

# IMPAX LABORATORIES INC

## FORM 10KSB (Annual Report (Small Business Issuers))

Filed 04/15/97 for the Period Ending 12/31/96

Address	30831 HUNTWOOD AVENUE HAYWARD, CA 94544
Telephone	510-240-6000
CIK	0001003642
Symbol	IPXL
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

# IMPAX LABORATORIES INC

## FORM 10KSB

(Annual Report (Small Business Issuers))

Filed 4/15/1997 For Period Ending 12/31/1996

Address	30831 HAYWARD AVE HAYWARD, California 94544
Telephone	215-289-2220
CIK	0001003642
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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# U.S. Securities and Exchange Commission

Washington, D.C. 20549

## Form 10-KSB

ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934 [Fee Required]

For the fiscal year ended December 31, 1996

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934 [No Fee Required]

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 33-99310-NY

### Global Pharmaceutical Corporation

(Name of small business issuer in its charter)

Delaware

65-0403311

-----  
(State or other jurisdiction of  
incorporation or organization)

-----  
(I.R.S. Employer  
Identification No.)

Castor & Kensington Aves., Philadelphia, PA 19124-5694

(Address of principal executive officers) (Zip Code)

Issuer's telephone number (215) 289-2220

Securities registered under Section 12(b) of the Exchange Act:

Title of each class None	Name of each exchange on which registered None
----- -----	----- -----

Securities registered under Section 12(g) of the Exchange Act:

Common Stock, \$.01 par value per share

(Title of class)

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

Check if there is no disclosure of delinquent filers in response to

Item 405 of Regulation S-B contained in this form, and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in part III of this Form 10-KSB or any amendment to this Form 10-KSB. [ X ]

State issuer's revenues for its most recent fiscal year. 0

The aggregate market value of voting stock held by non-affiliates of the registrant as of March 25, 1997 (based on the closing price for such shares on March 25, 1997 as reported by NASDAQ and the assumption for this computation only that all directors and executive officers of the registrant are affiliates) was \$27,430,120. As of March 25, 1997, the number of shares outstanding of each of the issuer's classes of common equity was 4,286,871 shares of common stock, (\$.01 par value per share).

Registrant's Proxy Statement to be filed with the Securities and Exchange Commission in connection with solicitations of proxies for Registrant's 1997 Annual Meeting of Stockholders scheduled to be held on June 24, 1997 is incorporated by reference in Part III, Items 9, 10, 11 and 12 of this Form 10-KSB.

## PART I

When used in this discussion, the words "believes", "anticipates", "expects", and similar expressions are intended to identify forward-looking statements. Such statements are subject to certain risks and uncertainties which could cause actual results to differ materially from those projected.

The Company's business and results of operations are affected by a wide variety of factors that could materially and adversely affect the Company and its actual results, including, but not limited to, the ability to obtain governmental approvals, the impact of competitive products and pricing, product demand and market acceptance, new product development, reliance on key strategic alliances, availability of raw materials and the regulatory environment. As a result of these and other factors, the Company may experience material fluctuations in future operating results on a quarterly or annual basis (including, to the extent appropriate governmental approvals are not obtained, the inability to manufacture and sell products), which could materially and adversely affect its business, financial condition, operating results, and stock price. An investment in the Company involves various risks, including those referred to above and those which are detailed from time-to-time in the Company's other filings with the Securities and Exchange Commission.

These forward-looking statements speak only as of the date hereof. The Company undertakes no obligation to publicly release the results of any revisions to these forward-looking statements which may be made to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

### Item 1. Description of Business

#### Introduction

Global Pharmaceutical Corporation (the "Company" or "Global") is a development stage company that will engage principally in the manufacture and sale of solid oral generic prescription and over-the-counter ("OTC") drugs. The Company currently owns 54 previously manufactured and marketed Abbreviated New Drug Applications ("ANDAs"), New Drug Applications ("NDAs") and New Animal Drug Applications ("NADAs"), more than 100 previously manufactured and marketed prescription and OTC formulations not subject to ANDA approval by the United States Food and Drug Administration ("FDA"), and a renovated 113,000 square foot manufacturing facility (the "Facility") located in Philadelphia, Pennsylvania. Those assets were purchased from Richlyn Laboratories, Inc. ("Richlyn"), which commenced business in 1947 but ceased operations as a generic drug manufacturer and distributor in 1992 for failure to comply with FDA regulations pertaining to current Good Manufacturing Practices ("cGMPs"). Many of the generic drugs the Company has begun to produce as well as those planned for future production are targeted at niche markets characterized by few, if any, generic competitors. The Company believes that of the approximately 154 generic drug formulations owned by the Company, currently 20 products would have no domestic generic competition and another 16 would have only one generic competitor. Each ANDA, NDA and NADA represents the government's permission to manufacture a specific drug product pursuant to specified processes at a specified location.

In addition to its strategy of building upon its base of previously FDA-approved generic niche market drugs, the Company intends to enter larger, more competitive generic markets at such times as it believes it can effectively compete in those markets. Positioning itself to effectuate this strategy, in January 1997, the Company entered into an agreement (the "Genpharm Agreement") with Genpharm, Inc. ("Genpharm"), a Canadian corporation and an indirect subsidiary of Merck KGaA, pursuant to which the Company will package a minimum of 30% of Genpharm's United States Ranitidine Form I ("Ranitidine") production requirements based on a five-year cost-plus and percentage of profits compensation arrangement following Genpharm's receipt of the requisite FDA Ranitidine approvals. Ranitidine is the generic equivalent of Glaxo Wellcome plc's ("Glaxo") patented prescription drug Zantac(R), currently one of the largest selling drugs in the United States with annual U.S. sales of approximately \$1.6 billion. In connection with the settlement of litigation between Glaxo and Genpharm, challenging the validity of Glaxo's basic Zantac(R) patent, Glaxo agreed that, commencing July 26, 1997, Genpharm and its licensees may produce Ranitidine for sale in the United States without being subject to claims by Glaxo of infringement of that patent. Genpharm filed an ANDA with the FDA for Ranitidine in 1995, and has the requisite formulation, procedures and raw material sources to produce Ranitidine. The Company is currently aware of at least four companies which received tentative approval to market Ranitidine products in competition with Zantac(R).

In addition to the manufacture and distribution of Ranitidine, the Genpharm Agreement provides the Company with the opportunity to develop products with the assistance of Merck KGaA that are marketed outside the U.S. Two products with total U.S. annual sales of over \$150 million, including limited generic competition, have already been selected. Development is currently underway with ANDAs anticipated to be filed by the Company by the fourth quarter of 1997, although no assurance can be given that the Company will be able to make the requisite filings or produce and distribute these products.

In order to commence manufacturing at its Facility and become "fully operational," the Company must receive FDA approval of the Facility and at least one of its ANDA or NDA products. The Company has received FDA certification of its laboratory, as well as of its packaging, warehousing, shipping, and receiving operations. The Company is continuing its efforts to obtain FDA certification of the plant manufacturing area and processes. See "FDA Approvals" below.

In a series of transactions from 1993 to December 1995, two investor groups, including one led by venture capital investor Frederick R. Adler, installed a new management team with generic drug industry experience and, together with Merck KGaA, have invested approximately \$5.2 million to fund the Company's plant renovation and the commencement of its validation and certification program. In addition to those investor funds, The Company has received \$1.5 million of low interest rate loans from a combination of the Pennsylvania Industrial Development Authority ("PIDA") and the Philadelphia Industrial Development Corporation ("PIDC").

In June 1996, the Company received approval for a \$1,000,000 loan with PIDA at 3.75% annually fixed for 15 years, the proceeds of which must be used for certain capital projects.

In August 1996, the Company received approval for a \$350,000 loan from the Delaware River Port Authority at 5.00% annually fixed for 10 years, the proceeds of which must be used for certain capital projects.

On December 19, 1995, the Company completed its initial public offering ("IPO") in which it sold 1,650,000 shares of common stock for net proceeds of \$11,489,000. An additional 247,500 shares of common stock were sold to the underwriter of the IPO in January 1996, upon the exercise of the underwriters' over-allotment option, for net proceeds to the Company of \$1,835,000.

The proceeds from the IPO and the subsequent over-allotment exercise were used primarily to fund the ongoing validation process for both the Facility and the expected products, the expansion of the Company's laboratory and research and development activities, the repayment of all outstanding indebtedness incurred in connection with the assets purchased from Richlyn, the purchase of production equipment and for working capital and other general corporate purposes.

### **FDA Approvals**

To meet the Company's goal of becoming fully operational, the Company must first receive Facility approval from FDA and thereafter must receive FDA approval of at least one of its ANDAs. Facility approval requires that the Company's laboratory, manufacturing, packaging and warehousing operations must each pass successfully through a cGMPs validation process, each step of which requires certification first by an independent consultant retained for this purpose by the Company and then by FDA, which reviews the consultant's report. The Company has received FDA certification of its laboratory, as well as of its packaging, warehousing, shipping, and receiving operations. The Company is continuing its efforts to obtain FDA certification of the plant manufacturing area and processes. The Company has recently met with senior officials of FDA Philadelphia District Office to discuss the most recent in a series of inspections conducted by FDA as part of this certification process, and has submitted to FDA a response to certain additional concerns raised by FDA. While there can be no assurance that FDA certification will be received in the near future, if at all, the Company believes that it has appropriately responded to the concerns raised by FDA. The failure of the Company to obtain FDA certification of the Facility will materially adversely affect the Company.

In addition to the foregoing, the first ANDA selected by the Company for production must pass through a similar process and must successfully complete a validation process that includes sample testing of three batches and multiple-batch stability testing. The sample and stability testing must first be certified by the Company's independent consultant and then by FDA, which reviews the consultant's report. Additionally, each ANDA product subsequently selected by the Company for production must successfully complete a similar validation process. Furthermore, FDA may request to complete a certification process for each product. The Company has selected Promethazine Hydrochloride, an antihistamine, as its first ANDA product for production and sale from its Facility, and will consider itself to be "fully operational" at the time it is approved to sell, and sells, that product from the Facility.

Because FDA has either previously approved the Company's 54 ANDAs, NDAs and NADAs or they were exempt from FDA approval, FDA's reapproval process for those generic drugs is expected by the Company to take between one and three months for each acceptably submitted drug. Generally, new ANDA applications for FDA approval currently take 18 to 24 months, based on published information. FDA reapproval of each ANDA, NDA and NADA is contingent upon its having first received approval by an independent consultant retained by the Company for this purpose.

## Products and Product Development

The Company's policy is to develop a broad product line composed of solid oral (tablets and capsules) prescription and over-the-counter generic drugs, various products that require isolation during their production, narcotic and other drug products that are heavily regulated by the United States Drug Enforcement Agency ("DEA") and dietary supplements. The Company also intends to seek to develop or license certain brand name pharmaceutical products. Although most of the Company's products are expected to be dedicated to the treatment of humans, some products may also be for the treatment of animals.

The Company plans to introduce eighteen to twenty generic drugs in 1997, including the following ANDA products:

Planned 1997 Generic Drug Introductions						
Generic Product Name	Dosage Form	Brand Name Equivalent(s)	Brand Name Manufacturer(s)	Prescribed Use	Number of Generic Competitors(1)	Estimated 1995 Market Size (\$000)(2)
Chlordiazepoxide	Capsule	Librium	Roche	Tranquilizer	1	10,600
Chloroquine Phosphate	Tablet	Aralen	Sanofi	Antimalarial	None	3,400
Cortisone Acetate	Tablet	Cortone	MSD Upjohn	Corticosteroid	1	2,000
Hydrocortisone	Tablet	Hydrocortone Cortef	MSD Upjohn	Corticosteroid	1	4,700
Meprobamate		Miltown Equanil	Wallace Wyeth Ayerst	Tranquilizer	2	4,300
Methyltestosterone	Tablet	Oreton, Testred, Android	ICN Pharmaceutical	Androgenic Steroid	None	10,000
Piperazine Citrate		Vermidol	Solvay	Anthelmintic	None	2,000
Prednisolone	Tablet	Meticortilone	Schering	Corticosteroid	1	2,000
Promethazine Hydrochloride	Tablet	Phenergan	American Home	Antihistamine	3	6,000

(Table I continued on following page)

TABLE I

(Table I continued from previous page)

Planned 1997 Generic Drug Introductions

Generic Product Name	Dosage Form	Brand Name Equivalent(s)	Brand Name Manufacturer(s)	Prescribed Use	Number of Generic Competitors(1)	Estimated 1995 Market Size (\$000)(2)
Propylthiouracil		Propylthiourac	Lederle	Anti-thyroid therapy	2	1,100
Tetracycline Hydrochloride	Capsule	Achromycin V Sumycin	Lederle Apothecon	Broad spectrum anti-infective	4	10,700

(1) Information is to the best of the Company's knowledge as of 12/31/96. The Company is aware of ANDAs on file with FDA regarding certain of the products included in the table that are owned by companies that, to the best of the Company's knowledge, are not competing with respect to those ANDAs and products at this time. Accordingly, the number of generic competitors set forth with respect to certain products included in the table could increase.

(2) Estimated on the basis of information contained in published industry sources, review of historic sales information, and input from customers and distributors.

The Company has selected certain of the products listed in Table I, above, to be among its first releases following its renewal of operations, either because those products are not subject to any generic competition currently or because they are niche market products that are subject to limited competition and which the Company believes are not likely to be significant enough to warrant attention from large potential competitors. The Company also plans to broaden its product mix to include products that are currently exempt from ANDA or NDA requirements and for which there is currently limited generic competition. The total number of these products expected to be introduced in 1997 is between seven and nine with a total current estimated U.S. market value of approximately \$70 million.

The Company also plans to manufacture and sell drugs that are regulated by DEA such as narcotics, barbiturates and certain tranquilizers, as well as certain products that require isolated manufacturing facilities, which the Company has provided by refurbishing and equipping a part of its existing facility. DEA regulations generally deal with the storage and dissemination of certain drugs and related raw materials and are designed to protect the security of those products and their dissemination against receipt by unauthorized persons. The Company believes that the DEA regulations that will be applicable to it will not materially increase the scope or expense of its regulatory compliance requirements.

The Company acquired from Richlyn 54 ANDAs, NDAs and NADAs and more than 100 previously marketed prescription and OTC formulations including pharmaceutical products not subject to FDA approval that were manufactured and sold by Richlyn. Table II contains a list of all the Company's ANDAs, NDAs and NADAs and sets forth certain additional information concerning each of them:

TABLE II

The Company's ANDAs, NDAs and NADAs

Generic Product Name	Brand Name Equivalent(s)/ Manufacturer(s)	Dosage Form, Administration and Strength	Prescribed Use(s)	Number of Generic Competitors(1)	Estimated Market Size (\$000)(2)
Human Use Drugs:					
Aminophylline	Aminophylline Searle	CT 100mg and 200mg ECT 100mg ECT 200mg	Bronchodilator Bronchodilator Bronchodilator	None None None	400

(Table II continued on following page)

TABLE II

(Table II continued from previous page)

## The Company's ANDAs, NDAs and NADAs

Generic Product Name	Brand Name Equivalent(s)/ Manufacturer(s)	Dosage Form, Administration and Strength	Prescribed Use(s)	Number of Generic Competitors(1)	Estimated Market Size (\$000)(2)
Chlordiazepoxide	Librium Roche	HSC 5, 10 and 25mg	Tranquilizer	1	10,600
Chloroquine Phosphate	Aralen Sanofi	CT 250mg	Anti-malarial	None	3,400
Cortisone Acetate	Cortone MSD and Upjohn	CT 25mg	Corticosteroid	1	2,000
Dexamethasone	Decadron MSD	CT 0.75mg	Corticosteroid	2	10,400
Diphenhydramine	Benadryl Parke Davis and Warner Chilcott	HSC 25 and 50mg	Antihistamine	6	31,000
Ergocalciferol	Drisdol Sanofi	SGC 1.25mg	Vitamin D Rickets Treatment	1	2,300
Folic Acid	Folvite Lederle	CT 1mg	Folic Acid Supplement	5	1,600
Hydralazine HCL	Apresoline Ciba Geigy	CT 25 and 50mg	Antihypertensive	3	5,250
Hydrochlorothiazide	Hydrodiuril MSD	CT 25, 50 and 100mg	Diuretic	4	6,100
Hydrocortisone	Hydrocortone MSD Cortef Upjohn	CT 20mg	Corticosteroid	1	4,700
Isoniazid	Nydravid Apothecon	CT 100mg	Anti-tuberculin	3	1,000
Meprobamate	Miltown Wallace Equanil Wyeth Ayerst	CT 200 and 400mg	Tranquilizer	2	4,300
Methocarbamol	Robaxin American Home	CT 500 and 750mg	Depressant for musculo-skeletal disorders	3	15,300
Methyltestosterone	Oreton, Testred, Android ICN Pharmaceutical	SLT 10mg CT 10mg CT 25mg	Androgenic Steroid	None	10,000
Niacin	Nicolar Rhone Poulenc Rorer Armour	CT 500mg	Peripheral Vasodilator	2	1,100

Oxytetracycline HCL	Terramycin Pfizer	HSC 250mg	Antibiotic	None	1,000
Piperazine Citrate	Vermidol Solvay	CT 250mg	Anthelmintic	None	2,000
Prednisolone	Meticortilone Schering	CT 5mg	Corticosteroid	1	2,000
Prednisone	Deltasone Upjohn Orasone Solvay	CT 5mg	Corticosteroid	6	20,700
Probenecid & Colchicine	Colbenemid MSD	CT 500mg	Uric Acid Reducer	2	4,500
Promethazine Hydrochloride	Phenergan American Home	CT 25mg	Antihistamine	3	6,000
Propantheline Bromide	Probanthine Searle	SCT 15mg	Anticholinergic	1	4,200
Propoxyphene HCL	Darvon 65 Lilly	HSC 65mg	Analgesic	2	3,950
Propylthiouracil	Propylthiouracil Lederle	CT 50mg	Anti-thyroid therapy	2	1,100

(Table II continued on following page)

TABLE II

(Table II continued from previous page)

## The Company's ANDAs, NDAs and NADAs

Generic Product Name	Brand Name Equivalent(s)/ Manufacturer(s)	Dosage Form, Administration and Strength	Prescribed Use(s)	Number of Generic Competitors(1)	Estimated Market Size (\$000)(2)
Human Drugs Continued:					
Pyrilamine Maleate	(No brand)	CT 25mg	Antihistamine	None	250
Quinidine Sulfate	Quinidine Sulfate Parke Davis	CT 200mg	Cardiac Arrhythmia	3	2,850
Rauwolfia Serpentina	Raudixin Apothecon	SCT 50 and 100mg	Anti- hypertensive	None	N/A
Reserpine	Serpasil Ciba Geigy	CT 0.1 and 0.25mg	Anti- hypertensive	3	1,000
Sulfadiazine	Microsulfon Consolidated Midland	CT 500mg	Antibacterial	1	4,000
Sulfa-Triple	Terfonyl Squibb	CT 500mg	Antibacterial	None	500
Sulfisoxazole	Gantrisin Roche	CT 500mg	Urinary Antiseptic	2	700
Tetracycline HCL-Human	Achromysin V Lederle Sumycin Apothecon	HSC 100, 250 and 500mg	Broad spectrum anti-infective	4	10,700
Thyroglobulin	Proloid Parke Davis	CT 64mg	Endocrine Therapeutic	None	10,000
Triamcinolone	Aristocort Lederle Kenacort Squibb	CT 4mg	Corticosteroid	1	1,200
Trichlormethiazide	Metahydrin MMD Naqua Schering	CT 4mg	Diuretic	1	1,200
Tripelennamine HCL	PBZ Ciba Geigy	CT 50mg	Antihistamine	1	2,200

Vitamin A Soluble	Aquasol-A Astra	SGC 50,000 units	Vitamin A deficiency	None	1,700
Vitamin A Natural	Del-Vi-A Del Ray	SGC 50,000 units	Vitamin A deficiency	3	100
Vitamin A Synthetic	Various	SGC 50,000 units	Vitamin A deficiency	2	100
Animal Use Drugs:					
Diclorophenal Toluene	(No brand)	SGC	Antihelmetic	1	2,000
n-Butyl Chloride V	(No brand)	SGC 1, 2, 5ml.	Antihelmetic	1	2,600
Tetracycline HCL-Veterinary	Achromysin V Lederle	HSC 50, 100, 250 and 500mg	Antibiotic	None	2,000

Key:

CT = Compressed tablet  
CCT = Chewable compressed tablet  
SGC = Soft gelatin capsules  
SLT = Sublingual tablet (Buccal)  
SCT = Sugar coated tablet  
HSC = Hard shell capsule  
ECT = Enteric coated tablet  
MLT = Multi-layer tablet

Notes:

- (1) Information is to the best of the Company's knowledge as of 12/31/96. The Company is aware of ANDAs on file with FDA regarding certain of the products included in the table that are owned by companies that, to the best of the Company's knowledge, are not competing with respect to those ANDAs and products at this time. Accordingly, the number of generic competitors set forth with respect to certain products included in the table could increase.
- (2) Estimated on the basis of information contained in published industry sources, review of historic sales information, and input from customers and distributors.

Before the Company can manufacture and sell any drug product from its plant, the Company's laboratory, manufacturing, packaging and warehousing operations at that Facility must each pass successfully through a cGMPs validation process, each step of which requires certification first by an independent consultant retained by the Company for this purpose and then by FDA, which reviews the consultant's report. Thereafter, the Company's selected products must pass through a similar process and must successfully complete a validation process that includes sample testing of three batches and multiple-batch stability testing. There can be no assurance as to whether the Company's ANDAs, NDAs and NADAs will receive the requisite FDA reapprovals, or that the Company will be able to successfully manufacture, market and sell its products. Delays in any part of that process or the inability of the Company to obtain regulatory approval of its products and Facilities could adversely affect the Company's quarterly and annual operating results.

