-----BEGIN PRIVACY-ENHANCED MESSAGE----- Proc-Type: 2001,MIC-CLEAR Originator-Name: webmaster@www.sec.gov Originator-Key-Asymmetric: MFgwCgYEVQgBAQICAf8DSgAwRwJAW2sNKK9AVtBzYZmr6aGjlWyK3XmZv3dTlNen TWSM7vrzLADbmYQaionwg5sDW3P6oaM5D3tdezXMm7z1T+B+twlDAQAB MIC-Info: RSA-MD5,RSA, PepAiG16bFqV3zVlxgFV7FyoXoca+OZufLc6MdROzR4JM7q4/0hmue42PFTKl6se bfvNjlPdt9quuqrCE6ZspQ== 0000921895-97-000986.txt : 19971231 0000921895-97-000986.hdr.sgml: 19971231 ACCESSION NUMBER: 0000921895-97-000986 CONFORMED SUBMISSION TYPE: 424B3 PUBLIC DOCUMENT COUNT: 1 FILED AS OF DATE: 19971230 SROS: AMEX FILER: COMPANY DATA: COMPANY CONFORMED NAME: SHEFFIELD PHARMACEUTICALS INC CENTRAL INDEX KEY: 0000894158 STANDARD INDUSTRIAL CLASSIFICATION: PHARMACEUTICAL PREPARATIONS [2834] IRS NUMBER: 133808303 STATE OF INCORPORATION: DE FISCAL YEAR END: 1231 FILING VALUES: FORM TYPE: 424B3 SEC ACT: SEC FILE NUMBER: 333-38327 FILM NUMBER: 97746763 BUSINESS ADDRESS: STREET 1: 30 ROCKEFELLER PLAZA STREET 2: SUITE 4515 CITY: NEW YORK STATE: NY ZIP: 10112 BUSINESS PHONE: 2129576600 MAIL ADDRESS: STREET 1: 30 ROCKEFELLER PLAZA STREET 2: SUITE 4515 CITY: NEW YORK STATE: NY ZIP: 10112 FORMER COMPANY: FORMER CONFORMED NAME: SHEFFIELD MEDICAL TECHNOLOGIES INC DATE OF NAME CHANGE: 19940606 424B3 SB424B3

PROSPECTUS

SHEFFIELD PHARMACEUTICALS, INC.

2,893,334 SHARES OF COMMON STOCK

This Prospectus relates to the offer and resale by certain selling stockholders (collectively, the "Selling Stockholders") of (i) 2,333,334 shares (the "Debenture Conversion Shares") of common stock, \$.01 par value ("Common Stock"), of Sheffield Pharmaceuticals, Inc. (the "Company") issuable upon conversion of the Company's 6% Convertible Subordinated Debentures Due September 22, 2000 (the "Convertible Debentures"), (ii) 420,000 shares of Common Stock issuable as interest payable in lieu of cash interest on Convertible Debentures and (iii) 140,000 shares of Common Stock issuable upon the exercise of certain stock purchase warrants of the Company originally issued to the purchasers of Convertible Debentures (the "Debenture Warrants"). This Prospectus also relates, pursuant to Rule 416 promulgated under the Securities Act of 1933, as amended (the "Securities Act"), to the offer and resale by certain Selling Stockholders of an indeterminate number of shares of Common Stock that may become issuable by reason of the anti-dilution provisions of the aforementioned securities and an indeterminate number of shares of Common Stock issuable upon conversion of Convertible Debentures and in lieu of cash interest payable thereon resulting from the fluctuating conversion rate of the Convertible Debentures that is determined based upon the market price of the Company's publicly-traded Common Stock as of the date of the applicable conversion thereof. See "Description of Securities - 6% Convertible Subordinated Debentures."

The Common Stock presently trades on the American Stock Exchange (the "AMEX") under the symbol "SHM". On December 5, 1997, the closing sale price of

The Selling Stockholders, directly or through broker-dealers, may sell the Common Stock offered hereby from time to time on the AMEX or on any other securities exchange on which Common Stock is listed or in privately negotiated transactions, at fixed prices that may be changed, at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at privately negotiated prices. The Selling Stockholders and any underwriters, brokers, dealers or agents that act in connection with the sale may be deemed to be "underwriters" within the meaning of the Securities Act and any commissions received by them and any profit on the resale of securities as principal might be deemed to be underwriting discounts under the Securities Act. The Company has agreed to indemnify the Selling Stockholders and certain other persons against certain liabilities, including liabilities under the Securities Act. See "Plan of Distribution."

THE SECURITIES OFFERED HEREBY INVOLVE A HIGH DEGREE OF RISK.
THE COMPANY EXPECTS TO INCUR ADDITIONAL OPERATING LOSSES
OVER THE NEXT SEVERAL YEARS WHICH RAISES SUBSTANTIAL
DOUBT ABOUT ITS ABILITY TO CONTINUE AS A
GOING CONCERN. SEE "RISK FACTORS" AT PAGES 9 - 14 BELOW.

THESE SECURITIES HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE SECURITIES AND EXCHANGE COMMISSION OR ANY STATE SECURITIES COMMISSION NOR HAS THE COMMISSION OR ANY STATE SECURITIES COMMISSION PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

No underwriting commissions or discounts will be paid by the Company in connection with this offering. Estimated expenses payable by the Company in connection with the offering are \$105,000. The aggregate proceeds to the Selling Stockholders from the sale of the Common Stock will be the purchase price of the Common Stock sold less the aggregate agents' commissions and underwriters' discounts, if any, and other expenses of issuance and distribution not borne by the Company. See "Plan of Distribution."

No person has been authorized to give any information or to make any representations in connection with this offering other than those contained in this Prospectus and, if given or made, such other information and representations must not be relied upon as having been authorized by the Company. Neither the delivery of this Prospectus nor any sale made hereunder shall, under any circumstances, create any implication that there has been no change in the affairs of the Company since the date hereof or that the information contained herein is correct as of any time subsequent to its date. This Prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities other than the registered securities to which it relates. This Prospectus does not constitute an offer to buy such securities in any circumstances in which such offer or solicitation is unlawful.

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AVAILABLE INFORMATION

The Company is subject to the informational requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and in accordance therewith files reports, proxy statements and other information with the Securities and Exchange Commission (the "Commission"). Such reports, proxy statements and other information can be inspected and copied at the public reference facilities maintained by the Commission at Room 1024, Judiciary Plaza, 450 Fifth Street, N.W., Washington, D.C. 20549 and at the Regional Offices of the Commission at Seven World Trade Center, 13th Floor, New York, New York 10048 and Northwestern Atrium Center, 500 West Madison Street, Chicago, Illinois 60611. Copies of such material can be obtained from the Public Reference Section of the Commission at Judiciary Plaza, 450 Fifth Street, N.W., Washington, D.C. 20549, at prescribed rates. Such material may also be accessed electronically by means of the Commission's home page on the Internet at http://www.sec.gov. In

addition, reports, proxy statements and other information concerning the Company can be inspected and copied at the offices of the AMEX at 86 Trinity Place, New York, New York 10006, on which the Common Stock of the Company is listed for trading (Symbol: SHM).

