

ASTEX PHARMACEUTICALS, INC

FORM 10-Q (Quarterly Report)

Filed 08/07/98 for the Period Ending 06/30/98

Address 4140 DUBLIN BLVD

SUITE 200

DUBLIN, CA, 94568

Telephone 9255600100

CIK 0000919722

SIC Code 2834 - Pharmaceutical Preparations

Industry Biotechnology & Medical Research

Sector Healthcare

Fiscal Year 12/31



SUPERGEN INC

FORM 10-Q (Quarterly Report)

Filed 8/7/1998 For Period Ending 6/30/1998

Address 4140 DUBLIN BLVD SUITE 200

DUBLIN, California 94568

Telephone 925-560-0100 CIK 0000919722

Industry Biotechnology & Drugs

Sector Healthcare

Fiscal Year 12/31



UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 1998 OR

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

FOR THE TRANSITION PERIOD FROM _____ TO ____

COMMISSION FILE NUMBER 0-27628

SUPERGEN, INC.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation or organization)

TWO ANNABEL LANE, SUITE 220, SAN RAMON,
CALIFORNIA
(Address of principal executive offices)

91-1841574
(IRS Employer Identification
Number)

94583 (Zip Code)

(925) 327-0200 (Registrant's telephone number, including area code)

NOT APPLICABLE

(Former name, former address and former fiscal year, if changed since last report)

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

APPLICABLE ONLY TO CORPORATE ISSUERS

The number of shares of the registrant's Common Stock, \$.001 par value, outstanding as of July 20, 1998, was 20,376,439.

TABLE OF CONTENTS

	PAGE NO.
PART I FINANCIAL INFORMATION	
Item 1Financial Statements	
Consolidated Balance Sheets as of June 30, 1998 and December 31, 1997	3
Consolidated Statements of Operations for the three and six month periods ended June 30, 1998 and 1997	4
Consolidated Statements of Cash Flows for the six month periods ended June 30, 1998 and 1997	5
Notes to Consolidated Financial Statements	6
Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations	8
PART II OTHER INFORMATION	
Item 2Changes in Securities and Use of Proceeds	14
Item 4Submission of Matters to a Vote of Security Holders	15
Item 6Exhibits and Reports on Form 8-K	15

SUPERGEN, INC. CONSOLIDATED BALANCE SHEETS (IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

(UNAUDITED)

ASSETS

	JUNE 30, 1998	DECEMBER 31, 1997
Current assets: Cash and cash equivalents	\$ 11,630 4,062 534 1,411 664 945	\$ 23,326 303 1,428 570 493
Total current assets	19,246	26,120
Property, plant and equipment, net. Developed technology at cost, net. Investment in preferred stock of related party. Due from related party. Other assets.	3,259 1,289 500 20 88	2,906 1,289 500 80 116
Total assets	, ,	\$ 31,011
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities: Accounts payable and accrued liabilities	\$ 1,418 94	\$ 1,243 239
Accrued compensation and related expenses	185	212 750
Total current liabilities		2,444
Stockholders' equity: Preferred stock, \$.001 par value; 2,000,000 shares authorized; none outstanding Common stock, \$.001 par value; 40,000,000 shares authorized; 20,376,439 and 20,177,696		
shares issued and outstanding at June 30, 1998 and December 31, 1997, respectively Accumulated other comprehensive loss	70,075 (132)	68,976 (93)
Accumulated deficit	(47,238)	
Total stockholders' equity		28,567
Total liabilities and stockholders' equity	\$ 24,402	\$ 31,011

See accompanying notes to consolidated financial statements

SUPERGEN, INC. CONSOLIDATED STATEMENTS OF OPERATIONS (IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

(UNAUDITED)

	THREE MONTHS ENDED JUNE 30,		JUNE	30,	
	1998	1997	1998	1997	
Net sales					
Operating expenses:					
Cost of sales	263	450	588	776	
Research and development	2,263	2,092	5,038	3,628	
Sales and marketing	804	497	1,447	791	
General and administrative	802	663	1,938	1,262	
Acquisition of in-process research and development					
Total operating expenses	4,132		9,011	7,288	
Loss from operations					
Interest income	245	128	537	267	
Net loss	\$ (3,093)	\$ (3,018)	\$ (6,922)	\$ (6,040)	
Basic loss per share					
Weighted average shares used in basic loss per share calculation	20,364	16,986	20,300	16,979	