Table III sets forth certain information concerning some of the ANDA exempt products owned by the Company:

TABLE III

The Company's ANDA Exempt Drug Products and Dietary Supplements

Generic Product Name	Brand Name Equivalent(s)/ Manufacturer(s)	Dosage Form, Administration and Strength	Prescribed Use(s)	Number of Generic Competitors(1)	Estimated Market Size (\$000)(2)
Acetaminophen	Tylenol regular Tylenol Extra Strength McNeil	CCT, HSC 325mg & 500mg	Analgesic, Fever Reducer	11	690,000
Amobarbital with Secobarbital	Tuinal Lilly	HSC 100mg	Short-term Hypnotic, Preanesthesia	None	120
Antacid #2	Tums Smith Kline Beecham Consumer Brands	CCT	Antacid w/calcium	2	45,000
Aspirin E.C.	Ecotrin Smith Kline Beecham Bayer Enteric Bayer	ECT 325mg	Analgesic, Fever Reducer	5	28,000
Bisacodyl	Dulcolax Boeringer	SCT 5mg	Laxative	5	12,800
Colchicine	Colchicine Lilly	CT .01 gr	Uric Acid Reducer	3	1,000
Digestozyme	Donnazyme American Home	ECT	Digestive Aid	None	10,000
Digoxin	Lanoxin Glaxo Wellcome	CT 0.125 & 0.25mg	Digitalis	1	86,000
Ephedrine Sulfate	Ephedrine Lilly	HSC 25 & 50mg	Beta-agonist	None	250
Ergotamine Tartrate w/caffeine	Caffergot Sandoz	SCT	Migraine & Headache Reliever	1	24,700
Ergotamine, Phenobarbital w/Belladonna	Bellergal S Sandoz	SCT	Anticholinergic & Headache Reliever	3	18,200
Ferrous Fumerate	Fumiron	SCT 325mg	Iron Supplement	1	300
Ferrous Gluconate	Fergon Sterling	SCT 325mg	Iron Supplement	4	3,300
Ferrous Sulfate	Feosol Spansule SKB SKB Tab	TDC 150mg SCT 325mg	Iron Supplement	2 7	3,000 8,500

(Table III continued on following page)

TABLE III

(Table III continued from previous page)

The Company's ANDA Exempt Drug Products and Dietary Supplements

Generic Product Name	Brand Name Equivalent(s)/ Manufacturer(s)	Dosage Form, Administration and Strength	Prescribed Use(s)	Number of Generic Competitors(1)	Estimated Market Size (\$000)(2)
Levothyroxine Sodium	Synthroid Boots Levothroid Forrest	CCT 0.05mg to .3mg	Thyroid Therapy	4	270,000
Meclizine Chewable	Bonine Pfizer Dramamine II Upjohn	CCT 25mg Lozenge	Antivertigo	1	5,000
Meclizine MLT	Antivert Roerig	MLT 12.5 & 25mg	Antivertigo	2	17,000
Methenamine Mandelate	Mandelamine Parke-Davis	ECT 0.5 & 1.0gm	Urinary Antiseptic	1	2,150
Phenobarbital	Solfoton ECR Pharmaceuticals	CT 15, 30, 60, 90mg	Sedative	4	3,800
Phenobarbital/Belladonna Alkaloids	Donnatol American Home	CCT	Antispasmodic	5	4,000
Phenyltoloxamine W/APAP	Percogesic PXG	CT 30 & 325mg	Analgesic	4	8,500
Pseudoephedrine	Sudafed Glaxo Wellcome	SCT 30mg CT 60mg	Vasoconstrictor	9 None	30,000 5,628
Pyridiate	Pyridium Parke-Davis	SCT 100 & 300mg	Urinary Analgesic	4	7,400
	Azostandard Polymedica	SCT 95mg		1	5,000
Quinine Sulfate	Quinine Sulfate Lilly	HSC 95mg 325mg	Antimalarial	4	12,000
Sodium Fluoride	Flouritab Flouritab	CT Lozenge 2.2mg	Anticaries	2	3,200

Theophylline, Ephedrine & Phenobarbital	Tedral Warner Lambert	CT	Xanthine Combination	None	500
Thyroid	Armour Thyroid Forrest	CCT 0.5, 1, 2, 3 & 5gr	Thyroid Therapy	1	18,200
Tripolidine Pseudoephedrine	Actifed Glaxo Wellcome	CT 25mg and 60mg	Antihistamine	4	14,800
Uritin Blue	Urised Polymedica	SCT	Urinary Analgesic	1	6,000
Dietary Supplements:					
Lipoid Caps	Lipoflavonoid Numark	HSC	Lipotropics	2	750
Methacholine	(No brand)	HSC	Lipotropics	2	1,000
Animal Use Drug:					
Diethylcarbamazine Citrate	(No brand)	CT 100, 200, 300, 400mg	Antihelmetic	None	5,000

Key:

CT = Compressed tablet  
 CCT = Chewable compressed tablet  
 SGC = Soft gelatin capsules  
 SLT = Sublingual tablet (Buccal)  
 SCT = Sugar coated tablet  
 HSC = Hard shell capsule  
 ECT = Enteric coated tablet  
 TDC = Timed disintegrating capsule (prolongsules)  
 MLT = Multi-layer tablet

Notes:

(1) Information is to the best of the Company's knowledge as of 12/31/96. Estimated on the basis of information contained in published industry sources and the experience of management. The number of generic competitors set forth with respect to certain products included in the table could increase.  
 (2) Estimated on the basis of information contained in published industry sources, review of historic sales information, and input from customers and distributors.

In addition, the Company intends to expand its line of generic products through a combination of a research and development program that is expected to result in new products owned by the Company and licensing of additional products owned by others. Generally, it is important that a new generic product be approved by FDA for marketing by, or shortly after, the patent expiration date of the equivalent brand name drug (plus any legislatively-granted extensions) in order to gain significant market share at attractive profit margins. As more generic products compete in the same market, which customarily occurs increasingly over time following the brand name product's patent expiration date (and extensions, if any), unit prices and profit margins decrease. As the development of a new generic drug product, including its formulation, testing and FDA approval, generally currently takes approximately three or more years, development activities may begin several years in advance of the patent expiration date of the brand name drug equivalent. Consequently, the Company may select drugs for development several years in advance of their anticipated entry to market. That program potentially will require that considerable capital be devoted to activities that do not concurrently provide an immediate return.

## **Raw Materials**

The raw materials that will be essential to the Company's business are expected to be bulk pharmaceutical chemicals which are generally available and purchased from numerous sources. Because FDA requires specification of raw material suppliers in applications for approval of drug products, if raw materials from a specified supplier were to become unavailable, the required FDA approval of a new supplier could cause a significant delay in the manufacture of the drug involved. Although the Company expects to specify more than one raw materials supplier with respect to each FDA application where that is possible, some materials are currently available from only one or a limited number of suppliers, as a result of which the Company would be subject to the special risks that are associated with limited sources of supply. In addition, all of the product the Company will require for the packaging of Ranitidine will be available to it only from Genpharm. The Company plans to institute a policy to purchase bulk pharmaceutical chemicals pursuant to multi-shipment contracts, typically of one year's duration, when it believes advance-ordered bulk purchases are advantageous to assure availability at a specified price. The Company believes that alternative sources could be found, or new sources would arise, should any of its sole or limited source raw materials become unavailable from current suppliers. Nevertheless, any curtailment of raw materials could be accompanied by production or other delays as well as increased raw materials costs, with consequent adverse effects on the Company's business and results of operations. Furthermore, as any new source of raw materials, whether domestic or foreign, would require FDA approval, any delays in obtaining FDA approval could also have a material adverse effect on the Company's business and operating results.

Following a general trend in the pharmaceutical industry, an increasing portion, anticipated to be a majority over time, of the Company's raw material supplies may come from foreign sources. Export and import policies of the United States and foreign countries therefore could also materially affect the availability and cost to the Company of certain raw materials at any time or from time to time.

## **Quality Control**

In connection with the manufacture of drugs, FDA requires testing procedures to monitor the quality of the product as well as the consistency of its formulation. The Company maintains a state of the art laboratory that performs, among other things, all analytical tests and measurements required to control and release raw materials and finished products.

Quality monitoring and testing programs and procedures have been established by the Company to assure that all critical activities associated with the production, control and distribution of its drug products will be carefully controlled and evaluated throughout the process. By following a series of systematically organized steps and procedures, the Company seeks to assure that established quality standards will be achieved and built into the product.

The Company's policy is to seek continually to meet the highest quality standards, with the goal of thereby assuring the purity and safety of each of its drug products. The Company believes that adherence to high operational quality standards will also promote more efficient utilization of personnel, materials and production capacity.

## **Sales and Marketing**

The Company's products are expected to be marketed and sold domestically directly and through independent distributors and wholesalers as well as manufacturer's representatives, primarily to independent pharmacies, retail chains and institutions, including managed health care organizations, hospitals and governmental agencies. The Company anticipates that, as its operations eventually reach regular, recurring status, a significant portion of its sales will be to independent distributors and other wholesalers.

Presently, the Company has agreements with three independent distribution organizations. In November 1995, the Company entered into an agreement, (the "Dey Agreement") with Dey Laboratories, Inc. ("Dey"), an indirect subsidiary of Merck KGaA, pursuant to which Dey has agreed to act as the Company's exclusive distributor in the United States for specified products and the Company has agreed to sell those products in the United States only through Dey. Initially, the Dey Agreement will cover two ANDAs pertaining to methyltestosterone, an androgenic steroid. The Company anticipates that additional products will be added by mutual consent of the Company and Dey periodically to the list of products that are subject to the Dey Agreement. With respect to each covered product, the Dey Agreement provides for a specific pricing mechanism and minimum annual volumes which, if not met, could result in the termination of exclusivity. The Dey Agreement's three-year term commences with the first delivery of a product by the Company to Dey.

In September 1995, the Company entered into an agreement with The Care Buying Alliance ("Care"), an association of eleven independent distributors, pursuant to which Care's member organizations have agreed to distribute mutually agreed upon specified volumes of selected Company products at prices that equal the most favorable price at which the same product is sold by the Company to any similar account. Additionally, the Company and Care have agreed to pay jointly certain amounts for nationally advertising those products. The Company's agreement with Care is effective for three years following the delivery of the Company's first selected product to a Care member.

In September 1996, the Company entered into a two year agreement with CARACO Pharmaceutical Laboratories, Ltd. ("Caraco") to manufacture the Company's products under the CARACO label. These private label products will be sold to previously agreed upon CARACO customers, including McKesson Drug Company, the largest provider of generic drugs in the U.S. The Company's strategy is to continue to diversify its sales network by entering into additional marketing alliances.

## **Competition**

The Company's sales are expected to be primarily directed to the generic sector of the pharmaceutical market (also known as the "multisource pharmaceutical market"). Competition in the generic industry is intense. The Company is in competition with numerous other companies in that industry, including major pharmaceutical concerns and other exclusively generic manufacturers.

The originator of a pharmaceutical product generally markets the product under its own brand name during the life of the product's patent and any statutory extensions of the patent. Companies introducing a product after the patent (and any extension) expires may market the product under a brand name and promote it to physicians and pharmacists to create a market for the product or may market the product under its generic name and rely on physicians, pharmacists and customers to specify the lower cost generic product. Producers of brand name pharmaceutical products are increasingly becoming more involved in the generic marketplace, due to their concurrent marketing of both generic and brand name versions of their products after their patents have expired.

Some of the Company's competitors may choose to augment their presence in the generic drug market through acquisitions and strategic alliances. This activity could result in consolidation and restructuring within the generic industry and could impair the Company's ability to compete effectively or effectively limit the number of new opportunities for the Company's products.

The principal competitive factors in the generic pharmaceutical market are the ability to introduce generic versions of products promptly after a patent expires, price, quality of products, customer service (including maintenance of inventories for timely delivery), breadth of product line and the ability to identify and market niche products. Approvals for new products may have a synergistic effect on a company's entire product line as orders for new products are frequently accompanied by, or bring about, orders for other products available from the same company. Price is usually the major competitive factor

facing a generic product, but as more generic products enter a given market, their prices, and hence their profit margins, decrease and competition thereafter is based primarily on quality of product and service. The Company's strategy, therefore, is to begin principally by reintroducing approximately eleven of the ANDAs it acquired from Richlyn that enjoy no or limited generic product competition. The Company currently owns 20 generic drug formulations that it believes presently would have no domestic generic competition and another 16 that are believed to would have only one generic competitor. The Company also plans to compete by broadening its product mix to include products not previously manufactured by Richlyn that also serve niche markets.

The Company's principal competitors among currently operating generic drug companies are initially expected to be Schein Pharmaceutical, Inc., a subsidiary of Henry Schein, Inc.; Geneva Pharmaceutical, Inc., a wholly-owned subsidiary of Novartis; West-Ward Pharmaceutical Corp., a subsidiary of Hikma Investment Co.; and Eon Labs, Inc. Among brand name drug companies, the Company's principal competitors are initially expected to be Wyeth Ayerst Laboratories (which distributes product under the Lederle brand name), a division of American Home Products Corporation, and Roxane Laboratories, Inc., a subsidiary of Boehringer-Ingelheim Corporation. Entry into the generic field by new competitors that do not have adequate plant and equipment assets is difficult in view of the need for substantial capital and regulatory expertise.

### **Proprietary Rights**

The Company does not own any patents and does not believe that patent protection is material to its business. The Company may in the future be required or may desire to obtain other licenses to develop, manufacture and market commercially viable products in the future. There can be no assurance that any licenses, if needed or desired by the Company, will be obtainable on commercially reasonable terms or that any licensed patents or proprietary rights will be valid and enforceable. Further, should the Company become subject to any claim that it is violating the patent rights of another person, the Company could be subject to costly litigation and, possibly, material liability. The Company carefully monitors trademarks used by pharmaceutical companies, including product trademarks, through regularly published and readily available sources. Further, as the Company's generic products will only be manufactured and sold by the Company after their respective brand name products' patents have expired, and as the Company sells its products under generic, chemical names, it believes the likelihood of it infringing on the patents of others is and will continue to be remote.

### **Government Regulation**

#### **Industry Regulation**

All pharmaceutical manufacturers are extensively regulated by the federal government, including the FDA, the DEA and various State agencies. The Federal Food, Drug, and Cosmetic Act, the Controlled Substances Act, the Generic Drug Enforcement Act of 1992 and other federal statutes and regulations govern or influence the manufacture, labeling, testing, storage, recordkeeping, approval, advertising and promotion of the Company's products. Noncompliance with applicable requirements can result in fines, recalls, seizure of products, suspension of production, refusal of the government to enter into supply contracts or to approve drug applications, and criminal prosecution.

FDA approval is required before any "new drug" may be distributed in interstate commerce. A "new drug" is one that is not generally recognized by qualified experts as safe and effective for its intended use. A drug that is the generic equivalent of a previously approved prescription drug (i.e., the reference drug), also requires FDA approval. Furthermore, each dosage form of a specific generic drug is treated as a separate drug product by FDA, and requires separate approval. Many over-the-counter drugs also require FDA pre-approval if the OTC drug is not covered by or does not conform with the conditions specified in an applicable OTC Drug Product Monograph. All facilities engaged in the manufacture of drug products must be registered with FDA and are subject to FDA inspection to ensure that drug products are manufactured in accordance with current Good Manufacturing Practices ("cGMPs").

Generally, two types of applications are used to obtain FDA approval of a new drug. They include the following:

1. New Drug Application ("NDA"). For drug products with active ingredients or indications not previously approved by FDA, a prospective manufacturer must submit a complete application which contains the results of clinical studies supporting the drug's safety and efficacy. An NDA may also be submitted for a drug with a previously approved active ingredient if the abbreviated procedure discussed below is not available. Currently, FDA approval of an NDA, on average, takes approximately 18 to 20 months.

2. Abbreviated New Drug Application ("ANDA"). The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Drug Price Act") established an abbreviated new drug application procedure for obtaining FDA approval of certain generic drugs. An ANDA is similar to an NDA except that the FDA waives the requirement for conducting clinical studies to demonstrate the safety and effectiveness of the drug. Instead, for drugs that contain the same active ingredient and are for the same route of administration, dosage form, strength and indication(s) as drugs already approved for use in the United States, FDA ordinarily only requires bioavailability data illustrating that the generic drug formulation is bioequivalent to the previously approved reference drug. "Bioavailability" indicates the rate of absorption and levels of concentration of a drug in the blood stream which are needed to produce a therapeutic effect. "Bioequivalence" compares the bioavailability of one drug product with another and, when established, indicates that the rate of absorption and the levels of concentration of a generic drug in the body do not show a significant difference from those of the previously approved equivalent drug. According to information published by FDA, it currently takes approximately two years on average to obtain FDA approval of an ANDA following the date of its first submission to FDA.

Although antibiotic drugs (as well as veterinary drugs) are classified separately for purposes of FDA approval, the approval procedure for drugs of those types conforms substantially to the NDA and ANDA procedures described above.

The Drug Price Act, in addition to establishing a new ANDA procedure, created new statutory protections for approved brand name drugs. Prior to enactment of the Drug Price Act, FDA gave no consideration to the patent status of a previously approved drug in deciding whether to approve an ANDA. Under the Drug Price Act, the effective date of approval of an ANDA can depend, under certain circumstances, on the patent status of the brand name drug. Additionally, the Drug Price Act, in certain circumstances, can extend the term of certain patents to cover a drug for up to five additional years. Any such extension is intended to compensate the patent holder for the reduction of the effective market life of a patent due to the time involved in federal regulatory review. With respect to certain drugs that are not covered by patents, the Drug Price Act sets specified time periods of two to ten years during which ANDAs for generic drugs cannot become effective or, under certain circumstances, be filed if the equivalent brand name drug was approved after December 31, 1981.

Among the requirements for new drug approval is the requirement that the prospective manufacturer's facility, production methods and recordkeeping practices among other factors conform to current Good Manufacturing Practices (cGMP's). The current GMP's must be followed at all times when the approved drug is manufactured. In complying with the standards set forth in the GMP regulations, the manufacturer must expend time, money and effort in the areas of production and quality control to ensure full technical compliance. Failure to comply can result in possible FDA actions such as the suspension of manufacturing or seizure of finished drug products. The Company also is governed by federal, state and local laws of general applicability, such as laws regulating working conditions.

The Company is also subject to the Maximum Allowable Cost Regulations ("MAC Regulations"), which limit reimbursements for certain multi-source prescription drugs under Medicare, Medicaid and other programs to the lowest price at which such drugs are generally available. In many instances, only generic prescription drugs fall within the MAC Regulations' limits. Generally, the methods of reimbursement and fixing of reimbursement levels are under active review by federal, state and local governmental entities as well as by private third-party reimbursers. The Company cannot predict the results of those reviews or their impact on the business of the Company.

The Generic Drug Enforcement Act of 1992 establishes penalties for wrongdoing in connection with the development or submission of an ANDA. FDA is authorized to temporarily bar companies or temporarily or permanently bar individuals from submitting or assisting in the submission of an ANDA and to temporarily deny approval and suspend applications to market off-patent drugs. FDA must bar companies or individuals convicted of a federal felony for conduct relating to the development or approval of an ANDA and may debar persons (i.e., prohibit them from submitting or assisting in the submission to FDA of any ANDA and from engaging in the manufacture or sale of an FDA-approved drug product)

convicted of other misconduct. In addition to debarment, FDA has numerous discretionary disciplinary powers. Among other things, the FDA may refuse to approve an ANDA (for up to 18 months) if the applicant is under active federal criminal investigation for bribery or making material false statements in connection with any ANDA, or if a significant question has been raised regarding the integrity of the approval process or the reliability of the data in the ANDA; it may also suspend the distribution of all drugs approved or developed in connection with certain wrongful conduct; it has authority to withdraw approval of an ANDA under certain circumstances and to seek civil penalties; and it can significantly delay the approval of a pending NDA or ANDA under its "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities Policy."

Legislation enacted in 1994, makes the use, offer for sale or sale within the United States or importation into the United States of a product that was made either domestically or abroad by a process covered by a U.S. patent, an infringement of the process patent. The Legislation defines the term "offer for sale" as that in which the sales will occur before the expiration of the term of the patent.

Virtually every state as well as the District of Columbia has enacted legislation permitting the substitution of equivalent generic prescription drugs for brand name drugs where authorized or not prohibited by the prescribing physician and currently 13 states mandate generic substitution in Medicaid programs.

To meet the Company's goal of becoming fully operational during 1997, the Company must first receive facility approval from FDA and thereafter must receive FDA approval of at least one of its ANDAs. Facility approval requires that the Company's laboratory, manufacturing, packaging and warehousing operations must each pass successfully through current GMP's validation process, each step of which requires certification by FDA. In addition to the foregoing, the first ANDA selected by the Company for production must pass through a similar process and must successfully complete a validation process that includes sample testing of three batches and multiple-batch stability testing. The sample and stability testing must be certified by the FDA. Additionally, each ANDA product subsequently selected by the Company for production must successfully complete a similar validation process. Furthermore, FDA may request to complete a certification process for each product.

The Company's laboratory received FDA certification on November 14, 1995, and its packaging, warehousing, shipping and receiving operations received FDA certification on February 28, 1995. In order to complete certification of its facility by FDA, in addition to the foregoing the Company must obtain FDA certification of the plant manufacturing area and processes (see Item 1. Description of Business - FDA Approvals). Although FDA approval of an ANDA customarily takes approximately 24 months, the Company believes its existing procedures will be validated and that release periods for the ANDAs and NDAs it currently owns will be approximately three months for each product because those products had been previously approved by FDA.

### **Environmental Laws**

The Company is and will remain subject to comprehensive federal, state and local Environmental Laws, including the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended, the Resource Conservation and Recovery Act and the Toxic Substance Control Act, which govern, among other things, all emissions, waste water discharge and solid and hazardous waste disposal, and the remediation of contamination associated with generation, handling and disposal activities. The Company is subject periodically to environmental compliance reviews by various regulatory offices.

A Phase I environmental study was conducted with respect to the Company's idled plant and operations in 1993 and certain environmental compliance issues identified at that time, including findings of asbestos in certain areas of the plant and underground oil storage tanks, have been addressed. Additionally, the Company will adopt a program pursuant to which it monitors regularly its compliance with any applicable Environmental Laws. There can be no assurance that future developments, administrative actions or liabilities relating to environmental matters will not have a material adverse effect on the Company's financial condition or results of operations.

### **Litigation and Product Liability**

The Company's operations are subject to an order ("the Richlyn Order") issued on May 25, 1993, by the United States District Court for the Eastern District of Pennsylvania. The Richlyn Order, among other things, permanently enjoined Richlyn from introducing into commerce any drug manufactured, processed, packed or labeled at Richlyn's manufacturing facility unless Richlyn

met certain stipulated conditions, including successful compliance with the validation and recertification program described under the caption "Products and Product Development." The Company, having acquired certain assets of Richlyn, is obligated by the terms of the Richlyn Order. The Richlyn Order also requires that the Company hire and retain a person, subject to FDA approval, who, by reason of training and expertise, is qualified to inspect the Company's drug manufacturing facilities to determine that its methods, facilities and controls are operated and administered in compliance with cGMPs. The Richlyn Order further requires that the person so retained both will inspect the Company's manufacturing facilities and its manner of operating them and will examine all drug products manufactured, processed, packed and held at the Company's Facility; and will certify in writing to FDA the Company's compliance with related cGMPs. The Company has retained an independent consultant to serve in respect of the Richlyn Order (see the caption "Government Regulation").