The Company has filed with the Securities and Exchange Commission a Registration Statement on Form S-3 under the Securities Act with respect to the Common Stock offered hereby. For further information with respect to the Company and the securities offered hereby, reference is made to the Registration Statement. Statements contained in this Prospectus as to the contents of any contract or other document are not necessarily complete, and in each instance, reference is made to the copy of such contract or document filed as an exhibit to the Registration Statement, each such statement being qualified in all respects by such reference.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The Company incorporates by reference the following documents heretofore filed with the Commission pursuant to the Exchange Act:

- (a) Annual Report of the Company on Form 10-KSB for the fiscal year ended December 31, 1996, as amended by Amendment Nos. 1 and 2 filed with the Commission on April 16, 1997 and July 30, 1997, respectively.
- (b) Quarterly Report of the Company on Form 10-Q for the quarterly period ended March 31, 1997 as filed with the Commission, as amended by Amendment No. 1 filed with the Commission on July 31, 1997.
- (c) Quarterly Report of the Company on Form 10-Q for the quarterly period ended June 30, 1997 as filed with the Commission.
- (d) Quarterly Report of the Company on Form 10-Q for the quarterly period ended September 30, 1997 as filed with the Commission.
- (e) The description of the Common Stock and other matters set forth in the Company's Registration Statement on Form 8-B filed with the Commission on July 7, 1995.

All documents filed by the Company after the date of this Prospectus pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act, prior to the termination of this offering, are deemed to be incorporated by reference in this Prospectus and shall be deemed to be a part hereof from the date of filing of such documents. Any statement contained in a document incorporated by reference in this Prospectus shall be deemed to be modified or superseded for purposes of this Prospectus to the extent that a statement contained herein (or in any other subsequently filed document which is also incorporated by reference in this Prospectus) modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this Prospectus.

The Company hereby undertakes to provide without charge to each person to whom a copy of this Prospectus has been delivered, on the written or oral request of any such person, a copy of any or all of the documents referred to above which have been or may be incorporated in this Prospectus by reference, other than exhibits to such documents. Written requests for such copies should be directed to Sheffield Pharmaceuticals, Inc., 425 South Woodsmill Road, Suite 270, St. Louis, Missouri 63017, Attention: Loren G. Peterson, Chief Executive Officer. Oral requests should be directed to Mr. Peterson at (314) 579-9899.

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THE COMPANY

The Company is engaged in the development of proprietary prescription pharmaceutical products targeted at patient markets with unmet medical needs over a range of therapeutic areas. The Company's strategy is to focus its resources on later stage projects that have a more rapid and predictable path to marketing approval. The Company's objective is to be a specialty pharmaceutical company that develops and markets its own proprietary products. The principal elements of the Company's business strategy consist of the following: (i) the acquisition of opportunities with unrealized commercial potential that address unmet medical needs and require only later stage development prior to regulatory approval; (ii) a focus initially on segments of the large, rapidly growing respiratory market, which includes certain chronic diseases requiring long-term therapy; (iii) the development of proprietary formulations of currently approved pharmaceutical compounds, which can reduce regulatory and development risks typically associated with the development of new chemical entities; (iv) the management of the clinical development and regulatory approval of its products that will be performed by clinical research organizations or organizations with similar development capabilities; (v) the contracting for the manufacture of its products by pharmaceutical manufacturers with a history of producing cost effective, high quality, U.S. Food and Drug Administration ("FDA") compliant products; and (vi) the marketing of its products directly through the Company's specialty sales force that will be built at such time as opportunities warrant.

As of the date of this Prospectus, the Company has acquired certain development and marketing rights in the following technologies:

MULTI-DOSE INHALER (MSI). The Company holds exclusive worldwide license rights to a multi-dose inhaler of Siemens AG (the "MSI Inhaler"). The MSI Inhaler is a drug delivery system that allows for the administration of a range of drugs to the lungs for asthma, chronic obstructive pulmonary disease and other respiratory diseases. In addition, the MSI Inhaler's delivery system may find application in the treatment of non-respiratory illnesses that may be treated by drug deliveries to the lungs. The Company plans to develop drug formulations for use with the MSI Inhaler.

ION PHARMACEUTICALS, INC. TECHNOLOGIES. The Company, through Ion Pharmaceuticals, a Delaware corporation and a wholly-owned subsidiary of the Company ("Ion"), holds exclusive worldwide license rights to certain compounds and their uses for the treatment of conditions characterized by unregulated cell proliferation or cell growth and sickle cell anemia (collectively, the "Ion")

Pharmaceuticals Technologies"). Ion's intellectual property portfolio consists of clotrimazole, its metabolites, and a number of proprietary new chemical entities co-owned by Ion termed the Trifens(TM). Such compounds have demonstrated promise in therapeutic applications for treating a number of conditions characterized by unregulated cell proliferation, such as cancer (including multiple drug resistant cancer) and certain dermatological conditions, as well as sickle cell anemia and secretory diarrhea.

RBC-CD4 ELECTROINSERTION TECHNOLOGY. The Company is the worldwide licensee of certain technology (the "RBC-CD4 Electroinsertion Technology") relating to the electroinsertion of full-length CD4 protein into the red blood cell membrane ("RBC-CD4") for use as a therapeutic in the treatment of the human immunodeficiency virus ("HIV") that leads to Acquired Immune Deficiency Syndrome ("AIDS"). The electroinsertion process inserts CD4, the protein that serves as the binding site of the HIV virus, into red blood cells. This altered cell complex acts as a decoy and is designed to cleanse the blood of infection by binding to and removing the HIV virus from circulation before it can infect other cells in the human immune system. The related Phase I/IIA clinical trial was conducted by The Johns Hopkins University Medical Center.

LIPOSOME-CD4 TECHNOLOGY. The Company is the worldwide licensee of certain technology (the "Liposome- CD4 Technology") relating to the incorporation of CD4 antigens into liposome bilayers and their use as a therapeutic agent in the treatment of HIV and AIDS. While RBC-CD4 Electroinsertion Technology is being developed by the Company to target HIV and HIV-infected cells in the blood, Liposome-CD4 Technology is being developed by the

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Company's exclusive sublicensee, Sequus Pharmaceuticals, to target infections in the human lymphatic system, a major reservoir for infection not reached by blood circulation.

HIV/AIDS VACCINE. The Company holds an exclusive worldwide license to a potential HIV/AIDS vaccine and diagnostic developed by Professor Jean-Claude Chermann, one of the original Pasteur Institute discoverers of HIV. The vaccine concept developed by Professor Chermann utilizes a cellular antigen that is incorporated into the membrane surface of HIV after the HIV virus has reproduced buds from infected cells. This cellular antigen does not appear to vary across the various strains of the virus and may provide a stable target to develop antibodies that can prevent infection. The Company believes this approach may also protect against both blood-born and sexual transmission of HIV. The Company's goal is to develop an oral formulation that would make the vaccine potentially less costly and easier to distribute to a broad population.

