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): SEPTEMBER 26, 1997

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

DELAWARE	0-19871	04-3078125
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

701 GEORGE WASHINGTON HIGHWAY
LINCOLN, RHODE ISLAND 02865

(Address of principal executive offices, including zip code)

(401) 288-1000

(Registrant's telephone number including area code)

TWO RICHMOND SQUARE
PROVIDENCE, RHODE ISLAND 02906

(Former name or address, if changed since last report)

This report may contain certain forward-looking statements regarding, among other things, CTI's results of operations, the progress of CTI's product development and clinical programs, the need for, and timing of, additional capital and capital expenditures, partnering prospects, the need for additional intellectual property rights, effects of regulations, the need for additional

facilities and potential market opportunities. CTI's actual results may vary materially from those contained in such forward-looking statements because of risks to which CTI is subject such as risks of delays in research, development and clinical testing programs, obsolescence of CTI's technology, lack of available funding, competition from third parties, failure of CTI's collaborators to perform, failure to consummate proposed transactions, regulatory constraints, litigation and other risks to which CTI is subject. See "Cautionary Factors Relevant to Forward-Looking Statements" filed herewith as Exhibit 99 and incorporated herein by reference.

ITEM 2. ACQUISITION OF ASSETS

On September 26, 1997, CytoTherapeutics, Inc. ("CTI") announced the closing of the merger of StemCells, Inc. ("StemCells") and a wholly-owned subsidiary of CTI. Through the merger, CTI acquired StemCells in exchange for 1,580,000 newly issued shares of CTI's common stock, $.01 par value. Simultaneously with the acquisition of StemCells, Richard M. Rose, M.D., became President, Chief Executive Officer and a Director of CTI and Dr. Irving Weissman became a Director of CTI.

Upon the consummation of the merger, CTI entered into consulting arrangements with the principal scientific founders of StemCells including, Dr. Weissman, of Stanford University, Fred Gage, Ph.D., of Salk Institute and David Anderson, of the California Institute of Technology and the Howard Hughes Medical Institute. Under the terms of the consulting arrangements, each of Drs. Weissman, Gage and Anderson will join CTI's Scientific Advisory Board with Dr. Weissman serving as the Chairman of the Scientific Advisory Board.

To attract and retain Drs. Rose, Weissman, Gage and Anderson, and to move CTI's expanded stem cell program forward, CTI awarded these individuals options to acquire a total of approximately one million six hundred thousand shares of CTI common stock, at an exercise price of $5.25 per share; approximately 94,000 of these options are excercisable immediately, 1.1 million of these options vest and become exercisable only on the achievement of specified milestones related to CTI's stem cell development program, such as corporate partnering events, the initiation of clinical trials and regulatory filings and approvals; and the remaining 500,000 options vest over eight years.

Conduct of the stem cells research following completion of the merger will be conducted pursuant to the provisions of an agreement between CTI and Drs. Weissman and Gage providing for a two year research plan. If the goals of the research plan are accomplished, the stem cells research will continue to be conducted under an extension of such Research Plan approved by a Research Committee consisting of two persons chosen by Drs. Gage and Weissman, two persons chosen by CTI and a fifth member appointed by Drs. Gage and Weissman, subject to the reasonable approval of CTI. Increases in stem cells research funding of not more than 25% a year approved by the Committee will be funded by CTI as long as the goals of the Research Plan are being met, provided, however, that CTI will retain the option of ceasing or reducing neural stem cell research even if all Research Plan goals are being met by accelerating the vesting of all

still-achievable performance-based options and ceasing or reducing non-neural stem cell research even if all Plan goals are being met by affording the scientific founders the opportunity to continue development of the non-neural stem cell research by licensing the technology related to such research to the founders in exchange for a payment to CTI equal to all funding for such research, plus royalty payments.