Additionally, the Company has assumed the liabilities of Richlyn in connection with Diethyl Stilbestrol ("DES"), which was manufactured by Richlyn and many other drug manufacturers during the late 1950's and early 1960's. DES was prescribed to pregnant women during that period and has been alleged to cause birth defects, in particular an increased risk of uterine cancer and sterility to female children whose mothers took DES during their pregnancy. There have been numerous claims brought against drug manufacturers in connection with DES. Since 1987, Richlyn's insurers have paid approximately \$117,000 on Richlyn's and the Company's behalf to settle approximately 130 DES-related suits. The Company is unaware of any other legal actions having been brought or threatened against Richlyn or the Company in connection with DES-related claims. The Company believes that all DES-related legal actions have been directed towards individual manufacturers and not been embodied in a class action, and, as such, does not expect to be held liable for DES-related claims other than claims based on products manufactured by Richlyn. While Richlyn's insurers have in the past defended those DES claims against Richlyn and paid settlements in connection therewith to date, those insurers have reserved their right to discontinue the defense of the claims and the payment of any settlements at any time. There can be no assurance or guarantee that the insurers will defend actions or pay claims in the future. Further, there can be no assurance that, if those insurers fail or refuse to pay any claim, the Company will have recourse against the insurers with respect thereto. Accordingly, there can be no assurance that the Company will not be exposed to the risk of substantial monetary judgments. Claims settlements to date have been based upon market share and Richlyn's share of the market during the periods in question was substantially less than 1%. The Company does not believe the Richlyn DES liabilities will have a material adverse effect on the Company's business.

Product liability claims by customers constitute a risk to all pharmaceutical manufacturers. The Company carries \$1 million of product liability insurance and plans to increase that amount to \$10 million in 1997. The Company believes that this increased insurance will be adequate for its foreseeable purposes and is comparable to product liability insurance carried by similar generic drug companies.

The Company believes there are no other pending or threatened legal actions, private or governmental, against the Company.

### **Employees**

As of March 31, 1997, the Company employed approximately 58 full-time persons in connection with its development stage activities. Of those employees, approximately 25 work the quality area, 22 in operations, 6 in administration, 4 in product development and 1 in sales and marketing. The Company may also employ part-time personnel from time to time to meet specific demands of its business should they arise. None of the Company's employees are expected to be subject to collective bargaining agreements with labor unions. The Company believes that its relations with its employees are satisfactory.

### **Executive Officers**

The following table sets forth certain information with respect to the executive officers and significant employees of the company:

Name ----	Age ---	Position -----
Max L. Mendelsohn	63	President, Chief Executive Officer and a Director
Cornel C. Spiegler	52	Chief Financial Officer and Vice President - Administration.
Joseph A. Storella	55	Vice President - Operations
Marc M. Feinberg	47	Vice President - Quality and Regulatory Affairs
Pieter J. Groenewoud	42	Vice President - Product Development
Mitchell Goldberg	45	Vice President - Sales and Marketing
Seymour Hyden, Ph.D.	63	Vice President - Scientific and Technical Affairs

Max L. Mendelsohn has been President and Chief Executive Officer since September 1995 and a director of the Company since December 1993. From 1970 to 1990, Mr. Mendelsohn was President and Chief Executive Officer of Barre-National, Inc., a manufacturer of liquid pharmaceutical products. From 1991 to 1995, Mr. Mendelsohn served as Vice President - Business Development of Pharmakinetics Laboratories, Inc., a provider of clinical and analytical services to United States and Canadian pharmaceutical companies. Mr. Mendelsohn has been a director of the Generic Pharmaceutical Industry Association since 1987 and was recently elected Secretary-Treasurer of that organization.

Cornel C. Spiegler has been Chief Financial Officer and Vice President--Administration since September 1995. From 1989 to 1995, Mr. Spiegler was Chief Financial Officer and Senior Vice President of United Research Laboratories, Inc. and Mutual Pharmaceutical Company, Inc., companies engaged in the generic pharmaceutical industry. From 1973 to 1989, Mr. Spiegler held a number of financial and operational management functions, including Vice President and Controller of Fischer and Porter, Inc., a manufacturer of process control equipment. From 1970 to 1973, Mr. Spiegler was employed by the accounting firm of Arthur Andersen and Co. Mr. Spiegler is a certified public accountant.

Joseph A. Storella has been Vice President - Operations since May 1996. From 1986 to 1996, Mr. Storella served as General Manager of Chelsea Laboratories, formally a division of Rugby-Darby Group Companies which, in 1993 was purchased by Marion Merrell Dow and subsequently purchased by The Hoechst Company. From 1977 to 1986, Mr. Storella served as Vice President - Operations of Analytab Products, Inc., a division of Ayerst Laboratories (which itself is a division of American Home Products). From 1966 to 1977, Mr. Storella held a number of operational management positions for Ayerst Laboratories.

Marc M. Feinberg has been Vice President - Quality and Regulatory Affairs since October 1996. Prior to joining the Company, from 1995 to 1996, Mr. Feinberg served as Vice President - Quality Assurance and Regulatory Affairs for the JWS Delavau Company, a contract manufacturer and packager of nutritional and over-the-counter products. From 1989 to 1995, Mr. Feinberg held the position of Vice President - Quality Assurance for Packaging Coordinators, Inc., a contract packager for the pharmaceutical industry. From 1985 to 1989, Mr. Feinberg served as Manager, Quality Assurance for ICI Pharmaceuticals Group. From 1972 to 1985, Mr. Feinberg served as Senior Drug Investigator for the U.S. Food and Drug Administration.

Pieter J. Groenewoud has been Vice President - Product Development since May 1996. From October 1995 to May 1996, Mr. Groenewoud served as Chief Operating Officer of the Company. From 1992 to 1995, Mr. Groenewoud served as General Manager of Vintage Pharmaceutical Inc., a manufacturer of generic drug pharmaceutical products. From 1990 to 1992, Mr. Groenewoud was Project Manager for Pennex Products Company Inc., a generic drug company. From 1988 to 1990, Mr. Groenewoud was Vice President of Quality Control at Medicopharma Inc., a manufacturer of pharmaceutical products, and formerly held the position of Vice President of Operations from 1986 to 1988.

Mitchell Goldberg has been Vice President - Sales and Marketing since March 1997. From October 1996 until March 1997, Mr. Goldberg served as Vice President - Sales and Marketing for Ethex Corporation, a generic manufacturing company. From 1985 to October 1996, Mr. Goldberg held a number of sales and marketing management positions with Schein Pharmaceutical, Inc., a major generic pharmaceutical company. From 1980 to 1985, Mr. Goldberg served in sales positions for Pharmavite Corporation, a nutritional supplement manufacturer.

Dr. Seymour Hyden has been Vice President - Scientific and Technical Affairs since March 1997. From November 1993 to March 1997, Dr. Hyden was the Vice President - Product Development of Chelsea Laboratories. From October 1992 to November 1993, Dr. Hyden was first the Vice President - Business Development for Interchem Corporation and then the Vice President - Technical Services for Block Drug Co., Inc. From March 1985 to October 1992, Dr. Hyden was Executive Vice President - Technical Affairs for Vitarine Pharmaceuticals, Inc. Prior to joining Vitarine Pharmaceuticals, Inc., Dr. Hyden served in a number of executive and management positions in the technical and scientific areas with companies engaged in the branded and generic pharmaceutical field. Dr. Hyden is the Chairman of the Science Committee of the Generic Pharmaceutical Industry Association and has a Ph.D. in Organic Chemistry from the New York University.

## **Item 2. Description of Property**

The executive offices and research, warehouse and production facilities of the Company occupy an aggregate of approximately 113,000 square feet at Castor and Kensington Avenues in Philadelphia, Pennsylvania. The Company's principal executive offices are part of that overall facility.

The Company owns its plant, which consists of three three-story brick interconnected buildings that were constructed between 1900 and 1930. The buildings are heated and substantially air conditioned. The interior of the plant has been substantially renovated and modernized since 1993 and includes a new dust collection system and special environmental control units for humidity and temperature. The land and the building serve as partial collateral for a PIDA loan. See Item 6, Management's Discussion and Analysis or Plan of Operation--Liquidity and Capital Resources.

Of the total 113,000 square foot area of the plant, approximately 25,000 square feet are used for warehousing and storage operations, (including high security DEA areas and designated areas for raw materials, processed goods, labels and packaging materials); approximately 17,000 square feet are devoted to manufacturing operations; approximately 17,000 square feet are for laboratory, quality assurance and quality control activities, including batch testing and multiple-batch stability testing operations; approximately 6,000 square feet are for labeling and packaging activities; approximately 6,500 square feet for product development; and approximately 10,000 square feet are for administrative functions. The unused balance of the plant, approximately 31,500 square feet, is available for future expansion.

The Company maintains an extensive equipment base, much of it new or recently reconditioned and automated, including manufacturing equipment for the production of tablets and capsules; packaging equipment, including fillers, cottoners, cappers and labelers; and a well-equipped, modern laboratory. The manufacturing equipment includes mixers and blenders for capsules and tablets, automated capsule fillers, tablet presses, particle reduction, sifting equipment and tablet coaters. The Company also maintains a broad variety of material handling and cleaning, maintenance and support equipment. The Company intends to purchase additional manufacturing equipment, improve its plant facilities and purchase additional equipment that will be dedicated to research and development activities.

Management believes that the Company's production facilities are sufficient for its current and reasonably anticipated operations. The Company owns substantially all its manufacturing equipment and believes that its equipment is well maintained and suitable for its requirements. Additionally, the Company maintains property and casualty and business interruption insurance in amounts it believes are sufficient and consistent with practices for companies of comparable size and business.

## **Item 3. Legal Proceedings**

The Company is not a party to, nor is any of its properties the subject of, any pending legal proceedings. See Item 1, Description of Business--Litigation and Product Liability for a description of certain legal matters with respect to the Company.

## **Item 4. Submission of Matters to a Vote of Security Holders**

None

## PART II

### Item 5. Market for Common Equity and Related Stockholder Matters

The Company's Common Stock is traded on the NASDAQ Small Cap Market under the symbol "GLPC". The following are the high and low per share bid prices of the Company's Common Stock on the NASDAQ Small Cap Market since December 19, 1995, the date of the Company's IPO. Such prices represent quotations or prices between dealers and do not include retail mark-up, mark-down or commission and may not necessarily represent actual transactions:

Quarter Ended	High	Low
December 31, 1995	\$10	\$ 9
March 31, 1996	\$12 5/8	\$11
June 30, 1996	\$11	\$10 1/8
September 30, 1996	\$9 1/4	\$8
December 31, 1996	\$8 7/8	\$6 1/2
March 31, 1997	\$9 5/8	\$6 7/8

On March 25, 1997, the last reported bid price of the Common Stock on the NASDAQ Small Cap Market was \$8 1/4 per share. As of March 25, 1997, there were approximately 64 holders of record of the Common Stock.

The Company has never paid cash dividends on its Common Stock and has no present plans to do so in the foreseeable future. The Company's current policy is to retain all earnings, if any, for use in the operation of its business. The payment of future cash dividends, if any, will be at the discretion of the Board of Directors and will be dependent upon the Company's earnings, financial conditions, capital requirements and other factors as the Board of Directors may deem relevant.

### Item 6. Management's Discussion and Analysis or Plan of Operation

#### General

The Company was formed in April 1993 to acquire the manufacturing plant, equipment and certain related assets (the "Facility") and the ANDAs, NDAs and NADAs of Richlyn. Richlyn operated as a generic pharmaceutical business from 1947 to 1992. Operations of the Facility have been idled since September 1992 for failure to comply with FDA regulations concerning cGMPs. See Item 1, Description of Business.

The Company was the surviving corporation in a merger effected on April 6, 1995 (the "Merger") with a shell acquisition corporation ("Toledex"), which had been incorporated in Delaware in March 1995.

Effective November 28, 1995, the Company effected a 39.182 -for-1 common stock split, and increased its authorized capital stock to 10 million common shares and 2 million shares of undesignated preferred stock.

On December 19, 1995, the Company completed its IPO in which 1,650,000 shares of common stock were sold for net proceeds of \$11,489,000. An additional 247,500 shares of common stock were sold to the underwriter of the IPO in January 1996, upon the exercise of the underwriters' over-allotment option for net proceeds to the Company of \$1,835,000.

During 1996, the Company incurred substantial costs related to the ongoing validation process for both the facility and the products, the expansion of its laboratory and research and development, production, quality and administrative activities. In September 1996, FDA approved independent consultants certified the manufacturing facility for FDA site review. Upon the October-November 1996 FDA site review and subsequent additional validation work by the Company, the FDA approved independent consultants recertified the manufacturing facility in February 1997. The Company is continuing its efforts to obtain FDA certification of the plant manufacturing area and processes. The Company has recently met with senior officials of FDA Philadelphia District Office to discuss the most recent in a series of inspections conducted by FDA as part of this certification process, and has submitted to FDA a response to certain additional concerns raised by FDA. While there can be no assurance that FDA certification will be received in the near future, if at all, the Company believes that it has appropriately responded to the concerns raised by FDA. The failure of the Company to obtain FDA certification of the Facility will materially adversely affect the Company.

The Company cannot currently predict whether its business will be seasonal in nature, but to the extent that it manufactures and distributes products that pertain to seasonal ailments such as allergies or colds, the Company may experience seasonal patterns in its sales and profitability. There can be no assurance that the potential seasonality of the Company's business will not have a material adverse effect on the Company. In addition, when the Company becomes operational, its revenues, and hence its profitability, if any, may vary significantly from fiscal quarter to fiscal quarter as well as in comparison to the corresponding quarter of the previous year as a result, among other factors, of the timing of process validation for particular generic drug products, the timing of any significant initial shipments of newly approved drugs and competitive pressures from other generic drug manufacturers who receive FDA approvals covering competing products.

In connection with the original agreement with Genpharm, the Company, on November 8, 1995, sold Merck KGaA 150,000 shares of Common Stock for \$300,000, as well as the Merck A Warrants to purchase 100,000 shares of Common Stock at an exercise price of \$2.00 per share. Simultaneously, the Company sold to Merck KGaA the Merck B Warrants which are exercisable for 40,000 shares of Common Stock for each aggregate \$1,000,000 in gross profit (as defined in the Genpharm Agreement), if any, earned by the Company in connection with its sale to Genpharm of Ranitidine and any other products mutually agreed to by the Company and Merck KGaA, up to a maximum of 17.33% of the issued and outstanding shares of Common Stock of the Company immediately following the IPO. The per share exercise price for each of the shares underlying the Merck B Warrants is \$8.50 (the IPO price per share). If the Company generates in excess of \$17,500,000 in gross profit (as defined in a warrant agreement between the Company and Merck KGaA (the "Merck KGaA Warrant Agreement"), which has the same definition of gross profit as is set forth in the Genpharm Agreement) from the sale in the United States of Ranitidine and any other products mutually agreed to by the Company and Merck KGaA, the aggregate number of shares of Common Stock that Merck KGaA will own and have the right to acquire will be equivalent to approximately 23.52% of the shares of Common Stock that are issued and outstanding immediately following the completion of the Company's IPO. Merck KGaA has certain registration rights with respect to the shares of Common Stock it owns and has the right to acquire pursuant to the Merck Warrants. The Merck Warrants are likely to be exercised only at a time when the exercise price is below the market price of the Common Stock, at which time the Company could issue shares and raise additional funds on terms superior to those of the Merck Warrants.

## **Results of Operations**

The Company has generated no revenues to date and, from inception until December 31, 1996, the Company accumulated a deficit of \$12,099,000.

Since its inception, the Company has devoted substantially all of its efforts to improving and renovating the Facility, establishing policies and procedures to bring the Facility into compliance with cGMPs, and obtaining all government approvals necessary to begin operating the Facility. The Facility is not currently operating; however, the Company believes it will receive necessary approvals such that it can begin selling one or more generic products in 1997, although there can be no assurance such approvals will be obtained. Accordingly, the Company is considered a development stage company as defined in Financial Accounting Standards No. 7. See Item 1. "Description of Business - FDA Approvals".

### **Year Ended December 31, 1996 Compared to Year Ended December 31, 1995**

The Company's net loss for the year ended December 31, 1996 was \$4,608,000 as compared to \$4,463,000 in the same period in 1995.

General and administrative expenses were \$5,121,000 in the year ending December 31, 1996 as compared to \$3,236,000 during the same period in 1995 due primarily to increased infrastructure costs required for the validation process such as for personnel, renovation and FDA approved consultant fees.

During the year ended December 31, 1996, the Company earned \$375,000 in interest income, primarily as a result of the investment of the IPO proceeds into highly rated money market funds, U.S. Government securities, treasury bills and short-term commercial paper. The interest expense for the year ended December 31, 1996 was \$40,000 as compared to \$242,000 incurred in the same period in 1995.

Other income of \$178,000 generated during the year ended December 31, 1996 was due primarily to a renegotiation of previously recognized legal expenses.

### **Liquidity and Capital Resources**

Until the completion of the Company's IPO in December 1995, the Company financed its activities primarily through the issuance of promissory notes to the family that previously controlled Richlyn, borrowings from Pennsylvania Industrial Development Authority ("PIDA") and Philadelphia Industrial Development Corporation ("PIDC"), proceeds from the private placement of its equity securities and loans from stockholders.

On December 19, 1995, the Company completed its IPO in which 1,650,000 shares of common stock were sold by the Company for net proceeds of \$11,489,000. An additional 247,500 shares of common stock were sold to the underwriter of the IPO in January 1996, upon the exercise of the underwriters' over-allotment option for net proceeds to the Company of \$1,835,000.

In June 1996, the Company received approval for a \$1,000,000 loan with PIDA at 3.75% annually fixed for 15 years, the proceeds of which must be used for certain capital projects.

In August 1996, the Company received approval for a \$350,000 loan from the Delaware River Port Authority at 5.00% annually fixed for 10 years, the proceeds of which must be used for certain capital projects.

The Company has expended, and will continue to expend funds to purchase production and laboratory equipment and to develop its manufacturing, sales and marketing, and product development capabilities. The Company will require additional funds in 1997 for these purposes and to continue as a development stage company prior to obtaining the government approvals necessary to begin operating the Facility. Additional funds are expected to be raised through subsequent equity or debt financings, collaborative arrangements with corporate partners, or through other sources. The Company's failure to obtain sufficient financing, to obtain necessary FDA and government approvals, or to produce and sell sufficient quantities of its products, would adversely affect its cash flows and operating and development plans.

### **Item 7. Financial Statements and Supplementary Data**

The financial statements and supplementary data required by this Item begin on page F-1 of this Annual Report on Form 10-KSB.

### **Item 8. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures**

During the year ended December 31, 1996, the Company neither changed its accountants nor had any disagreement with its accountants on any matter of accounting principle or practice, financial statement disclosure or auditing scope or procedure.

## **PART III**

### **Item 9. Directors, Executive Officers, Promoters and Control Persons; Compliance with Section 16(a) of the Exchange Act**

The information contained under the heading "Proposal No. 1 - Election of Directors" in the Company's definitive Proxy Statement (the "Proxy Statement") relating to the Company's Annual Meeting of Stockholders scheduled to be held on or about June 24, 1997, to be filed pursuant to Regulation 14A of the Securities Exchange Act of 1934 with the Securities and Exchange Commission is incorporated herein by reference. For information concerning the executive officers and other significant employees of the Company, see "Business - Executive Officers" in Item 1 above of this Annual Report.

### **Item 10. Executive Compensation**

The response to this item will be included in the Company's Proxy Statement to be used in connection with the Annual Meeting of Stockholders scheduled to be held on June 24, 1997 and is incorporated herein by reference.

## Item 11. Security Ownership of Certain Beneficial Owners and Management

The response to this item will be included in the Company's Proxy Statement to be used in connection with the Annual Meeting of Stockholders scheduled to be held on June 24, 1997 and is incorporated herein by reference.

## Item 12. Certain Relationships and Related Transactions

The response to this item will be included in the Company's Proxy Statement to be used in connection with the Annual Meeting of Stockholders scheduled to be held on June 24, 1997 and is incorporated herein by reference.