UGIF TECHNOLOGY. The Company holds an exclusive worldwide license to a potential prostate cancer therapy. The related technology focuses on a urogenital sinus derived growth inhibitory factor that may inhibit the growth of transformed cells and tumors in the human prostate. The related research has been conducted by scientific and medical investigators affiliated with Baylor College of Medicine and headed by Dr. David R. Rowley.

MEMBRANE ATTACK COMPLEX (MAC)/COMPLEMENT TECHNOLOGY. The Company holds exclusive worldwide license rights to certain membrane attack complex

(MAC)/complement technology relating to the loading of therapeutic and diagnostic molecules into cells. Through the use of certain complement proteins, pores or channels can be formed in various cell membranes, allowing a pathway for the entry of molecules of various sizes into such cells. This technology could provide for the selective delivery of various therapeutic and diagnostic agents to target, I.E., cancer cells or viruses. The related research has been conducted by scientific and medical investigators affiliated with Harvard Medical School and headed by Dr. Jose Halperin.

The Company's research and development of its technologies are at various stages of progress. The Company's research and development activities to date have not resulted in a commercial product. Most of the Company's technologies are at early stages of research and development and are at least several years away from receiving FDA approval or from commercialization. Management currently believes its MSI Inhaler will be its first technology to receive FDA approval, which approval is currently estimated to be received in approximately three to four years. However, there can be no assurance that any of the Company's technologies will receive final approval from the FDA or will result in a commercialized product.

The table below indicates (i) the Company's direct research and development expenses by project for the nine months ended September 30, 1997, for the fiscal year ended December 31, 1996 and from the Company's inception to September 30, 1997, (ii) the Company's current estimate by project of committed and/or anticipated funding requirements after September 30, 1997 and (iii) revenues received to date by project.

DIRECT RESEARCH AND DEVELOPMENT EXPENSES (IN DOLLARS)

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| | | | COMMITTED | | | | | | | |
|---------------------------------|------------------------|-----------------------|----------------------|-----------------------|--------------------|--|--|--|--|--|
| | AND/OR | | | | | | | | | |
| NINE | | | | ITICIPATED | | | | | | |
| MONTHS FISCAL YEAR | | | | R&D FUNDING | | | | | | |
| ENDED | ENDE | D INCEP | TION TO | AFTER | REVENUE | | | | | |
| R&D PROJECT 9/ | /30/97 1 | 2/31/96 | 9/30/97 | 9/30/97* | RECEIVED | | | | | |
| | | | | | | | | | | |
| Marile: Dana India dan (MCI) | 454504 | 1.1.1.100 | 4.647.427 | 45 402 00 | .0 | | | | | |
| Multi-Dose Inhaler (MSI) | • | 144,409 | 1,617,127 | 15,102,0 0 | | | | | | |
| Ion Pharmaceuticals, | 220,528 | 2,097,020 | 4,819,711 | 93,000 | 10,000 | | | | | |
| -Inc. Technologies | | | | | | | | | | |
| RBC-CD4 Electroinsertion | 1 -0- | 515,036 | 6,254,185 | -0- | -0- | | | | | |
| | | -Technology | | | | | | | | |
| Liposome-CD4 Technology | -0- | 60,449 | 2,322,322 | -0- | 500,000 | | | | | |
| HIV/AIDS Vaccine | 12,500 | 414,849 | 1,211,618 | 137,500 | -0- | | | | | |
| UGIF Technology | 20,018 | 16,398 | 223,437 | 20,000 | -0- | | | | | |
| Membrane Attack Complex | < 60,936 | 5 121,87 4 | 4 365,61 | 8 -0- | | | | | | |
| -(MAC)/Complement | | | | | | | | | | |
| -Technology | | | | | | | | | | |

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* These amounts constitute management's estimate of anticipated direct R&D expenses as of the date of this Prospectus. The amounts and rate of application of the Company's funds to any particular project are expected to fluctuate and will depend in part on the Company's successful completion of various stages of research, the availability of additional financing and the Company's identification and acquisition of rights in new technologies in the future.

The Company is a party to license agreements pursuant to which the Company has obtained worldwide exclusive licenses to its technologies. Each of these license agreements require the Company to pay the licensors royalties on proceeds received by the Company from the commercialization of related products. The royalty rates payable by the Company under these license agreements generally range from 3.75% to 50% of gross compensation received by the Company in respect of related commercialized product. These license agreements also require the Company to develop the related technology and grant the Company the right, under certain circumstances, to sublicense the related technologies. In addition, the Company is a party to a sublicense agreement with Sequus Pharmaceuticals, Inc. ("Sequus") pursuant to which the Company has granted Sequus an exclusive sublicense to develop and commercialize its Liposome CD-4 Technology. The sublicense agreement requires Seguus to pay the Company royalties in varying amounts on proceeds received by Sequus in connection with commercialization of the related technology by Sequus. The amount of interest that the Company will maintain in a particular technology is a factor of the amount of net income retained by the Company after payment of royalties payable by the Company to the related technology licensor and any related third party contractors (E.G., research institutions or private companies) and the amount of royalties received by the Company from any sublicensees of the technology, which retained amount of interest will vary among each of the Company's technologies.

The Company was organized under Canadian law in October 1986 as Sheffield Strategic Metals, Inc. The Company commenced operations in the United States in January 1992. Effective May 19, 1992, Sheffield Pharmaceuticals, Inc. became domesticated as a Wyoming corporation without reincorporation pursuant to a "continuance" procedure under Wyoming corporation law. On June 13, 1995, the Company changed its state of incorporation to Delaware by means of a merger with and into a newly-formed wholly-owned Delaware subsidiary of the Company. Such merger and the resulting change of the Company's state of incorporation to Delaware was approved by the Company's stockholders in January 1995. The Company

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changed its name from "Sheffield Medical Technologies Inc." to "Sheffield Pharmaceuticals, Inc." effective June 27, 1997. Unless the context otherwise indicates, the "Company" as used herein means Sheffield Pharmaceuticals, Inc., its predecessors and its wholly-owned subsidiaries Ion and CP Pharmaceuticals, Inc.

The Company's headquarters are located at 425 South Woodsmill Road, Suite 270, St. Louis, Missouri 63017 and its telephone number is (314) 579-9899.

RISK FACTORS

PURCHASERS SHOULD BE AWARE THAT THE PURCHASE OF SUCH SECURITIES INVOLVES A HIGH DEGREE OF RISK. IN ADDITION TO OTHER INFORMATION IN THIS PROSPECTUS, THE FOLLOWING FACTORS SHOULD BE CONSIDERED CAREFULLY IN EVALUATING THE COMPANY BEFORE PURCHASING THE SECURITIES OFFERED HEREBY. THIS PROSPECTUS CONTAINS FORWARD- LOOKING STATEMENTS WHICH INVOLVE RISKS AND UNCERTAINTIES. THE COMPANY'S ACTUAL RESULTS COULD DIFFER MATERIALLY FROM THOSE ANTICIPATED IN THESE FORWARD-LOOKING STATEMENTS AS A RESULT OF CERTAIN FACTORS, INCLUDING THOSE SET FORTH IN THE FOLLOWING RISK FACTORS AND ELSEWHERE IN THIS PROSPECTUS.

