

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO

SECTION 13 OR 15(D) OF

THE SECURITIES EXCHANGE ACT OF 1934

DATE OF REPORT (DATE OF EARLIEST EVENT REPORTED): JULY 10, 1996

CYTOTHERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

DELAWARE

0-19871

94-3078125

(State or other jurisdiction (Commission File Number)
of incorporation)

(I.R.S. Employer
Identification Number)

2 RICHMOND SQUARE
PROVIDENCE, RHODE ISLAND 02906

(Address, of principal executive offices, including zip code)

(401) 272-3310

(Registrant's Telephone number including area code)

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Item 5.

CytoTherapeutics, Inc. ("CytoTherapeutics" or the "Company") announced the establishment of Modex Therapeutiques SA as a 50% owned, Swiss company to pursue extensions of CytoTherapeutics' broad-based, encapsulated-cell technology for applications outside the central nervous system. Modex, headquartered in Lausanne, Switzerland, will integrate technologies developed at three universities located in Lausanne -- the University of Lausanne, the Centre Hospitalier Universitaire Vaudois (CHUV), the Ecole Polytechnique Federale de Lausanne (EPFL) -- as well as from the Albert Einstein College of Medicine of Yeshiva University in New York City and CytoTherapeutics to develop products to treat diseases such as diabetes, obesity and blood disorders.

CytoTherapeutics has initially invested \$2 million in Modex, with a commitment to invest an additional \$2 million on the second anniversary of the agreement if Modex has, prior to that time, achieved one or more specified scientific milestones, in exchange for a 50% stake in Modex. An investment fund managed by Lombard Odier & Cie, a Swiss private bank, has invested \$2 million in Modex, with a commitment to invest an additional \$1 million on the second anniversary of the agreement, in exchange for a 15% stake in the company.

CytoTherapeutics has granted to Modex an exclusive, royalty-bearing license to CytoTherapeutics' proprietary encapsulated-cell technology for three applications outside the central nervous system (diabetes, obesity and anemia). Modex granted to CTI an exclusive royalty-bearing license to any technology developed or obtained by Modex for application to diseases, conditions and disorders which affect the central nervous system. In addition to its royalty obligations, CTI is also obligated under this agreement to issue to Modex up to 300,000 shares of CTI Common Stock on the achievement by Modex of certain scientific milestones. Substantially all of these shares are expected to be awarded by Modex as incentive compensation to Modex's founding scientists and other researchers upon the achievement of such milestones.

Under the terms of its agreement with the fund managed by Lombard Odier, during the first two years following closing, CytoTherapeutics has the right to acquire the fund's interest in Modex for approximately \$3 million. Following this two year period, CytoTherapeutics has the right to purchase the fund's interest in Modex at 110% of fair market value. Following the second anniversary of the agreement and prior to the tenth anniversary of the agreement, if no public market exists for the Common Stock of Modex, the fund has the right to require CytoTherapeutics to purchase the fund's interest in Modex for 90% of the fair market value of such interest. Any purchase made by CytoTherapeutics under any of the circumstances described in this paragraph may be made, at CytoTherapeutics' option, in cash or shares of CytoTherapeutics Common Stock valued at the market price at the time of purchase.

The scientific founders of Modex are Patrick Aebischer, M.D., Ph.D., Professor of Surgery and Director of Surgical Research and the Gene Therapy Center at the CHUV; Max Wilhelm, Ph.D., who will serve as Modex's Chief Executive Officer and was previously Director

of Pharmaceutical Research and Development at Ciba-Geigy Corporation where he was responsible for worldwide research and development operations; Bernard Thorens, Ph.D., Professor at the Institute of Pharmacology at the University of Lausanne, and Shimon Efrat, Ph.D., Associate Professor at the Department of Molecular Pharmacology at Albert Einstein College of Medicine at Yeshiva University. Dr. Aebischer is also a scientific founder of CytoTherapeutics and a member of its Board of Directors.

Under the terms of the agreement between CytoTherapeutics and the scientific founders of Modex, CytoTherapeutics has the right to acquire, and the founders have the right to require CytoTherapeutics to acquire, the founders' initial equity interest in Modex in exchange for the issuance of an aggregate of approximately 92,000 shares of CytoTherapeutics Common Stock.

Certain statements in this current report include forward looking comments regarding, among other things, product development programs, CytoTherapeutics' obligations under certain agreements and the Company's dependence on outside parties. The Company's actual results may vary materially from those forward looking statements due to risks and uncertainties to which the Company is subject. "Cautionary Factors Relevant to Forward Looking Statements" filed herewith as Exhibit 99 and incorporated herein by reference.