See accompanying notes to consolidated financial statements

SUPERGEN, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(IN THOUSANDS)

(UNAUDITED)

	SIX MONTHS ENDED JUNE 30,		
	1998	1997	
Operating activities: Net loss		\$ (6,040)	
Depreciation and amortization	214 170	144	
Accounts receivable	(231) 17	(62) 441	
Prepaid expenses and other assets		(138) (117) (334)	
Net cash used in operating activities.			
Investing activities: Purchases of marketable securities. Sale of marketable security. Purchase of property and equipment. Acquisition of developed technology. Purchase of preferred stock of related party.	(5,138) 1,076 (567)	(1,910) (150) (500)	
Net cash used in investing activities. Financing activities: Issuance of common stock. Common stock subscription.	(4,629) 179	(2,560) 311 15,300	
Net cash provided by financing activities		15,611	
Net increase (decrease) in cash and cash equivalents		13,915	
Cash and cash equivalents at end of period			

See accompanying notes to consolidated financial statements

SUPERGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 1998 (UNAUDITED)

NOTE 1. BASIS OF PRESENTATION

The accompanying unaudited consolidated financial statements of SuperGen, Inc. ("SuperGen" or "the Company") have been prepared in accordance with generally accepted accounting principles for interim financial information on a basis consistent with the audited financial statements for the year ended December 31, 1997, and in accordance with the instructions to Form 10-Q. The consolidated financial statements include the accounts of two wholly owned subsidiaries, which are immaterial. The statements include all adjustments (consisting of normal recurring accruals) which in the opinion of the Company's management are necessary for a fair presentation of the results for the periods presented. Certain prior year amounts have been reclassified to conform to the current year's presentations. The interim results are not necessarily indicative of results that may be expected for the full year. The accompanying financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 1997, which are included in the Company's Annual Report on Form 10-K.

NOTE 2. CASH, CASH EQUIVALENTS AND MARKETABLE SECURITIES

Cash and cash equivalents include bank demand deposits, certificates of deposit, marketable securities with maturities of three months or less and an interest in money market funds which invest primarily in U.S. government obligations and commercial paper. These instruments are highly liquid and are subject to insignificant risk.

Marketable securities consist of corporate or government debt securities and an equity security that have readily ascertainable market values and are readily marketable. These investments are reported at fair value. All marketable securities are designated as available-for-sale, with unrealized gains and losses included in equity.

The following is a summary of available-for-sale securities as of June 30, 1998 (in thousands):

	ORTIZED	UNRE	ROSS EALIZED		TIMATED
	COST	GAINS	(LOSSES)	FAI	R VALUE
U.S. corporate debt securities	9,151 999 167	\$	(3) 1 (130)		9,148 1,000 37
Total	\$ 10,317	\$	(132)		10,185
	ORTIZED COST	UNRE	EROSS EALIZED (LOSSES)		TIMATED R VALUE
Amounts included in cash and cash equivalents	6,086 4,064 167	\$	(2) (130)	\$	6,086 4,062 37
Total	\$ 10,317	\$	(132)	\$	10,185

Available-for-sale securities at June 30, 1998, by contractual maturity, are shown below (in thousands):

	 TIMATED R VALUE
Debt securities: Due in one year or less Due after one year through three years	7,096
Marketable equity security	10,148 37
	\$ 10,185

Realized gains and losses for the six months ended June 30, 1998 were not material. The Company held no marketable securities at any time in the six months ended June 30, 1997.

NOTE 3. INVENTORIES

Inventories consisted of (in thousands):

	JUNE	30, 1998	DECEMBE	ER 31, 1997
Raw material Work in process Finished goods		265 726 420	\$	235 720 473
	\$	1,411	\$	1,428

NOTE 4. COMPREHENSIVE LOSS

During the second quarters of 1998 and 1997, total comprehensive losses amounted to \$3,097,000 and \$3,018,000 respectively. During the first six months of 1998 and 1997, total comprehensive losses amounted to \$6,961,000 and \$6,040,000 respectively. There was no other comprehensive loss in the first six months of 1997.