DEVELOPMENT STAGE COMPANY; HISTORY OF OPERATING LOSSES AND ACCUMULATED DEFICIT; GOING CONCERN OPINION

The Company is in the development stage. The Company commenced its biotechnology operations in the United States in January 1992 through a wholly-owned subsidiary to acquire, develop and commercialize what it believed to be promising medical technologies. On January 10, 1996, Ion was formed as a wholly-owned subsidiary of the Company. At that time, Ion acquired the Company's rights to the Company's anti-proliferative technology. The Company has been principally engaged to date in research funding and licensing efforts, and has experienced significant operating losses. The Company experienced operating losses of \$7,008,889 and \$7,978,323 for the fiscal year ended December 31, 1996 and for the nine months ended September 30, 1997, respectively, and as of September 30, 1997, the Company had an accumulated deficit of \$34,680,075. The independent auditors' report dated February 12, 1997, except for Note 9 as to which the date is March 14, 1997, on the Company's consolidated financial statements stated that the Company has generated only minimal operating revenue, has incurred recurring operating losses and requires additional capital and that these conditions raise substantial doubt about its ability to continue as a going concern. The Company expects that it will continue to have a high level of operating expenses and will be required to make significant up-front expenditures in connection with license and development agreements with independent companies, universities and other institutions for research and development and product development activities. As a result, the Company anticipates significant additional operating losses for 1997 and that such losses will continue thereafter until such time, if ever, as the Company is able to generate sufficient revenues to sustain its operations.

The Company's ability to achieve profitable operations is dependent in large part on regulatory approvals of its products and technologies and on its ability to enter into manufacturing and marketing agreements with other pharmaceutical, biomedical or medical companies. There can be no assurance that the Company will ever achieve profitable operations.

SIGNIFICANT LIQUIDITY RESTRAINTS

The Company's cash available for funding its operations as of September 30, 1997 was \$1,005,106. As of such date, the Company had trade payables and accrued liabilities of \$797,001, current research obligations of \$135,037 and other liabilities of \$144,487. In addition, the Company is obligated to fund between September 30, 1997 and September 30, 1998 approximately \$1,850,000 in the

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additional funds for its business through operations or equity or debt financings, collaborative arrangements with corporate partners or from other sources. No assurance can be given that these funds will be available for the Company to finance its development on acceptable terms, if at all. If adequate funds are not available from operations or additional sources of funding, the Company's business will suffer a material adverse effect. As of the date of this Prospectus there were 25,500 shares of the Company's Series A Cumulative Convertible Redeemable Preferred Stock (the "Series A Preferred Stock") issued and outstanding. The Series A Preferred Stock is redeemable by holders for \$125 per share in the event of (i) any reclassification or change of outstanding shares of Common Stock issuable upon Conversion of Series A Preferred Stock (other than a change in par value), (ii) any consolidation or merger to which the Company is a party other than a merger in which the Company is the continuing corporation and which does not result in any reclassification of, or certain changes in, outstanding shares of Common Stock or (iii) any sale or conveyance of all or substantially all of the property or business of the Company as an entirety. In addition, upon the occurrence of certain changes of control, Series A Preferred Stock holders may redeem their shares of Series A Preferred Stock for an amount per share equal to the greater of (a) \$125 and (b) the product of the aggregate number of shares of Common Stock into which a share of Series A Preferred Stock is otherwise convertible on the date preceding the change of control multiplied by the then current market price of a share of Common Stock.

NEED FOR ADDITIONAL FINANCING

Since the Company does not expect to generate substantial revenues from the sale of any products or technologies in the immediate future, the Company will require substantial additional funds from other sources to complete its research and development, to conduct additional clinical tests and to establish manufacturing and marketing relationships with pharmaceutical, biomedical or medical companies. The Company will attempt to acquire funds for these purposes through operations, additional equity or debt financings, collaborative arrangements with corporate partners or from other sources. Management estimates that, based on the status of the Company's current projects, the Company will require \$8,000,000 to satisfy its cash requirements for research and development and \$3,100,000 to satisfy its cash requirements for general and administrative costs during the next twelve months. The Company is currently in discussions with various parties that may be interested in providing the Company with financing but, as of the date of this Prospectus, no commitment has been received from potential sources of additional funding. No assurance can be given that these funds will be available for the Company to finance its development on acceptable terms, if at all. If adequate funds are not available from operations or additional sources of funding, the Company's business will suffer a material adverse effect.

LONG TERM DEVELOPMENT OF TECHNOLOGIES; NO COMMERCIALIZATION OF PRODUCTS TO DATE

The Company has not yet begun to generate revenues from the sale of products or technologies. The Company is funding research that began, in some cases, many years before the Company acquired rights in such projects. The Company's products and technologies will require significant additional development, laboratory and clinical testing and investment prior to commercialization. The Company does not expect regulatory approval for commercial sales of any of its products or technologies in the immediate future. There can be no assurance that such products or technologies will be

successfully developed, prove to be safe and efficacious in clinical trials, meet applicable regulatory standards, obtain required regulatory approvals, be capable of being produced in commercial quantities at reasonable costs or be successfully commercialized and marketed.

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ROYALTY PAYMENT OBLIGATIONS

The owners and licensors of the technology rights acquired by the Company are entitled to receive up to 50% of all royalties and payments in lieu of royalties received by the Company from commercialization, if any, of products in respect of which the Company holds licenses. Accordingly, in addition to its substantial investment in research and development of technologies, the Company will be required to make substantial payments to others in connection with revenues derived from commercialization of products, if any, in respect of which the Company holds licenses. Consequently, the Company will not receive the full amount of any revenues that may be derived from commercialization of products derived from the Company's technologies to fund ongoing operations.

POTENTIAL LOSS OF RIGHTS UPON DEFAULT

Under the terms of existing agreements, the Company is obligated to make periodic installments to finance research and development activities according to specified budgets. The Company is obligated to fund approximately \$1,850,000 in the aggregate under existing agreements during the twelve-month period following September 30, 1997. In the event that the Company defaults in the payment of an installment under the terms of an existing licensing agreement, its rights thereunder could be forfeited. As a consequence, the Company could lose all rights under a license agreement to the related licensed technology, notwithstanding the total investment made through the date of the default. There can be no assurance that unforeseen obligations or contingencies will not deplete the Company's financial resources and, accordingly, the Company's resources may not be available to fulfill the Company's commitments.

DEPENDENCE ON PRINCIPAL INVESTIGATORS

The Company is dependent upon the active participation of its principal investigators in the advancement of the research and development associated with their related projects. The loss of a principal investigator, particularly in the early stages of the development of a technology, could have a material adverse effect on the related project and the Company's prospects. To date, the Company has not suffered the loss of any of its principal investigators on any projects that are under active development.

