

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934

For the quarter ended:

0-19871

June 30, 1998

Commission File Number

CYTOTHERAPEUTICS, INC.

-----  
(Exact name of registrant as specified in its charter)

DELAWARE

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(State or other jurisdiction of  
incorporation or organization)

94-3078125

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(I.R.S. Employer  
identification No)

701 GEORGE WASHINGTON HIGHWAY  
LINCOLN, RI 02865

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

(401) 288-1000

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(Registrant's telephone number, including area code)

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

At July 31, 1998, there were 18,277,906 shares of Common Stock, \$.01 par value, issued and outstanding. There were no issued and outstanding shares of Preferred Stock.

CYTOTHERAPEUTICS, INC.

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## PART I - ITEM 1 - FINANCIAL STATEMENTS

CYTOTHERAPEUTICS, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 1998 (unaudited)	December 31, 1997 (audited)
	-----	-----
Assets		
Current assets:		
Cash and cash equivalents	\$ 12,864,589	\$ 15,941,701
Marketable securities	10,430,726	13,108,497
Receivables from collaborative agreement	190,455	150,880
Other current assets	1,309,589	978,314
	-----	-----
Total current assets	24,795,359	30,179,392
Property, plant and equipment, net	8,346,898	7,922,751
Other assets	6,492,699	6,199,323
	-----	-----
Total assets	\$ 39,634,956	\$ 44,301,466
	-----	-----
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,066,606	\$ 4,109,351
Deferred revenue	1,758,648	16,144
Current maturities of capitalized lease obligations	354,342	419,095
Current maturities of long term debt	971,737	658,986
	-----	-----
Total current liabilities	7,151,333	5,203,576
Capitalized lease obligations, less current maturities	3,405,000	3,552,500
Long term debt, less current maturities	1,250,000	555,525
Redeemable common stock	5,248,610	5,583,110
Common stock to be issued	48,375	506,600
Stockholders' equity		
Common stock	176,905	175,262
Additional paid in capital	122,546,371	121,472,844
Accumulated deficit	(98,603,164)	(91,036,254)
Deferred compensation	(1,585,062)	(1,702,820)
Unrealized gain (loss) on marketable securities	(3,412)	(8,877)
	-----	-----
Total stockholders' equity	22,531,638	28,900,155
	-----	-----
Total liabilities and stockholders' equity	\$ 39,634,956	\$ 44,301,466
	-----	-----

See accompanying notes to condensed consolidated financial statements.

## PART I - ITEM 1 - FINANCIAL STATEMENTS

CYTOTHERAPEUTICS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	1998	1997	1998	1997
Revenue from collaborative arrangements	\$ 1,906,588	\$ 5,084,864	\$ 3,749,563	\$ 6,941,486
Operating expenses:				
Research and development	4,917,357	4,449,727	9,417,019	9,099,227
General and administrative	1,264,249	1,684,917	2,411,255	3,481,347
	6,181,606	6,134,644	11,828,274	12,580,574
Earnings (loss) from operations	(4,275,018)	(1,049,780)	(8,078,711)	(5,639,088)
Other income (expense):				
Investment income	351,522	467,769	745,496	1,116,399
Interest expense	(124,877)	(70,583)	(233,695)	(246,094)
Other income (loss)	0	(15,360)	0	(110,780)
	226,645	381,826	511,801	759,525
Net earnings (loss)	(\$ 4,048,373)	(\$ 667,954)	(\$ 7,566,910)	(\$ 4,879,563)
Net earnings (loss) per share	(\$0.22)	(\$0.04)	(\$0.42)	(\$0.30)
Shares used in calculation	18,199,870	16,498,374	18,192,212	16,484,864

See accompanying notes to condensed financial statements.

## PART I - ITEM 1 - FINANCIAL STATEMENTS

CYTOTHERAPEUTICS, INC.