NOTE 5. BASIC LOSS PER SHARE

Basic loss per share information is computed using the weighted average number of shares of common stock outstanding during each period. The exercise of options and warrants is not assumed since the result would be antidilutive.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF

FINANCIAL CONDITION AND RESULTS OF OPERATIONS

PRELIMINARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

THIS QUARTERLY REPORT ON FORM 10-Q CONTAINS FORWARD-LOOKING STATEMENTS WITHIN THE MEANING OF SECTION 27A OF THE SECURITIES ACT OF 1933, AS AMENDED, AND SECTION 21E OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED. THESE FORWARD-LOOKING STATEMENTS REPRESENT THE COMPANY'S EXPECTATIONS OR BELIEFS CONCERNING FUTURE EVENTS AND INCLUDE STATEMENTS, AMONG OTHERS. REGARDING:

- THE TIMING AND PROGRESS OF THE DEVELOPMENT OF THE COMPANY'S PROPOSED PRODUCTS,
- FILING FOR AND RECEIVING REGULATORY APPROVALS,
- ACQUIRING ADDITIONAL PRODUCTS AND TECHNOLOGIES,
- ANTICIPATING THE MARKET OPPORTUNITIES FOR ITS EXTRA AND OTHER PROPRIETARY PRODUCTS,
- MARKETING CURRENT AND PROPOSED PRODUCTS,
- DEVELOPING PARTNERSHIP RELATIONSHIPS.
- INCURRING OPERATING EXPENSES AND LOSSES AND REQUIRING ADDITIONAL CAPITAL, AND
- INCURRING CAPITAL EXPENDITURES.

ACTUAL RESULTS COULD DIFFER MATERIALLY FROM THOSE PROJECTED IN THE FORWARD-LOOKING STATEMENTS AS A RESULT OF A VARIETY OF FACTORS, INCLUDING THOSE SET FORTH UNDER "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS--FACTORS AFFECTING FUTURE OPERATING RESULTS" AND ELSEWHERE IN THIS REPORT.

OVERVIEW

SuperGen, Inc. (the "Company" or "SuperGen") is an emerging pharmaceutical company dedicated to the acquisition, rapid development and commercialization of products for the treatment of life-threatening diseases, particularly cancer. The Company's primary oncology programs target leukemias and lymphomas, solid tumors and the development of the Company's proprietary Extra technology (its enhanced line of already established anticancer drugs). SuperGen also seeks to expand its portfolio of anticancer drugs through the acquisition of products and product candidates that complement its portfolio and provide the Company with promising market opportunities. The Company also has non-oncology programs in the large market areas of anemias and other blood cell disorders, obesity/diabetes and certain autoimmune diseases. The Company intends to seek partnership opportunities in these areas. A key element of the Company's strategy is to identify, acquire and develop pharmaceutical products in the later stages of development. The Company believes this strategy will shorten the research and development cycle and thereby minimize the time, expense and technical risk associated with drug development.

Beginning in late 1996, the Company has actively marketed several pharmaceutical products. Sales of Nipent-Registered Trademark-(pentostatin for injection) were responsible for virtually all product revenues in the first six months of 1998 and for approximately 80% of product revenues in the same period in 1997. The Company acquired this proprietary drug, along with associated North American marketing rights, in 1996. In December 1997, the Company received governmental approval to sell Nipent-Registered Trademark- manufactured under its own Supplemental New Drug Application. Nipent-Registered Trademark- is indicated for the treatment of Hairy Cell Leukemia and has Orphan Drug Designation for both chronic lymphocytic leukemia and cutaneous T-cell lymphoma. In April of 1998, the Company received FDA approval to market the generic drug mitomycin for injection. Mitomycin, originally developed and marketed by Bristol-Myers Squibb Company under the tradename

Mutamycin-Registered Trademark-, is approved in the U.S. for the treatment of adenocarcinoma of the stomach and pancreas in combination with other approved chemotherapeutics. The Company commenced commercial sales of mitomycin in June of 1998. Remaining product sales in 1997 consisted of sales of several generic products purchased in 1997 and 1996. Sales of those generic products are not expected to be significant in 1998 and beyond.

