, the provisions governing termination of the S-Enantiomer License Agreement (including provisions for arbitration) in the event of a default by a party (the "defaulting party") and the rights and remedies of the parties in respect hereof shall be deemed to apply equally to the terms and conditions hereof, subject only to the provisions of Section 10.2.

**10.2** In the event this Agreement is terminated pursuant to Section 10.1 and Lundbeck is the defaulting party, Forest Ireland shall be deemed to have a perpetual royalty-free License to the Patents, Technology and Trademark related to the Compound and Finished Product and Lundbeck shall remain obligated to continue to supply Compound and to perform the technology transfer and related cooperation provided by Section 9.2. In the event this Agreement is terminated and Forest Ireland is the defaulting party, the License shall be terminated and Forest Ireland shall remain obligated to deliver all necessary documents and instruments as may reasonably be required to vest in Lundbeck all Forest Ireland Technology, the Trademark and related assets and information related to Compound or Finished Product.

**11. Force Majeure.**

Neither party shall be liable for non-performance of any provision of this Agreement due to force majeure. Force majeure will have the meaning stated below under Section 11.1:

**11.1** Strikes, lockouts, other industrial disturbances; rebellions; mutinies; epidemics; landslides, lightning, earthquakes, fires, storms, floods, sinking, drought; civil disturbances; explosions; act or decision of duly constituted municipal, state or National Governmental authorities or of Courts of Law including but not limited to the FDA; impossibility to obtain equipment, supplies, fuel or other required materials; unexpected drug toxicity findings; unexpected serious adverse drug reactions or any other causes similar or completely different, all beyond the control of the party pleading *force majeure* preventing the party from performing its rights and obligations and not to be overcome by due diligence of such party; provided neither party shall have any obligation to settle a labor dispute in order to exercise due diligence.

**11.2** In view of the complexity of the pharmaceutical development and production scale up of Compound, both parties agree to define delays in pharmaceutical development or production scale up caused by unexpected problems of a chemical or technical nature (for example, stability) as events of force majeure within the meaning of Section 11.1

**11.3** The parties agree that if either of them find themselves wholly or partly unable to fulfill their respective obligations in this Agreement by reasons of force majeure, the party pleading force majeure will as soon as possible notify the other party of its inability to perform giving a detailed explanation of the occurrence which excuses performance. If said notice is given, the performance of the notifying party shall be abated for so long as performance may be prevented by force majeure. Except for the payment of funds that are due and payable prior to any force majeure, neither party shall be required to make up for any performance that is prevented by force majeure. However, if a force majeure situation prevails for more than six (6) months, the Supply Term can be terminated immediately, and Section 9.2 will apply.

**12. Assignability And Sub-Licenses.**

**12.1** Forest Ireland is entitled to sub-license its rights under this Agreement, subject to Lundbeck's consent, which consent shall not be unreasonably withheld. Reasons for a reasonable refusal to furnish consent include, but shall not be limited to, the proposed sublicensee having a material interest in a pharmaceutical product competing directly with the Finished Products, unless there is no resulting Impairment, as such term is defined in Section 11 of the S-Enantiomer License Agreement. Forest Ireland may sublicense its rights to an Affiliate, provided such Affiliate is a wholly owned subsidiary of its corporate parent, without any such consent.

**13. Warranties And Representations.**

**13.1** Lundbeck hereby represents and warrants the following:

**13.1.1** Lundbeck is free to enter into this Agreement and does not have any agreement with respect to the Patents or Technology applicable to Compound or Finished Product which would conflict with the rights granted hereunder.

**13.1.2** All Compound supplied by Lundbeck shall comply with the Specifications, the requirements of the NDA for Finished Product and all applicable laws and regulations applicable to the manufacture, storage and shipment of drug substance. The representations set forth in this Section 13.1.2 shall be deemed restated at the time of each shipment of Compound by Lundbeck to Forest Ireland.

**13.1.3** Lundbeck controls the right, title and interest in and to the Patents or Technology applicable to compound or Finished Product and that Lundbeck, subject to the exception set forth in Section 2.1, has and will continue for the term hereof to have the sole right to grant licenses under and disclose Patents and Technology under the License Agreement.

**13.1.4** To the best of Lundbeck's knowledge, each Patent applicable to Compound or Finished Product is valid and enforceable and was not fraudulently procured from the relevant governmental patent granting authority.

**13.1.5** Lundbeck is not presently aware of any patent owned by an independent third party that would be infringed by the manufacture, use or sale of Finished Product.

**13.1.6** There are no actions, suits or claims pending or alleged anywhere in the world with respect to Compound, or Patents or Technology related to the Compound or Finished Product.

**13.2** Forest Ireland hereby represents and warrants the following:

**13.2.1** Forest Ireland is acknowledged by the authorities/FDA in the USA as an approved manufacturer and marketer of drugs and is as such under the inspection of said authorities.

**14. Notice.**

**14.1** All notices hereunder shall be in writing and shall be delivered personally or mailed by registered or certified (air) mail, postage prepaid, or delivery service for which receipt is given, to the following addresses of the respective of the respective parties with a copy to the addressee's general counsel:

If to Forest Ireland:	Forest Laboratories (Ireland) Limited Clonshaugh Industrial Estate Clonshaugh, Dublin 17 Republic of Ireland
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If to Lundbeck  
(Legal Department)

Attention: Raymond Stafford  
Facsimile: 353 1 8672226

H. Lundbeck A/S  
Ottiliavej 9  
DK-2500 Copenhagen-Valby  
Denmark

Attention: Legal Department  
Facsimile: 45 36 30 27 32

Such notice shall be effective upon receipt.

**15. Entire Agreement And Modifications.**

**15.1 Incorporation of Addendum.** The Addendum to Supply Agreement between Forest Inc. and Lundbeck dated August 15, 2000 ("Supply Addendum") shall form an integral part of this S-Enantiomer Supply Agreement and shall be regarded as incorporated into this S-Enantiomer Supply Agreement in every respect as from August 15, 2000; provided that, references in such Supply Addendum to the "Agreement" shall be deemed references to this S-Enantiomer Supply Agreement, references to License Agreement shall be deemed references to the S-Enantiomer License Agreement, and references to "Forest" shall be deemed references to Forest Ireland. All other terms and conditions of this S-Enantiomer Supply Agreement shall remain in force unchanged.

**15.2** This S-Enantiomer Supply Agreement; the Umbrella Agreement of even date herewith by and among Forest Inc., Forest Ireland, and Lundbeck; and the S-Enantiomer License Agreement by and between Forest Ireland and Lundbeck (collectively, the "**Agreements**") constitute the entire agreement between Forest Inc. or Forest Ireland and Lundbeck with respect to the subject matter thereof. The Agreements supercede any and all other agreements, written or oral, between Forest Inc. or Forest Ireland and Lundbeck with respect to the subject matter thereof. No variation or modification of the terms of this Agreement nor any waiver of any of the terms or provisions hereof shall be valid unless in writing and signed by an authorized representative of each party or by the party against whom enforcement thereof may be sought. The headings contained in this Agreement are for convenience and reference purposes only and shall not affect the meaning or interpretation of this Agreement.

**15.3** Wherever this Agreement requires the consent of Lundbeck to any proposed action, such consent shall not be unreasonably withheld or delayed.