## Item 13. Exhibits, Lists and Reports on Form 8-K

### a) Exhibits

Exhibit Number	Description of Document
2.1	Agreement and Plan of Merger among the Company, Management Stockholders and Toledex Acquisition Corporation, dated as of April 6, 1995. (1)
2.2	Certification of Merger between Toledex Acquisition Corporation and the Company, dated April 6, 1995. (1)
3.1	Restated Certificate of Incorporation of the Company. (1)
3.2	By-laws of the Company. (1)
4.1	Specimen Certificate of the Company's Common Stock, par value \$.01 per share. (1)
4.2	Form of Representative's Warrant Agreement between the Company and the Representative, including form of Representative's Warrant Certificate. (1)
10.1	Employment Agreement of Pieter Groenewoud, dated as of October 1, 1995. (1)
10.2	Employment Agreement of Cornel C. Spiegler, dated as of September 27, 1995. (1)
10.3	Employment Agreement of Max L. Mendelsohn, dated as of September 1, 1995. (1)
10.4	Consulting Agreement between the Company and Andromeda Enterprises, Inc., dated as of April 6, 1995. (1)
10.5	Consulting Agreement between the Company and Gary R. Dubin, dated as of August 9, 1995. (1)
10.6	The Company's 1995 Stock Incentive Plan. (1)
10.7	Distribution Agreement by and between The Care Buying Alliance and the Company, dated as of October 19, 1995. (1)
10.8	Exclusive Supply Agreement between Dey Laboratories LP and the Company, dated November 1, 1995. (1)
10.9	Form of Amended Agreement between the Company and Merck Kommanditgesellschaft auf Aktien regarding the issuance of Common Stock Purchase Warrants, dated as of November , 1995. (1)
10.10	Form of Amended Manufacturing Agreement between the Company and Genpharm, Inc., dated as of November , 1995. (1)

- 10.11 Loan Agreement between the Company, the Toledano Group, the Dubin Group, and Frederick R. Adler, dated as of April 6, 1995, including forms of Promissory Notes. (1)
- 10.12 First Amendment to Loan Agreement, dated November 3, 1995. (1)
- 10.13 Secured Party Consent and Agreement, among the Company, Adjo, Inc., Sidney Weinberg and Gertrude Weinberg, dated as of April 6, 1995. (1)
- 10.14 \$50,000 Loan Agreement between American Generics, Inc. and the Company, dated January 20, 1995. (1)
- 10.15 Unsecured \$70,000 Promissory Note from Global Pharmaceutical Corporation, a Florida corporation ("GPC Florida"), to Tony Tabatznik, dated March 1, 1995. (1)
- 10.16 Stockholders' Agreement among the Company and its existing stockholders, dated as of April 6, 1995. (1)
- 10.17 Form of First Amendment to Stockholders' Agreement, dated as of November 3, 1995. (1)
- 10.18 Acquisition Agreement between PIDC-Financing Corporation and GPC Florida, dated September 17, 1993. (1)
- 10.19 Security Agreement by and between the Company and PIDC Local Development Corporation, dated October 15, 1993, with related Note and Commitment, and Waiver and Consent dated November 13, 1995. (1)
- 10.20 Promissory Note from GPC Florida in favor of Richlyn Laboratories, Inc. in the amount of \$583,654.44, dated as of August 18, 1993. (1)
- 10.21 Loan Agreement by and between PIDC Financing Corporation and the Pennsylvania Industrial Development Authority ("PIDA") for a loan in a principal amount not to exceed \$1,026,000, dated April 18, 1994, with Waiver and Consent dated November 13, 1995. (1)
- 10.22 Open-End Mortgage between PIDC Financing Corporation and PIDA dated April 18, 1994. (1)
- 10.23 Mortgage and Financing Statement Subordination Agreement by and among PIDC Financing Corporation, Sidney Weinberg and Gertrude Weinberg, GPC Florida and the PIDA, dated as of April 18, 1994. (1)
- 10.24 Mortgage and Financing Statement Subordination Agreement by and among PIDC Financing Corporation, Richlyn Laboratories, Inc., GPC Florida and the PIDA, dated as of April 18, 1994. (1)
- 10.25 Assignment of Installment Sale Agreement by and among PIDC Financing Corporation, PIDA and GPC Florida, dated April 18, 1994. (1)
- 10.26 Installment Sale Agreement by and between PIDC Financing Corporation and GPC Florida dated April 18, 1994. (1)
- 10.27 PIDC Financing Corporation Note to the PIDA, dated April 18, 1994. (1)
- 10.28 Secured \$500,000 Note from the Company to PIDC Local Development Corporation. (1)

- 10.29 Consent, Subordination and Assumption Agreement by and among GPC Florida, PIDC Financing Corporation and PIDA, dated April 18, 1994. (1)
  - 10.30 Toledano Group Agreement by and among Udi Toledano, the Toledano Group and the Toledano Family, dated as of April 6, 1995. (1)
  - 10.31 Dubin Loan Group Agreement by and among Gary R. Dubin and the Dubin Loan Group, dated as of April 6, 1995. (1)
  - 10.32 Restated and Amended Asset Purchase Agreement by and among GPC Florida, and Richlyn Laboratories, Inc. and Sidney and Gertrude Weinberg, dated June 18, 1993. (1)
  - 10.33 Waiver Agreement by and among the Company, Adjo, Inc., formerly known as Richlyn Laboratories, Inc., Richard R. Weinberg and various members of the Weinberg family, dated as of November 7, 1995. (1)
  - 10.34 Forms of Loan Agreements by and between the Company and each of Udi Toledano, Frederick R. Adler, Gary Escandon, Max L. Mendelsohn and Cornel C. Spiegler, dated November 23, 1995. (1)
  - 10.35 Employment Agreement of Gabriel Lebovic, dated as of December 1, 1995. (1)
  - 10.36 Letter Agreement, dated December 14, 1993, between Moty Hermon and Frederick R. Adler. (1)
  - 10.37 Form of Escrow Agreement by and among the Company, the Representative and Continental Stock Transfer and Trust Company. (1)
  - 10.38 Supply and Marketing Agreement by and between the Company and Caraco Supply and Pharmaceutical Laboratories Ltd. dated September 20, 1996. (2)
  - 10.39 Employment agreement by and between the Company and Marc M. Feinberg dated September 30, 1996. (2)
  - 10.40 Technical Collaboration Agreement by and between the Company and Genpharm Inc. dated January 8, 1997.
  - 10.41 Employment agreement by and between the Company and Dr. Seymour Hyden dated February 7, 1997.
  - 10.42 Employment agreement by and between the Company and Mitchell Goldberg dated March 13, 1997.
  - 11.1 Statement Regarding Computation of Earnings Per Share. (1)
  - 23.1 Consent of Price Waterhouse LLP. (1)
  - 27 Financial Data Schedule
  - 99.1 Court Order issued May 25, 1993 by the United States District Court for the Eastern District of Pennsylvania against Richlyn Laboratories, Inc. (1)
- (1) Previously filed with the Commission as Exhibits to, and incorporated herein by reference from, the Registrant's Registration Statement on Form SB-2 (File No. 33-99310-NY)

(2) Previously filed with the Commission as Exhibits to, and incorporated herein by referenced from, the Registrant's Quarterly Report on Form 10-QSB for the quarterly period ended September 30, 1996.

b) Reports on Form 8-K.

No reports on Form 8-K were filed during the last quarter of the year ended December 31, 1996.

## SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

### GLOBAL PHARMACEUTICAL CORPORATION

By /s/Max L. Mendelsohn

-----  
Max L. Mendelsohn, President and Chief Executive Officer

**Date April 11, 1997**

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/s/ MAX L. MENDELSON ----- Max L. Mendelsohn)	President and Chief Executive Officer and Director (Principal Executive Officer)
s/ CORNEL C. SPIEGLER ----- (Cornel C. Spiegler)	Chief Financial Officer, Vice President--Administration (Principal Financial and Accounting Officer)
/s/ FREDERICK R. ADLER ----- (Frederick R. Adler)	Director
/s/ PHILIP R. CHAPMAN ----- (Philip R. Chapman)	Director
/s/ GARY ESCANDON ----- (Gary Escandon)	Director
/s/ GEORGE F. KEANE ----- (George F. Keane)	Director
/s/ JOHN W. ROWE ----- (John W. Rowe)	Director
/s/ UDI TOLEDANO ----- (Udi Toledano)	Director
/s/ RICHARD N. WIENER ----- (Richard N. Wiener)	Director

**GLOBAL PHARMACEUTICAL CORPORATION**  
(a development stage company)

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All financial statement schedules are omitted because they are not required.	

## **REPORT OF INDEPENDENT ACCOUNTANTS**

To the Board of Directors  
and Stockholders of Global Pharmaceutical Corporation

In our opinion, the accompanying balance sheet and the related statements of operations, of cash flows and of changes in stockholders' equity present fairly, in all material respects, the financial position of Global Pharmaceutical Corporation (the Company), a development stage company, at December 31, 1995 and 1996, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 1996 and for the period from April 20, 1993 (inception) through December 31, 1996, in conformity with generally accepted accounting principles. 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 of these statements in accordance with generally accepted auditing standards which 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for the opinion expressed above.

The Company has not obtained necessary certifications from the United States Food and Drug Administration to commence its operations, and cannot predict when such approvals will be obtained. Without such certifications, the Company will require additional financing. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans with regard to these matters are described in Note 1. The accompanying financial statements have been prepared assuming the Company will continue as a going concern, and do not include any adjustments that might result from the outcome of this uncertainty.

### **PRICE WATERHOUSE LLP**

Philadelphia, Pennsylvania  
April 11, 1997

**GLOBAL PHARMACEUTICAL CORPORATION**  
(a development stage company)

**BALANCE SHEET**

(in thousands, except share and share data)

	December 31,	
	----- 1995 -----	----- 1996 -----
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents.....	\$ 9,518	\$ 4,044
Prepaid expenses and other.....	30	49
	-----	-----
Total current assets.....	9,548	4,093
Property, plant and equipment, net.....	2,105	4,135
Intangible assets .....	1,177	1,177
Deferred financing costs, net.....	25	35
	-----	-----
Total assets.....	\$12,855	\$ 9,440
	=====	=====
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Current portion of long-term debt.....	\$ 182	\$ 90
Accounts payable.....	459	383
Accrued expenses.....	810	419
	-----	-----
Total current liabilities.....	1,451	892
Long-term debt.....	1,280	1,197
	-----	-----
	2,731	2,089
	-----	-----
Commitments and contingencies (Note 10)		
Stockholders' equity :		
Preferred stock, \$.01 par value, 2,000,000 authorized, none issued.....	--	--
Common stock, \$.01 par value, 10,000,000 authorized and 4,039,392 and 4,286,871 shares issued and outstanding.....	40	43
Additional paid-in capital.....	17,575	19,407
Deficit accumulated during the development stage.....	(7,491)	(12,099)
	-----	-----
Total stockholders' equity .....	10,124	7,351
	-----	-----
Total liabilities and stockholders' equity.....	\$12,855	\$ 9,440
	=====	=====

The accompanying notes are an integral part of these financial statements.

**GLOBAL PHARMACEUTICAL CORPORATION**  
(a development stage company)

**STATEMENT OF OPERATIONS**

(in thousands, except share and per share data)

	Twelve Months Ended December 31,			April 20, 1993 (inception) to December 31,
	1994	1995	1996	1996
General and administration.	\$ 1,781	\$ 3,236	\$ 5,121	\$ 11,148
Debt conversion expense....	--	47	--	47
Loss on sale of common stock and warrants...	--	938	--	938
Sale of marketable securities.....	50	--	--	50
Interest expense.....	157	242	40	469
Interest income.....	--	--	(375)	(375)
Other income.....	--	--	(178)	(178)
Net loss.....	\$ (1,988)	\$ (4,463)	\$ (4,608)	\$ (12,099)
Net loss per share.....	\$ (.92)	\$ (1.80)	\$ (1.08)	
Weighted average common shares outstanding....	2,166,872	2,430,543	4,269,967	

The accompanying notes are an integral part of these financial statements.

**GLOBAL PHARMACEUTICAL CORPORATION**  
(a development stage company)

**STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY**

(dollars and shares in thousands)

	Common stock		Additional	Deficit	Total
	Number of	Par	paid-in	accumulated	stockholders'
	shares	value	capital	during the	equity
	-----	-----	-----	development	(deficit)
	-----	-----	-----	stage	-----
Issuance of common stock and common stock warrants:					
Inception (April 20, 1993) and stock and					
warrants issued for purchase of Richlyn					
facility (August 18, 1993).....	1,217	\$12	\$ 42	\$ --	\$ 54
September 30, 1993 private placement.....	177	2	498	--	500
December 15, 1993 sale of stock and warrants....	356	4	996	--	1,000
Stock issued for services rendered.....	27	--	75	--	75
Warrants issued for services rendered.....	--	--	3	--	3
Exercise of warrants.....	71	--	250	--	250
Net loss.....	--	--	--	(1,040)	(1,040)
	-----	-----	-----	-----	-----
Balances at December 31, 1993.....	1,848	18	1,864	(1,040)	842
Issuance of common stock:					
September 1, 1994 private placement.....	84	1	479	--	480
Stock issued for services rendered.....	10	--	50	--	50
Net loss.....	--	--	--	(1,988)	(1,988)
	-----	-----	-----	-----	-----
Balances at December 31, 1994.....	1,942	19	2,393	(3,028)	(616)
Issuance of common stock:					
Conversion of stockholder loans.....	297	4	2,473	--	2,477
Stock and warrants issued to Merck KGaA.....	150	1	299	--	300
Sale of stock to Merck KGaA.....	--	--	938	--	938
Initial public offering.....	1,650	16	11,472	--	11,488
Net loss.....	--	--	--	(4,463)	(4,463)
	-----	-----	-----	-----	-----
Balances at December 31, 1995.....	4,039	40	17,575	(7,491)	10,124
Issuance of common stock for over-allotment exercise					
on January 29, 1996.....	248	3	1,832	--	1,835
Net loss.....	--	--	--	(4,608)	(4,608)
	-----	-----	-----	-----	-----
Balances at December 31, 1996.....	4,287	\$43	\$19,407	\$(12,099)	\$( 7,351)
	=====	===	=====	=====	=====

The accompanying notes are an integral part of these financial statements.

**GLOBAL PHARMACEUTICAL CORPORATION**  
(a development stage company)

**STATEMENT OF CASH FLOWS**

(dollars in thousands)

	Year Ended December 31,			April 20,
	1994	1995	1996	1993 (inception) to December 31, 1996
	-----	-----	-----	-----
Cash flows from operating activities:				
Net loss .....	\$(1,988)	\$(4,463)	\$(4,608)	\$(12,099)
Adjustments to reconcile net loss to net cash used by operating activities:				
Depreciation and amortization.....	114	214	281	653
Expenses paid through issuance of common stock and warrants	50	--	--	128
Loss on sale of common stock and warrants.....	--	938	--	938
Loss on debt conversion.....	--	47	--	47
Loss on sale of marketable securities.....	50	--	--	50
Change in assets and liabilities:				
(Increase) decrease due from/to related party.....	14	(13)	2	--
(Increase) decrease in prepaid expenses and other assets	20	24	(21)	(45)
Decrease in note receivable from stockholders.....	129	135	--	264
Decrease in accounts payable and accrued expenses .....	240	229	(467)	164
	-----	-----	-----	-----
Net cash used for operating activities.....	(1,371)	(2,889)	(4,813)	(9,900)
	-----	-----	-----	-----
Cash flows from investing activities:				
Purchases of property, plant and equipment.....	(929)	(345)	(2,311)	(3,786)
Sales (purchases) of marketable securities.....	450	--	--	(50)
	-----	-----	-----	-----
Net cash used for investing activities.....	(479)	(345)	(2,311)	(3,836)
	-----	-----	-----	-----
Cash flows from financing activities:				
Long-term debt:				
Borrowings.....	1,026	70	--	1,596
Payments.....	(54)	(126)	(175)	(357)
Payment of financing costs.....	(13)	(3)	(10)	(40)
Long-term debt, related party:				
Borrowings .....	72	2,683	--	2,755
Payments.....	(110)	(1,667)	--	(1,777)
Issuance of common stock and warrants:				
September 30, 1993 private placement.....	--	--	--	500
December 15, 1993 sale of stock and warrants .....	--	--	--	1,000
September 1, 1994 private placement.....	480	--	--	480
November 8, 1995 stock and warrants issued to Merck KGaA	--	300	--	300
December 19, 1995 initial public offering .....	--	11,488	--	11,488
January 29, 1996 over-allotment exercise.....	--	--	1,835	1,835
	-----	-----	-----	-----
Net cash provided by financing activities.....	1,401	12,751	1,650	17,780
	-----	-----	-----	-----
Net increase (decrease) in cash and cash equivalents.....	(449)	9,517	(5,474)	4,044
Cash and cash equivalents, beginning of period.....	450	1	9,518	--
	-----	-----	-----	-----
Cash and cash equivalents, end of period.....	\$ 1	\$ 9,518	\$ 4,044	\$ 4,044
	=====	=====	=====	=====
Cash paid for interest.....	\$ 139	\$ 215	\$ 40	\$ 397
	=====	=====	=====	=====

For other supplemental disclosure of non-cash investing and financing activities, see Notes 2 and 3.

The accompanying notes are an integral part of these financial statements.

**GLOBAL PHARMACEUTICAL CORPORATION**  
(a development stage company)

**NOTES TO FINANCIAL STATEMENTS**

1. Formation and Operation of the Company

**Purpose**

Global Pharmaceutical Corporation (the "Company") was formed in April 1993 to acquire the manufacturing plant, equipment and certain related assets and liabilities (the "Facility") and the Abbreviated New Drug Applications ("ANDAs"), New Drug Applications ("NDAs") and New Animal Drug Applications ("NADAs") of Richlyn Laboratories, Inc. ("Richlyn"). Richlyn operated a generic pharmaceutical business from 1947 to 1992; operations of the Facility had been idled since September 1992 for failure to comply with Food and Drug Administration ("FDA") regulations concerning current Good Manufacturing Practices ("cGMP").

Since its inception, the Company has devoted substantially all of its efforts to improving and renovating the Facility, establishing policies and procedures to bring the Facility into compliance with cGMP, and obtaining all government approvals necessary to begin operating the Facility. The Facility is not currently operating; however, the Company believes it will receive necessary approvals to begin selling one or more generic products in 1997, although there can be no assurance such approvals will be obtained in 1997, or at all. Accordingly, the Company is considered a development stage company as defined in Statement of Financial Accounting Standards No. 7.

**Organization**

The Company was incorporated in Florida on April 20, 1993 ("Inception"). On March 29, 1995, the Company reincorporated in Delaware through a merger with a wholly-owned subsidiary of the same name by exchange of the Company's common stock for 1.814 shares of common stock of the wholly owned subsidiary (the "Reincorporation").

On April 6, 1995, the Company was the surviving corporation in a merger (the "Merger") with a shell acquisition corporation ("Toledex") which had been incorporated in Delaware in March 1995. The Merger was effected to recapitalize the Company; shareholders of Toledex provided loan commitments of up to \$3 million to the Company simultaneously with the Merger (see Note 7). At the time of Merger, Toledex had no assets or liabilities, and 78% of its common stock was held by stockholders of the Company; accordingly, the assets and liabilities of the Company subsequent to the Merger are recorded at historical cost in a manner similar to a pooling of interests.

Effective November 28, 1995, the Company effected a 39.182-for-one common stock split, and increased its authorized capital stock to 10 million common shares and 2 million shares of undesignated preferred stock (collectively, the "Stock Split").

All references to share and per share amounts of common stock and preferred stock for all periods presented have been adjusted to give effect to the Reincorporation, the Merger and the Stock Split.

**Funding of Activities**

To date, the Company has funded its efforts to engage in the manufacture, repackaging and sale of solid oral prescription and over-the-counter generic drugs and dietary supplements through equity and debt financings.

The Company has expended and will continue to expend funds to purchase production and laboratory equipment and to develop its manufacturing, sales and marketing and product development capabilities. The Company will require additional funds in 1997 for these purposes and to continue as a development stage company prior to obtaining the government approvals necessary to begin operating the facility. Additional funds are expected to be raised through subsequent equity or debt financings, collaborative arrangements with corporate partners, or through other sources.

**GLOBAL PHARMACEUTICAL CORPORATION**  
(a development stage company)

**NOTES TO FINANCIAL STATEMENTS (continued)**

The Company's failure to obtain sufficient financing, to obtain necessary FDA and government approvals, or to produce and sell sufficient quantities of its products, would adversely affect its cash flows and operating and development plans.

In June 1996, the Company received approval for a \$1,000,000 loan from the Pennsylvania Industrial Development Authority ("PIDA") at 3.75% annually fixed for 15 years, the proceeds of which must be used for certain capital projects.

In August 1996, the Company received approval for a \$350,000 loan from the Delaware River Port Authority ("DRPA") at 5.00% annually fixed for 10 years, the proceeds of which must be used for certain capital projects.

## 2. Summary of Significant Accounting Policies

### Cash and cash equivalents

Cash and cash equivalents are stated at cost which approximates market value. Cash equivalents include only securities having a maturity of three months or less at the time of purchase.

### Concentration of credit risk

Financial instruments which potentially subject the Company to concentrations of credit risk are cash and cash equivalents. The Company limits its credit risk associated with cash and cash equivalents by placing its investments with highly rated money market funds, U.S. Government securities, treasury bills and short-term commercial paper. When operations commence, the Company plans to limit its credit risk with respect to accounts receivable by performing ongoing credit evaluations and, when deemed necessary, requiring letters of credit, guarantees, or collateral.

### Property, plant and equipment

Property, plant and equipment are recorded at cost. Maintenance and repairs are charged to expense as incurred and costs of improvements and renewals are capitalized. Costs incurred in connection with the construction or major renovation of facilities, including interest directly related to such projects, are capitalized as construction in progress. Depreciation is recognized using the straight-line method based on the estimated useful lives of the related assets.

### Intangible assets

Intangible assets comprise ANDAs, NDAs and NADAs acquired from Richlyn and are recorded at fair value. Amortization will be recognized on a straight-line basis over a five year period upon the commencement of operations.

The Company complies with Statement of Financial Accounting Standards No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of". Accordingly, the carrying value of long-lived assets and certain identifiable intangible assets are evaluated whenever changes in circumstances indicate the carrying amount of such assets may not be recoverable. In performing such review for recoverability, the Company compares expected future cash flows to the carrying value of long-lived assets and identifiable intangibles. If the expected future cash flows (undiscounted) are less than the carrying amount of such assets, the Company recognizes an impairment loss for the difference between the carrying amount of the assets and their estimated fair value.

**GLOBAL PHARMACEUTICAL CORPORATION**  
(a development stage company)

**NOTES TO FINANCIAL STATEMENTS (continued)**

Deferred financing costs

Deferred financing costs are amortized on a straight-line basis over the terms of the respective debt instrument.

Income taxes

The Company utilizes the liability method of accounting for income taxes as set forth in Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes". Under this method, deferred tax liabilities and assets are recognized for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. Valuation allowances are provided on deferred tax assets for which it is more likely than not that some portion or all will not be realized.

Richlyn financial information

On August 18, 1993, the Company acquired certain assets and liabilities from Richlyn (see Note 1) and from Gertrude and Sidney Weinberg (the "Weinbergs"), stockholders of Richlyn, for cash of \$50,000, notes issued of \$1,500,000 (the "promissory note"), and warrants valued at \$3,000 to purchase up to 5% of the outstanding common stock of the Company for \$50,000 for each 1% acquired, with related transaction costs of \$150,000. The acquisition was accounted for using the purchase method of accounting. Accordingly, the purchase price was allocated to the assets and liabilities acquired based upon their estimated fair values at the date of acquisition.

Accounting estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and disclosure of contingencies at the date of the financial statements and the reported expenses during the reporting period. Differences from those estimates are recorded in the period they become known.

Pro forma loss per share

The Company's past capital structure is not indicative of its structure effective with its December 19, 1995 initial public offering of stock (the "IPO") due to (i) the conversion of loans from stockholders into common stock concurrent with the closing of the IPO (see Note 7), and (ii) the shares of common stock and warrants sold under the November 8, 1995 Genpharm Agreement (see Note 3). Accordingly, historical net loss per common share for the years ended December 31, 1994 and 1995 is not considered meaningful and has not been presented herein; rather, a pro forma net loss per share is presented for these years in the accompanying statement of operations. The calculation of the shares used in computing pro forma net loss per share includes the effect of the conversion of loans from stockholders described in Note 7 into shares of common stock concurrent with the closing of the IPO if they were converted into common shares when the loans were made. Also, pursuant to Securities and Exchange Commission Staff Accounting Bulletin No. 83, common stock sold or issued at prices below the anticipated initial public offering price per share in the twelve months preceding the initial filing (including the common stock and warrants sold pursuant to the Genpharm Agreement) have been included in the calculation as if outstanding for all periods presented. Common stock shares sold, or equivalent shares from stock options and warrants issued, more than twelve months preceding the initial filing of the IPO are excluded from the computation as the effect of their inclusion would be antidilutive.