RAPID TECHNOLOGICAL CHANGE; COMPETITION

The medical research field is subject to rapid technological change and innovation. Pharmaceutical and biomedical research and product development are rapidly evolving fields in which developments are expected to continue at a rapid pace. Reports of progress and potential breakthroughs are occurring with increasing frequency. There can be no assurance that the Company will have a competitive advantage in its fields of technology or in any of the other fields in which the Company may concentrate its efforts.

The Company's success will depend upon its ability to develop and maintain a competitive position in the research, development and commercialization of products and technologies in its areas of focus. Competition from pharmaceutical, chemical, biomedical and medical companies, universities, research and other institutions is intense and is expected to increase. All, or substantially all, of these competitors have substantially greater research and development capabilities, experience, and manufacturing, marketing, financial and managerial resources. Further, acquisitions of competing companies by large pharmaceutical or other companies could enhance such competitors' financial, marketing and other capabilities. There can be no assurance that developments by others will not render the Company's products or technologies obsolete or not commercially viable or that the Company will be able to keep pace with technological developments.

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GOVERNMENT REGULATION

The Company's ongoing research and development projects are subject to rigorous FDA approval procedures. The preclinical and clinical testing requirements to demonstrate safety and efficacy in each clinical indication (the specific condition intended to be treated) and regulatory approval processes of the FDA can take a number of years and will require the expenditure of substantial resources by the Company. Delays in obtaining FDA approval would adversely affect the marketing of products to which the Company has rights and the Company's ability to receive product revenues or royalties. Moreover, even if FDA approval is obtained, a marketed product, its manufacturer and its manufacturing facilities are subject to continual review and periodic inspections by the FDA, and a later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on such product or manufacturer. Failure to comply with the applicable regulatory requirements can, among other things, result in fines, suspensions of regulatory approvals, product recalls, operating restrictions and criminal prosecution. Additional government regulation may be established which could prevent or delay regulatory approval of the Company's products. Sales of pharmaceutical products outside the United States are subject to foreign regulatory requirements that vary widely from country to country. Even if FDA approval has been obtained, approval of a product by comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing the product in those countries. The time required to obtain such approval may be longer or shorter than that required for FDA approval. The Company has no experience in manufacturing or marketing in foreign countries nor in matters such as currency regulations, import-export controls or other trade laws. To date, the Company has not received final regulatory approval from the FDA or any other comparable foreign regulatory authority in respect of any product or technology. Management currently believes that its MSI Inhaler will be its first technology to receive final FDA approval, which approval is currently estimated to be received in approximately three to four years; however, there can be no assurance that such approval will be granted by the FDA.

RISKS INCIDENT TO PATENT APPLICATIONS AND RIGHTS

The Company's success will depend in part on its ability to obtain

patent protection for products and processes and to maintain trade secret protection and operate without infringing the proprietary rights of others. The degree of patent protection to be afforded to pharmaceutical, biomedical or medical inventions is an uncertain area of the law. There can be no assurance that the Company will develop or receive sublicenses or other rights related to proprietary technology which are patentable, that any patents pending will issue, or that any issued patents will provide the Company with any competitive advantages or will not be challenged by third parties. Furthermore, there can be no assurance that others will not independently duplicate or develop similar technologies to those developed by or licensed to the Company.

The Company supports and collaborates in research conducted at universities and other institutions. There can be no assurance that the Company will have or be able to acquire exclusive rights to inventions or technical information derived from such collaborations or that disputes will not arise as to such exclusive rights or any derivative or related research programs. If the Company is required to defend against charges of patent infringement or to protect its own proprietary rights against third parties, substantial costs will be incurred and the Company could lose rights to certain products and technologies.

RELIANCE ON THIRD PARTIES; NO MARKETING OR MANUFACTURING CAPABILITIES

The Company does not intend to manufacture or market products it may develop using its technologies. The Company will attempt to enter into manufacturing and marketing agreements with one or more established pharmaceutical, biomedical and medical companies for any products that are developed. There can be no assurance that other pharmaceutical, biomedical or

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medical companies will be interested in the Company's products or technologies or be willing to enter into manufacturing or marketing agreements on terms acceptable to the Company. Further, there can be no assurance that pharmaceutical, biomedical or other medical companies will succeed in manufacturing and marketing the Company's products or technologies or that the Company will derive revenues from its products or technologies.

DEPENDENCE UPON OBTAINING HEALTHCARE REIMBURSEMENT

The Company's ability to commercialize human therapeutic and diagnostic products may indirectly depend in part on the extent to which costs for such products and technologies are reimbursed by private health insurance or government health programs. The uncertainty regarding reimbursement may be especially significant in the case of newly approved products. There can be no assurance that price levels will be sufficient to provide a return to the Company on its investment in new products and technologies.

ADEQUACY OF PRODUCT LIABILITY INSURANCE

The use of the Company's proposed products and processes during testing, and after approval, may entail inherent risks of adverse effects which could expose the Company to product liability claims. Product liability claims could have a material adverse effect on the business and financial condition of the Company. The Company plans to obtain, and plans to require its licensees to

obtain, product liability insurance at an appropriate stage of product development and commercialization. There can be no assurance that the Company and its licensees will be able to maintain or obtain adequate product liability insurance on acceptable terms or that such insurance will provide adequate coverage against all potential claims.

VOLATILITY OF MARKET PRICE OF SECURITIES

The market price of securities of firms in the biotechnology industry has tended to be volatile. Announcements of technological innovations by the Company or its competitors, developments concerning proprietary rights and concerns about safety and other factors may have a material adverse effect on the Company's business or financial condition. The market price of the Common Stock may be significantly affected by announcements of developments in the medical field generally or the Company's research areas specifically. The stock market has experienced volatility in market prices of companies similar to the Company that has often been unrelated to the operating results of such companies. This volatility may have a material adverse effect on the market price of the Common Stock.

OUTSTANDING OPTIONS AND WARRANTS; DILUTION

As of September 30, 1997, the Company had reserved approximately 4,515,000 shares of Common Stock for issuance upon exercise of outstanding options and warrants, including shares of Common Stock issuable upon the exercise of options and warrants held by officers and directors of the Company. The Company has filed registration statements with the Commission covering the resale of substantially all of the shares of Common Stock underlying such options and warrants. The exercise of options and outstanding warrants and sales of Common Stock issuable thereunder could have a significant dilutive effect on the market price of shares of Common Stock and could materially impair the Company's ability to raise capital through the future sale of its equity securities.

NO DIVIDENDS

Holders of Common Stock are entitled to receive such dividends as may be declared by the Board of Directors of the Company. To date, the Company has not declared or paid any dividends on its Common Stock, and the Company does not anticipate paying cash dividends in the foreseeable future. Rather, the Company

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intends to apply any earnings to the expansion and development of its business.