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 hereunto duly authorized.

CYTOTHERAPEUTICS, INC.

By /s/ Frederic A. Eustis
Title: Vice President

Date: July 15, 1996

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CAUTIONARY FACTORS RELEVANT TO FORWARD-LOOKING INFORMATION

CytoTherapeutics, Inc. (the "Company") wishes to caution readers that the following important factors, among others, in some cases have affected and in the future could affect the Company's results and could cause actual results and needs of the Company to vary materially from forward-looking statements made in this Current Report by the Company on the basis of management's current expectations. The business in which the Company is engaged is rapidly changing, extremely competitive and involves a high degree of risk, and accuracy with respect to forward-looking projections is difficult.

EARLY STAGE DEVELOPMENT; HISTORY OF OPERATING LOSSES - Substantially all of the Company's revenues to date have been derived, and for the foreseeable future substantially all of the Company's revenues will be derived, from collaborative agreements, research grants and income earned on invested funds. The Company will incur substantial operating losses in the future as the Company conducts its research, development, clinical trial and manufacturing activities. There can be no assurance that the Company will achieve revenues from product sales or become profitable.

FUTURE CAPITAL NEEDS; UNCERTAINTY OF ADDITIONAL FUNDING - The development of the Company's products will require the commitment of substantial resources to conduct the time-consuming research, preclinical development and clinical trials that are necessary for regulatory approvals and to establish production and marketing capabilities if such approvals are obtained. The Company will need to raise substantial additional funds to continue its product development efforts and intends to seek such additional funds through partnership, collaborative or other arrangements with corporate sponsors, public or private equity or debt financings, or from other sources. Future cash requirements may vary from projections based on changes in the Company's research and development programs, progress in preclinical and clinical testing, the Company's ability to enter into, and perform successfully under, collaborative agreements, competitive and technological advances, the need to obtain proprietary rights owned by third parties, facilities requirements, regulatory approvals and other factors. Lack of necessary funds may require the Company to delay, reduce or eliminate some or all of its research and product development programs or to license its potential products or technologies to third parties. No assurance can be given that funding will be available when needed, if at all, or on terms acceptable to the Company.

UNCERTAINTIES OF CLINICAL DEVELOPMENT AND NEW MODE OF THERAPY - None of the Company's proposed products has been approved for commercial sale or entered Phase II or III clinical trials. Even if the Company's proposed products appear to be promising at an early stage of research or development such products may later prove to be ineffective, have adverse side effects, fail to receive necessary regulatory approvals, be difficult or uneconomical to manufacture or market on a commercial scale, be adversely affected by government price controls or limitations on reimbursement, be precluded from commercialization by proprietary rights of third parties or be subject to significant competition from other products. There can be no assurance that the

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Company will be able to demonstrate, as required, that its implants, on a consistent basis and on a commercial scale, among other things: (i) successfully isolate transplanted cells from the recipient's immune system; (ii) remain biocompatible with the tissue into which they are implanted, including, for certain implants, brain tissue; (iii) adequately maintain the viability of cells contained within the membrane; (iv) safely permit the therapeutic substances produced by the cells within the membrane to pass through the membrane unto the patient in controlled doses for extended periods; and (v) are sufficiently durable for the intended indication.

DEPENDENCE ON OUTSIDE PARTIES - The Company's strategy for the research, development, commercialization and marketing of its products contemplates that the Company will enter into various arrangements with corporate sponsors, pharmaceutical companies, universities, research groups and others. There is no assurance that the Company will be able to enter into any additional arrangements on terms acceptable to the Company, or successfully perform its obligations under its existing or any additional arrangements. If any of the Company's collaborators fails to perform its obligations in a timely manner or

terminate their agreement with the Company, the development or commercialization of the Company's product candidate or research program under such collaborative agreement may be adversely affected.

NEED FOR AND UNCERTAINTY OF OBTAINING PATENT PROTECTION - Patent protection for products such as those the Company proposes to develop is highly uncertain and involves complex factual and evolving legal questions. No assurance can be given that any patents issued or licensed to the Company will not be challenged, invalidated or circumvented, or that the rights granted under such patents will provide competitive advantages to the Company.