In September 1997, the Company acquired exclusive worldwide rights to a patented anticancer compound (RFS2000), which is currently in Phase II human trials for pancreatic cancer, the fifth leading cause of cancer death. It has also shown activity against an array of solid tumors in animal and initial human studies with a favorable side effect profile. At the end of 1997, SuperGen filed for governmental approval for its first Extra product, Mito Extra. The Food and Drug Administration accepted that filing for review in February 1998. The Company intends to file for approval for several additional Extra and generic anticancer products over the next several years. Also, the Company has continued development of a proprietary blood cell disorder product for the treatment of aplastic anemia (and other anemias associated with chemotherapy, radiotherapy, and renal failure). SuperGen's proprietary obesity/diabetes pill, which has shown promise in early preclinical and human studies, is currently in Phase II clinical trials for a genetic disorder leading to chronic obesity and is expanding into multi-center Phase I/II trials for Type II diabetes. To date, the Company has received Orphan Drug Designations for its aplastic anemia agent and obesity pill for the treatment of a genetic disorder leading to chronic obesity. The Company has also received a grant from the U.S. government for aplastic anemia clinical trials.

The Company has incurred losses in each year since its inception and has accumulated approximately \$47.2 million in net losses through June 30, 1998. While the Company's products are being sold in the United States and certain international markets, there can be no assurance that revenue from future product sales or other sources will increase or be sufficient to fund operations or that the Company will achieve profitability or positive cash flow.

The Company expects its research and development expenses to increase as a result of expanded clinical trials of Nipent-Registered Trademark-, RFS 2000, the Extra product line and other drugs. The Company expects its marketing and sales expenses to increase as it expands its United States direct sales and marketing organization. As of June 30, 1998, the Company's United States sales team consisted of ten individuals experienced in the sale of pharmaceutical products, with particular emphasis on oncology.

The Company's future quarterly operating results will depend on a variety of factors, including

- the price, volume and timing of sales of the Company's products,
- the mix between Nipent-Registered Trademark- sales in the United States and those under a supply agreement for sale outside North America,
- variations in gross margins of the Company's products, which may be affected by the sales mix referred to above and by competitive pricing pressures,
- regulatory approvals of new products or expanded labeling of existing products,
- changes in the Company's level of research and development, including the timing of any expansion of clinical trials, and
- acquisitions of products or technology.

In addition, sales of any product in any given period may include a significant amount of orders for inventory by distributors and wholesalers and may not be indicative of actual demand for products by physicians and patients. There can be no assurance that distributors or wholesalers will be able to forecast demand for product accurately. The Company expects quarterly operating results to continue to fluctuate in the future.

RESULTS OF OPERATIONS

THREE MONTHS ENDED JUNE 30, 1998 COMPARED TO THREE MONTHS ENDED JUNE 30, 1997.

Total revenues were \$794,000 in the second quarter of 1998 compared to \$556,000 in the same period in 1997. The increase in revenue was due primarily to higher sales volumes of Nipent-Registered Trademark-, which resulted from the initial sales of Nipent-Registered Trademark- under a supply agreement for sale outside North America. Product revenues in the second quarter of 1998 consisted almost entirely of sales of Nipent-Registered Trademark-. Gross margin was 67% in the second quarter of 1998 compared to 19% in the same period in 1997. This increase was due primarily to the lower unit cost of Nipent-Registered Trademark- sold in the second quarter of 1998 compared to the same period in 1997 partially offset by lower selling prices for Nipent-Registered Trademark- sold under the supply agreement. Nipent-Registered Trademark- sold in the second quarter of 1998 consisted entirely of inventory manufactured by the Company while Nipent-Registered Trademark- sales in the second quarter of 1997 consisted entirely of inventory acquired from Warner-Lambert Company. The unit cost of manufactured Nipent-Registered Trademark- is, and is expected to continue to be, significantly lower than the unit cost assigned to the Nipent-Registered Trademark- inventory acquired from Warner-Lambert Company. However, manufactured Nipent-Registered Trademark- unit costs may vary significantly in the future. The Company is in the early stages of Nipent-Registered Trademark- sales and manufacturing, and current margins may not be indicative of future margins due to possible future variations in selling prices and manufacturing costs.