## CONDENSED STATEMENTS OF CASH FLOWS

(unaudited)

	Six Months Ended June 30,	
	1998	1997
	-----	-----
Cash flows from operating activities:		
Net earnings (loss)	(\$ 7,566,910)	(\$ 4,879,563)
Adjustments to reconcile net earnings (loss) to net cash used for operating activities:		
Depreciation and amortization	1,039,208	967,350
Compensation expense relating to the grant of stock options	117,758	27,413
Loss on sale of fixed assets	--	825
Changes in operating assets and liabilities	1,377,593	(1,963,479)
	-----	-----
Net cash used in operating activities	(5,032,351)	(5,847,454)
	-----	-----
Cash flows from investing activities:		
Proceeds from sale of marketable securities	13,634,045	9,936,929
Purchases of marketable securities	(10,952,827)	(6,104,205)
Purchase of property, plant and equipment	(1,226,809)	(4,504,373)
Proceeds from the sale of fixed assets	--	1,941
Acquisition of other assets	(576,588)	(572,576)
	-----	-----
Net cash provided by (used in) investing activities	877,821	(1,242,284)
	-----	-----
Cash flows from financing activities:		
Proceeds from the exercise of stock options	282,445	375,825
Proceeds from financing transactions	1,259,300	--
Principal payments under capitalized lease obligations and mortgage payable	(464,327)	(538,485)
	-----	-----
Net cash provided by (used in) financing activities	1,077,418	(162,660)
	-----	-----
Effect of exchange rate on cash and cash equivalents	--	(234,206)
	-----	-----
Decrease in cash and cash equivalents	(3,077,112)	(7,486,604)
Cash and cash equivalents, January 1	15,941,701	19,921,584
	-----	-----
Cash and cash equivalents, June 30	\$ 12,864,589	\$ 12,434,980
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See accompanying notes to condensed financial statements.

PART I - ITEM 1 - FINANCIAL STATEMENTS

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

June 30, 1998 and 1997

NOTE 1. BASIS OF PRESENTATION

The accompanying, unaudited, condensed consolidated financial statements have been prepared by the Company in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, the accompanying financial statements include all adjustments, consisting of normal recurring accruals considered necessary for a fair presentation of the financial position, results of operations and cash flows for the periods presented. Results of operations for the three and six months ended June 30, 1998 are not necessarily indicative of the results that may be expected for the entire fiscal year ended December 31, 1998.

For further information, refer to the audited financial statements and footnotes thereto as of December 31, 1997 included in the Company's Annual Report to Stockholders and the Annual Report on Form 10-K filed with the Securities and Exchange Commission.

NOTE 2. NET LOSS PER SHARE

Net loss per share is computed using the weighted average number of shares of common stock outstanding. Common equivalent shares from stock options and warrants are excluded as their effect is antidilutive.

NOTE 3. ADOPTION OF NEW ACCOUNTING PRONOUNCEMENT

As of January 1, 1998, the Company adopted Statement 130, Reporting Comprehensive Income. Statement 130 establishes new rules for reporting and display of comprehensive income and its components; however, the adoption of this Statement had no impact on the Company's net income or shareholders' equity. Statement 130 requires unrealized gains or losses on the Company's available-for-sale securities and foreign currency translation adjustments, which prior to adoption were reported separately in shareholders' equity to be included in other comprehensive income.

For the three months end June 30, 1998 and 1997, total comprehensive loss amounted to \$4,047,000 and \$655,000. For the first six months of 1998 and 1997, total comprehensive loss amounted to \$7,561,000 and \$4,962,000.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF  
FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of the financial condition and results of operations of the Company for the three and six months ended June 30, 1998 and 1997 should be read in conjunction with the accompanying unaudited condensed consolidated financial statements and the related footnotes thereto.

This report may contain certain forward-looking statements regarding, among other things, the Company's results of operations, the progress of the Company'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. The Company's actual results may vary materially from those contained in such forward-looking statements because of risks to which the Company is subject, such as risks of delays in research, development and clinical testing programs, obsolescence of the Company's technology, lack of available funding, competition from third parties, intellectual property rights of third parties, failure of the Company's collaborators to perform, regulatory constraints, litigation and other risks to which the Company is subject. See "Cautionary Factors Relevant to Forward-Looking-Information" filed herewith as Exhibit 99 and incorporated herein by reference.

#### Overview

Since its inception in August 1988, the Company has been primarily engaged in research and development of human therapeutic products. No revenues have been derived from the sale of any products, and the Company does not expect to receive revenues from product sales for at least several years. The Company expects that its research and development expenditures will increase in future years as research and product development efforts accelerate and clinical trials are initiated or broadened. The Company has incurred annual operating losses since inception and expects to incur substantial operating losses in the future. As a result, the Company is dependent upon external financing from equity and debt offerings and upon revenues from collaborative research arrangements with corporate sponsors to finance its operations. The Company's results of operations have varied significantly from year to year and from quarter to quarter, and may vary significantly in the future due to the occurrence of material, nonrecurring events, including without limitation, the receipt of one-time, nonrecurring licensing and milestone payments.