AUTHORIZATION OF SERIES A PREFERRED STOCK

The Company's Certificate of Incorporation authorizes the issuance of "blank check" preferred stock with such designations, rights and preferences as may be determined from time to time by the Board of Directors, without shareholder approval. In the event of issuance, such preferred stock could be utilized, under certain circumstances, as a method of discouraging, delaying or preventing a change in control of the Company and preventing shareholders from receiving a premium for their shares in connection with a change of control. Except for the issuance of shares of Series A Preferred Stock that occurred in

connection with the consummation of a private placement in February 1997, the Company has no present intention to issue any shares of its preferred stock; however, there can be no assurance that the Company will not issue additional shares of its preferred stock in the future.

EXERCISE OF SERIES A WARRANTS AND CONVERSION OF SERIES A CUMULATIVE CONVERTIBLE REDEEMABLE PREFERRED STOCK

As of the date of this Prospectus, there are 25,500 shares of Series A Preferred Stock outstanding that are convertible into shares of Common Stock. See "Selling Stockholders." Each share of Series A Preferred Stock earns a cumulative dividend payable in shares of Common Stock at a rate per share equal to 7.0% per annum of the original \$100.00 purchase price per share of the Series A Preferred Stock. Cumulative stock dividends on shares of Series A Preferred Stock are payable at the time of conversion. Each share of Series A Preferred Stock may be converted after May 29, 1997 at varying rates of conversion. The conversion rate on Series A Preferred Stock will be adjusted, and the number of shares beneficially owned by the holders thereof will vary, to reflect changes in the market price of the Common Stock, stock dividends, stock splits and certain other circumstances. For a further description of the rights of holders of Series A Preferred Stock, see the Certificate of Designation of Series A Cumulative Convertible Redeemable Preferred Stock filed as an exhibit to the Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1996. Holders of Series A Preferred Stock also hold warrants (the "Series A Warrants") entitling such holders to acquire a total of 351,539 shares of Common Stock at an exercise price of \$3.65 per share, subject to adjustment upon the occurrence of certain events. The exercise of Series A Warrants, the conversion of shares of Series A Preferred Stock and the subsequent sale of such shares of Common Stock issuable upon such exercise and conversion could have a significant negative effect on the market price of the Common Stock and could materially impair the Company's ability to raise capital through the future sale of equity securities.

USE OF PROCEEDS

The Company will receive a total of \$392,000 in the event that all shares of Common Stock offered hereby that are issuable upon exercise of the Debenture Warrants have been issued upon such exercise. The Company anticipates that the net proceeds will be used as to fund the research and development relating to the MSI Inhaler and for working capital and general corporate purposes of the Company, including the possible acquisitions of rights in new drug development opportunities. The amounts and rate of application of such net proceeds will be subject, among other things, to successful completion of the various stages of research of each of the Company's research projects and the Company's identification and acquisition of rights in new technologies after the date of this Prospectus, which amounts and rate cannot be precisely determined at this time. Until such proceeds are fully used, the Company intends to invest such proceeds in investment grade, short-term interest-bearing obligations or U.S. government obligations. The Company will not receive any proceeds from the offer and resale of the Common Stock offered hereby.

Holders of Common Stock are entitled to receive such dividends as may be declared by the Board of Directors of the Company. The Company presently intends to retain earnings, if any, for use in its business and does not anticipate paying dividends (other than stock dividends payable on shares of Series A Preferred Stock) on its outstanding capital stock in the foreseeable future. Future payments of cash dividends will depend upon the financial condition, results of operations and capital requirements of the Company as well as other factors deemed relevant by the Board of Directors.

RECENT DEVELOPMENTS

On April 25, 1997, Camelot Pharmacal, L.L.C., a Missouri limited liability company ("Camelot"), merged with and into CP Pharmaceuticals, Inc., a newly formed subsidiary of the Company. The principals of Camelot at the time of the merger were Loren G. Peterson, Carl F. Siekmann and David A. Byron. Pursuant to the related agreement and plan of merger, Messrs. Peterson, Siekmann and Byron each received 200,000 shares of Common Stock. The 200,000 shares of Common Stock were issued pursuant to the exemption from registration under Section 4(2) of the Securities Act. Each of Messrs. Peterson, Siekmann and Byron executed agreements in which they represented that they were "accredited investors" and had been given the opportunity to meet with Company management and to receive such documentation relating to the Company's operations and financial condition as they deemed necessary. Following the consummation of the merger, each of Messrs. Peterson, Siekmann and Byron entered into employment agreements with Sheffield and received stock options providing each individual the right to purchase up to 400,000 shares of Common Stock. The Company has agreed to reimburse Messrs. Peterson, Siekmann and Byron upon the occurrence of certain events for certain income taxes payable by them upon exercise of their stock options in an amount of up to \$250,000 per person. At the time of the merger, Anthony B. Alphin, Jr., Bernard Laurent, Stephen Sohn and Michael Zeldin resigned as Directors of the Company and Mr. Peterson was elected a Director of the Company.

In May 1997, the Company reported findings from its Phase I/II clinical trial to assess the safety and antiviral activity of a single infusion of the Company's HIV/AIDS therapeutic, RBC-CD4. The trial, conducted in 19 HIV-infected subjects, had as its primary objectives to confirm the previously reported long half-life for RBC-CD4 and to measure safety and tolerability with a secondary objective to assess activity of a single dose of RBC-CD4. Study results confirmed the half-life of RBC-CD4 and the related safety data indicated that RBC-CD4 was safe and well-tolerated by the HIV-infected patients. The secondary objective of the trial was to assess the activity of two dose levels of RBC-CD4 in HIV-infected patients. The outcome measures suggest that little sustained activity was seen from a single infusion of RBC-CD4 at either of the two doses. The data suggests that the frequency of a positive response, when reported, was greater at the early time points. It should be emphasized that RBC-CD4 in this study was evaluated as a single-dose monotherapy. The Company also announced at such time its intention to seek a partner for the RBC-CD4 technology.

On September 22, the private placement of \$1,750,000 of Convertible Debentures was consummated. The Company received net proceeds of \$1,600,000 in such private placement. See "Description of Securities - 6% Convertible Subordinated Debentures" below.

On December 3, 1997, Ion entered into assignment and license agreements with a subsidiary of Immutec Pharma Inc. Pursuant to these agreements, Ion assigned and granted license rights to a series of compounds for the treatment of cancer, Kaposi's sarcoma and actinic keratosis for which Immutec Pharma will provide funding and management of the development program.