Research and development expenses were \$2,263,000 in the second quarter of 1998 compared to \$2,092,000 in 1997. Since the second quarter of 1997, the research and development group has grown by 11 employees, primarily in the areas of product development and clinical trials administration. The increase in research and development expenses in 1998 was due primarily to the resultant increase in personnel and related costs. Variations in other costs were largely offsetting. In the second quarter of 1998, the Company incurred charges of approximately \$300,000 relating to ongoing development and clinical trials for RFS2000. In the second quarter of 1997, the Company incurred a charge of \$400,000 related to a supply agreement for a source of bulk paclitaxel. While the Company continues to develop its own version of paclitaxel, there have been no further charges relating to this supply agreement.

Sales and marketing expenses were \$804,000 in the second quarter of 1998 compared to \$497,000 in the same period in 1997. This increase was primarily due to the expansion of the sales and marketing group to 15 at June 30, 1998, resulting in higher personnel and related costs. Expanded participation at selected trade shows and Nipent-Registered Trademark- media advertising costs also contributed to the higher level of expense in 1998.

General and administrative expenses were \$802,000 in the second quarter of 1998, compared to \$663,000 in 1997. The increase was due principally to costs relating to investor relations, higher facilities and legal expenses and higher personnel expenses reflecting a slight increase in administrative staff.

SIX MONTHS ENDED JUNE 30, 1998 COMPARED TO SIX MONTHS ENDED JUNE 30, 1997.

Total revenues were \$1,552,000 in the first six months of 1998 compared to \$981,000 in the same period in 1997. The increase in revenue was due primarily to higher sales volumes of Nipent-Registered Trademark- in 1998, which resulted principally from the initial sales of Nipent-Registered Trademark- under a supply agreement for sale outside North America. Product revenues in the first six months of 1998 consisted almost entirely of sales of Nipent-Registered Trademark-. Gross margins were 62% in the first six months of 1998 compared to 21% in the same period in 1997. This increase was due primarily to the lower unit cost of Nipent-Registered Trademark- sold in the first six months of 1998 partially offset by lower selling prices for Nipent-Registered Trademark- sold under the supply agreement. The Company is in the early stages of Nipent-Registered Trademark- sales and manufacturing, and current margins may not be indicative of future margins due to possible future variations in selling prices and manufacturing costs.

Research and development expenses were \$5,038,000 in the first six months of 1998 compared to \$3,628,000 in the same period in 1997. Product formulation and development costs associated with RFS 2000 contributed to the overall increase in expense. The Company added staff, primarily in the areas of

product development and clinical trials administration, which also contributed to the increase in expense as did the investment in a related party in the first quarter of 1998.

Sales and marketing expenses were \$1,447,000 in the first six months of 1998 compared to \$791,000 in the same period in 1997. This increase was primarily due to higher costs reflecting the expansion of the sales and marketing group to 15 at June 30, 1998. Also, in 1998 the Company initiated media advertising and increased its presence at selected trade shows.

General and administrative expenses were \$1,938,000 in the first six months of 1998, compared to \$1,262,000 in the same period in 1997. The increase was due principally to costs relating to investor relations, patent related legal fees and enhancements in information technology. Higher facilities and personnel costs also contributed to the overall increase in expense. The Company moved into larger administrative offices in March of 1997 and the administrative staff has grown slightly to accommodate the overall increase in headcount and business activities.

The Company incurred a charge for the acquisition of in-process research and development of \$831,000 in the first quarter of 1997 related to the acquisition of the generic anticancer drug etoposide.