**16. Severability.**

**16.1** The provisions of this Agreement are separate and divisible, and the invalidity or unenforceability of any part shall not affect the validity or enforceability of any remaining part or parts, all of which shall remain in full force and effect. However, the parties agree to substitute any invalid or unenforceable provision by a valid and enforceable arrangement which achieves to the greatest extent possible the financial balance and mutual understanding already established between the parties.

**17. Governing Law.**

**17.1** This Agreement shall be governed by, and construed in accordance with, the laws of England.

**17.2** The arbitration provisions of the S-Enantiomer License Agreement (Section 13 thereof) shall be deemed to apply to and govern any dispute by the parties pursuant to the terms of this Agreement.

**18. Miscellaneous.**



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The provisions of Sections 16.3, 16.6, 16.7, 16.8 and 16.9 of the S-Enantiomer License Agreement are specifically incorporated by reference in this Agreement as if set forth in full herein.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

FOREST LABORATORIES (IRELAND)  
LIMITED

By: /s/Raymond Stafford  
Name: Raymond Stafford  
Title: Chief Executive

H. LUNDBECK, A/S

By: /s/Erik Sprunk-Jansen  
Name: Erik Sprunk-Jansen  
Title: Chairman and President

EXHIBIT 13

QUARTERLY STOCK MARKET PRICES

	<u>High</u>	<u>Low</u>
April-June 2000	\$51.625	\$37.375
July-September 2000	60.344	40.000
October-December 2000	70.656	53.938
January-March 2001	72.120	55.656
April-June 2001	78.280	53.500
July-September 2001	82.250	63.750
October-December 2001	83.190	65.760
January-March 2002	85.000	76.150

As of June 5, 2002 there were 1,875 stockholders of record of the Company's common stock.

SELECTED FINANCIAL DATA

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March 31, ( <i>In thousands</i> )	<u>2002</u>	<u>2001</u>	<u>2000</u>	<u>1999</u>	<u>1998</u>
Financial Position:					
Current Assets	\$1,195,112	\$ 884,149	\$ 676,472	\$527,061	\$396,774
Current Liabilities	324,968	223,618	242,329	154,660	155,016
Net Current Assets	870,144	660,531	434,143	372,401	241,758
Total Assets	1,951,873	1,446,930	1,128,881	899,797	769,450
Total Shareholders' Equity	1,625,089	1,222,114	884,690	743,512	614,161
Years Ended March 31, ( <i>In thousands</i> , except per share data)					
	<u>2002</u>	<u>2001</u>	<u>2000</u>	<u>1999</u>	<u>1998</u>
Summary of Operations:					
Net Sales	\$1,566,626	\$1,174,527	\$872,822	\$546,266	\$427,086
Other Income	35,198	30,647	26,479	77,722	47,618
Costs and Expenses	1,131,646	906,447	741,854	513,185	419,932
Income Before Income Tax Expense	470,178	298,727	157,447	110,803	54,772
Income Tax Expense	132,224	83,631	44,759	33,630	18,075
Net Income	337,954	215,096	112,688	77,173	36,697
Net Income Per Share:					
Basic	\$1.90	\$1.23	\$0.67	\$0.47	\$0.23
Diluted	\$1.82	\$1.18	\$0.64	\$0.45	\$0.22
Weighted Average Number of Common and Common Equivalent Shares Outstanding (Note A):					
Basic	177,695	174,528	167,566	162,890	161,812
Diluted	185,242	182,984	175,890	171,912	166,850

No dividends were paid on common shares in any period.

A. Basic net income per share was computed by dividing net income by the weighted average number of common shares outstanding during each year. Diluted net income per share includes the potential dilution that could occur if dilutive options and warrants outstanding were included in the weighted average number of common shares outstanding for the period.

FOREST LABORATORIES, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

YEARS ENDED MARCH 31, 2002, 2001 AND 2000

REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

Board of Directors and Shareholders  
Forest Laboratories, Inc.  
New York, New York

We have audited the accompanying consolidated balance sheets of Forest Laboratories, Inc. and Subsidiaries as of March 31, 2002 and 2001, and the related consolidated statements of income, comprehensive income, shareholders' equity and cash flows for each of the three years in the period ended March 31, 2002. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Forest Laboratories, Inc. and Subsidiaries as of March 31, 2002 and 2001, and the results of their operations and their cash flows for each of the three years in the period ended March 31, 2002 in conformity with accounting principles generally accepted in the United States of America.

BDO SEIDMAN, LLP

New York, New York  
April 19, 2002

FOREST LABORATORIES, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS  
*(In thousands)*

MARCH 31,

	<u>2002</u>	<u>2001</u>
<u>Assets</u>		
Current assets:		
Cash (including cash equivalent investments of \$441,399 in 2002 and \$378,955 in 2001)	\$ 459,861	\$ 379,549
Marketable securities	151,660	25,724
Accounts receivable, less allowance for doubtful accounts of \$13,641 in 2002 and \$11,123 in 2001	116,290	115,591
Inventories, net	348,215	263,957
Deferred income taxes	90,710	64,357
Refundable income taxes	12,733	25,024
	<u>15,643</u>	<u>9,947</u>
Other current assets	<u>1,195,112</u>	<u>884,149</u>
Total current assets	<u>281,347</u>	<u>100,451</u>
Marketable securities		
Property, plant and equipment:		
Land and buildings	123,949	109,547
Machinery and equipment	88,372	71,671
	<u>13,732</u>	<u>11,235</u>
Vehicles and other	226,053	192,453
	<u>67,014</u>	<u>55,544</u>
Less accumulated depreciation	<u>159,039</u>	<u>136,909</u>
Other assets:		
Goodwill, net	14,965	14,965
License agreements, product rights and other intangible assets, net	265,314	274,587

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Deferred income taxes	16,364	11,210
	<u>19,732</u>	<u>24,659</u>
Other		
	<u>316,375</u>	<u>325,421</u>
	\$1,951,873	\$1,446,930
	=====	=====

See accompanying notes to consolidated financial statements.

FOREST LABORATORIES, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS  
(In thousands, except for par values)

	<u>MARCH 31,</u>	
	<u>2002</u>	<u>2001</u>
<u>Liabilities and Shareholders' Equity</u>		
Current liabilities:		
Accounts payable	\$ 79,396	\$ 41,921
Accrued expenses	164,250	139,138
	<u>81,322</u>	<u>42,559</u>
Income taxes payable	—	—
Total current liabilities	<u>324,968</u>	<u>223,618</u>
	<u>1,816</u>	<u>1,198</u>
Deferred income taxes		
Commitments and contingencies		

## Shareholders' equity:

Series A junior participating preferred stock, \$1.00 par; shares authorized 1,000; no shares issued or outstanding		
Common stock \$.10 par; shares authorized 500,000; issued 214,753 shares in 2002 and 212,052 shares in 2001	21,475	21,205
Capital in excess of par	618,674	546,649
Retained earnings	1,298,072	960,118
Accumulated other comprehensive loss	( <u>23,290</u> )	( <u>19,573</u> )
	1,914,931	1,508,399
	<u>289,842</u>	<u>286,285</u>
Less common stock in treasury, at cost (35,497 shares in 2002 and 35,451 shares in 2001)	<u>1,625,089</u>	<u>1,222,114</u>
	\$1,951,873	\$1,446,930
	=====	=====

See accompanying notes to consolidated financial statements.