#### Results of Operations

Three months ended June 30, 1998 and 1997

For the quarter ended June 30, 1998 and 1997, revenues from collaborative

agreements totaled \$1,907,000 and \$5,085,000, respectively. The revenues were earned primarily from a Development, Marketing and License Agreement with Astra AB, which was signed in March 1995. Included in the 1997 revenues is a \$3,000,000 milestone payment from Astra related to the Phase II clinical trial program for the Company's cell-containing, pain-control implant.

Research and development expenses totaled \$4,917,000 for the three months ended June 30, 1998, compared with \$4,450,000 for the same period in 1997.

General and administrative expenses were \$1,264,000 for the three months ended June 30, 1998, compared with \$1,685,000 for the same period in 1997. The decrease of \$421,000, or 25%, from 1997 to 1998 was primarily attributable to a reduction in legal expenses, as well as a reduction in employee expenses.

Interest income for the three months ended June 30, 1998 and 1997 was \$352,000 and \$468,000, respectively. The decrease in interest income in 1998 is attributable to the lower average investment balances, \$23,669,00 vs. \$34,672,000 in the second quarter of 1998 and 1997, respectively.

Interest expense was \$125,000 for the three months ended June 30, 1998, compared with \$71,000 for the same period in 1997. The increase from 1997 to 1998 is attributable to the capitalization of interest for the new facility in 1997 in the amount of \$99,000.

Net loss for the three months ended June 30, 1998 was \$4,048,000, or \$0.22 per share, as compared to net loss of \$668,000, or \$0.04 per share, for the comparable period in 1997. The consolidated results for the second quarter of 1998 include a \$502,000 net loss attributable to StemCells, Inc., the Company's wholly owned subsidiary, compared to the consolidated results for the second quarter of 1997 which include a \$544,000 net loss attributable to Modex Therapeutiques SA, the Company's formerly 50% owned Swiss subsidiary.

#### Results of Operations

Six months ended June 30, 1998 and 1997

For the six months ended June 30, 1998 and 1997, revenues from collaborative agreements totaled \$3,750,000 and \$6,941,000. The revenues were earned primarily from a Development, Marketing and License Agreement with Astra AB.

Research and development expenses totaled \$9,417,000 for the six months ended June 30, 1998, compared with \$9,099,000 for the same period in 1997.

General and administrative expenses were \$2,411,000 for the six months ended June 30, 1998, compared with \$3,481,000 for the same period in 1997. The



decrease of \$1,070,000 or 31%, from 1997 to 1998 was primarily attributable to a reduction in legal fees, as well as a reduction in employee expenses.

Interest income for the six months ended June 30, 1998 and 1997 was \$745,000 and \$1,116,000, respectively. The average investment balances were \$25,329,000 and \$37,555,000 for the first six months of 1998 and 1997, respectively.

Interest expense was \$234,000 for the six months ended June 30, 1998, compared with \$246,000 for the same period in 1997.

Net loss for the six months ended June 30, 1998 was \$7,567,000, or \$0.42 per share, as compared to a net loss of \$4,880,000, or \$0.30 per share, for the comparable period in 1997.

#### Liquidity and Capital Resources

Since its inception, the Company has financed its operations through the sale of common and preferred stock, the issuance of long-term debt and capitalized lease obligations, revenues from collaborative agreements, research grants and interest income.

The Company had unrestricted cash, cash equivalents and marketable securities totaling \$23,295,000 at June 30, 1998. Cash equivalents and marketable securities are invested in agencies of the U.S. government, investment grade corporate bonds and money market funds.

In May 1996, the Company secured an equipment loan facility with a bank in the amount of \$2,000,000. The Company has borrowed \$2,000,000 under this agreement as of June 30, 1998. The loan required interest payments only for the first two years; principal payments are payable over a three-year period beginning in August 1998. The loan is secured by equipment purchased with the proceeds of the credit facility.

In October 1997, the Company completed a series of transactions which resulted in the establishment of its previously 50%-owned Swiss subsidiary, Modex Therapeutiques, SA, as an independent company. In the transactions, the Company reduced its ownership interest from 50% to approximately 25% in exchange for \$4 million cash and elimination of its prior contingent obligation to contribute an additional Sfr 2.4 million (approximately \$1.7 million) to Modex in July 1998. In the transactions, all of the put and call arrangements between the Company and other stockholders of Modex were eliminated. In April 1998, Modex completed a financing, in which the Company elected not to participate, which resulted in a reduction of its ownership interest to approximately 20%.