Accounting for stock-based compensation

In October 1995, SFAS No. 123, "Accounting for Stock Based Compensation" ("SFAS 123") was issued. This statement requires the fair value of stock options and other stock-based compensation issued to employees to either be recognized as compensation expense in the income statement, or be disclosed as a pro forma effect on net income in the footnotes to the Company's financial statements. As of December 31, 1996, the Company adopted SFAS 123 on a disclosure basis only.

**GLOBAL PHARMACEUTICAL CORPORATION**  
(a development stage company)

**NOTES TO FINANCIAL STATEMENTS (continued)**

**3. Related Party Transactions**

On November 8, 1995, the Company entered into an agreement ( the "Genpharm Agreement") with Genpharm, Inc., a Canadian corporation ("Genpharm"), an indirect subsidiary of Merck KGaA. Subsequently, in January 1997, the Company revised its agreement with Genpharm, pursuant to which the Company will package a minimum of 30% of Genpharm's United States Ranitidine production requirements based on a five-year cost-plus and percentage of profits compensation arrangement following the receipt of the requisite FDA Ranitidine approvals.

In addition to the manufacture and distribution of Ranitidine, the Genpharm Agreement provides the Company with the opportunity to develop products with the assistance of Merck KGaA that are marketed outside the U.S. Two products with total U.S. annual sales of over \$150 million including limited generic competition, have already been selected. Development is currently underway with ANDA anticipated to be filed by the Company by the fourth quarter of 1997, although no assurance can be given that the Company will be able to make the requisite filings or produce and distribute these products.

In connection with the Genpharm Agreement in 1995, the Company sold to Merck KGaA 150,000 shares of common stock for \$300,000, and a warrant to purchase 100,000 shares of common stock at an exercise price of \$2.00 per share (the "A Warrant"). In addition, the Company granted to Merck KGaA additional warrants to purchase up to 700,000 shares, at an exercise price of \$8.50 per share (the IPO price per share), whose exercise is contingent upon the gross profit (as defined in the agreement), if any, earned by the Company under the Genpharm Agreement.

The Company recognized a non-recurring, non-cash expense in 1995 of \$937,500, representing the number of shares of common stock sold and A Warrants issued to Merck KGaA, multiplied by the difference between the then estimated market value of the Company's common stock (\$5.75) and \$2.00 (the price per share of the common stock sold and the exercise price of the warrants issued).

**4. Property, Plant and Equipment**

Property, plant and equipment consist of the following:

	Estimated useful life 1993 (years)	December 31,	
		1995	1996
		(dollars in thousands)	
Land.....		\$ 53	\$ 53
Building.....	25	212	212
Building improvements.....	15	1,263	1,900
Production equipment.....	10	458	1,039
Laboratory equipment.....	7	440	626
Office furniture and equipment.....	5	46	117
Construction in progress.....	--	--	836
		-----	-----
		2,472	4,783
Less: Accumulated depreciation.....		367	648
		-----	-----
		\$2,105	\$4,135
		=====	=====

**GLOBAL PHARMACEUTICAL CORPORATION**  
(a development stage company)

**NOTES TO FINANCIAL STATEMENTS (continued)**

5. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	1995	1996
	-----	-----
	(in thousands)	
Accrued maintenance and repairs.....	\$145	\$ 34
Accrued professional fees .....	244	195
IPO costs .....	251	--
Other accrued expenses.....	170	190
	-----	-----
	\$810	\$419
	=====	=====

6. Income Taxes

Due to the Company's losses during its development stage, no provision for income taxes is recorded for any period. The difference between the federal statutory tax rate and the Company's effective income tax rate is attributable to losses and future tax deductions for which no tax benefits have been recognized.

Deferred tax assets consist of the following:

	December 31,	
	1995	1996
	-----	-----
	(in thousands)	
Net operating losses.....	\$ 286	\$ --
Deferred start-up and organization costs.....	2,474	4,734
Depreciation and amortization.....	159	281
	-----	-----
Gross deferred tax assets.....	2,919	5,015
Deferred tax asset valuation allowance.....	(2,919)	(5,015)
	-----	-----
	\$ --	\$ --
	=====	=====

Due to historical losses incurred by the Company and limitations on the future use of net operating losses due to changes in the Company's ownership, a full valuation allowance for net deferred tax assets has been provided. If the Company achieves profitability, certain of these net deferred tax assets would be available to offset future income taxes.

7. Long-Term Debt

	December 31,	
	1995	1996
	-----	-----
	(in thousands)	
2% loan payable in 180 monthly installments of \$6,602 commencing June 1, 1994 through May 1, 2009.....	\$ 923	\$ 867
3.75% loan payable in 84 monthly installments of \$3,672 commencing January 1, 1994, with a balance of \$304,000 due on December 1, 2000.....	445	420
6% notes payable to vendors in three annual installments commencing August 1, 1994.....	24	--
8% note payable due on February 28, 1996.....	70	--
	-----	-----
	1,462	1,287
Less: Current portion of long-term debt.....	(182)	(90)
	-----	-----
	\$1,280	\$1,197
	=====	=====

On October 15, 1993, the Company received a \$500,000 loan from the Philadelphia Industrial Development Corporation, ("PIDC"). The loan is secured by the Company's equipment. On April 18, 1994, the Company received a \$1,026,000 loan from the Pennsylvania Industrial Development Authority, ("PIDA"). The loan is secured by land, building and building improvements.

**GLOBAL PHARMACEUTICAL CORPORATION**  
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**NOTES TO FINANCIAL STATEMENTS (continued)**

The PIDA and PIDC loans contain financial and non-financial covenants, including certain covenants regarding levels of employment which are not effective until the Company commences operations. The Company received a waiver with respect to a non-financial covenant.

Scheduled maturities of long-term debt as of December 31, 1996 were as follows:

1997.....	\$ 90,000
1998.....	93,000
1999.....	95,000
2000.....	399,000
2001.....	67,579
Thereafter.....	542,421
	-----
Total .....	\$1,287,000
	=====

A mortgage note payable was issued to the Weinbergs on August 18, 1993 as consideration for the purchase of the land and buildings of the Richlyn Facility (the "Weinberg Note"). The mortgage note, and the promissory note, (collectively "Richlyn Notes"), were issued on August 18, 1993 as consideration for the purchase of certain assets from Richlyn (see Notes 1 and 2). Upon completion of the IPO, the Company repaid the Weinberg and Richlyn Notes.

In connection with the Merger, the Toledex stockholders entered into loan agreements, pursuant to which the stockholders committed to make loans to the Company on a monthly basis up to an aggregate maximum amount outstanding at any time of \$3 million, at an interest rate of 8%. At December 19, 1995, the amount of principal and accrued interest outstanding on these loans of \$2,383,000 was converted into 280,301 shares of common stock at the IPO price of \$8.50 per share and commitments to make additional loans were terminated.

Other stockholder advances of \$47,000 were made in 1995 and, as a result of inducements offered by the Company, were converted into common stock having a value of \$94,000 in 1995. Debt conversion expense of \$47,000 was recognized as a result of this induced conversion. On November 23, 1995, the Company borrowed an aggregate of \$300,000 from certain stockholders of the Company. In consideration of these loans, which were repaid in full with interest at the rate of prime plus 2% per annum from the proceeds of the IPO, the Company issued 5-year warrants exercisable in the last four years of the warrants' term at the IPO price per share for an aggregate of 42,000 shares of Common Stock.

#### 8. Stockholders' Equity

##### **Preferred Stock**

The Company authorized 2,000,000 shares of preferred stock, \$.01 par value per share (the "Preferred Stock"). No shares of Preferred Stock have been issued.

##### **Common Stock**

On December 19, 1995, the Company completed its IPO in which 1,650,000 shares of common stock were sold for net proceeds to the Company of \$11,488,000. In connection with the IPO, the underwriter received an option to purchase up to 247,500 shares of common stock at \$8.50 per share (the "over-allotment"). The underwriter exercised this option on January 29, 1996 and the Company sold 247,500 shares of common stock for net proceeds of \$1,835,000.

**GLOBAL PHARMACEUTICAL CORPORATION**  
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**NOTES TO FINANCIAL STATEMENTS (continued)**

9. Stock Options

The Company's 1995 Stock Incentive Plan was adopted by the Company's Board of Directors on November 9, 1995 for the purpose of securing for the Company and its stockholders the benefits arising from the ownership of Company stock options by non-employee directors and key employees who are expected to contribute to the Company's future growth and success.

During September and October 1995, the Company committed to grant non-qualified stock options to purchase an aggregate of 37,500 shares of common stock at \$5.75 per share, the then estimated market value of the Company's common stock. In addition, immediately prior to the IPO, the Company granted to each of two directors options to purchase 30,000 shares of common stock at an exercise price equal to the IPO price.

The exercise price of the outstanding options at December 31, 1996 ranges from \$5.75 to \$11.25. Options vest over a three to four year period and have a maximum term of ten years. The weighted average fair value of options granted during 1996 and 1995 was \$3.37 and \$3.36, respectively. The fair value of each option was estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions: (i) no expected dividend yield in 1995 and 1996, (ii) expected stock price volatility of 30% in 1995 and 1996, (iii) weighted average risk free interest rate of 5.5% in 1995 and 6% in 1996, and (iv) expected life of options of five years in 1995 and 1996.

Stock option transactions were:

	1995		1996	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at January 1	--	--	236,000	\$8.07
Granted	236,000	\$8.07	111,700	\$8.87
Canceled	--	--	(50,000)	\$7.13
	-----		-----	
Options outstanding at December 31	236,000	\$8.07	297,700	\$8.53
	=====		=====	
Options exercisable at December 31	0		75,306	
Options available for grant at December 31	164,000		252,300	

Had compensation cost for the Company's 1995 and 1996 grants for stock-based compensation plans been recognized under the provisions of SFAS 123, the Company's net loss, and net loss per common share for 1995 and 1996 would approximate the pro forma amounts below (in thousands, except for per share data):

	For the Year Ended December 31, 1995		For The Year Ended December 31, 1996	
	As Reported	Pro Forma	As Reported	Pro Forma
Net loss	(\$4,463)	(\$4,469)	(\$4,608)	(\$4,817)
Net loss per common share	(\$ 1.80)	(\$ 1.80)	(\$ 1.08)	(\$ 1.13)

The pro forma results may not be representative of the effect on reported operations for future years.

**GLOBAL PHARMACEUTICAL CORPORATION**  
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**NOTES TO FINANCIAL STATEMENTS (continued)**

The following table summarizes information concerning currently outstanding and exercisable options:

		Options Outstanding		Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remining Contractural Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$5.75 to \$ 8.50	251,900	9.2	\$8.34	75,306	\$8.30
\$9.13 to \$11.25	45,800	9.4	\$9.57	--	--
	----- 297,700	9.3	\$8.53	----- 75,306	\$8.30
	=====			=====	

10. Commitments and Contingencies

**Richlyn Order**

The Company is in compliance with a May 25, 1993 order, which was entered by the United States District Court for the Eastern District of Pennsylvania (the "Richlyn Order"). The Richlyn Order, among other things, permanently enjoined Richlyn from introducing into commerce any drug manufactured, processed, packed or labeled at its manufacturing facility unless it met certain stipulated conditions. The Company, as a purchaser of the Richlyn facility, remains obligated by the terms of the Richlyn Order.

Product liability and insurance

The Company assumed the liabilities of Richlyn in connection with Diethyl Stilbestrol ("DES"), which was manufactured by Richlyn during the late 1950's and early 1960's. DES was prescribed to pregnant women during that period and has been alleged to cause birth defects. There have been numerous claims brought against drug manufacturers in connection with DES. While Richlyn's insurers have in the past defended those DES claims against Richlyn and paid all settlements in connection therewith to date, the insurers have reserved their right to discontinue the defense of the claims and the payment of settlements at any time. Claims settlements to date have been based upon market share, and Richlyn's share of the market during the periods in question was less than 1%. While there can be no assurance as to the ultimate resolution of these matters, in the opinion of Management, the ultimate liabilities resulting from such lawsuits and claims will not materially adversely affect the financial position, operating results or cash flow of the Company.

## **TECHNICAL COLLABORATION AGREEMENT**

THIS TECHNICAL COLLABORATION AGREEMENT (the "Agreement") is entered into as of this day of January, 1997, by and between (Global Pharmaceutical Corporation ("Global"), a Delaware corporation with its principal place of business at Castor and Kensington Avenues, Philadelphia, Pennsylvania 19124-5694, and Genpharm, Inc., a Canadian corporation ("Genpharm"), with its principal place of business at 37 Advance Road, Etobicoke, Ontario, Canada M8Z 2S6.

### **WITNESSETH:**

WHEREAS, Global and Genpharm are parties to that certain Agreement, dated as of December 15, 1995 (as amended, the "Genpharm Agreement"), providing for, among other things, the manufacture by Global of Ranitidine on behalf of Genpharm; and

WHEREAS, both Global and Genpharm have mutually agreed that as a result of the occurrence of certain events subsequent to the execution of the Genpharm Agreement, it is in their respective best interests for the Genpharm Agreement to be terminated, effective upon and conditioned upon execution and delivery of this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants hereinafter set forth and other good and valuable consideration, receipt of which is hereby acknowledged, the parties agree as follows:

### **ARTICLE I**

#### **TERMINATION OF GENPHARM AGREEMENT**

Section 1.01. Each of Genpharm and Global hereby agrees that, effective upon the execution of this Agreement, and notwithstanding the provisions of Article 12 of the Genpharm Agreement, the Genpharm Agreement shall be terminated, with neither party thereto having any further responsibilities or liabilities thereunder. No prior or existing default on the part of either Genpharm or Global with respect to the performance of any of its responsibilities, duties or obligations under the Genpharm Agreement shall be deemed to have occurred, with any such default being hereby waived in all respects. Notwithstanding the foregoing, it is understood and agreed that the Merck Warrant (as such term is defined in Section 4.09 hereof) shall be unaffected by the termination of the Genpharm Agreement and shall continue in full force and effect in accordance with its terms, except as and to the extent modified by Section 4.09 hereof.

Section 1.02. (a) During the term of this Agreement, at Genpharm's option, Global shall supply to Genpharm or any of its affiliates packaging with respect to Ranitidine. If Global does supply such packaging, Genpharm shall pay to Global "Global's Cost" (as hereinafter defined) within thirty (30) calendar days of the date of Global's invoice for such amounts, notwithstanding the terms of Section 4.03(c) hereof. Global's Cost shall mean all direct costs of the packaging of that quantity of Ranitidine requested by Genpharm to be packaged by Global limited solely to supplies and labor costs (including costs of handling, quality assurance, quality control, packaging mechanics and packaging personnel) used to package such Ranitidine, plus an additional twenty percent (20%) with respect to amounts packaged by Global, if any, constituting the Excess (as defined in Section 4.03 hereof). In no event shall costs include depreciation or costs associated with the sales department, research and development, administration or plant overhead (which is limited to utilities, insurance and real estate taxes). Global's agreement to provide such packaging shall be subject to the applicable terms of Section 4.03 hereof.

(b) Genpharm shall provide to Global in writing a twelve (12) month rolling forecast of Genpharm's packaging requirements for Ranitidine (the "Forecast"). The first Forecast shall be delivered to Global at least sixty (60) days prior to the first scheduled shipment date pursuant to a purchase order for Ranitidine packaging, and the first such scheduled shipment date will begin the commencement of Year 1. On or before the same numerical day in each of the other calendar months of each year (a "Forecast Date") throughout the term of this Agreement, Genpharm will provide a written Forecast (i) by quarter, for each of the next four (4) quarters commencing on such applicable Forecast Date and (ii) by month, for each of the next three months commencing on such applicable Forecast Date. The initial quarterly and monthly forecasts will be provided to Global by Genpharm at the same time as the delivery of the first Forecast. If Genpharm elects to have Global provide packaging, Genpharm shall provide to Global, not less than once per calendar month, with a purchase order which shall represent a firm order (a "Firm Order") for the packaging of Ranitidine. Each Firm Order shall be accompanied (or preceded) by a sufficient supply of Ranitidine in order for Global to satisfy the packaging requirements of such Firm Order. Global shall have sixty (60) days from the date of its receipt of the Firm Order and such sufficient supply of Ranitidine to fulfill the packaging requirements of such Firm Order

Global will not be deemed in default of the terms of this Agreement if it fails to meet Genpharm's packaging requirements for a specified month which either (x) exceed ten (10) percent of the original forecast for that month included in the monthly forecast delivered pursuant to subsection (ii) of the preceding paragraph (y) exceed by ten (10) percent the original forecast for the month preceding that month, included in the monthly forecast delivered pursuant to subsection (ii) of the preceding paragraph; provided, however, Global shall use its commercially reasonable efforts to fulfill the

packaging requirements of each Firm Order which are in excess of the forecasted requirements.

## **ARTICLE II**

### **RESPONSIBILITIES OF GENPHARM**

Section 2.01. Genpharm shall continue to render to Global all available information in Genpharm's possession or, to the extent Genpharm has not heretofore commenced to render to Global such information, promptly following the execution of this Agreement shall render to Global all available information in its possession, in all instances to help Transfer to Global Genpharm's "know-how" relating to the manufacturing process of producing the Products set forth on Schedule I hereto (the "Products", which term shall include the Additional Products provided for in Section 2.02 below) in solid dosage form. This "know-how" shall include, but not be limited to, to the extent in Genpharm's possession, all biological, chemical, pharmacological, toxicological, pharmaceutical, physical, analytical, safety, quality control, manufacturing and clinical data and information, if any, and all instructions, processes, formulae, files, raw material sources expert opinions, bio-equivalent study results and information, if any, relating to the manufacture, use, sale or marketing of any of the Products.

Section 2.02. Genpharm and Global shall each use its respective good faith efforts to mutually agree upon at least two additional products (the "Additional Products") to be designated as "Products" hereunder and included in Schedule I hereto, by not later January 15, 1997.

Section 2.03. Genpharm shall use its good faith efforts to provide Global with true, correct and complete information and know-how with respect to the Products; provided, however, that subject to the foregoing, Genpharm makes no representations or warranties whatsoever with respect to the Products or the factual accuracy or completeness of any of the files or other information given by Genpharm to Global with respect to the Products. Genpharm shall have no further obligation other than delivering the aforementioned information to Global.

## **ARTICLE III**

### **RESPONSIBILITIES OF GLOBAL**

Section 3.01. Based upon the information provided to it pursuant to Article II above, Global shall be responsible for, and shall pay the financial cost associated with, the further (development of the Products and for the cost of regulatory submissions including the bio-equivalence studies relating to the Products. Global shall

use its good faith commercially reasonable efforts to pursue such development and submit such studies as promptly as practicable.

Section 3.02. Based upon the information provided to it pursuant to Article II above and such further development of the Products by Global as provided in Section 3.01 hereof, Global shall use its good faith efforts to file with the United States Food and Drug Administration (the "FDA") not less than the following number of Abbreviated New Drug Applications ("ANDAs") for approval to manufacture and sell Products within the time periods set forth below:

- (a) the first ANDA to be filed by not later than November 30, 1997;
- (b) the second ANDA to be filed by not later than December 31, 1997;
- (c) the third ANDA to be filed by not later than May 31, 1998; and
- (d) the fourth ANDA to be filed by not later than December 31, 1998.

Global shall provide written notice to Genpharm on or prior to the date six (6) months before each of the respective dates on which ANDAs must, be filed with the FDA, as provided in subsections

(a) through (d) above, indicating the Product with respect to which such ANDA will be filed (the "Product Notice").

In the event Global fails to file an ANDA by the required date indicated, then the following percentages of profits to Global generated by the sale of Ranitidine shall be lost:

Missed Filing Date -----	Percentage of Profit Lost -----
(i) one ANDA by November 30, 1997 and one ANDA by December 31, 1997	75%

(ii) May 31, 1998 50%

(ii) December 31, 1998 25%

Thus, for example, Global's profit from sales of Ranitidine shall be reduced by 75% unless both the first ANDA is filed by November 30, 1997 and the second ANDA is filed by December 31, 1997. As a further example, if the first two ANDAs are not filed by November 30, 1997 and December 31, 1997, respectively and the third or fourth ANDA is not filed by its required date, then Global shall not be entitled to any profits from sales of Ranitidine. Or, for example, if the first two ANDAs are timely filed and the third ANDA is not filed by May 31, 1998, then Global's profit from sales of Ranitidine shall be reduced by 50%.

Notwithstanding anything to the contrary contained in this

Section 3.02 or Section 3.03 hereof, in the event the Additional Products are not so designated by January 15, 1997, then (i) the "May 31, 1998" date referred to in this Section 3.02 and the "June 30, 2001" date referred to in Section 3.03 below shall be extended by one day for each day beyond January 15, 1997 that occurs until the first Additional Product is so designated, and (ii) the "December 31, 1998" date referred to in this Section 3.02 and the "July 31, 2001" date referred to in Section 3.03 below shall be extended by one day for each day beyond January 15, 1997 that occurs until the second Additional Product is so designated. Thus, for example, if the first Additional Product is agreed upon and designated as such on January 31, 1997 and the second Additional Product is agreed upon and designated as such on February 15, 1997, then the dates May 31, 1998 and December 31, 1998 appearing in this Section 3.02 shall instead refer to June 16, 1998 and January 31, 1999, respectively, and the dates June 30, 2001 and July 31, 2001 appearing in Section 3.03 below shall instead refer to July 16, 2001 and August 31, 2000, respectively.

Section 3.03. Global shall use its good faith reasonable efforts to secure approvals from the FDA ("Regulatory Approvals") for the first two ANDAs (as provided for above in Section 3.02) by April 30, 2000 and May 31, 2000, respectively, and the third and fourth ANDA approvals (as provided for above in Section 3.02) by June 30, 2001 and July 31, 2001, respectively (collectively the "Approval Dates," which term shall refer to the applicable extended date, if any, in accordance with the provisions of the last paragraph of Section 3.02 hereof). In this regard, Global shall use its good faith commercially reasonable efforts to conduct such preparations, validations, testings and analysis and to make such reports to the FDA in order to enable Global to obtain such approval of the FDA.