FOREST LABORATORIES, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF INCOME  
*(In thousands, except per share data)*

	<u>YEARS ENDED MARCH 31,</u>		
	<u>2002</u>	<u>2001</u>	<u>2000</u>
Net sales	\$1,566,626	\$1,174,527	\$872,822
	<u>35,198</u>	<u>30,647</u>	<u>—</u>
Other income			<u>26,479</u>
	<u>1,601,824</u>	<u>1,205,174</u>	<u>899,301</u>

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Costs and expenses:			
Cost of sales	371,061	284,079	215,651
Selling, general and administrative	602,791	516,662	455,911
	<u>157,794</u>	<u>105,706</u>	<u>70,292</u>
Research and development			
	<u>1,131,646</u>	<u>906,447</u>	<u>741,854</u>
Income before income tax expense	470,178	298,727	157,447
	<u>132,224</u>	<u>83,631</u>	<u>44,759</u>
Income tax expense			
Net income	\$ 337,954	\$ 215,096	\$112,688
	=====	=====	=====
Earnings per common and common equivalent share:			
Basic	\$1.90	\$1.23	\$0.67
	=====	=====	=====
Diluted	\$1.82	\$1.18	\$0.64
	=====	=====	=====
Weighted average number of common and common equivalent shares outstanding:			
Basic	177,695	174,528	167,566
	=====	=====	=====
Diluted	185,242	182,984	175,890
	=====	=====	=====

See accompanying notes to consolidated financial statements.

FOREST LABORATORIES, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME  
(In thousands)

YEARS ENDED MARCH 31,

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	<u>2002</u>	<u>2001</u>	<u>2000</u>
Net income	\$337,954	\$215,096	\$112,688
Other comprehensive loss, net of tax:			
Foreign currency translation losses	( 424)	( 6,620)	( 6,770)
Unrealized gains (losses) on securities:			
Unrealized holding gain (loss) arising	( <u>3,293</u> )	<u>1,359</u>	
during the period (available-for-sale)			( <u>367</u> )
Other comprehensive loss	( <u>3,717</u> )	( <u>5,261</u> )	( <u>7,137</u> )
Comprehensive income	\$334,237	\$209,835	\$105,551
	=====	=====	=====

See accompanying notes to consolidated financial statements.

FOREST LABORATORIES, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY  
YEARS ENDED MARCH 31, 2002, 2001 AND 2000

(In thousands)

	<u>Common stock</u>		Capital in excess of	Retained	Accumulated other comprehensive	<u>Treasury stock</u>	
	<u>Shares</u>	<u>Amount</u>	<u>par</u>	<u>earnings</u>	<u>loss</u>	<u>Shares</u>	<u>Amount</u>
Balance, April 1, 1999	201,708	\$20,171	\$380,665	\$ 632,334	(\$ 7,175)	35,366	\$282,482
Shares issued upon exercise of stock options and warrants	3,020	302	20,085				
Treasury stock acquired from employees							



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upon exercise of stock options					40	1,092	
Tax benefit related to stock options exercised by employees			16,331				
Other comprehensive loss					( 7,137)		
					_____	_____	_____
Net income				<u>112,688</u>			
Balance, March 31, 2000	204,728	20,473	417,081	745,022	( 14,312)	35,406	283,574
Shares issued upon exercise of stock options and warrants	7,324	732	51,879				
Treasury stock acquired from employees upon exercise of stock options						45	2,711
Tax benefit related to stock options exercised by employees			77,689				
Other comprehensive loss					( 5,261)		
					_____	_____	_____
Net income				<u>215,096</u>			
Balance, March 31, 2001	212,052	21,205	546,649	960,118	( 19,573)	35,451	286,285
Shares issued upon exercise of stock options	2,701	270	34,482				
Treasury stock acquired from employees upon exercise of stock options						46	3,557
Tax benefit related to stock options exercised by employees			37,543				
Other comprehensive loss					( 3,717)		
					_____	_____	_____
Net income				<u>337,954</u>			

Balance, March 31, 2002	214,753	\$21,475	\$618,674	\$1,298,072	(\$23,290)	35,497	\$289,842
	=====	=====	=====	=====	=====	=====	=====

See accompanying notes to consolidated financial statements.

FOREST LABORATORIES, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
(In thousands)

	<u>YEARS ENDED MARCH 31,</u>		
	<u>2002</u>	<u>2001</u>	<u>2000</u>
Cash flows from operating activities:			
Net income	\$337,954	\$215,096	\$112,688
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation	14,320	10,623	8,231
Amortization	40,308	32,663	32,413
Deferred income tax benefit	( 21,534)	( 9,512)	( 8,837)
Foreign currency translation gain	( 667)	( 55)	( 1,202)
Tax benefit realized from the exercise of stock options by employees	28,188	79,973	23,681
Net change in operating assets and liabilities:			
Decrease (increase) in:			
Accounts receivable, net	( 699)	( 23,782)	( 9,815)
Inventories, net	( 84,258)	( 86,159)	( 45,123)
Refundable income taxes	12,291	( 13,703)	1,090
Other current assets	( 5,696)	( 1,590)	( 2,183)
Increase (decrease) in:			
Accounts payable	37,475	( 30,055)	5,303
Accrued expenses	25,112	13,376	62,948
Income taxes payable	38,763	( 2,032)	19,418
	<u>4,927</u>	<u>( 4,587)</u>	
Decrease (increase) in other assets			<u>( 2,387)</u>

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	<u>426,484</u>	<u>180,256</u>	<u>196,225</u>
Net cash provided by operating activities			
Cash flows from investing activities:			
Purchase of property, plant and equipment, net	( 36,446)	( 30,872)	( 35,322)
Purchase of marketable securities:			
Available-for-sale	( 680,467)	( 113,672)	( 15,997)
Redemption of marketable securities:			
Available-for-sale	373,635	40,136	41,354
Purchase of license agreements, product rights and other intangible assets	( <u>31,045</u> )	( <u>44,030</u> )	( <u>100,231</u> )
Net cash used in investing activities	( <u>374,323</u> )	( <u>148,438</u> )	( <u>110,196</u> )
Cash flows from financing activities:			
Net proceeds from common stock options			
	<u>31,195</u>	<u>49,900</u>	
exercised by employees under stock option plans			<u>19,296</u>
Effect of exchange rate changes on cash	( <u>3,044</u> )	( <u>4,769</u> )	( <u>3,693</u> )
Increase in cash and cash equivalents	80,312	76,949	101,632
	<u>379,549</u>		<u>200,968</u>
Cash and cash equivalents, beginning of year		<u>302,600</u>	
Cash and cash equivalents, end of year	\$459,861	\$379,549	\$302,600
	=====	=====	=====

See accompanying notes to consolidated financial statements.

FOREST LABORATORIES, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
(In thousands)

YEARS ENDED MARCH 31,

2002      2001      2000

Supplemental disclosures of cash flow  
information:

Cash paid during the year for:

Income taxes	\$74,977	\$29,212	\$9,910
	=====	=====	=====

See accompanying notes to consolidated financial statements.