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SELLING STOCKHOLDERS

Set forth below is information at October 15, 1997 concerning the beneficial ownership of Common Stock of each of the Selling Stockholders who are offering shares of Common Stock in this offering.

| | Shares Beneficially Owned Prior to Offering(1)(2) | | Shares to be Sold in Offering | | Shares Beneficially Owned After Offering(3) | |
|---|---|--------------------------------|-------------------------------------|----------------------|---|---------|
| NAME(1) | NUMBER | PERCEN | T | NUN | MBER | PERCENT |
| The Shaar Group Ltd. Shaar Advisory Service | 946,515 es Ltd. 108,5 | (4)(5) 518(4)(6) | 7.0% | 2,595,734 297,600 | — ———————————————————————————————————— | * |

- * Less than 1%.
- (1) The persons named in the table, to the Company's knowledge, have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to community property laws where applicable and the information contained in the footnotes hereunder.
- (2) Determined in accordance with Rule 13-3(d) of the Exchange Act.
- (3) Assumes all shares of Common Stock offered hereby are sold pursuant to the registration statement of which the prospectus constitutes a part.
- (4) The number of shares of Common Stock issuable upon conversion of Convertible Debentures and in respect of interest in lieu of cash issuable thereon will vary based upon the market value of the Company's publicly-traded Common Stock prior to the date of conversion. For a description of the method of determining the number of shares of Common Stock issuable upon conversion of shares of Convertible Debentures, see "Description of Securities - Convertible Debentures." Consequently, due to the fluctuating conversion rate of the Convertible Debentures, the number of shares of Common Stock that a holder of Convertible Debentures may receive upon conversion or in lieu of cash interest may exceed the number of shares of Common Stock such holder beneficially owns as determined pursuant to Section 13-3(d) of the Exchange Act. For purposes of the disclosure of Shares Beneficially Owned Prior to Offering, it has been assumed (i) that the applicable conversion price will be \$1.9125 (calculated in accordance with the applicable terms of the Convertible Debentures as of the date of issuance of the

Convertible Debentures on September 22, 1997), (ii) that all Convertible Debentures beneficially owned by the Selling Stockholder are converted into shares of Common Stock at such conversion price in accordance with the applicable terms of the Convertible Debentures, (iii) that all Debenture Warrants beneficially owned by the Selling Stockholder have been exercised for shares of Common Stock and (iv) that no shares of Common Stock have been issued to holders of Convertible Debentures in lieu of cash interest thereon. For purposes of the disclosure of Shares Beneficially Owned After the Offering, it has been assumed that the applicable Selling Stockholder (x) has converted all Convertible Debentures beneficially owned by it into shares of Common Stock and has received no Common Stock issuable in lieu of cash interest on such Convertible Debentures, (y) has exercised all Debenture Warrants beneficially owned by it and (z) has sold all such shares of Common Stock received by it.

- (5) Consists of (i) 820,915 shares of Common Stock issuable upon conversion of Conversion Debentures and (ii) 125,600 shares of Common Stock issuable upon exercise of Debenture Warrants.
- (6) Consists of (i) 94,118 shares of Common Stock issuable upon conversion of Convertible Debentures and (ii) 14,400 shares of Common Stock issuable upon exercise of Debenture Warrants.

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DESCRIPTION OF SECURITIES

The Company is currently authorized to issue 30,000,000 shares of Common Stock, \$.01 par value per share, of which 12,604,770 shares were issued and outstanding on the date of this Prospectus, and 3,000,000 shares of preferred stock, \$.01 par value per share, of which 25,500 shares of Series A Preferred Stock were issued and outstanding on the date of this Prospectus.

COMMON STOCK

Holders of shares of Common Stock are entitled to one vote per share on all matters to be voted on by shareholders and do not have cumulative voting rights. Subject to the rights of holders of outstanding shares of Series A Preferred Stock and other holders of preferred stock of the Company, if any, the holders of Common Stock are entitled to receive such dividends, if any, as may be declared from time to time by the Board of Directors in its discretion from funds legally available therefor, and upon liquidation or dissolution, are entitled to receive all assets available for distribution to the shareholders. The Common Stock has no preemptive or other subscription rights, and there are no conversion rights of redemption or sinking fund provisions with respect to such shares. All of the outstanding shares of Common Stock are fully paid and nonassessable.

PREFERRED STOCK

The Board of Directors is authorized to issue the preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions, including the dividend rights, conversion rights, voting rights, rights and terms of redemption, redemption price or prices, liquidation preferences and the number of shares constituting any series or the designations of such series, without any further vote or action by the stockholders. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of the Company without further actions of the stockholders. The issuance of preferred stock with voting and conversion rights may adversely affect the voting power of the holders of Common Stock, including the loss of voting control to others.

SERIES A PREFERRED STOCK

THE DESCRIPTION OF THE SERIES A PREFERRED STOCK PROVIDED BELOW IS QUALIFIED IN ITS ENTIRETY BY THE RELATIVE RIGHTS, PREFERENCES, PRIVILEGES, POWERS AND RESTRICTIONS OF THE SERIES A PREFERRED STOCK SET FORTH IN THE FORM OF CERTIFICATE OF DESIGNATION FOR THE SERIES A PREFERRED STOCK INCLUDED IN EXHIBIT 4.2 TO THE COMPANY'S ANNUAL REPORT ON FORM 10-KSB FOR THE FISCAL YEAR ENDED DECEMBER 31, 1996, WHICH IS INCORPORATED BY REFERENCE INTO THIS PROSPECTUS.

There are 25,500 shares of Series A Preferred Stock outstanding as of the date of this Prospectus. Holders of Series A Preferred Stock have the right, exercisable commencing May 29, 1997 and ending February 28, 1999, to convert shares of Series A Preferred Stock into shares of Common Stock. The number of shares of Common Stock issuable upon conversion of Series A Preferred Stock will equal the number of shares of Series A Preferred Stock to be so converted multiplied by a fraction, the numerator of which is 100 and the denominator of which shall equal (a) \$3.31875 in respect of conversions occurring on or before June 27, 1997, (b) the lesser of (i) \$3.31875 and (ii) the "current market price" per share of Common Stock as of the applicable conversion date in respect of conversions occurring from June 28, 1997 to and including August 26, 1997 and (c) the lesser of (i) \$3.31875 and (ii) 85% of the "current market price" per share of Common Stock as of the applicable conversion date in respect of conversions occurring after August 26, 1997, where "current market price" means, with certain exceptions, the average of the closing bid prices of Common Stock for the 10 consecutive trading days ending the last trading day before the applicable conversion date. Each share of Series A Preferred Stock earns a cumulative dividend payable in shares of Common Stock at a rate per share equal to 7.0% of the original \$100 purchase price per share of the Series A Preferred Stock. Accrued stock dividends payable in respect of the Series A Preferred Stock are payable at the time of conversion. Under certain circumstances, cash is payable to holders of Series A Preferred Stock in lieu of Common Stock.

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The Series A Preferred Stock is redeemable by holders for \$125 per share in the event of (i) any reclassification or change of outstanding shares of Common Stock issuable upon conversion of Series A Preferred Stock (other than a change in par value), (ii) any consolidation or merger to which the Company is a party other than a merger in which the Company is the continuing corporation and which does not result in any reclassification of, or change (other than a change in name, or par value, or from par value to no par value, or from no par value to par value, or as a result of a subdivision or combination) in, outstanding shares of Common Stock or (iii) any sale or conveyance of all or substantially all of the property or business of the Company as an entirety. In addition, upon the occurrence of a Change of Control, Series A Preferred Stock holders may redeem their shares of Series A Preferred Stock for an amount per

share equal to the greater of (a) \$125 and (b) the product of the aggregate number of shares of Common Stock into which a share of Series A Preferred Stock is otherwise convertible on the date preceding the change of control multiplied by the then current market price of a share of Common Stock. A "Change in Control" shall be deemed to have occurred at such time as either Douglas R. Eger and Thomas M. Fitzgerald cease to be either a director or officer of the Company.