EXISTENCE OF THIRD PARTY PATENTS AND PROPRIETARY RIGHTS; NEED TO OBTAIN LICENSES - - There are pending patent applications or issued patents held by others relating to the Company's proposed products or the technology to be utilized by the Company in the development of its proposed products. If such patents or other patents are determined by the Company or a court to be valid and infringed, the Company may be required to alter its products or processes, pay licensing fees or royalties or cease certain activities. In particular, the Company is aware of one issued patent claiming certain methods for treating defective, diseased or damaged cells in the mammalian CNS by grafting genetically modified donor cells from the same mammalian species. In addition, each of the neurotrophic factors which the Company is currently investigating for use in its proposed products is the subject of one or more claims in patents or patent applications of third parties, and certain other neurotrophic factors are the subject of third party patent applications. The Company may also be required to seek licenses in regard to other cell lines, the techniques used in creating or obtaining such cell lines, the materials used in the manufacture of its implants or otherwise. There can be no assurance that the Company will be able to establish collaborative arrangements or obtain licenses to the foregoing technology or to other necessary or desirable technology on acceptable terms, if at all, or that the patents underlying any such licenses will be valid and enforceable.

GOVERNMENT REGULATION - The Company's research, preclinical development and clinical trials, as well as the manufacturing and marketing of its potential products, are subject to extensive regulation by governmental authorities in the United States and other countries. The process of

obtaining FDA and other required regulatory approvals is lengthy, expensive and uncertain. There can be no assurance that the Company or its collaborators will be able to obtain the necessary approvals to commence or continue clinical testing or to manufacture or market its potential products in anticipated time frames, if at all. In addition, several legislative proposals have been made to reform the FDA. If such proposals are enacted they may result in significant changes in the regulatory environment the Company faces. These changes could result in different, more costly or more time consuming approval requirements for the Company's products, in the dilution of FDA resources available to review the Company's products, or in other unpredictable consequences.

SOURCES OF CELLS AND OTHER MATERIALS - The Company's potential products require genetically engineered cell lines or living cells harvested from animal or human sources. There can be no assurance that the Company will successfully identify or develop sources of the cells required for its potential products and obtain such cells in quantities sufficient to satisfy the commercial requirements of its potential products. These supply limitations may apply, in particular, to primary cells which must be drawn directly from animal or human sources, such as the bovine adrenal chromaffin cells currently used in the Company's product for the treatment of pain. As an alternative to primary cells, the Company is developing products based on the use of genetically altered cells. Intellectual property rights to important genetic constructs used in developing such cells, including the constructs used to develop cells producing neurotrophic factors, are or may be claimed by one or more companies, which could prevent the Company from using such cells.

MANUFACTURING UNCERTAINTIES - The Company's pilot manufacturing plant, may not have sufficient capacity to permit the Company to produce all the products for clinical trials it anticipates developing. In addition, the Company has not developed the capability to commercially manufacture any of its proposed products and is unaware of any other company which has manufactured any membrane-encapsulated cell product on a commercial scale. There can be no assurance that the Company will be able to develop the capability of manufacturing any of its proposed products at a cost or in the quantities necessary to make a commercially viable product, if at all.

COMPETITION - Competitors of the Company are numerous and include major pharmaceutical and chemical companies, biotechnology companies, universities and other research institutions. Currently, several of these competitors market and sell therapeutic products for the treatment of chronic pain, Parkinson's disease and other CNS conditions. In addition, most of the Company's competitors have substantially greater capital resources, experience in obtaining regulatory approvals and, in the case of commercial entities, experience in manufacturing and marketing pharmaceutical products, than the Company. A number of other companies are attempting to develop methods of delivering therapeutic substances within or across the blood brain barrier. There can be no assurance that the Company's competitors will not succeed in developing technologies and products that are more effective than those being developed by the Company or that would render the Company's technology and products obsolete or non-competitive.

DEPENDENCE ON KEY PERSONNEL - The Company is highly dependent on the principal members of its management and scientific staff and certain of its outside consultants. Loss of the services of any of these individuals could have a material adverse effect on the Company's operations. In addition, the Company's operations are dependent upon its ability to attract and retain additional qualified scientific and management personnel. There can be no assurance the Company will be able to attract and retain such personnel on acceptable terms given the competition among pharmaceutical, biotechnology and health care companies, universities and research institutions for experienced personnel.

REIMBURSEMENT AND HEALTH CARE REFORM - In both domestic and foreign markets, sales of the Company's potential products will depend in part upon the availability and amounts of reimbursement from third-party health care payor organizations, including government agencies, private health care insurers and other health care payors such as health maintenance organizations and self-insured employee plans. There is considerable pressure to reduce the cost of therapeutic products. There can be no assurance that reimbursement will be provided by such payors at all or without substantial delay, or, if such reimbursement is provided, that the approved reimbursement amounts will provide sufficient funds to enable the Company to sell its products on a profitable basis.