ITEM 5. OTHER EVENTS

Construction of CTI's new headquarters and research and development facility has recently been completed at a cost of approximately $7.5 million. CTI is currently in negotiations regarding the possible sale and leaseback of such facility. In addition, CTI is also involved in active discussions with a group of potential investors regarding a possible investment in CTI's 50% owned subsidiary, Modex Therapeutiques S.A., including the possible sale to such investors of a portion of CTI's current ownership interest. As currently anticipated, CTI would reduce its current ownership in Modex to a minority position, receive cash, be relieved of certain future funding and milestone obligations, expand the field of encapsulated products outside the central nervous system which are exclusively licensed to Modex and enter into arrangements to manufacture Modex products based on such licensed technology.

The two proposed transactions described above are the subject of ongoing negotiations and no definitive agreements have been reached with respect to either transaction; there can be no assurance that either transaction will be completed or, if completed, will be completed on the terms described above.

ITEM 7. EXHIBITS

Exhibit 99 Cautionary Factors Relevant to Forward-Looking Statements

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 III

Title: Executive Vice President

Date: October 2, 1997

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EXHIBIT 99

CAUTIONARY FACTORS RELEVANT TO FORWARD-LOOKING STATEMENTS

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 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. Cross-references in this Exhibit refer to the sections of the Company's Annual Report on Form 10-K.

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 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, may be precluded from development by new regulations, 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 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 into the patient in controlled doses for extended periods; and (v) are sufficiently durable for the intended indication.

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. See "Government Regulation."

There has been increasing regulatory concern about the risks of cell transplantation. Concern has focused on cells derived from cows (such as are used in the Company's pain program) and cells from primates and pigs. The United Kingdom has adopted a moratorium on xenotransplantation pending further research and discussion and the EC Commission has introduced a ban on the use of "high-risk material" from cattle and sheep in the Member States of the European Union in the manufacture of pharmaceuticals (this ban would apparently not include cells used in the Company's pain program). In addition, the FDA has recently proposed guidelines which impose significant constraints on the conduct of clinical trials utilizing xenotransplantation. Furthermore, the FDA has published a "Proposed Approach to Regulation of Cellular and Tissue-Based Products" which relates to use of human cells. The Company cannot presently determine the effects of such actions nor what other actions may be taken. Restrictions on the testing or use of cells (whether nonhuman or human) as human therapeutics could materially adversely affect the Company's product development programs and the Company itself. See "Government Regulation."

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 terminates its 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 - -- A number of pharmaceutical, biotechnology and other companies, universities and research institutions have filed patent applications or have been issued patents relating to cell therapy and encapsulation and other technologies potentially relevant to or required by the Company's expected products. The Company cannot predict which, if any, of such applications will issue as patents or the claims which might be allowed. The Company is aware of a number of third-party

patent applications and patents relating to cell encapsulation or claiming use of genetically modified cells to treat disease, disorder or injury. In particular, the Company is aware of a third-party U.S. patent which relates to the use of cells for alleviating chronic pain in humans and of two issued U.S. patents claiming certain methods for treating defective, diseased or damaged cells in the mammalian CNS by grafting genetically modified cells. The Company cannot predict the effect of existing patent applications and patents on future unencapsulated products. In addition, the Company is aware of third-party patents and patent applications claiming rights to the neurotrophic factors (such as CNTF, NT 4/5, Neurturin, and CT-1) which the Company hopes to deliver with its technology, and to the production of these factors through the use of genetically modified cells. The Company expects to use genetically modified cells to produce these factors for use in its products. 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. See "Patents, Proprietary Rights and Licenses."

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 all of the 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, consistency 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 noncompetitive. See "Competition."

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. Vacancies have occurred and are likely to occur from time to time among the Company's senior management and scientific staff. Loss of the services of any of the Company's key employees or consultants or the continued existence of such vacancies 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 healthcare companies, universities and research institutions for experienced personnel.

REIMBURSEMENT AND HEALTHCARE 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 healthcare payor organizations, including government agencies, private healthcare insurers and other healthcare 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. See "Reimbursement and Healthcare Cost Control."