LIQUIDITY AND CAPITAL RESOURCES

The Company's cash, cash equivalents and marketable securities totaled \$15.7 million at June 30, 1998 compared to \$23.3 million at December 31, 1997. The net cash used in operating activities of \$7.2 million in the first six months of 1998 reflected the net loss for the period of \$6.9 million and prepayments for insurance and other purposes. Cash used for purchases of property and equipment was \$569,000, principally for equipment, fixtures and other costs associated with the Company's recently established research facility in Pleasanton, California.

The Company believes that its current cash, cash equivalents and marketable debt securities will satisfy its budgeted cash requirements for at least the next twelve months, based on the Company's current operating plan. The primary planned uses of cash during that period are:

- funding operations,
- conducting clinical testing of potential proprietary and Extra products,
- commercialization and marketing of any new products or expanded indications for Nipent-Registered Trademark- that may be developed,
- continuing research and development programs, and
- acquisition and licensing of additional products or technologies.

The Company is actively considering future contractual arrangements that would require significant financial commitments, particularly with respect to acquiring rights to additional drug candidates and for clinical trials for existing and new drug candidates. The Company does not anticipate significant capital expenditures for the remainder of 1998. If the Company experiences currently unanticipated cash requirements, it could require additional capital prior to the second quarter of 1999. The Company may seek such additional funding through public or private financings or collaborative or other arrangements with third parties. The Company has no credit facility or other committed sources of capital. There can be no assurance that additional funds will be available on acceptable terms, if at all. See "Factors Affecting Future Operating Results."

FACTORS AFFECTING FUTURE OPERATING RESULTS

The future operating results of the Company cannot be predicted with any degree of certainty. In assessing potential future outcomes, the following factors should be carefully reviewed together with the other information contained in this quarterly report on Form 10-Q.

- HISTORY OF OPERATING LOSSES. The Company has incurred losses in every fiscal period to date and expects to continue to incur significant operating losses. The likelihood of the long-term success of the Company must be considered in light of the expenses, difficulties and delays frequently encountered in the development, commercialization and manufacturing of new pharmaceutical products, as well as competition and the burdensome regulatory environment in which the Company operates. The Company has limited experience in each of these areas. There can be no assurance that the Company will ever achieve significant revenues, profitable operations or positive cash flow.
- EARLY STAGE OF PRODUCT DEVELOPMENT; UNCERTAINTY OF FINAL PRODUCT DEVELOPMENT. While the Company's proposed proprietary products are in the development rather than the research stage, significant development remains prior to the time any of these proposed products may be brought to market. The Company has obtained clearance from the FDA related to its Nipent-Registered Trademark- and mitomycin manufacturing processes and sources of bulk drugs for certain of its Extra and generic products. However, it has yet to receive marketing approval for any of its internally developed products. There can be no assurance that any of the Company's products currently under development will be successfully developed, receive required governmental regulatory approvals, become commercially viable or achieve market acceptance.
- ADDITIONAL FINANCING REQUIREMENTS. The Company's need for additional funding is expected to be substantial and will be determined by the progress and cost of the acquisition, development and commercialization of its products and other activities. Based on the Company's current operating plan, additional funds will be needed after approximately twelve months. If the Company experiences unanticipated cash requirements during that twelve month period, the Company could require funds much sooner. There can be no assurance that additional funds will be available at terms favorable to the Company, if at all. Failure to obtain adequate financing in a timely manner would have a material adverse effect on the Company's business, results of operations and cash flows.
- DEPENDENCE ON KEY PERSONNEL. The Company's success is dependent on certain key management and scientific personnel, including Dr. Joseph Rubinfeld, the loss of whose services could significantly affect the ability of the Company to achieve its planned objectives. The loss of key personnel, or the inability to attract and retain the additional, highly skilled personnel required for the expansion of the Company's activities, could have a material adverse effect upon the Company's business, results of operations and cash flows.
- MANUFACTURING LIMITATIONS; RELIANCE ON THIRD PARTIES. The Company currently relies on foreign and domestic manufacturers and vendors for Nipent-Registered Trademark- related manufacturing activities, for storage of crude concentrate, for production of certain of its bulk Extra and generic formulations and for production of sufficient quantities of compounds to conduct clinical trials for its proposed proprietary products. There can be no assurance that these manufacturers or vendors will perform satisfactorily or that relationships with these manufacturers or vendors will continue on terms favorable to the Company or that the Company will be able to retain other qualified manufacturers or vendors in the event that current manufacturers or vendors do not perform satisfactorily. Failure of one or more of these manufacturers or vendors to satisfactorily perform could have a material adverse effect upon the Company's business, results of operations and cash flows, as could the failure of the Company to retain other qualified manufacturers or vendors in the event of a termination of a relationship with a current manufacturer or vendor.
- NEED TO COMPLY WITH GOVERNMENTAL REGULATION AND TO OBTAIN PRODUCT APPROVALS. The research, testing, manufacturing, labeling, distribution, marketing and advertising of the Company's existing and proposed products are subject to extensive regulation by governmental and regulatory authorities in the U.S. and other countries. The Company cannot predict with certainty if or when it might