FOREST LABORATORIES, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of significant accounting policies:

Basis of consolidation:

The consolidated financial statements include the accounts of Forest Laboratories, Inc. (the "Company") and its subsidiaries, all of which are wholly owned. All significant intercompany accounts and transactions have been eliminated.

Foreign currency translation:

An Irish subsidiary of the Company reports its financial position and results of operations in the reporting currency of the Company. The financial position and results of operations of the Company's other foreign subsidiaries, which are in aggregate immaterial, are determined using the respective local currency.

Cash equivalents:

Cash equivalents consist of short-term, highly liquid investments (primarily municipal bonds with interest rates that are re-set monthly) which are readily convertible into cash at par value (cost).

Inventories:

Inventories are stated at the lower of cost or market, with cost determined on the first-in, first-out basis.

Marketable securities:

Marketable securities are stated at fair value or historical cost in accordance with Statement of Financial Accounting Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities," and consist of investments in municipal bonds maturing through 2004.

Property, plant and equipment and depreciation:

Property, plant and equipment are stated at cost. Depreciation is provided over the estimated useful lives of the assets primarily by the straight-line method.

Intangible assets:

In April 2001, the Company adopted Statements of Financial Accounting Standards No. 141 ("SFAS 141"), "Business Combinations," and No. 142 ("SFAS 142"), "Goodwill and Other Intangible Assets." SFAS 141 requires the use of the purchase method of accounting and prohibits the use of the pooling-of-interests method of accounting for business combinations initiated after June 30, 2001. SFAS 141 also requires that the Company recognize acquired intangible assets apart from goodwill if the acquired intangible assets meet certain criteria. It also requires, upon adoption of SFAS 142, that the Company reclassify if necessary, the carrying amounts of intangible assets and goodwill based on the criteria in SFAS 141. The Company has determined that the classification and useful lives utilized for its other intangible assets, which consist primarily of license and product rights agreements are appropriate (refer to Note 6). SFAS 142 requires, among other things, that companies no longer amortize goodwill, but instead test goodwill for impairment at least annually. In addition, SFAS 142 requires that the Company identify reporting units for the purposes of assessing potential future impairments of goodwill, reassess the useful lives of other existing recognized intangible assets, and cease amortization of intangible assets with an indefinite useful life. The Company's goodwill relates to prior acquisitions, which operations have been integrated into the Company. Goodwill is tested at the end of the fiscal year. No impairment in the recorded goodwill was identified as of March 31, 2002.

The Company's previous business combinations were accounted for using both the pooling-of-interests and purchase methods. At March 31, 2001, the net carrying amount of goodwill from prior purchase transactions was \$14,965,000, which was being amortized by \$626,000 each year. Annual amortization of this amount ceased effective April 1, 2001.

Revenue recognition:

Sales are recorded in the period the merchandise is shipped. Provisions for estimated sales allowances, returns, rebates and other pricing adjustments are accrued at the time revenues are recognized as a direct reduction of such revenue. Certain provisions are reflected either as a direct reduction to accounts receivable or, to the extent that they are due to entities other than customers, as accrued expense. Adjustments to estimates, which have not been material, are recorded when customer credits are issued or payments made to third parties.

Shipping and handling costs:

Presently, the Company does not charge its customers for any freight costs. The amounts of such costs are included in selling, general and administrative expenses and are not material.

Research and development:

Expenditures for research and development, including licensing fees of early-stage development products, are charged to expense as incurred.

Savings and profit sharing plan:

Substantially all non-bargaining unit employees of the Company's domestic subsidiaries may participate in the savings and profit sharing plan after becoming eligible (as defined). Profit sharing contributions are primarily at the discretion of the Company. The savings plan contributions include a matching contribution made by the Company. Savings and profit sharing contributions amounted to approximately \$11,000,000, \$8,200,000 and \$6,800,000 for fiscal years 2002, 2001 and 2000, respectively.

Earnings per share:

Basic earnings per share includes no dilution and is computed by dividing income available to common shareholders by the weighted average number of common shares outstanding for the period. Diluted earnings per share reflect, in periods in which they have a dilutive effect, the effect of common shares issuable upon exercise of stock options and warrants. The two-for-one stock split effected as a 100% stock dividend in December 2000 has been reflected retroactively for all outstanding common stock and stock options.

Accumulated other comprehensive loss:

Other comprehensive loss refers to revenues, expenses, gains and losses that under generally accepted accounting principles are excluded from net income as these amounts are recorded directly as an adjustment to shareholders' equity. Accumulated other comprehensive loss is comprised of the cumulative effects of foreign currency translation and unrealized gains (losses) on securities which amounted to approximately (\$20,726,000) and (\$20,302,000), and (\$2,564,000) and \$729,000 at March 31, 2002 and March 31, 2001, respectively.

Income taxes:

The Company accounts for income taxes using the liability method. Under the liability method, deferred income taxes are provided on the differences in bases of assets and liabilities between financial reporting and tax returns using enacted tax rates.

Use of estimates:

The preparation of financial statements in conformity with generally accepted accounting principles requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company reviews all significant estimates affecting the financial statements on a recurring basis and records the effect of any adjustments when necessary.

Long-lived assets:

Long-lived assets, such as intangible assets, property and equipment and certain sundry assets, are evaluated for impairment when events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable through the estimated undiscounted future cash flows from the use of these assets. When any such impairment exists, the related assets will be written down to fair value.

Stock-based compensation:

The Company accounts for its stock option awards to employees under the intrinsic value based method of accounting prescribed by Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees." Under the intrinsic value based method, compensation cost is the excess, if any, of the quoted market price of the stock at grant date or other measurement date over the amount an employee must pay to acquire the stock. The Company makes pro forma disclosures of net income and earnings per share as if the fair value based method of accounting had been applied as required by Statement of Financial Accounting Standards No. 123 ("SFAS 123"), "Accounting for Stock-Based Compensation." The Company has never granted options below market price on the date of grant.

Fair value of financial instruments:

The carrying amounts of cash, accounts receivable, accounts payable, accrued expenses and income taxes payable are reasonable estimates of their fair value because of the short maturity of these items.

Recent accounting standards:

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In August 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 144 ("SFAS 144"), "Accounting for the Impairment or Disposal of Long-Lived Assets." This statement supersedes Statement of Financial Accounting Standards No. 121 ("SFAS 121"), "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of " and amends Accounting Principles Board Opinion No. 30, "Reporting Results of Operations - Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions." SFAS 144 retains the fundamental provisions of SFAS 121 for recognition and measurement of impairment, but amends the accounting and reporting standards for segments of a business to be disposed of. SFAS 144 is effective for fiscal years beginning after December 15, 2001, and interim periods within those fiscal years. The provisions of SFAS 144 generally are to be applied prospectively. The Company believes that the adoption of SFAS 144 will not have a material impact on the Company's financial position or results of operations.

2. Earnings per share

:

A reconciliation of shares used in calculating basic and diluted earnings per share follows:

(In thousands)	<u>2002</u>	<u>2001</u>	<u>2000</u>
Basic	177,695	174,528	167,566
Effect of assumed conversion of employee stock options and warrants	<u>7,547</u>	<u>8,456</u>	<u>8,324</u>
Diluted	185,242	182,984	175,890
	=====	=====	=====

Options and warrants to purchase approximately 2,295,800, 2,407,400 and 63,000 shares of common stock at exercise prices ranging from \$33.38 to \$82.97 per share were outstanding during a portion of fiscal 2002, 2001 and 2000, respectively, but were not included in the computation of diluted earnings per share because they were anti-dilutive. These options and warrants expire through 2010.