6% CONVERTIBLE SUBORDINATED DEBENTURES

THE DESCRIPTION OF THE CONVERTIBLE DEBENTURES PROVIDED BELOW IS QUALIFIED IN ITS ENTIRETY BY THE TERMS THEREOF SET FORTH IN THE FORM OF 6% CONVERTIBLE SUBORDINATED DEBENTURE DUE SEPTEMBER 22, 2000 INCLUDED AS EXHIBIT 10.1 TO THE REGISTRATION STATEMENT ON FORM S-3 OF WHICH THIS PROSPECTUS CONSTITUTES A PART.

On September 22, 1997, the Company consummated a private placement of \$1,750,000 principal amount of its 6% Convertible Subordinated Debentures due September 22, 2000. The Convertible Debentures are convertible at the option of holders from December 22, 1997 until maturity, subject to certain limitations, into a number of shares of Common Stock equal to (i) the principal amount of the Convertible Debenture being so converted divided by (ii) 75% of the market price of the Common Stock as of the date of conversion. For purposes of any conversion of Convertible Debentures, "market price" generally means the average of the closing prices of the Common Stock for the five trading day period preceding the applicable conversion date. The Convertible Debentures also earn interest at a rate of 6.0% per annum that is payable by the Company, at the option of the holders and subject to certain conditions, in share of its Common Stock at a conversion rate generally equal to the average of the closing prices of the Common Stock for the ten trading days preceding the applicable interest payment date. Subject to certain limitations, the Convertible Debentures are subject to mandatory redemption in full upon the occurrence of certain changes of control events or upon an issuance of the Company's equity or debt resulting in gross proceeds to the Company of at least \$6,000,000, in each case at a premium above the principal amount of Convertible Debentures so redeemed. The Convertible Debentures are subject to optional redemption in whole or in part by the Company at any time at a premium over the principal amount of Convertible Debentures so redeemed. In connection with the sale of the Convertible Debentures, purchasers thereof also received Debenture Warrants entitling the holders thereof to purchase a total of 140,000 additional shares of Common Stock upon payment of an exercise price of \$2.80 per share, subject to certain adjustments. The Company has granted the holders of the Convertible Debentures certain registration rights in respect of the shares of Common Stock issuable upon conversion of the Convertible Debentures, in lieu of cash interest on the Convertible Debentures and upon exercise of the Debenture Warrants. The registration statement of which this prospectus constitutes a part is intended to satisfy the Company's registration obligations to the holders of the Convertible Debentures.

TRANSFER AGENT

The Company's transfer agent for its issued and outstanding Common Stock is Harris Trust and Savings Bank, Houston, Texas.

PLAN OF DISTRIBUTION

The Common Stock offered hereby may be offered from time to time on the

AMEX or on any other securities exchange on which Common Stock is listed or in privately negotiated transactions, at fixed prices that may be changed, at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at

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privately negotiated prices. Selling Stockholders may effect such transactions by selling such shares of Common Stock to or through one or more underwriters, brokers, dealers or agents and all such underwriters, brokers, dealers and agents may receive compensation in the form of discounts, concessions, or commissions from stockholders and/or the purchasers of shares for whom such broker-dealers may act as agent or to whom they sell as principal, or both (which compensation as to a particular underwriter, broker, dealer or agent might be in excess of customary commissions). The Company has agreed to indemnify the Selling Stockholders against certain liabilities, including civil liabilities under the Securities Act.

Any broker-dealer acquiring Common Stock offered hereby may sell such securities either directly, in its normal market-making activities, through or to other brokers on a principal or agency basis or to its customers. Any such sales may be at prices then prevailing on the AMEX, at prices related to such prevailing market prices or at negotiated prices to its customers or a combination of such methods. The Selling Stockholders and any underwriters, brokers, dealers or agents that act in connection with the sale might be deemed to be "underwriters" within the meaning of Section 2(11) of the Securities Act and any commissions received by them and any profit on the resale of securities as principal may be deemed to be underwriting discounts and commissions under the Securities Act. Any such commissions, as well as any applicable transfer taxes, are payable by the applicable Selling Stockholder.

LEGAL MATTERS

The validity of the issuance of the securities being offered hereby has been passed upon for the Company by Olshan Grundman Frome & Rosenzweig LLP, New York, New York. Daniel J. Gallagher, an attorney at such firm, is the holder of options to purchase 15,000 shares of Common Stock.

EXPERTS

The consolidated financial statements of Sheffield Pharmaceuticals, Inc. and subsidiaries (a development stage enterprise) appearing in Sheffield Pharmaceuticals, Inc.'s Annual Report (Form 10-KSB) for the years ended December 31, 1996 and 1995, have been audited by Ernst & Young LLP, independent auditors, as set forth in their report thereon (which contains an explanatory paragraph with respect to conditions that raise substantial doubt about the Company's ability to continue as a going concern as further described in Note 1 to the consolidated financial statements) included therein and incorporated herein by reference. The consolidated financial statements of Sheffield Pharmaceuticals, Inc. and subsidiary (a development stage enterprise) as of and for the year ended December 31, 1994 incorporated by reference herein have been audited by Ernst & Young LLP, independent auditors, as set forth in their report thereon (which contains an explanatory paragraph with respect to conditions that raise substantial doubt about the Company's ability to continue as a going concern as

further described in Note 7 to the consolidated financial statements) included therein and incorporated herein by reference. Such consolidated financial statements are, and audited financial statements to be included in subsequently filed documents will be, incorporated herein in reliance upon the reports of Ernst & Young LLP pertaining to such financial statements (to the extent covered by consents filed with the Securities and Exchange Commission) given upon the authority of such firm as experts in accounting and auditing.

The consolidated financial statements of Sheffield Pharmaceuticals, Inc. and subsidiary (a development stage enterprise) as of December 31, 1993 and for the period from October 17, 1986 (inception) to December 31, 1993 and the years ended December 31, 1992 and 1993 have been incorporated by reference herein and in the registration statement of which this Prospectus constitutes a part in reliance upon the report of KPMG Peat Marwick LLP, independent certified public accountants, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

The report of KPMG Peat Marwick LLP covering the December 31, 1993 consolidated financial statements contains an explanatory paragraph that states that the Company's recurring losses and net deficit position raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

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ADDITIONAL INFORMATION

The Company has filed with the Commission a Registration Statement on Form S-3 under the Securities Act (the "Registration Statement") with respect to certain of the shares of Common Stock offered hereby. For further information with respect to the Company and the securities offered hereby, reference is made to the Registration Statement. Statements contained in this Prospectus as to the contents of any contract or other document are not necessarily complete, and in each instance, reference is made to the copy of such contract or document filed as an exhibit to the Registration Statement, each such statement being qualified in all respects by such reference.

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----END PRIVACY-ENHANCED MESSAGE-----