Section 3.04. Upon receipt of such Regulatory Approval for a Product, Global shall manufacture such Product for sale in the United States (the "Territory") in accordance with the Regulatory Approval, the good manufacturing practices prescribed from time to time by the FDA and all other requirements of the FDA to ensure that such Product may be marketed in the Territory. Global shall deliver to Genpharm copies of all notices and correspondence between Global and the FDA regarding good manufacturing practice inspections of any and all manufacturing facilities operated by Global within ten (10) days of receipt or delivery thereof, as the case may be.

Section 3.05. Upon receipt of Regulatory Approval for a Product, Global agrees to use its commercially reasonable good faith efforts to promote the sale of, solicit orders for, and stimulate interest in such Product in the Territory, such efforts to be not less than those that it uses to promote the sale of similar product marketed by it.

Section 3.06. Global agrees that it shall not, during the term of this Agreement, use any, of the know-how transferred hereunder to obtain Regulatory Approval to market any of the Products outside of the Territory nor will it, during the term of this Agreement, sell the Products outside of the Territory or to anyone inside the Territory if Global reasonably expects that person to sell or export the Product outside of the Territory. If Global is notified by Genpharm that one of its customers is exporting a Product outside of the Territory in any material respect (unless such customer is a branch of the United States government or a branch of any state or local government thereof), Global shall either cease to supply such customer or obtain (and enforce, if necessary) an undertaking from such customer not to sell such Product outside of the Territory. In the event the foregoing provisions are or become unenforceable or are unlawful in the Territory, then the unenforceable or unlawful provisions thereof shall be deemed replaced by the most restrictive comparable provision on marketing or sale of the Product outside of the Territory as is lawful and enforceable in the Territory. Genpharm acknowledges that Global will use reasonable efforts to prevent its customers from exporting the Product out of the Territory, but shall not be held responsible if, despite such efforts, it is unsuccessful in so doing (subject to Global's obligations to cease to supply or to obtain and enforce the undertakings as contemplated above).

Section 3.07. Global shall comply with all applicable laws, rules and regulations relating to the manufacturing, labelling, advertising and marketing of the Products within the Territory as well as to the packaging of Ranitidine, if requested to do so under Section 1.02 hereof, and shall assume sole responsibility for all credit risks and collection of receivables with respect to the Products sold by it or by any third party selling the Products pursuant to contractual arrangements with Global (hereafter referred to as a "Distributor" and collectively as "Distributors") and in respect of all dealings between Global and its customers and any third parties from whom Global sources any goods, or services required by it in connection with the manufacture, marketing or sale of the Products. Global shall be solely responsible for conducting all quality control tests as it deems necessary prior to the sale or other release of the Products in the Territory.

Section 3.08. Global shall not specifically discount the price of the Product for the benefit of Global's other products or otherwise use the Product as a loss leader or incentive to procure the sale of Global's other products. Rebate programs generally available to customers of Global on the purchase of pharmaceutical products shall not be prohibited by this Section 3.08.

## **ARTICLE IV**

### **PROFITS**

Section 4.01. In connection with the commercial sale of any Products, Global and Genpharm shall allocate the gross profits on any such sales between them ("Percentage Royalty") at the rate of 80% for Global and 20% for Genpharm, respectively. As used herein, the terms "gross profit" shall mean with respect to a particular quantity of Product sold, net revenue received from the sale of that quantity of Product less the Production cost for that quantity of Product; "net revenue" shall mean gross revenue less, without duplication, (i) bona fide allowances (excluding allowances for uncollected receivables), rebates, credits and returns accepted or made in the ordinary course of business and (ii) all taxes and delivery fees charged to the customer and shown separately on the invoices; and "production cost" shall mean with respect to a particular quantity of Product, all direct costs of producing and packaging that quantity of Product plus an allocation of indirect costs of producing that quantity of Product limited solely to labor cost (wages and overtime for personnel directly involved in manufacturing the Product), supplies used in the manufacturing of the Product and maintenance of equipment used in the manufacture of the Product. In no event shall indirect costs include depreciation or costs associated with sales department, research and development or administration. For avoidance of doubt, there shall be no deduction for sales and marketing costs in determining "gross profit".

Section 4.02. In addition to the profit participation provided for in Section 4.01 above, to the extent Genpharm or any of its affiliates (i) directly purchases for the purpose of resale any Product and (ii) such Products are shipped directly to Genpharm or any of its affiliates, Global shall pay to Genpharm a commission for sales and distribution of 12.5% of such net sales of Products sold to Genpharm or any of its affiliates for further resale. The term "net sales" shall mean gross sales less, without duplication, (x) bona fide allowances (excluding allowances for uncollected receivables), rebates, credits and returns accepted or made in the ordinary course of business and (y) all taxes and delivery fees charged to Genpharm or any of its affiliates and shown separately on the invoices. Genpharm shall provide Global, not less than monthly, with a list of all sales made during the preceding month of Products purchased hereunder from Global claimed to have been sold and distributed by Genpharm or any of its affiliates, together with specific detailed information to support such claim. Global shall have thirty (30) days from receipt of such list to dispute that any such sales were directly sold and distributed by Genpharm or any of its affiliates. Neither Genpharm nor any of its affiliates shall specifically discount the price of any Products so sold for the benefit of any of Genpharm's or any of its affiliates' other products, or otherwise use any such Product as a loss leader or incentive to procure the sale of any of Genpharm's or any of its affiliates' other products; it being understood and agreed that rebate programs generally available to customers of Genpharm or any of its affiliates on the purchase of pharmaceutical products shall not be prohibited by the provisions of this sentence. All costs incurred in connection with such sales and distribution, other than the direct cost of producing and packaging the Product sold, shall be borne by Genpharm. All commissions due to Genpharm pursuant to this Section 4.02 shall be payable quarterly.

Section 4.03. (a) Until the date six months after the date of the initial United States shipment of Ranitidine by other than Glaxo Wellcome plc. (the "Initial Shipment"), but in no event before December 31, 1997, Global shall be entitled to receive its "Applicable Percentage" (as defined in Section 4.03(d) hereof of "Genpharm's Gross Profits of Ranitidine" herein defined as (i) the monies actually received by Genpharm and its affiliates (solely for the purposes of this Section 4.03, collectively, "Genpharm") in connection with the United States sales of Ranitidine by Genpharm, or by third parties authorized by Genpharm to sell Ranitidine, less (ii) production costs (as defined in 4.01 above). For avoidance of doubt, there shall be no deduction for sales and marketing costs in determining "Genpharm's Gross Profits of Ranitidine".

(b) Commencing on the date six months after the date of the Initial Shipment, but in no event before December 31, 1997, and thereafter, Global shall be entitled to receive its Applicable Percentage of Genpharm's Gross Profits of Ranitidine.

(c) All amounts to be received by Global hereunder shall be paid, and the record keeping requirements of the applicable party shall be performed, in the same manner and on the same timing as set forth in this Article IV for Products. Notwithstanding the foregoing (except as provided in Section 1.02 hereof), until and through September 30, 1997, all such amounts due to Global from Genpharm shall accrue and shall not be payable to Global, with all such accrued payments to be made by Genpharm to Global in a lump sum on October 1, 1997. All sales (including pricing terms) of Ranitidine in the United States by Genpharm to any of its affiliated entities shall be made on no more favorable terms than those given to any entity not affiliated with Genpharm. In addition, Genpharm shall not specifically discount the price of Ranitidine sold by it in the United States for the benefit of Genpharm's other products or otherwise use Ranitidine as a loss leader or incentive to procure the sale of Genpharm's other products.

(d) The Applicable Percentage under 4.03(a) shall be as follows:

(i) Provided Global in any given calendar year provides packaging for 30% or less of Ranitidine sold in the United States which generated Genpharm's Gross Profits of Ranitidine during such calendar year, Global shall be entitled to receive an amount equal to 5% of 30% of Genpharm's Gross Profit of Ranitidine in such calendar year (or part thereof);

(ii) Provided Global in any given calendar year provides packaging for more than 30% of Ranitidine sold in the United States which generated Genpharm's Gross Profits of Ranitidine during such calendar year (the "Excess"), Global shall be entitled to receive in amount equal to 5% of 30% of Genpharm's Gross Profit of Ranitidine in such calendar year (or part thereof) plus, with respect to the Excess only in such calendar year (or part thereof), an amount equal to (x) 2% of the Excess over 30% of Genpharm's Gross Profits of Ranitidine resulting from sales of Ranitidine for

which Global actually provided packaging and (y) an overhead recovery on the Excess packaged limited to no more than \$3.00 per 1,000 tablets packaged.

The Applicable Percentage under 4.03(b) shall be as follows:

(iii) Provided Global in any given calendar year provides packaging for 30% or less of Ranitidine sold in the United States which generated Genpharm's Gross Profits of Ranitidine during such calendar year, Global shall be entitled to receive an amount equal to 10% of 30% of Genpharm's Gross Profit of Ranitidine in such calendar year.

(iv) Provided Global in any given calendar year provides packaging for more than 30% of Ranitidine sold in the United States which generated Genpharm's Gross Profits of Ranitidine during such calendar year (the "Excess"), Global shall be entitled to receive an amount equal to 10% of 30% of Genpharm's Gross Profit of Ranitidine in such calendar year plus, with respect to the Excess only in such calendar year, an amount equal to (x) 2% of the excess over 30% of Genpharm's Gross Profits of Ranitidine resulting from sales of Ranitidine for which Global actually provided packaging and (y) an overhead recovery on the Excess packaged limited to no more than \$3.00 per 1,000 tablets packaged.

Notwithstanding anything to the contrary contained herein, in the event Global shall fail to supply at least 80% of a Firm Order for packaging pursuant to the provisions of Section 1.02 hereof after Genpharm's election to require Global to provide such packaging, Global shall not be entitled to share in any portion of Genpharm's Gross Profits of Ranitidine with respect to such Firm Order, and in the event that Global supplies at least 80% of a Firm Order but fails to supply 100% of such Firm Order, Global's right to share in Genpharm's Gross Profits of Ranitidine with respect to such Firm Order shall be reduced by 1% for each 1% of the Firm Order not supplied; provided, however, that Global will not be in default under this Agreement and the foregoing will not apply to the extent that Global fails to supply packaging in excess of the amounts presented in the Forecast, subject to the terms of Section 1.02(b) hereof. For example, if Genpharm requests packaging for 1,000,000 bottles and Global packages 900,000 bottles, and Genpharm's Gross Profit of Ranitidine for the sale of that 1,000,000 bottles of Ranitidine is \$2,000,000, at a time when Global is entitled to receive 10% of 30% of Genpharm's Gross Profit of Ranitidine, Global shall receive \$54,000 (as opposed to \$60,000), assuming no Excess.

By way of examples:

If Genpharm's Gross Profits of Ranitidine prior to the date which is six months after the date of the Initial Shipment is \$5 million, and Global packaged

30% or less of Ranitidine manufactured by Genpharm for sale in the United States, Global is entitled to receive from Genpharm \$75,000;

(2) If Genpharm's Gross Profit of Ranitidine subsequent to the date which is six months after the date of the Initial Shipment is \$20 million, and Global packaged 30% or less of Ranitidine manufactured by Genpharm for sale in the United States. Global is entitled to receive from Genpharm \$600,000.

(3) If Genpharm's Gross Profits of Ranitidine subsequent to the date which is six (6) months after the date of the Initial Shipment is \$5 million, and Global packaged 40% of Ranitidine manufactured by Genpharm for sale in the United States, Global is entitled to receive from Genpharm \$160,000 (\$150,000 plus \$10,000) plus overhead recovery on the Excess packaged limited to no more that \$3.00 per 1,000 tablets packaged.

Section 4.04. Percentage Royalty shall be payable quarterly, within thirty (30) days after the end of each calendar quarter with respect to the sales of the Product in the applicable calendar quarter. Said quarters shall terminate on the last day of March, June, September and December. Each Percentage Royalty payment to Genpharm shall be accompanied by the following:

(a) a sales summary reasonably satisfactory to Genpharm showing all sales of the Product during the months in the immediately preceding calendar quarter;

(b) a detailed statement showing all returns and all credits, rebates, allowances and other debits and credits relevant to the calculation of gross profits for the months in the immediately preceding calendar quarter, or any prior quarter to the extent not previously accounted for, together with copies of all documentation to support allowable adjustments used in computing gross profits during the period in question;

(c) a certificate signed by the Chief Financial Officer of Global certifying that, to the best of his knowledge, information and belief, after reasonable investigation, the foregoing statements contemplated in (a) and (b) above are true and correct and do not omit any material information required to be provided pursuant to this Section 4.04; and

(d) a summary of the calculation of the Percentage Royalty payable to Genpharm on such date.

For purposes of this Agreement a sale shall be considered to have been made at the time the Product is shipped to the customer.

Section 4.05. Global shall provide to Genpharm, promptly following a request therefor, additional information concerning any sales (including, without limitation, in respect of any sale, the date of the shipment, the name of the customer or code number designated by Global for such purpose if it does not wish to reveal the name of such customer to Genpharm, the number of units of the Product in each strength involved and the invoice price charged by Global), credits, returns, allowances and other credits and debits previously reported to Genpharm pursuant to Section 4.04 hereof.

Section 4.06. The obligation to pay Percentage Royalty contained herein and to provide the reports and information contemplated herein and the right of Genpharm to have access to the records and to conduct audits or investigations pursuant to Section 4.07 hereof shall survive the expiration or termination of this Agreement and shall apply to the Products sold by Global on or prior to the effective date of the termination or expiration of this Agreement and to the Products sold following such effective (date of termination or expiration of this Agreement in respect of which Global received orders prior to such effective date of termination of this Agreement.

Section 4.07. (a) Global shall keep complete and accurate records and books of account containing all information required for the computation and verification of the "production cost" and the amounts to be paid to Genpharm hereunder as well as records and information relating to Global's cost of packaging Ranitidine and shall, upon reasonable written notice from Genpharm, make available or, at Genpharm's request, supply to Genpharm copies of such records. Global further agrees that at the request of Genpharm, it will permit one or more accountants selected by Genpharm, except any to whom Global has some reasonable objection, on not less than two (2) business days' notice, to have access during ordinary working hours to such records as may be necessary to audit, with respect to any payment report period ending prior to such request, the correctness of any report or payment made under this Agreement, or to obtain information as to the payments due for any such period in the case of failure (of Global to report or make payment pursuant to the terms of this Agreement.

(b) Should any such accountant discover information indicating inaccuracy in any of Global's reports or payments or non-compliance by Global with any of such terms and conditions, and should Global fail to acknowledge in writing to Genpharm the deficiency or non-compliance discovered by such accountant within ten (10) business days of being advised of same in writing by the accountant, the accountant shall have the right to make and retain copies (including photocopies) of any pertinent portions of the records and books of account which relate to or disclose the claimed deficiency or non-compliance (to the extent not acknowledged by Global). Global shall provide full and complete access to the accountant to Global's Pertinent books and records. In the event that the accountant shall have questions which are not in its judgment answered

by such books and records, the accountant shall have the right to confer with officers of Global, including Global's Chief Financial Officer, upon reasonable notice and during reasonable working hours. The accountant shall use his good faith efforts to minimize any disruption to the business activities of Global. Genpharm shall be solely responsible for all costs and expenses relating to such investigation/audit, except in the event, any audit under this Section shall reveal an underpayment or understatement of the amount payable to Genpharm by more than five percent (5%) for the period in question, in which case Global shall reimburse Genpharm for all costs and expenses relating to such investigation/audit. It is understood and agreed that Genpharm shall only have the right to audit such books and records of Global pursuant to this

Section 4.07 no more often than one time in any contract year unless earlier in such contract year or prior contract year such investigation revealed a discrepancy of more than five percent (5%) with respect to any reporting period, as aforesaid, in which case Genpharm shall have the right to audit such books and records three times in such contract year. For purposes of this Agreement, a contract year shall be a period of twelve (12) months commencing on either the date of this Agreement or on an anniversary thereof. Unless the disclosure of same is reasonably required by Genpharm in connection with any litigation or arbitration arising out of such audit, the accountant shall not reveal to Genpharm the name or address (or other information reasonably tending to identify the location of a customer) of any customer of Global but shall identify such customer to Genpharm, if necessary, by the customer code number used by Global in its reporting obligations to Genpharm. Global may, as a condition to providing any accountant access to its books and records, require such accountant to execute a reasonable confidentiality agreement consistent with the terms of this Section 4.07.

(C) Genpharm shall keep full and accurate books and records, in accordance with good accounting practice, and relating to Ranitidine and the transactions described in this Agreement. Global shall have the right, by its authorized representative, to, at its expense, inspect, copy and make excerpts from Genpharm's books and records relating to the transactions described in this Agreement on reasonable notice and at reasonable times.

Section 4.08. If any payment is not made within ten (10) days of its due date hereunder, then such overdue payments shall bear interest from the date the same is due until paid, calculated at the floating rate of two percent (2%) above Chemical Bank's announced prime rate in the United States or the highest rate permitted by law, whichever is less. Any adjustment to the prime rate as quoted by Chemical Bank from time to time shall result in a corresponding adjustment to the rate of interest payable hereunder, the rate of interest quoted by Chemical Bank at the close of business on each day to be the rate applicable for such date. In the event such prime rate quoted by Chemical Bank is not available, then Genpharm and Global shall jointly in good faith select, in lieu thereof, the prime rate (or its equivalent) quoted by any other bank located in New York City.

Section 4.09. In the event an FDA approval referred to in Section 3.03 hereof is not obtained on or before the Approval Date specified therefor, then, solely for purposes of computing the number of shares of common stock, \$.01 par value, of Global issuable in connection with that certain Common Stock Purchase Warrant, Series B, dated November 8, 1995 (the "Merck Warrant"), issued to Merck KGaA (in accordance with the second paragraph of the textual portion of such warrant), all profits Global receives hereunder from that missed Approval Date and forward that are generated by sales of Ranitidine and all other Products as to which Genpharm transferred its substantive know-how relating to the manufacturing process of producing the Products in solid dosage form (pursuant to Article II hereof) shall be multiplied by two. The provisions of this Section 4.09 shall survive any termination of this Agreement.

## **ARTICLE V**

### **CUSTOMERS**

Section 5.01. Upon approval of each ANDA by the FDA, Global and Genpharm shall each have the right to market and sell Products to their existing customers. In the event any existing customer of Global or Genpharm is not also an existing customer of the other, such other party shall not sell any Products to such customer for so long as this Agreement is in effect. Each of Genpharm and Global shall furnish to the other a list of their respective existing customers with respect to proposed sales of the Products. This list shall be updated monthly by each of Genpharm and Global.

Section 5.02. If at the time of an approval by the FDA both Global and Genpharm are selling products to the same customer, then Global and Genpharm agree to negotiate in good faith a mutually satisfactory resolution with respect to sales of Products to the customer. If no resolution is reached, each of Global and Genpharm shall be allowed to continue to sell Products to that customer.

Section 5.03. Should a conflict occur as to whether Genpharm or Global shall sell to a particular customer that neither is currently selling, then the parties shall alternate as to which of them shall have the right to sell to such prospective customer; provided that the first party to sell each such prospective customer shall be that party that Genpharm and Global shall mutually agree would be the one most likely to generate the greatest sales; provided, further, that in the event Genpharm or Global is not in a position to supply the Product to such customer on the terms and conditions customarily required by that customer (e.g., manufacturer's label vs. private label), and it is that party's "turn" to have the right to sell to such prospective customer, then the other party shall be given the right to sell the Product to that customer, with the party who has foregone on the opportunity to sell to the prospective customer receiving a

"credit" to be applied to the next prospective customer as to which such party can supply product as required.

## **ARTICLE VI**

### **CONFIDENTIALITY**

Section 6.01. Under the terms of this Agreement, Genpharm or Global (either one, in such capacity, being referred to as the "Disclosing Party") may disclose or reveal to Global or Genpharm (in such capacity, the "Receiving Party") either orally, in writing, or by inspection, information that may be non-public, proprietary or confidential in nature. Such information, simply referred to herein as "Information", might include, but is not limited to, files, raw material sources, processes, formulations, manufacturing techniques, trade secrets, bio-equivalence study results and other information that is not ascertainable from public or published information or trade sources. The Receiving Party shall treat the Information received by it as confidential, and neither the Receiving Party, nor any affiliate or any other entity controlled by the Receiving Party, nor, any officer, agent or employee of any of them shall disclose such Information to any third party, or use such Information for any purpose unrelated to the matters contemplated by this Agreement, except Information which (a) the Receiving Party can show was in the Receiving Party's possession or was known to the public or in the published literature prior to disclosure or the availability of such Information to the Receiving Party, or (b) subsequent to the time of disclosure or the availability of such Information to the Receiving Party, the Information becomes known to the public or finds its way into the published literature through no fault of the Receiving Party, its officers, agents or employees, or (c) is lawfully acquired by the Receiving Party from a third party who is not under confidentiality agreement with the Disclosing Party with respect to such Information.

Section 6.02. All Information received by the Receiving Party from the Disclosing Party shall remain the property of the Disclosing Party, and all written Information, with all copies and extracts thereof, shall forthwith be delivered to the Disclosing Party upon its request.

Section 6.03. The parties hereto agree that the restrictions on the Receiving Party contained herein are necessary for the protection of the Disclosing Party and any breach thereof could possibly cause the Disclosing Party irreparable damage for which there is no adequate remedy at law. Accordingly, if the Disclosing Party has reason to believe that the Receiving Party is about to breach or is breaching this Agreement in such a manner as to cause the Disclosing Party irreparable harm and, if the Disclosing Party has so notified the Receiving Party and the Receiving Party has not indicated a willingness to refrain from taking the action which the Disclosing Party claims would constitute or is a breach on the Receiving Party's part and that

would cause the Disclosing Party irreparable harm, then the Disclosing Party may file suit with a court of competent jurisdiction in order to seek an injunction in favor of enjoining such threatened or continued breach of the Receiving Party's obligations hereunder. The right of the Disclosing Party to obtain injunctive relief shall not be considered a waiver of the Disclosing Party's rights to pursue any other remedies it may have at law or in equity.