3. Business operations:

The Company and its subsidiaries, which are located in the United States, Ireland and the United Kingdom, manufacture and market ethical and other pharmaceutical products. The Company operates in only one segment. Sales are made primarily in the United States and European markets. The net sales and long-lived assets for the years ended March 31, 2002, 2001 and 2000, are from the Company's or one of its subsidiaries' country of origin, as follows:

(In thousands)	<u>2002</u>		<u>2001</u>		<u>2000</u>	
	<u>Net sales</u>	<u>Long-lived assets</u>	<u>Net sales</u>	<u>Long-lived assets</u>	<u>Net sales</u>	<u>Long-lived assets</u>
United States	\$1,531,100	\$347,026	\$1,138,156	\$365,619	\$836,191	\$365,206
Ireland	6,019	108,517	6,003	82,090	5,475	46,577
United Kingdom	<u>29,507</u>	<u>3,507</u>	<u>30,368</u>	<u>4,253</u>	<u>31,156</u>	<u>4,045</u>
	\$1,566,626	\$459,050	\$1,174,527	\$451,962	\$872,822	\$415,828
	=====	=====	=====	=====	=====	=====

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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.

Sales of Celexa™, a selective serotonin reuptake inhibitor ("SSRI") for the treatment of depression, launched in September 1998, accounted for 69%, 61% and 49% of the Company's net sales for the years ended March 31, 2002, 2001 and 2000, respectively.

4. Inventories:

Inventories, net of reserves for obsolescence, consist of the following:

March 31, <i>(In thousands)</i>	<u>2002</u>	<u>2001</u>
Raw materials	\$186,646	\$135,844
Work in process	14,480	11,709
Finished goods	<u>147,089</u>	<u>116,404</u>
	\$348,215	\$263,957
	=====	=====

5. Marketable securities

:

The composition of the investment portfolio at March 31 was:

(In thousands)	<u>Cost</u>	<u>Gross unrealized gains</u>	<u>Gross unrealized losses</u>	<u>Market value</u>
<u>2002</u>				
<u>Available-for-sale</u>				
:				
State and local obligations	\$435,571		(\$2,564)	\$433,007
	=====		=====	=====
<u>2001</u>				
<u>Available-for-sale</u>				
:				
State and local obligations	\$123,446	\$729		\$124,175
<u>Held-to-maturity</u>				
:				
Foreign government obligations	<u>2,000</u>	<u>6</u>		<u>2,006</u>
	\$125,446	\$735		\$126,181
	=====	=====		=====



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The contractual maturities of debt securities at March 31, 2002, regardless of their balance sheet classification, consist of the following:

<i>(In thousands)</i>	Amortized <u>cost</u>	Fair <u>value</u>
<u>Available-for-sale</u>		
:		
Less than one year	\$152,291	\$151,660
One to two years	<u>283,280</u>	<u>281,347</u>
	\$435,571	\$433,007
	=====	=====

The net unrealized holding losses from available-for-sale securities of approximately \$2,564,000 and \$630,000 at March 31, 2002 and 2000, respectively, as well as the net unrealized holding gains from available-for-sale securities of approximately \$729,000 at March 31, 2001 are included in Shareholders' equity: Accumulated other comprehensive loss.

6. Intangible assets:

License agreements, product rights and other intangible assets consist of the following:

<i>(In thousands, except for amortization periods which are stated in years)</i>	<u>March 31, 2002</u>			<u>March 31, 2001</u>	
	Weighted average <u>amortization</u> <u>period</u>	Gross carrying <u>amount</u>	Accumulated <u>amortization</u>	Gross carrying <u>amount</u>	Accumulated <u>amortization</u>
Amortized intangible assets:					
License agreements	15	\$198,709	\$ 48,081	\$186,022	\$ 44,092
Product rights	16	32,226	11,951	42,191	17,705
Buy-out of royalty agreements	9	95,061	28,262	95,061	16,912
Trade names	34	34,190	12,713	34,190	11,583
Non-compete agreements	9	22,987	20,833	22,987	19,602
Other	2	<u>8,847</u>	<u>4,866</u>	<u>8,847</u>	<u>4,817</u>
Total	14	\$392,020	\$126,706	\$389,298	\$114,711
		=====	=====	=====	=====

Amortization of license agreements, product rights and other intangible assets for fiscal years ended 2002, 2001 and 2000 amounted to approximately \$40,308,000, \$32,037,000 and \$31,787,000, respectively. The annual amortization expense expected for fiscal years 2003 through 2007 is \$22,790,000, \$20,610,000, \$19,060,000, \$19,060,000 and \$19,040,000, respectively.

During fiscal 2002, new competitive products as well as the introduction of a generic equivalent resulted in significantly reduced sales of the Company's product Flumadine®, for treating type A flu. The Company determined that the intangible asset was impaired and wrote off the unamortized balance of \$16,375,000.

License agreements:

In October 2001, the Company entered into a licensing agreement with Lipha S.A., a subsidiary of Merck KGaA, for the product acamprosate for the treatment of alcohol dependence. The cost incurred upon signing this agreement will be amortized, using the straight-line method, over the estimated life of the product upon launch.

Marketing agreements:

In December 2001, the Company signed a marketing agreement with Sankyo Pharma Inc. to co-promote Benicar™ for the treatment of hypertension. The Company will co-promote the product for a period of six years and receive a share of the product profits during that period as defined. The Company will receive a reduced share of the product profits thereafter. Benicar will be commercially launched in the first quarter of fiscal 2003, at which time the Company will pay Sankyo \$43,960,000. The costs incurred for Benicar will be included in other intangible assets and will be amortized in the future based on estimated revenues.

7. Accrued expenses:

Accrued expenses consist of the following:

March 31, (In thousands)	<u>2002</u>	<u>2001</u>
Employee compensation and other benefits	\$ 45,498	\$ 35,070
Rebates	73,237	60,859
Clinical research and development costs	23,408	27,341
Other	<u>22,107</u>	<u>15,868</u>
	\$164,250	\$139,138
	=====	=====

8. Commitments

:

Leases:

The Company leases manufacturing, office and warehouse facilities, equipment and automobiles under operating leases expiring through 2018. Rent expense approximated \$18,802,000, \$15,034,000 and \$9,797,000 for fiscal years ended March 31, 2002, 2001 and 2000, respectively. Aggregate minimum rentals under noncancellable leases are as follows:

Year ending March 31, (In thousands)

2003	\$ 25,370
2004	21,743
2005	17,700
2006	11,698
2007	11,490
Thereafter	<u>82,978</u>
	\$170,979
	=====

Royalty agreements:

The Company has royalty agreements on certain of its licensed products. Royalties are paid based on a percentage of sales, as defined. For fiscal years ended March 31, 2002, 2001 and 2000, royalties amounted to \$19,938,000, \$19,977,000 and \$17,039,000, respectively.

License agreements

: The Company has entered into several license agreements for products currently under development. The Company may be obligated in future periods to pay additional amounts subject to the achievement of certain product milestones as defined.