submit its products currently under development for regulatory review. Once the Company submits its potential products for review, there can be no assurance that FDA or other regulatory approvals for any pharmaceutical products developed by the Company will be granted on a timely basis or at all. Failure to obtain FDA and other regulatory approvals would delay product sales and would have a material adverse affect on the Company's business, results of operations and cash flows.

- PATENTS AND PROPRIETARY TECHNOLOGY; UNCERTAINTY OF PROTECTION THEREOF. The Company has licenses to or assignments of numerous issued U.S. patents. However, there can be no assurance that the Company's patent position will provide it with significant protection against competitors. Failure to comply with the terms of licenses and agreements could result in loss of the Company's underlying rights to one or more of its potential proprietary products. There can be no assurance that claims against the Company will not be raised based on patents held by others or that, if raised, such claims will not be successful. If the Company becomes involved in any litigation, that process could consume a substantial portion of the Company's resources regardless of the outcome of such litigation.
- COMPETITION. There are many companies, both public and private, including well-known pharmaceutical companies that are engaged in the development and sale of products for many of the applications being pursued by the Company. The industry in which the Company competes is highly competitive and is characterized by extensive research and development efforts and rapid technological progress. Price erosion is also characteristic of this industry, particularly with regard to products such as the Company's proposed Extra and generic drugs. The Company's competitive position will be affected by many factors, including but not limited to:
- discoveries by others,
- the ability of the Company to establish or maintain proprietary positions,
- the Company's ability to obtain necessary government approvals,
- the number of competitors, and
- market selling prices and their effects upon the Company's gross margins.

The above factors are not intended to be inclusive and there are numerous other factors which could contribute to the business risk inherent in the Company's operations. Some of these factors are described in the Company's 1997 Annual Report on Form 10-K. Failure to satisfactorily achieve any of the Company's objectives or avoid any of these risks may have a material adverse effect on the Company's business, results of operations and cash flows.

SUPERGEN, INC.

PART II--OTHER INFORMATION

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

On March 13, 1996, the Company commenced its initial public offering (the "IPO") of 4,025,000 units (a unit consisted of one share of Common Stock \$0.001 par value per share, and a warrant to purchase one share of Common Stock at \$9.00), including the underwriter's overallotment option consisting of 525,000 units at a public offering price of \$6.00 per unit pursuant to a registration statement on Form S-B (file no. 333-476 LA) filed with the Securities and Exchange Commission. Of the units registered, 4,024,302 were sold. Paulson Investment Company was the managing underwriter of the IPO. Aggregate gross proceeds to the Company from the IPO (prior to deduction of underwriting discounts and commissions and expenses of the offering and any exercises of the warrants) were \$24,146,000. All of the shares registered for the exercise of the warrants have not yet been sold. There were no selling stockholders in the IPO.

The Company paid underwriting discounts, commissions and expenses of \$1,992,000 and other expenses of approximately \$623,000 in connection with the IPO. The total expenses paid by the Company in the IPO were \$2,615,000, and the net proceeds to the Company from the IPO through June 30, 1998, including the subsequent exercise of warrants to purchase common stock, were \$23,424,000.