## **ARTICLE VII**

### **REPRESENTATIONS AND WARRANTIES OF GLOBAL**

Section 7.01. Global represents and warrants to Genpharm as follows: Global is a corporation, duly authorized and existing under the laws of Delaware; Global has the corporate power and authority to execute, deliver and perform this Agreement and the transactions contemplated hereby and the execution and delivery of this Agreement have been duly authorized by Global; the execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby do not and will not violate or conflict with any provision of Global's Certificate of Incorporation or Bylaws or, to the best knowledge of the individuals signing this Agreement, any agreement, instrument, law or regulation to which Global is a party or by which Global is bound; except as provided herein, no other governmental approval or authorization of this Agreement or the acts or transactions contemplated hereby is required by law or otherwise in order to make this Agreement binding upon Global; and this Agreement and all other instruments required hereby to be executed and delivered to Genpharm by Global are, or when delivered to Genpharm in accordance herewith, will be, legal, valid and binding instruments of Global enforceable in accordance with their respective terms. GLOBAL MAKES NO REPRESENTATIONS OR WARRANTIES EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT.

## **ARTICLE VIII**

### **REPRESENTATIONS AND WARRANTIES OF GENPHARM**

Section 8.01. Genpharm represents and warrants to Global as follows: Genpharm is a corporation duly authorized and existing under the laws of Canada; Genpharm has the power and authority to execute, deliver and perform this Agreement and the transactions contemplated hereby, and the execution and delivery of this Agreement have been duly authorized by Genpharm; the execution, delivery and performances of this Agreement and the consummation of the transactions contemplated hereby do not and will not violate or conflict with any provision of Genpharm's Certificate of Incorporation or Bylaws (or other organizational and governing documents) or, to the best of the knowledge of the individuals signing this Agreement,

any agreement, instrument, law or regulation to which Genpharm is a party or by which Genpharm is bound; except as provided herein, no other approval or authorization of this Agreement or the acts or transactions contemplated hereby is required by law or otherwise in order to make this Agreement binding upon Genpharm; and this Agreement, and all other instruments required hereby to be executed and delivered to Global by Genpharm are, or when delivered will be, legal, valid and binding instruments of Genpharm enforceable in accordance with their respective terms.

GENPHARM MAKES NO REPRESENTATIONS OR WARRANTIES EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT.

## **ARTICLE IX**

### **WARRANTIES AND INDEMNIFICATION**

Section 9.01. With respect to its activities and obligations hereunder, each party warrants and covenants that it will use its best efforts to fully comply with all federal, state and local laws, regulations, standards and guidelines, and those of any other governmental body (including foreign laws, regulations, standards, and guidelines, if any) having jurisdiction over the conduct of such tests and activities that are required under the terms of this Agreement.

Section 9.02. Global shall defend, indemnify and hold Genpharm and its affiliates and the officers, directors and employees of Genpharm and its affiliates harmless from and against any and all claims, demands, loss, damage, liability, settlement amounts costs or expenses whatsoever (including reasonable attorneys' fees and cost) arising from or related to any claim, action or proceeding made or brought against such party by a third party as a result of any breach of representation or warranty by Global hereunder, or as a result of any act or omission by Global hereunder, unless such liability arises from a breach of this Agreement or the act or omission by Genpharm.

Section 9.03. Genpharm shall defend, indemnify and hold Global and the officers, directors and employees of Global harmless from and against any and all claims, demands, loss, damage, liability, settlement amounts, costs of expenses whatsoever (including reasonable attorneys' fees and costs) arising from or related to any claim, action or proceeding made or brought against such party by a third party as a result of any act or omission by Genpharm in connection with the manufacture and sale of Ranitidine, unless such liability arises from a breach of this Agreement or the act or omission by Global.

Section 9.04. In the event of any claim, action or proceeding for which a party is entitled to indemnity hereunder, the party seeking indemnity ("Claimant") shall notify the other party ("Indemnitor") of such matter in writing, providing copies of all

relevant documents. Indemnitor shall promptly assume responsibility for and shall have full control of the defense of such matter, including settlement negotiations and any legal proceedings. Claimant shall fully cooperate in Indemnitor's handling and defense thereof.

## **ARTICLE X**

### **TERM**

Section 10.01. The rights and duties under this Agreement shall commence on signing of this Agreement and shall continue in effect until July 26, 2002. This Agreement may be terminated only as expressly provided in this Agreement or upon the mutual written agreement of the parties hereto.

Section 10.02. Notwithstanding anything herein to the contrary, the obligations of the parties under Articles VI and IX shall survive any termination of this Agreement.

## **ARTICLE XI**

### **DEFAULT AND TERMINATION**

Section 11.01. (a) Subject to the terms of Section 3.02 hereof, Genpharm may terminate this Agreement as to a specific Product if Global does not submit an ANDA for such Product to the FDA on or prior to the date nine (9) months following the date such Product is proposed to be filed as indicated in the respective Product Notice. At such time as Genpharm elects to terminate this Agreement with respect to a Product pursuant to this Section 11.01(a), Global shall transfer to Genpharm all the "know-how" with respect to such Product in Global's possession.

(b) Genpharm may terminate this Agreement as to a specific Product if Global does not obtain the Regulatory Approval for such Product by the respective date set forth in Section 3.03 (as such date is determined by reference to the respective Product Notice); provided, however, that Genpharm may not terminate this Agreement as to such Product if failure to receive the Regulatory Approval with respect to such Product is the result of delays caused solely by the FDA. The burden of proof with respect to the cause of delays in receipt of any Regulatory Approval shall be on Global, and such burden of proof as to the delay being caused solely by the FDA shall be satisfied if Global can demonstrate that it has timely filed and diligently prosecuted the ANDA with respect to such Product. At such time as Genpharm elects to terminate this Agreement with respect to a Product pursuant to this Section 11.01(b), Global shall

transfer to Genpharm all the "know-how" with respect to such Product in Global's possession,

Section 11.02. Genpharm shall have the right to terminate this Agreement upon written notice to Global in the event that any one or more of the following events shall become applicable to Global:

- (a) and order is made or a resolution or other action of Global is taken for the dissolution, liquidation, winding up or other termination of its corporate existence;
- (b) Global commits an act of bankruptcy, becomes insolvent, makes an assignment for the benefit of its creditors or proposes to its creditors a reorganization, arrangement, composition or re-adjustment of its debts or obligations or otherwise proposes to take advantage of or shelter under any statute in force in the United States for the protection of debtors;
- (c) if any proceeding is taken with respect to a compromise or arrangement, or to have Global declared bankrupt, or to have a receiver appointed in respect of Global or a substantial portion of its property, and such proceeding is instituted by Global or is not opposed by Global or if such proceeding is instituted by a person other than Global and Global does not proceed diligently and in good faith to have such proceeding withdrawn forthwith;
- (d) a receiver or a receiver and manager of any of the assets of Global is appointed and such receiver or receiver and manager is not removed within sixty (60) days of such appointment unless Global diligently contests, in good faith, the validity of the appointment of such receiver or receiver and manager; or
- (e) Global ceases or takes steps to cease to carry on its business;

provided, however, that Genpharm shall not have the right to terminate this Agreement upon the occurrence of the events set forth in subsections (a) through (e) hereof as long as, following the occurrence of any such events, Global continues to operate its business with respect to the transactions described herein.

Section 11.03. In the event that Global is unable to produce a Product at any time following receipt of a Regulatory Approval with respect to such Product (the "Terminating Product"), Global shall provide written notice to Genpharm (the "Terminating Notice") stating that it is unable to produce the Terminating Product and Global shall use its commercially reasonable good faith efforts to appoint a substitute manufacturer for the Terminating Product reasonably acceptable to Genpharm. On the date six (6) months after the date of the Terminating Notice, if Global has neither resumed production of the Terminating Product nor appointed a substitute

manufacturer reasonably acceptable to Genpharm, Genpharm shall have the right to terminate this Agreement with respect to the Terminating Product and upon such termination Global shall transfer the "know-how" in its possession with respect to the Terminating Product to Genpharm. Thereafter, Genpharm or its affiliates may either endeavor to manufacture the Terminating Product or Genpharm may designate another manufacturer for the Terminating Product (Genpharm or its affiliates, if any of them propose to manufacture the Terminating Product, or such substitute manufacturer designated by Genpharm are hereinafter referred to as the "Alternate Manufacturer"). Global shall have the right to purchase the Terminating Product from the Alternate Manufacturer upon the same terms as set forth in Sections 4.01, 4.02 and 4.04 hereof, except that references in such Sections to "Genpharm" shall mean "Global" and references to "Global" in such Sections shall mean "Genpharm".

Section 11.04 Nothing contained in this Article XI shall be construed or interpreted to diminish or in any way limit any other rights which may be provided for elsewhere in this Agreement, including without limitation those set forth in Section 4.09 hereof, nor shall such rights limit the provisions hereof.

## **ARTICLE XII**

### **INSURANCE**

Section 12.01. (a) Genpharm and Global shall each maintain insurance in at least the following amounts prior to the first shipment of any Products as contemplated by this Agreement:

(i) Commercial General Liability insurance, including premises, products, operations, and contractual coverage, in the total amount of not less than \$1,000,000 per claim and annual aggregate; and

(ii) Workers' Compensation insurance in the amount required by law.

(b) Genpharm and Global shall each maintain insurance in at least the following amounts subsequent to the first shipment of any Products as contemplated by this Agreement:

(i) Commercial General Liability insurance, including premises, products, operations, and contractual coverage, in the total amount of not less than \$2,000,000 per claim and annual aggregate;

(ii) Umbrella insurance, including premises, products, operations, and contractual coverage, in the total amount of not less than \$5,000,000 per occurrence and annual aggregate; and

(iii) Workers' Compensation insurance in the amount required by law.

Section 12.02. Genpharm shall have its insurance carrier or carriers furnish to Global certificates that all insurance required under this Agreement is in force, such certificates to indicate any deductible and/or self-insured retention, and the effective expiration dates of policies, and such certificates to stipulate that Global shall be given thirty (30) days' written notice of any cancellation, non-renewal or material change in the policy.

Global shall have its insurance carrier or carriers furnish to Genpharm certificates that all insurance required under this Agreement is in force, such certificates to indicate any deductible and/or self-insured retention, and the effective expiration dates of policies, and such certificates to stipulate that Genpharm shall be given thirty (30) days' written notice of any cancellation, non-renewal or reduction in insurance coverage below the amounts specified in Section 12.01 above or other material change in the policy.

Section 12.03. Global shall name Genpharm, and Genpharm shall name Global, as additional insured parties under their respective Commercial General Liability and umbrella insurance policies described in Section 12.01 hereof.

### **ARTICLE XIII**

#### **MISCELLANEOUS**

Section 13.01. Each of Global and Genpharm is solely responsible for the safety and health of its employees and compliance with the federal, state, provincial and local safety and health regulations governing their respective facilities, including but not limited to providing its employees with all required information and training concerning any potential hazards involved in the manufacture, receipt, storage, handling and supply of the Products and Ranitidine, as applicable, and taking any precautionary measures to protect its employees from such hazards.

Section 13.02. This Agreement embodies the entire agreement of the parties on the subject matter herein. All prior understandings, writings, discussions, and agreements relating to the subject matter of this Agreement are hereby expressly superseded by this Agreement.

Section 13.03 Nothing in this Agreement or in the performance hereof shall have the effect of making Global and Genpharm partners, joint venturers or each other's agents, and neither shall have the right to act on behalf of or bind the other except as expressly provided hereunder or otherwise expressly agreed in writing.



With a copy to: Sheldon G. Nussbaum  
Fulbright & Jaworski L.L.P.  
666 Fifth Avenue  
New York, New York 10103  
FAX: (212) 752-5958

To Genpharm: Genpharm, Inc.  
37 Advance Road  
Etobicoke, Ontario, Canada M8Z 2S6  
Attn: Neil Tabaznik  
FAX: (416) 236-2940

With a copy to: Richard N. Wiener  
Stern, Wiener & Levy LLP  
930 Third Avenue  
New York, New York 10022  
FAX: (212) 371-3215

Any party may change such party's address for notices by notice duly given pursuant to this Section 13.08.

Section 13.09. Neither this Agreement nor any right or obligation arising hereunder may be assigned by Global in whole or in part, without the prior written consent of Genpharm, which consent may be withheld in the absolute discretion of Genpharm. This Agreement shall be binding upon any assignee and, subject to the restrictions on assignment herein set forth, inure to the benefit of the successors and assigns of each of Genpharm.

Section 13.10. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original; but such counterparts shall together constitute but one and the same instrument.

Section 13.11. No right or license shall be deemed to have been granted under this Agreement to either party under any patents or proprietary information of the other, except as expressly set forth herein. Upon expiration or termination of this agreement, each party shall return to the other any samples received from the other party as well as any documents embodying or containing confidential information of the other party, or provide the other party with assurances that all such samples and documents and any copies, extracts or digests thereof have been destroyed, except that one archival copy of documents received from the other may be retained to show what was received.

Section 13.12. (a) Words importing the singular shall include the plural and vice versa; words importing a person shall include an individual, corporation, partnership, association, cooperation, joint venture or any other form of business or social entity recognized under law.

(b) "Affiliate" of a party hereto shall mean an entity which controls, is controlled by, or its under common control with such party. For the purposes of this definition, an entity shall be deemed to control another entity if it owns or controls, directly, or indirectly, at least twenty percent (20%) of the voting equity of such other entity (or other comparable ownership interest for any entity other than a corporation); provided, however, that with respect to Section 4.02 hereof, an entity shall be deemed to control another entity if it owns or controls, directly or indirectly, at least fifty percent (50%) of the voting equity of such other entity (or other comparable ownership interest for any entity other than a corporation).

(C) Terms parenthetically defined elsewhere in this Agreement shall, throughout this Agreement, have the meaning therein provided.

Section 13.13. All disputes arising out of, or in relation to, this Agreement (other than disputes arising out of any claim by a third party in an action commenced against a party), shall be referred for decision forthwith to a senior executive of each party not involved in the dispute. If no agreement can be reached through this process within thirty (30) days of request by one party to the other to nominate a senior executive for dispute resolution, then either party hereto shall be entitled to refer such dispute to a single arbitrator for arbitration to be held in New York, New York on an expedited basis in accordance with the rules and regulations of the American Arbitration Association for the resolution of international disputes. Any party demanding arbitration shall, with service of its demand for arbitration, propose a neutral arbitrator selected by it. In the event that the parties cannot agree upon a neutral arbitrator within thirty (30) days after the demand for arbitration, an arbitrator shall be appointed by the American Arbitration Association who shall be a partner in a New York, New York law firm having at least ten (10) partners.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be signed by their duly authorized representatives, intending to be legally bound hereby, as of the day and year first written.

**GLOBAL PHARMACEUTICAL CORPORATION**

By: /s/ Max L. Mendelsohn  
-----  
Name: Max L. Mendelsohn  
Title: President

**GENPHARM, INC.**

By: /s/ J. N. Tabatznik  
-----  
Name: J. N. Tabatznik  
Title: Chairman

By: /s/ H. Koziarski  
-----  
Name: H. Koziarski  
Title: CEO

**AGREED TO WITH RESPECT  
TO SECTION 4.09 ONLY:**

**MERCK KGaA**

By: /s/ Richard N. Wiener  
-----  
Name: Richard N. Wiener  
Title: Authorized Agent

**SCHEDULE I**

**PRODUCTS**

**Oxybutinin**

**Minocycline**

Additional Products to be mutually agreed upon

## **EMPLOYMENT AGREEMENT**

AGREEMENT made as of February 7, 1997 by and between GLOBAL PHARMACEUTICAL CORPORATION, a Delaware corporation (hereinafter referred to as the "Corporation"), and SEYMOUR HYDEN (hereinafter referred to as "Executive").

In consideration of the mutual promises set forth herein the parties hereto agree as follows:

### **ARTICLE I.**

#### **Term of Employment**

A. Upon the terms and subject to the conditions set forth herein, the Corporation will employ Executive on the terms provided in this Agreement from March 31, 1997 (the "Effective Date"), until the date the employment of Executive shall terminate pursuant to Article IV or Article V. (The period during which Executive is employed hereunder is referred to herein as the "term of employment.") Executive will work for the Corporation during the term of employment in accordance with, and subject to the terms and conditions of, this Agreement.

### **ARTICLE II.**

#### **Duties**

A. During the term of employment Executive will:

(a) use his best efforts to promote the interests of the Corporation, and shall devote his full time and efforts to its business and affairs;

(b) serve as the Vice President, Scientific & Technical Affairs reporting solely to the Corporation's Chief Executive Officer and Board of Directors; and

(c) perform duties which will include but not be limited to responsibility for product development including supervision of pilot plant operations; analytical methods; managing new projects and establishing priorities for the introduction of products; responsibility for the oversight of all biostudies in conjunction with ANDA and NDA filings and the oversight of the regulatory activities of the Corporation as they pertain to submissions to FDA which would include: NDA's, ANDA's, supplements and associated labeling; and other duties as the Corporation may from time to time assign to him.

### **ARTICLE III.**

#### **Compensation**

A. The Corporation will compensate Executive for the duties performed by him hereunder by payment of a salary (the "Salary") at the rate of \$130,000 per annum. The Salary shall be payable in equal installments, which the Corporation shall pay at semi-monthly intervals or, at the Corporation's election, more frequently, and shall be subject to such payroll deductions as are required by law. The salary paid to the Executive will be reviewed annually by the Board of Directors in conjunction with the recommendation of the President, and may be increased at the discretion of the Company's Board of Directors or Compensation Committee, which shall take into account the performance of the Executive, the productivity of the Company and other factors which it deems relevant.

### **ARTICLE IV.**

Term: Termination

A. Unless terminated sooner as hereinafter provided, the initial term of employment of Executive under this Agreement shall be for a period of three (3) years from the Effective Date hereof (the "Initial Term"). The term of employment of Executive shall continue thereafter for an additional one year period commencing on the third anniversary of the Effective Date, unless either party has notified the other no later than three (3) months prior to that third anniversary that he or it does not wish to continue the term of employment of Executive under this Agreement or unless Executive's employment is terminated sooner as hereinafter provided. Thereafter, Executive's term of employment under this Agreement shall continue for additional one (1) year periods, unless either party has notified the other no later than three (3) months prior to the end of any of those additional one (1) year periods that he or it does not wish to continue Executive's term of employment under this Agreement or unless Executive's term of employment is terminated sooner as hereinafter provided.

B. The Corporation may terminate the employment of Executive hereunder

(i) for Cause (as defined below) at any time and without prior notice or (ii) for any other reason on two (2) weeks notice in writing to Executive.

1. If the Corporation terminates Executive's employment for Cause or pursuant to Section IV.D. hereof then the Corporation shall, within fifteen (15) days after the termination date, pay Executive all accrued and unpaid Salary and benefits (including accrued but unused vacation time) through the termination date.

2. If the Corporation terminates Executive's employment other than for Cause, then in lieu of any other payments otherwise required hereunder, the Corporation shall, subject to the Executive's compliance with Article V hereof, pay Executive, as liquidated

damages and not as a penalty, (a) within 15 days after the termination date, all accrued and unpaid Salary and benefits (including accrued but unused vacation time) through the termination date and (b) an amount equal to his Salary payments at the time of the termination, in accordance with the Corporation's then payment policy, and benefits during the six-month period following the termination date; provided, however, that if such termination occurs prior to the first anniversary of the Effective Date, then in addition to the items referred to in subsection (a) and (b) above, Executive shall be entitled to continue to receive, in accordance with the Corporation's then payment policy, an amount equal to his Salary payments and, to the extent Executive is not otherwise employed, health benefits, until the first anniversary of the Effective Date.

3. The phrase "Cause" means any of the following:

(a) breach by Executive of Article V of this Agreement;

(b) material breach of any other provision of this Agreement by Executive (other than any such breach resulting from Executive's incapacity due to physical or mental illness which shall be governed by IV.D. hereof), if that breach is not remedied (or the remedy commences and is diligently continued until actually remedied) within 30 days after written notice to Executive describing the acts alleged to constitute Cause;

(c) any act of fraud, misappropriation, embezzlement or similar willful and malicious conduct by Executive against the Corporation; or

(d) indictment of Executive for a felony or any conviction of, or guilty plea by Executive to, a crime involving moral turpitude if that crime of moral turpitude tends or would reasonably tend to bring the Corporation into disrepute.

C. Executive may terminate his employment hereunder at any time for any reason on two (2) weeks written notice in writing to the Corporation.

1. If Executive terminates his employment without "Good Reason" (as defined below), then the Corporation shall, within fifteen (15) days after the termination date, pay Executive all accrued and unpaid Salary and benefits (including accrued but unused vacation time) through the termination date.

2. If Executive terminates his employment with "Good Reason", then the Corporation shall, subject to Executive's compliance with Section V hereof,

(i) pay Executive within fifteen (15) days after the termination date, all accrued and unpaid Salary and benefits (including accrued but unused vacation time) through the termination date and (ii) continue to pay Executive an amount equal to Executive's Salary and benefits, in accordance with the Corporation's then payment policy, during the six-month period following the termination date.

3. The phrase "Good Reason" means a material breach of this Agreement or the intentional disregard or violation of the Food, Drug and Cosmetic Act as amended in any material respect (other than through the actions of the Executive) in any case by the Corporation, which has not been cured within thirty (30) days after written notice thereof from the Executive.

D. If Executive dies or becomes incapacitated, his employment hereunder shall terminate on the date of his death or incapacitation, as the case may be. For purposes hereof, the term "incapacitated" shall mean such mental or physical illness as shall render Executive incapable of substantially performing his duties hereunder on a regular basis at the Company's

offices for a period of three (3) consecutive months or for a period of six (6) months in any twelve-month period, all as determined by a physician or psychiatrist, as the case may be, selected by the Company.

## **ARTICLE V.**

### **Covenants**

A. While Executive is employed hereunder by the Corporation, he shall not, without the prior written consent of the Corporation, engage, directly or indirectly, in any other trade, business or employment, or have any interest, direct or indirect, in any other business, firm or corporation; provided however, that he may continue to own or may hereafter acquire (i) any securities of any class of any publicly-owned company or (ii) any passive investment in a privately held entity which is not engaged in the pharmaceutical business.

B. Executive shall treat as confidential and keep secret the affairs of the Corporation (including specifically the terms and conditions of this Agreement) and shall not at any time during the term of employment or thereafter, without the prior written consent of the Corporation, or unless required by law, divulge, furnish or make known or accessible to, or use for the benefit of, any one other than the Corporation and its subsidiaries and affiliates any information of a confidential or proprietary nature related in any way to the business of the Corporation or its subsidiaries or affiliates or their clients. Executive shall be entitled to disclose the terms of this Agreement to potential employers of Executive and to lending institutions from whom Executive seeks to borrow.

C. All records, papers and documents kept or made by Executive relating to the business of the Corporation or its subsidiaries or affiliates or their clients shall be and remain the property of the Corporation.