9. Shareholders' equity:

Preferred stock purchase rights:

On September 30, 1994, the Company's Board of Directors declared a dividend of one preferred share purchase right ("Right") for each outstanding share of the Company's common stock, par value \$.10 per share. Each Right will entitle the holder to buy one quarter of one-hundredth of a share of authorized Series A Junior Participating Preferred Stock, par value \$1.00 per share ("Series A Preferred Stock") at an exercise price of \$250 per Right, subject to adjustment. Prior to becoming exercisable, the Rights are evidenced by the certificates representing the common stock and may not be traded apart from the common stock. The Rights become exercisable on the tenth day after public announcements that a person or group has acquired, or obtained the right to acquire, 20% or more of the Company's outstanding common stock, or an announcement of a tender offer that would result in a beneficial ownership by a person or group of 20% or more of the Company's common stock.

If, after the Rights become exercisable, the Company is a party to certain merger or business combination transactions, or transfers 50% or more of its assets or earning power, or if an acquirer engages in certain self-dealing transactions, each Right (except for those held by the acquirer) will entitle its holder to buy a number of shares of the Company's Series A Preferred Stock or, in certain circumstances, a number of shares of the acquiring company's common stock, in either case having a value equal to two-and-one-half times the exercise price of the Right. The Rights may be redeemed by the Company at any time up to ten days after a person or group acquires 20% or more of the Company's common stock at a redemption price of \$.001 per Right. The Rights will expire on September 30, 2004.

The Company has reserved 900,000 shares of Series A Preferred Stock for the exercise of the Rights.

Stock options:

The Company has various Employee Stock Option Plans whereby options to purchase an aggregate of 26,000,000 shares of common stock have been or remain to be issued to employees of the Company and its subsidiaries at prices not less than the fair market value of the common stock at the date of grant. Both incentive and non-qualified options may be issued under the plans. The options are exercisable up to the tenth anniversary of the date of issuance.

SFAS No. 123 requires the Company to provide pro forma information regarding net income and earnings per share as if compensation cost for the Company's stock option plans had been determined in accordance with the fair value of each stock option at the grant date by using the Black-Scholes option-pricing model with the following weighted average assumptions used for grants: dividend yield of zero for all three years; expected volatility of 27.62% in fiscal 2002, 43.59% in fiscal 2001 and 38.25% in fiscal 2000; risk-free interest rates of 5.4% in fiscal 2002, between 4.9% and 6.5% in fiscal 2001 and 6% in fiscal 2000; and expected lives of 5 to 10 years for all three years.

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Under the accounting provisions of SFAS No. 123, the Company's net income and earnings per share would have been reduced to the pro forma amounts indicated below:

(In thousands, except per share data)	<u>2002</u>	<u>2001</u>	<u>2000</u>
Net income:			
As reported	\$337,954	\$215,096	\$112,688
Pro forma	272,295	169,815	89,836

Net income per common share:

Basic:			
As reported	\$1.90	\$1.23	\$0.67
Pro forma	1.53	0.97	0.54

Diluted:

As reported	\$1.82	\$1.18	\$0.64
Pro forma	1.47	0.93	0.51

The following table summarizes information about stock options outstanding at March 31, 2002:

Range of <u>exercise prices</u>	<u>Options outstanding</u>			<u>Options exercisable</u>	
	Number outstanding at 3/31/02	Weighted average remaining contractual life	Weighted average exercise price	Number exercisable at 3/31/02	Weighted average exercise price
\$ 7.42 to \$30.00	9,577,193	3.9	\$16.92	6,839,577	\$15.44
30.01 to 60.00	2,020,704	4.0	44.81	222,769	44.60
60.01 to 82.97	<u>4,737,970</u>	<u>7.1</u>	<u>72.00</u>	<u>2,115,325</u>	<u>69.18</u>
	16,335,867	4.8	\$36.35	9,177,671	\$28.53

Transactions under the stock option plans and individual non-qualified options not under the plans are summarized as follows:

	<u>Shares</u>	<u>Weighted average exercise price</u>
Shares under option at March 31, 1999 (at \$5.42 to \$24.18 per share)	19,190,840	\$10.08
Granted (at \$24.58 to \$33.38 per share)	3,311,700	26.08
Exercised (at \$5.42 to \$24.18 per share)	( 2,662,356)	7.82
Cancelled	( <u>456,330</u> )	14.59

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Shares under option at March 31, 2000		
(at \$6.06 to \$33.38 per share)	19,383,854	13.02
Granted (at \$42.17 to \$66.91 per share)	4,659,750	56.40
Exercised (at \$6.06 to \$33.38 per share)	( 6,840,706)	7.63
Cancelled	( <u>216,260</u> )	30.12

Shares under option at March 31, 2001		
(at \$7.42 to \$66.91 per share)	16,986,638	26.87
Granted (at \$62.85 to \$82.97 per share)	2,442,050	76.96
Exercised (at \$7.42 to \$66.91 per share)	( 2,701,361)	12.87
Cancelled	( <u>391,460</u> )	42.17

Shares under option at March 31, 2002		
(at \$7.42 to \$82.97 per share)	16,335,867	\$36.35
	=====	

Options exercisable at March 31:		
2000	10,443,796	\$ 9.29
2001	6,816,828	\$14.94
2002	9,177,671	\$28.53

Weighted average fair value

of options granted during:

2000	\$14.27
2001	\$31.60
2002	\$30.64

At March 31, 2002, 2001 and 2000, 5,726,022, 7,817,532 and 4,256,400 shares, respectively, were available for grant.

In connection with the acquisition of product rights in fiscal 1995, the Company issued 1,120,000 warrants, which expire on July 7, 2004, at an exercise price of \$11.43 per share, which was equal to the then fair market value of the Company's common stock. As of March 31, 2002, 65,728 warrants remain outstanding.

10. Contingencies:

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.

#### 11. Other income:

Other income consists of the following:

Years ended March 31, (In thousands)	<u>2002</u>	<u>2001</u>	<u>2000</u>
Interest and dividends	\$27,464	\$22,067	\$12,473
Contract revenue	5,899	6,827	8,976
Other income	<u>1,835</u>	<u>1,753</u>	<u>5,030</u>
	\$35,198	\$30,647	\$26,479
	=====	=====	=====

The Company recorded \$5,899,000, \$6,827,000 and \$8,976,000 in fiscal years 2002, 2001 and 2000, respectively, for Climara® contract revenue. The Company also recorded other income of \$3,000,000 in fiscal 2000 from the final installment of the settlement with Pharmacia & Upjohn, Inc. with respect to the Company's claimed option to negotiate for the rights to Detrol®.

#### 12. Income taxes:

The Company and its U.S. subsidiaries file a consolidated federal income tax return.

Income before income tax expense includes income from foreign operations of \$122,660,000, \$111,891,000 and \$67,827,000 for the years ended March 31, 2002, 2001 and 2000, respectively.