From March 13, 1996, the effective date of the registration statement, to June 30, 1998, (the Company's fiscal 1998 second quarter end), the approximate amount of net proceeds used were:

Construction of plant, building and facilities	\$1,246,000
Purchase and installation of machinery and equipment	295,000
Purchase of real estate	744,000
Working capital used in operations	16,862,000
Repurchase of common stock	3,557,000
Purchase of equity investment	500,000
Acquisition of developed technology	220,000

None of such payments consisted of direct or indirect payments to directors, officers, owners of more than 10% of the outstanding stock of the Company or affiliates of the Company, with the exception of:

- the payment to repurchase common stock, which was made to a stockholder that, immediately prior to the repurchase, owned more than 10% of the then outstanding common stock of the Company,
- \$279,000 which was paid to director under a consulting agreement and is included in working capital used in operations,
- compensation to directors and officers as compensation for services provided to the Company.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

The Company's Annual Meeting of Stockholders was held on May 7, 1998. The results of the voting were as follows:

Proposal 1: Election of the Board of Directors of the Company.

NOMINEE	VOTES FOR	VOTES WITHHELD
- 1 - 1 ' 6 11	16 141 514	140 455
Joseph Rubinfeld	16,141,714	142,457
Lawrence J. Ellison	16,141,864	142,307
Denis Burger	16,116,964	167,207
David M. Fineman	16,124,564	159,607
J. Gregory Swendsen	16,138,364	145,807
Julius A. Vida	16,138,664	145,507
Daniel Zurr	16,031,564	252,607

Proposal 2: Amendment of the Company's Amended and Restated 1993 Stock Option Plan to increase the number of shares reserved for issuance by 750,000 shares to 3,250,000 shares.

Votes For: 15,187,364
Votes Against: 317,973
Votes Abstaining: 101,916
Broker Non-Votes: 676,918

Proposal 3: Ratification and Approval of the 1998 Employee Stock Purchase Plan.

Votes For: 16,091,282
Votes Against: 145,806
Votes Abstaining: 47,083
Broker Non-Votes: --

Proposal 4: Ratification of Ernst & Young LLP as the independent auditors of the Company for the fiscal year ending December 31, 1998.

Votes For: 16,198,412
Votes Against: 33,400
Votes Abstaining: 52,359
Broker Non-Votes: --

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(b) No reports were filed on Form 8-K during the quarter for which this report is filed.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: August 7, 1998

By /s/ JOSEPH RUBINFELD

Joseph Rubinfeld, Ph.D.
CHIEF EXECUTIVE OFFICER, PRESIDENT, AND
DIRECTOR
(PRINCIPAL EXECUTIVE AND FINANCIAL
OFFICER)

By /s/ KEVIN C. LEE

Kevin C. Lee
CONTROLLER (PRINCIPAL ACCOUNTING OFFICER)

ARTICLE 5

THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM SUPERGEN, INC. JUNE 30, 1998 CONSOLIDATED FINANCIAL STATEMENTS

MULTIPLIER: 1,000

PERIOD TYPE	6 MOS
FISCAL YEAR END	DEC 31 1998
PERIOD START	JAN 01 1998
PERIOD END	JUN 30 1998
CASH	11,630
SECURITIES	4,062
RECEIVABLES	544
ALLOWANCES	10
INVENTORY	1,411
CURRENT ASSETS	19,246
PP&E	3,843
DEPRECIATION	584
TOTAL ASSETS	24,402
CURRENT LIABILITIES	1,697
BONDS	0
PREFERRED MANDATORY	0
PREFERRED	0
COMMON	70,075
OTHER SE	0
TOTAL LIABILITY AND EQUITY	24,402
SALES	1,552
TOTAL REVENUES	1,552
CGS	588
TOTAL COSTS	0
OTHER EXPENSES	8,423
LOSS PROVISION	0
INTEREST EXPENSE	0
INCOME PRETAX	(6,922)
INCOME TAX	0
INCOME CONTINUING	(6,922)
DISCONTINUED	Ó
EXTRAORDINARY	0
CHANGES	0
NET INCOME	(6,922)
EPS PRIMARY	(0.34)
EPS DILUTED	(0.34)
	(3.2.1)

End of Filing



© 2005 | EDGAR Online, Inc.