D. All articles invented by Executive, processes discovered by him, trademarks, designs, advertising copy and art work, display and promotion materials and, in general everything of value conceived or created by him pertaining to the business of the Corporation of any of its subsidiaries or affiliates during the term of employment, and any and all rights of every nature whatever relating thereto, shall immediately become the property of the Corporation, and Executive shall assign, transfer and deliver all patents, copyrights, royalties, designs and copy, and any and all interests and rights whatever thereto and thereunder to the Corporation, without further compensation, upon notice to him from the Corporation.

E. Following the termination of Executive's employment hereunder (including the expiration of this Agreement) for any reason, Executive shall not, for a period of two (2) years from such termination solicit any employee of the Corporation to leave such employ or to enter the employ of Executive or of any corporation or enterprise with which Executive is then associated or solicit any customer of the Corporation to terminate its relationship with the Corporation.

F. During the one-year period following Executive's termination of employment by Executive without Good Reasons or by the Corporation for Cause (the "Restricted Period"), Executive shall not render any services, directly or indirectly, as an employee, officer, consultant or in any other capacity, to any individual, firm, corporation or partnership engaged in any business or activities which is competitive with any activities or

business engaged in by the Corporation during his employment by the Corporation (such activities being herein called the "Corporation's Business"). During the Restricted Period, Executive shall not, without the prior written consent of the Corporation, hold an equity interest in any firm, partnership or corporation which competes with the Corporation's Business, except that beneficial ownership by Executive (including ownership by any one or more members of his immediate family and any entity under his direct or indirect control) of less than five (5%) percent of the outstanding shares of capital stock of any corporation which may be engaged in any of the same lines of business as the Corporation's Business, if such stock is listed on a national securities exchange or publicly traded in over-the-counter market, shall not constitute a breach of the covenants contained in this Article V.

G. The provisions contained in this Article V as to the time periods, scope of activities, persons of entities affected, and territories restricted shall be deemed divisible so that, if any provision contained in this Article V is determined to be invalid or unenforceable, such provisions shall be deemed modified so as to be valid and enforceable to the full extent lawfully permitted.

H. During the term of this Agreement, the Corporation shall maintain a D & O policy providing such coverage for the Directors and Officers of the Corporation as the Corporation's Board of Directors shall reasonably determine.

**ARTICLE VI.**

**Bonuses**

A. The Board of Directors of the Corporation will consider, and nothing herein shall preclude the Corporation's Board of Directors from, awarding Executive bonuses based on performance as they may, at any time or from time to time, determine.

**ARTICLE VII.**

**Stock Award**

A. The Corporation will grant to Executive an option to purchase 36,000 shares of the Corporation's common stock at a price per share equal to the fair market value of the Corporation's common stock (the "Award") on the date the Compensation Committee of the Board of Directors grants this Award, which so long as Executive remains in the continuous employ of the Corporation on a given vesting date, shall vest in Executive in accordance with the following schedule:

(i) one-third of the Award shall vest on March 31, 1998, and (ii) the remaining two-thirds of the Award shall vest in increments of one-twenty fourth per month for the twenty four (24) months then following.

B. The option shall be granted pursuant to, and shall be subject to the terms of the stock option plan adopted by the Corporation.

**ARTICLE VIII.**

**Other Employment Benefits**

A. The Corporation shall provide Executive with medical and hospitalization insurance coverage and retirement plans which in each case are no less favorable to Executive than those plans provided to the Corporation's senior executive officers generally (it being

understood that to the extent the plans provide coverage for dependents of employees, Executive shall be entitled to such coverage for his dependents under the same terms as senior executives generally). The Corporation shall also provide Executive with life insurance coverage having a death benefit payable to a beneficiary selected by Executive equal to \$250,000 and disability insurance which provides salary replacement benefits, not to exceed \$250,000 in the aggregate, in the event Executive becomes incapacitated.

B. During the term of employment, Executive shall be entitled to three weeks of paid vacation each year and to participate in or receive benefits under any other employee benefit plan, arrangement or perquisite made available by the Corporation now or in the future to its senior executive officers generally, subject to and on a basis consistent with the terms, conditions and overall administration of such plans, arrangement and perquisites.

C. The Corporation shall reimburse Executive for all reasonable expenses incurred by Executive for promoting the business of the Corporation, including expenses for travel and similar items, from time to time upon presentation by Executive of an itemized account of such expenditures, all in accordance with the Corporation's policies for incurrence and reimbursement.

D. The Corporation shall pay the reasonable lodging costs of the Executive in the Philadelphia, PA metropolitan area for a period not to exceed four (4) months at a mutually agreed upon location, and the reasonable transportation costs of the Executive between Cincinnati, OH and Philadelphia, PA as are mutually agreed to by Executive and the Corporation, until Executive makes a permanent move to the Philadelphia, PA metropolitan area.

Such a permanent move shall occur within a reasonable time from the date hereof, but in no event later than one (1) year from the Effective Date.

E. The Corporation shall reimburse Executive up to \$12,000 for expenses incurred pursuant to Executive's permanent move to the Philadelphia, PA metropolitan area. These expenses must be supported by the appropriate documentation and may include expenses such as moving, title closing and real property taxes due and owing upon the title closing.

#### **ARTICLE IX.**

##### **Key Man Insurance**

A. The Corporation may, in its sole and absolute discretion, at any time after the date hereof, apply for and procure as owner for its own benefit life insurance on Executive, in such amount and in such form or forms as the Corporation may determine. Executive shall, at the Corporation's requests subject to such medical examinations, supply such information and execute such documents as may be required by the insurance company or companies to whom the Corporation has applied for such insurance.

#### **ARTICLE X.**

##### **Assignment**

A. The Agreement shall be binding upon and shall inure to the benefit of the successors and assigns of the Corporation. Neither this Agreement nor any rights hereunder shall be assignable by Executive and any such purported assignment by him shall be void

**ARTICLE XI.**

**Entire Agreement**

A. This Agreement constitutes the entire understanding between the Corporation and Executive concerning his employment by the Corporation or any of its subsidiaries and supersedes any and all previous agreements between Executive and the Corporation or any of its subsidiaries concerning such employment. This Agreement may not be changed orally.

**ARTICLE XII.**

**Applicable Law**

A. The Agreement shall be governed by and construed in accordance with the laws of the State of Pennsylvania.

**GLOBAL PHARMACEUTICAL CORPORATION**

*By: /s/ Max L. Mendelsohn*

-----  
*Max L. Mendelsohn, President  
and CEO*

*/s/ Seymour Hyden*

-----  
*Seymour Hyden*

## **EMPLOYMENT AGREEMENT**

AGREEMENT made as of March 13, 1997 by and between GLOBAL PHARMACEUTICAL CORPORATION, a Delaware corporation (hereinafter referred to as the "Corporation") and MITCHELL GOLDBERG (hereinafter referred to as "Executive")

In consideration of the mutual promises set forth herein the parties hereto agree as follows:

### **ARTICLE I.**

#### **Term of Employment**

A. Upon the terms and subject to the conditions set forth herein, the Corporation will employ Executive on the terms provided in this Agreement from March 17, 1997 (the "Effective Date") until the date the employment of Executive shall terminate pursuant to Article IV hereof. (The period during which Executive is employed hereunder is referred to herein as the "term of employment.") Executive shall work for the Corporation during the term of employment in accordance with, and subject to the terms and conditions of, this Agreement.

### **ARTICLE II.**

#### **Duties**

During the term of employment Executive will:

- (a) use his best efforts to promote the interests of the Corporation, and shall devote his full time and efforts to its business and affairs;
- (b) serve as the Vice President, Sales & Marketing, reporting solely to the Corporation's Chief Executive Officer and Board of Directors; and

(c) perform such duties consistent with, and customarily provided in connection with, the office described in subsection (b) above as the Corporation may from time to time assign to him, and Executive shall not engage any duties or pursuits which may interfere with or be inimical or contrary to the best interests of the Corporation.

### **ARTICLE III.**

#### **Compensation**

A. The Corporation will compensate Executive for the duties performed by him hereunder by payment of a salary (the "Salary") at the rate of \$110,000 per annum. The Salary shall be payable in equal installments, which the Corporation shall pay at semi-monthly intervals or, at the Corporation's election, more frequently, and shall be subject to such payroll deductions as are required by law. The Salary paid to the Executive will be reviewed annually by the Board of Directors in conjunction with the recommendation of the President, and may be increased at the discretion of the Corporation's Board of Directors or Compensation Committee, which shall take into account the performance of the Executive, the productivity of the Corporation and other factors which it deems relevant.

### **ARTICLE IV.**

#### **Term; Termination**

A. Unless terminated sooner as hereinafter provided, the initial term of employment of Executive under this Agreement shall be for a period of three (3) years from the Effective Date hereof (the "Initial Term"). The term of employment of Executive shall continue thereafter for an additional one (1) year period commencing

on the third anniversary of the Effective Date, unless either party has notified the other no later than three (3) months prior to that third anniversary that he or it does not wish to continue the term of employment of Executive under this Agreement or unless Executive's employment is terminated sooner as hereinafter provided. Thereafter, Executive's term of employment under this Agreement shall continue for additional one (1) year periods, unless either party has notified the other no later than three (3) months prior to the end of any of those additional one (1) year periods that he or it does not wish to continue Executive's term of employment under this Agreement or unless Executive's term of employment is terminated sooner as hereinafter provided.

B. The Corporation may terminate the employment of Executive hereunder

(i) for Cause (as defined below) at any time and without prior notice or (ii) for any other reason on two (2) weeks notice in writing to Executive.

1. If the Corporation terminates Executive's employment for Cause or pursuant to Article IV.D. hereof, then the Corporation shall, within fifteen (15) days after the termination date, pay Executive all accrued and unpaid Salary and benefits (including accrued but unused vacation time) through the termination date.

2. If the Corporation terminates Executive's employment other than for Cause or pursuant to Article IV.D. hereof, then in lieu of any other payments otherwise recurred hereunder, the Corporation shall, subject to Executive's compliance with Article V hereof, pay Executive, as liquidated damages and not as a penalty, (a) within fifteen (15) days after the termination date, all accrued and unpaid Salary and benefits (including accrued but unused vacation time) through the termination date and (b) the lesser of (i) an amount equal to his Salary payments at the time of the

termination in accordance with the Corporation's then payment policy, and benefits provided for herein during the six-month period following the termination date, and (ii) the entire amount of the Salary remaining due and payable from the date of such termination to the scheduled expiration of this Agreement; provided however, that if such termination occurs prior to the first anniversary of the Effective Date, then in addition to the items referred to in subsections (a) and (b) above, Executive shall be entitled to continue to receive, in accordance with the Corporation's then payment policy, an amount equal to his Salary payments and, to the extent Executive is not otherwise employed, health benefits, until the first anniversary of the Effective Date.

3. The phrase "Cause" means any of the following:

(a) breach by Executive of any provision of Article V of this Agreement;

(b) breach of any other provision of this Agreement by Executive (other than any such breach resulting from Executive's incapacity due to physical or mental illness, which shall be governed by Article IV.D. hereof), including without limitation the failure to satisfactorily perform his duties as provided herein, if that breach is not remedied within thirty (30) days after written notice to Executive describing the acts alleged to constitute Cause;

(c) any act of fraud, misappropriation, embezzlement or similar willful and malicious conduct by Executive against the Corporation; or

(d) indictment of Executive for a felony or any conviction of, or guilty plea by Executive to, a crime involving moral turpitude if that crime of moral turpitude tends or would reasonably tend to bring the Corporation into disrepute.

C. Executive may terminate his employment hereunder at any time for any reason upon two (2) weeks written notice to the Corporation.

1. If Executive terminates his employment without "Good Reason" (as defined below), then the Corporation shall, within fifteen (15) days after the termination date, pay Executive all accrued and unpaid Salary and benefits (including accrued but unused vacation time) through the termination date.

2. If Executive terminates his employment with "Good Reason", then the Corporation shall, subject to Executive's compliance with Article V hereof, (i) pay Executive, with fifteen (15) days after the termination date, all accrued and unpaid Salary and benefits (including accrued but unused vacation time) through the termination date and (ii) continue to pay Executive an amount equal to Executive's Salary and benefits, accordance with the Corporation's then payment policy during the six-month period following the termination date.

3. The phrase "Good Reason" means a material breach of this Agreement or the intentional disregard or violation of the Food, Drug and Cosmetic Act as amended in any material respect (other than through the actions of the Executive) by the Corporation, which has not been cured within thirty (30) days after written notice thereof from the Executive.

D. If Executive dies or becomes incapacitated, his employment hereunder shall terminate on the date of his death or incapacitation, as the case may be. For purposes hereof, the term "incapacitated" shall mean such mental or physical illness as shall render Executive incapable of substantially performing his duties hereunder on a regular basis at the Corporation's offices for a period of three (3)

consecutive months or for a period of six (6) months in any twelve-month period, all as determined by a physician or psychiatrist, as the case may be, selected by the Corporation.

## **ARTICLE V.**

### **Covenants**

A. While Executive is employed hereunder by the Corporation and during any time thereafter that the Corporation shall continue to pay to Executive his Salary and benefits, he shall not, without the prior written consent of the Corporation, engage, directly or indirectly, in any other trade, business or employment, or have any interest, direct or indirect, in any other business, firm or corporation; provided, however, that he may continue to own or may hereafter acquire (i) any securities of any class of any publicly-owned company or (ii) any passive investment in a privately held entity which is not engaged in the pharmaceutical business.

B. Executive shall treat as confidential and keep secret the affairs of the Corporation (including specifically the terms and conditions of this Agreement) and shall not at any time during the term of employment or thereafter, without the prior written consent of the Corporation, or unless required by law, divulge, furnish or make known or accessible to, or use for the benefit of, anyone other than the Corporation and its subsidiaries and affiliates any information of a confidential or proprietary nature related in any way to the business of the Corporation or its subsidiaries or affiliates or their clients. Executive shall be entitled to disclose the terms of this Agreement to potential employers of Executive and to lending institutions from whom Executive seeks to borrow.

C. All records, papers and documents kept or made by Executive relating to the business of the Corporation or its subsidiaries or affiliates or their clients shall be and remain the property of the Corporation.

D. All articles invented by Executive, processes discovered by him, trademarks, designs, advertising copy and art work, display and promotion materials and, in general, everything of value conceived or created by him pertaining to the business of the Corporation or any of its subsidiaries or affiliates during the term of employment, and any and all rights of every nature whatever relating thereto, shall immediately become the property of the Corporation, and Executive shall assign, transfer and deliver all patents, copyrights, royalties, designs and copy, and any and all interests and rights whatever thereto and thereunder to the Corporation, without further compensation, upon notice to him from the Corporation.

E. Following the termination of Executive's employment hereunder (including, the expiration of this Agreement) for any reason, Executive shall not, for a period of two (2) years from such termination solicit any employee of the Corporation to leave such employ or to enter the employ of Executive or of any corporation or enterprise with which Executive is then associated or solicit any customer of the Corporation to terminate its relationship with the Corporation.

F. During the one-year period following Executive's termination of employment by Executive without Good Reason or by the Corporation for Cause (the "Restricted Period"), Executive shall not render any services, directly or indirectly, as an employee, officer, consultant or in any other capacity, to any individual, firm, corporation or partnership engaged in any business or activity which is competitive

with any activity or business engaged in by the Corporation during his employment by the Corporation (such activities being herein called the "Corporation's Business"). During the Restricted Period, Executive shall not, without the prior written consent of the Corporation, hold an equity interest in any firm, partnership or corporation which competes with the Corporation's Business, except that beneficial ownership by Executive (including ownership by any one or more members of his immediate family and any entity under his direct or indirect control) of less than five percent (5%) of the outstanding shares of capital stock of any corporation which may be engaged in any of the same lines of business as the Corporation's Business, if such stock is listed on a national securities exchange or publicly traded in an over-the-counter market, shall not constitute a breach of the covenants contained in this Article V.

G. The provisions contained in this Article V as to the time periods, scope of activities, persons or entities affected, and territories restricted shall be deemed divisible so that, if any provision contained in this Article V is determined to be invalid or unenforceable, such provisions shall be deemed modified so as to be valid and enforceable to the full extent lawfully permitted.

H. During the term of this Agreement, the Corporation shall maintain a Directors' and Officers' insurance policy providing such coverage for the Directors and Officers of the Corporation as the Corporation's Board of Directors shall reasonably determine.

## ARTICLE VI.

### Bonuses

A. The Corporation shall pay Executive a \$10,000 sign-on bonus, one-half of which shall be paid thirty (30) days from the Effective Date and one-half of which shall be paid sixty (60) days from the Effective Date; provided, however, that in the event Executive's employment hereunder terminates at any time within the first year of his term of employment (other than by the Executive for Good Reason or by the Corporation without Cause), Executive shall repay to the Corporation (pro rated based on a twelve month term and calculated on a monthly basis) the dollar amount of the sign-on bonus that had been paid that represents the amount of time during that first year that Executive will not be employed by the Corporation.

B. During 1997, the Corporation shall pay Executive a bonus of \$5,000 per quarter in any quarter in which Executive reaches the projected sales numbers that have been established by the Corporation. In the event Executive exceeds such projected sales numbers in any quarter by a factor of 1.25, the bonus for such quarter shall be \$6,250,

C. During 1998, the Corporation shall pay Executive a bonus of \$10,000 per quarter in any quarter in which Executive reaches the projected sales and gross margin numbers that have been established by the Corporation.

D. The Board of Directors of the Corporation may consider, and nothing herein shall preclude the Corporation's Board of Directors from, awarding Executive any other bonuses based on performance as they may, at any time or from time to time, determine.

## **ARTICLE VII**

### **Stock Option Award**

A. The Corporation will grant to Executive an option to purchase 36,000 shares of the Corporation's common stock (the "Award") at a price per share equal to the fair market value of the Corporation's common stock on the date the Compensation Committee of the Board of Directors grants this Award, which so long as Executive remains in the continuous employ of the Corporation on a given vesting date, shall vest in Executive in accordance with the following schedule: (i) one-third of the Award shall vest on the date one (1) year from the Effective Date, and (ii) the remaining two-thirds of the Award shall vest in increments of one-twenty fourth per month for the twenty four (24) months then following.

B. The option shall be granted pursuant to, and shall be subject to the terms of, the stock option plan adopted by the Corporation.

## **ARTICLE VIII.**

### **Other Employment Benefits**

A. The Corporation shall provide Executive with medical and hospitalization insurance coverage and retirement plans which in each case are no less favorable to Executive than those plans provided to the Corporation's senior executive offices generally (it being understood that to the extent the plans provide coverage for dependents of employees, Executive shall be entitled to such coverage for his dependents under the same terms as senior executives generally). The Corporation shall also provide Executive with life insurance coverage having a death benefit payable to a beneficiary selected by Executive equal to \$250,000 and disability insurance which

provides salary replacement benefits, not to exceed \$250,000 in the aggregate, in the event Executive becomes incapacitated.

B. During the term of employment, Executive shall be entitled to three weeks of paid vacation each year and to participate in or receive benefits under any other employee benefit plan, arrangement or perquisite made available by the Corporation now or in the future to its senior executive officers generally, subject to and on a basis consistent with the terms, conditions and overall administration of such plans, arrangements and perquisites; provided, however, that Executive shall not be entitled to carry over unused vacation time in any given year to subsequent years.

C. The Corporation shall reimburse Executive for all reasonable expenses incurred by Executive for promoting the business of the Corporation, including expenses for travel and similar items (such as automobile mileage at the Corporation's standard rates), from time to time upon presentation by Executive of an itemized account of such expenditures, all in accordance with the Corporation's policies for incurrence and reimbursement. To the extent permitted by law, the Corporation will not withhold Philadelphia city wage taxes for the days Executive travels out of town on business.

D. The Corporation will provide Executive with a cellular telephone and a lap-top computer for use in performing his duties hereunder during the term of employment.

**ARTICLE IX.**

**Key Man Insurance**

A. The Corporation may, in its sole and absolute discretion, at any time after the date hereof, apply for and procure as owner for its own benefit life insurance on Executive, in such amount and in such form or forms as the Corporation may determine. Executive shall, at the Corporation's request, subject to such medical examinations, supply such information and execute such documents as may be required by the insurance company or companies to whom the Corporation has applied for such insurance.

**ARTICLE X.**

**Assignment**

A. This Agreement shall be binding upon and shall inure to the benefit of the successor and assigns of the Corporation. Neither this Agreement nor any rights hereunder shall be assignable by Executive and any such purported assignment by him shall be void.

**ARTICLE XI.**

**Entire Agreement**

A. This Agreement constitutes the entire understanding between the Corporation and Executive concerning his employment by the Corporation or any of its subsidiaries and supersedes any and all previous agreements between Executive and the Corporation or any of its subsidiaries concerning such employment. This Agreement may not be changed orally.

**ARTICLE XII.**

**Applicable Law**

A. The Agreement shall be governed by and construed in accordance with the laws of the State of Pennsylvania.

**GLOBAL PHARMACEUTICAL CORPORATION**

**By Max L. Mendelsohn**

Max L. Mendelsohn, President, and CEO

*/s/ Mitchell Goldberg*

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*Mitchell Goldberg*

## ARTICLE 5

THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE CONSOLIDATED BALANCE SHEET AND THE CONSOLIDATED STATEMENT OF INCOME FOR THE TWELVE MONTHS ENDED DECEMBER 31, 1996 AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

MULTIPLIER: 1,000

PERIOD TYPE	12 MOS
FISCAL YEAR END	DEC 31 1996
PERIOD START	JAN 01 1996
PERIOD END	DEC 31 1996
CASH	4,044
SECURITIES	0
RECEIVABLES	0
ALLOWANCES	0
INVENTORY	0
CURRENT ASSETS	4,093
PP&E	4,783
DEPRECIATION	648
TOTAL ASSETS	9,440
CURRENT LIABILITIES	892
BONDS	0
PREFERRED MANDATORY	0
PREFERRED	0
COMMON	43
OTHER SE	7,308
TOTAL LIABILITY AND EQUITY	9,440
SALES	0
TOTAL REVENUES	0
CGS	0
TOTAL COSTS	0
OTHER EXPENSES	5,121
LOSS PROVISION	0
INTEREST EXPENSE	40
INCOME PRETAX	(4,608)
INCOME TAX	0
INCOME CONTINUING	0
DISCONTINUED	0
EXTRAORDINARY	0
CHANGES	0
NET INCOME	(4,608)
EPS PRIMARY	(1.08)
EPS DILUTED	(1.08)

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