The provision for income taxes consists of the following:

<u>Years ended March 31, (In thousands)</u>	<u>2002</u>	<u>2001</u>	<u>2000</u>
Current:			
U.S. federal	\$101,393	(\$ 1,017)	\$19,566

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State and local	10,000	2,670	4,087
Foreign	<u>14,177</u>	<u>11,517</u>	<u>6,262</u>
	<u>125,570</u>	<u>13,170</u>	<u>29,915</u>
Deferred:			
Domestic	( 22,152)	( 8,848)	( 8,949)
Foreign	<u>618</u>	<u>( 664)</u>	<u>112</u>
	( <u>21,534</u> )	( <u>9,512</u> )	( <u>8,837</u> )
Charge in lieu of income taxes, relating to the tax effect of stock option tax deduction	<u>28,188</u>	<u>79,973</u>	<u>23,681</u>
	\$132,224	\$83,631	\$44,759
	=====	=====	=====

No provision has been made for income taxes on the undistributed earnings of the Company's foreign subsidiaries of approximately \$441,558,000 at March 31, 2002 as the Company intends to indefinitely reinvest such earnings.

The reasons for the difference between the provision for income taxes and expected federal income taxes at statutory rates are as follows:

<u>Years ended March 31, (percentage of income before income tax expense)</u>	<u>2002</u>	<u>2001</u>	<u>2000</u>
U.S. statutory rate	35.0%	35.0%	35.0%
Effect of foreign operations (principally Ireland)	( 6.0)	( 7.8)	( 6.4)
State and local taxes, less federal tax benefit	1.3	1.2	1.6
Permanent differences and other	( <u>2.2</u> )	( <u>0.4</u> )	( <u>1.8</u> )
	28.1%	28.0%	28.4%
	===	===	===

The Company's effective tax rate is lower than the statutory rate principally as a result of the operations of the Company's Irish subsidiary which operates under tax incentives that currently expire in 2010. The Company's Irish subsidiary is the licensee and manufacturer of Celexa and several other products under development. The Irish subsidiary shares in the income and expense of those products pursuant to Section 482 and other related regulations of the U.S. tax code which are subject to Internal Revenue ("IRS") review.

The IRS has completed and closed its audits of our tax returns through fiscal 1995.

Net deferred income taxes consist of the following:

<u>March 31, (In thousands)</u>	<u>2002</u>	<u>2001</u>
Inventory valuation	\$ 14,402	\$10,129
Receivable reserves and other allowances	56,979	45,807
Depreciation	( 2,609)	( 2,730)
Amortization	8,231	2,143
Tax credits and other carryforwards	264	264
Accrued liabilities	7,415	6,084
Expenses deferred for tax purposes	6,757	7,595
Employee stock option tax benefits	15,137	6,269
Other	( <u>1,318</u> )	( <u>1,192</u> )
	\$105,258	\$74,369
	=====	=====

### 13. Quarterly financial data (unaudited):

(In thousands, except per share data)

	<u>Net sales</u>	<u>Gross profit</u>	<u>Net income</u>	<u>Diluted earnings per share</u>
<u>2002</u>				
First quarter	\$350,508	\$267,316	\$74,046	\$0.40
Second quarter	376,267	287,274	79,960	0.43
Third quarter	403,100	307,452	87,395	0.47
Fourth quarter	436,751	333,523	96,553	0.52
<u>2001</u>				
First quarter	\$259,227	\$195,286	\$28,258	\$0.16
Second quarter	280,963	211,032	51,738	0.28
Third quarter	310,086	236,231	65,913	0.36
Fourth quarter	324,251	247,899	69,187	0.38

## FOREST LABORATORIES, INC. AND SUBSIDIARIES

### MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

#### Critical Accounting Policies



The following accounting policies are important in understanding the Company's financial condition and results of operations and should be considered as an integral part of any financial review. Refer to Note 1 to the consolidated financial statements, "Summary of significant accounting policies" for additional policies.

#### Estimates and Assumptions

The preparation of financial statements in conformity with generally accepted accounting principles requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and of revenues and expenses during the reporting period. Estimates are made when accounting for sales allowances, returns, rebates and other pricing adjustments, depreciation, amortization and certain contingencies. The Company is subject to risks and uncertainties, which may include, however not be limited to competition, federal or local legislation and regulations, litigation and overall changes in the healthcare environment that may cause actual results to vary from estimates. The Company reviews all significant estimates affecting the financial statements on a recurring basis and records the effect of any adjustments when necessary. Certain of these risks, uncertainties and assumptions are discussed further under the section entitled "Forward Looking Statements".

#### Goodwill and Other Intangible Assets

The Company has made acquisitions in the past that include goodwill, license agreements, product rights and other intangible assets. Through fiscal 2001, these assets were amortized over their estimated useful lives, and were tested periodically to determine if they were recoverable from operating earnings on an undiscounted basis over their useful lives.

Effective with fiscal 2002, goodwill was no longer amortized but is subject to an annual impairment test based on its estimated fair value. License agreements, product rights and other intangible assets will continue to be amortized over their useful lives and will also be subject to an impairment test based on estimated fair value

#### Revenue Recognition

Sales are recorded in the period the merchandise is shipped. Provisions for estimated sales allowances, returns, rebates and other pricing adjustments are accrued at the time revenues are recognized as a direct reduction of such revenue. Certain provisions are reflected either as a direct reduction to accounts receivable or, to the extent that they are due to entities other than customers, as accrued expense. Adjustments to estimates, which have not been material, are recorded when customer credits are issued or payments made to third parties.

#### Financial Condition and Liquidity

During fiscal year 2002 net current assets increased by \$209,613,000 due to ongoing operations. Increases in cash and marketable securities, accounts receivable, inventories, accounts payable and accrued expenses resulted primarily from increases in sales, particularly Celexa™. Celexa, (citalopram HBr), a selective serotonin reuptake inhibitor ("SSRI") for the treatment of depression, is our leading product and continued to show strong growth. The increase in inventory levels is also attributable to the pre-launch stocking of Lexapro™ (escitalopram oxalate), the single isomer of Celexa for depression, which we anticipate launching during the first half of fiscal 2003. During the year, the Company increased its investment in long-term marketable securities in order to receive more favorable rates of return on invested funds.

Property, plant and equipment increased as the result of the continuing expansion of the Company's facilities in order to meet current and future product demands and an expanding workforce. Included was an expansion of the Company's Irish manufacturing facility, the build-out of a recently acquired research and development facility on Long Island, New York and renovations to newly leased office space in New Jersey. Further expansions and acquisitions are likely in order to meet the needs from increased sales and related production, warehousing and

distribution, and for products under development.

The change in license agreements, product rights and other intangible assets before amortization, included a marketing agreement with Lipha S.A. for acamprosate (Campral®), a novel drug for the treatment of alcohol dependence, which the Company anticipates launching early in fiscal 2004. Forest also entered into a co-promotion arrangement with Sankyo Pharma Inc. for its angiotensin receptor blocker, Benicar™, which we will launch with Sankyo in the first quarter of fiscal 2003. At that time, the Company will pay \$43,960,000 to Sankyo for the co-promotion rights. The Company will co-promote the product for a period of six years and receive a share of the product profits as defined. The Company will continue to receive a reduced residual share of the product profits thereafter. During fiscal 2002, new competitive products as well as the introduction of a generic equivalent resulted in significantly reduced sales of the Company's product Flumadine®, for treating type A flu. The Company determined that the intangible asset was impaired and wrote off the unamortized balance of \$16,375,000. Amortization expense related to the product write-off was included in selling, general and administrative expense in fiscal 2002.

The Company is a party to several license agreements for products currently under development. Forest may be obligated in future periods to pay additional amounts subject to the achievement of certain product milestones as defined.

The Company leases manufacturing, office and warehouse facilities, equipment and automobiles under operating leases expiring through 2018. Aggregate minimum rentals under noncancellable leases currently total \$170,979,000. Refer to Note 8 to the consolidated financial statements, "Commitments".

Management believes that current cash levels, coupled with funds to be generated by ongoing operations, will continue to provide adequate liquidity to facilitate potential acquisitions of products and capital investments.

### Results of Operations

Net sales in fiscal 2002 increased by \$392,099,000 to \$1,566,626,000, a 33% increase from fiscal 2001. Forest's leading product, Celexa, accounted for most of the increase with sales of \$1,087,794,000, an increase of \$373,435,000 or 52% from last year, of which \$21,777,000 was due to higher average net selling prices. Celexa has continued its strong growth in the antidepressant market, which is now considered the largest therapeutic market within the U.S. pharmaceutical industry. As of March 31, 2002 Celexa had captured a 17.0% share of total prescriptions in the SSRI market. Tiazac® sales increased \$13,223,000 in fiscal 2002 of which \$5,400,000 was due to volume increases and \$7,823,000 was due to price. Sales of Aerobid® declined \$15,998,000 during fiscal 2002 from a combination of competition in the inhaled steroid market and lower average selling prices realized due to a significant increase in government sales. Sales of Forest's generic and older unpromoted product lines increased by \$21,439,000 from fiscal 2001 due principally to price increases.

Net sales in fiscal 2001 increased \$301,705,000 to \$1,174,527,000, a 35% increase from fiscal 2000. Forest's leading product, Celexa, accounted for most of the increase with sales of \$714,359,000, an increase of \$287,017,000 or 67% from fiscal 2000. As of March 31, 2001, Celexa had captured a 14.2% share of total prescriptions in the SSRI market. Tiazac, increased \$18,665,000 in fiscal 2001 of which \$27,136,000 was due to volume increases, offset by \$8,471,000 of net price declines which were principally the result of increases in government sales at a discount. Sales of Infasurf®, Forest's lung surfactant for the prevention and treatment of respiratory distress syndrome in premature infants, which was launched during the third quarter of fiscal 2000, were \$12,886,000, an increase of \$8,093,000. Sales of Aerobid, which continued to experience competition in the inhaled steroid market, declined \$2,146,000 or 3% during fiscal 2001 due to volume declines. Sales of Forest's generic products increased by \$9,151,000 from fiscal 2000. The remainder of the net sales change was due principally to volume declines on the Company's older unpromoted product lines.

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Increases in other income in fiscal years 2002 and 2001 were the result of higher interest income resulting from increases in funds available for investment. Included in other income for all periods were royalties on sales of Climara®, a transdermal estrogen product, which amounted to \$5,899,000, \$6,827,000, and \$8,976,000 in fiscal years 2002, 2001 and 2000, respectively. Other income in fiscal year 2000 included \$3,000,000 from the final installment of the settlement with Pharmacia & Upjohn, Inc. with respect to the Company's claimed option to negotiate for the rights to Detrol®.

Cost of sales as a percentage of sales was 24% in fiscal years 2002 and 2001 as compared to 25% in fiscal year 2000. The improvement was the result of an increase in overall plant utilization and of product mix as Celexa, with a lower cost of goods, comprised a larger portion of total sales.

Selling, general and administrative expenses increased by \$86,129,000 in fiscal 2002 and \$60,751,000 in fiscal 2001. In both periods, the majority of the increase was the result of salesforce expansions. Prior to the April 30, 2000 termination of our arrangement with the Warner-Lambert Company to co-promote Celexa, we increased our salesforce by almost 70%, from 850 representatives and managers to 1,425 persons. Early in fiscal 2002, Forest added 75 representatives to the salesforce to better serve our hospital and government business. In anticipation of several planned product launches, we began another expansion of approximately 600 representatives and managers in the third quarter of fiscal 2002. Forest expects to complete this expansion during the first quarter of fiscal 2003, which will facilitate the launches of Lexapro and Benicar. At that time, the Company's salesforce will number approximately 2,100 representatives and managers.

The increases in research and development expense during each of the years presented were due primarily to costs associated with ongoing clinical trials and from staff increases and associated costs required to support currently marketed products and products in various stages of development. During the current fiscal year, particular emphasis was placed on the start-up of clinical trials for several of the Company's recently licensed products, including memantine and dexloiglumide. Memantine is being developed for the treatment of Alzheimer's Disease and neuropathic pain and the Company hopes to file an NDA for that product for Alzheimer's Disease in fiscal 2003. Dexloiglumide, for the treatment of constipation-prone irritable bowel syndrome, is currently in Phase III clinical testing. Spending also continued for ongoing trials for Lexapro, for which Forest received an Approvable Letter from the FDA on January 23, 2002 and expects to launch in the first half of fiscal 2003. Other products currently in our pipeline for which clinical studies are being conducted include: neramexane, an NMDA receptor antagonist, which is currently in Phase II clinical trials and is being tested for various CNS disorders; Aerospan®, for asthma which is currently under final review with the FDA; and lercanidipine for the treatment of hypertension, for which an NDA was filed in October 2001. Forest hopes to launch both Aerospan and lercanidipine in early fiscal 2004. As a result of the growing pipeline of products, the Company anticipates further increases in research and development for next year and beyond. During fiscal 2002, Forest terminated development programs for ALX-0646 for migraine headaches and ML3000 for osteoarthritis as a result of product development or efficacy problems encountered in the drug development process.

The effective income tax rate was 28% for the current year, unchanged from the previous fiscal years presented. Forest expects the proportion of income recognized by its Irish subsidiary, which is both the licensee and manufacturer of Celexa and several other products under development, to increase next year. Because of tax incentives in Ireland, the Company expects its overall effective tax rate to decline in the future.

The Company expects to continue its profitability into fiscal 2003 with continued growth in its principal promoted products.

Inflation has not had a material effect on the Company's operations for the periods presented.

### Forward Looking Statements

Except for the historical information contained herein, the Management Discussion and other portions of this annual report contain 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 timely development and launch of new products and the risk factors listed from time to time in the Company's filings with the SEC, including the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2002.

Quantitative and Qualitative Disclosures About Market Risk

In the normal course of business, operations of the Company may be exposed to fluctuations in currency values and interest rates. These fluctuations can vary the costs of financing, investing and operating transactions. Because the Company had no debt and only minimal foreign currency transactions, there was no material impact on earnings of fluctuations in interest and currency exchange rates.

EXHIBIT 23

CONSENT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

Forest Laboratories, Inc.  
New York, New York

We hereby consent to the incorporation by reference in the Registration Statements of Forest Laboratories, Inc. on Forms S-8, filed with the Securities and Exchange Commission on October 28, 1994, October 18, 1998 and October 26, 2000 and Form S-3 filed with the Securities and Exchange Commission on November 30, 1993, respectively, of our reports dated April 19, 2002 on the consolidated financial statements and schedule of Forest Laboratories, Inc. appearing in the Annual Report on Form 10-K as of and for the year ended March 31, 2002.

/s/ BDO Seidman, LLP  
BDO Seidman, LLP

New York, New York  
June 27, 2002