The Company and Modex also modified the terms of their existing royalty-bearing Cross License Agreement to (i) expand the field in which Modex is exclusively licensed to apply the Company's proprietary encapsulated cell technology to include, in addition to the original field of diabetes, obesity and anemia, the treatment of hemophilia A and B utilizing Factor VIII and/or Factor IX and two additional applications to be agreed upon by the Company and Modex; (ii) eliminate the Company's requirement to make future milestone payments to Modex of up to 300,000 shares of CytoTherapeutics' Common Stock; (iii) limit the scope of the Company's technology licensed to Modex to existing and future encapsulation technology; and (iv) specify the terms under which the Company will manufacture any products Modex may develop based on the Company's technology and grant Modex an option to manufacture, or to have manufactured, such products on payment of a higher royalty. The Cross License Agreement continues to provide for the payment of royalties from Modex to the Company on the sale of any licensed products. The revised agreement also limits the scope of the Modex technology exclusively licensed, on a royalty-bearing basis, to the Company for the application of diseases, conditions and disorders of the central nervous system to existing and future encapsulation technology and certain additional existing technology. In addition to the purchase of Modex's Common Stock from the Company, investors participating in the transaction also invested \$1.6 million directly in Modex.

In September 1997, a merger of a wholly-owned subsidiary of the Company and StemCells, Inc. was completed in the form of a purchase. Through the merger, the Company acquired StemCells for a purchase price totaling approximately \$9,475,000, consisting of 1,320,691 shares of the Company's Common Stock and options and warrants for the purchase of 259,296 of CytoTherapeutics' Common Shares at nominal consideration, valued at \$7,900,000 in the aggregate, the assumption of certain liabilities of \$934,000 and transaction costs of \$641,000. The purchase price was allocated, through a valuation, to license agreements valued at \$1,131,000, to be amortized over three years, and to acquired research and development of \$8,344,000 which has been expensed. As part of the acquisition of StemCells, Richard M. Rose, MD, became President, Chief Executive Officer and a director of the Company and Dr. Irving Weissman became a director of the Company.

Upon consummation of the merger, the Company entered into consulting arrangements with the principal scientific founders of StemCells: Dr. Irving Weissman, Dr. Fred H. Gage and Dr. David Anderson. Additionally, in connection with the merger, the Company was granted an option by the former principal shareholders of StemCells to repurchase approximately 500,000 of the Company's shares of Common Stock exchanged for StemCells shares, upon the occurrence of certain events as defined.

To attract and retain Drs. Rose, Weissman, Gage and Anderson, and to expedite the progress of the Company's stem cell program, the Company awarded these individuals options to acquire a total of approximately 1.6 million shares of the Company's common stock, at an exercise price of \$5.25 per share, the quoted market price at the grant date; approximately 100,000 of these options are exercisable immediately, 1,031,000 of these options vest and become exercisable only upon the achievement of specified milestones related to the Company's stem cell development program. The remaining 469,000 options vest over eight years. In connection with the 469,000 options issued to a non-employee, Dr. Anderson, the Company has recorded deferred compensation of \$1,750,000, the fair value of such options at the date of grant, which will be amortized over an eight-year period. If the milestones specified relating to the 1,031,000 option grant are achieved, at that time the Company will record compensation expense for the excess of the quoted market price of the Common Stock over the exercise price of \$5.25 per share for 562,000 options and the fair market value for 469,000 of such options determined using the Black-Scholes method. The Company has also designated a pool of 400,000 options to be granted to persons in a position to make a significant contribution to the success of the stem cells program.

Stem cells research will be conducted pursuant to the provisions of an agreement between the Company and Drs. Weissman and Gage providing for a two-year research plan. If the goals of the research plan are accomplished, the Company has agreed to fund continuing stems cells research. Increases in stem cells research funding of not more than 25% per year will be funded by the Company as long as the goals of the research plan are being met. However, the Company will retain the option of (i) ceasing or reducing neural stem cell research even if all research plan goals are met, but will be required to accelerate the vesting of all still-achievable performance-based stock options, and (ii) ceasing or reducing non-neural stem cell research even if all plan goals are being met by affording the scientific research 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 the Company equal to all prior Company funding for such research, plus royalty payments.

In April 1997, CytoTherapeutics entered into an agreement with NeuroSpheres Ltd. replacing all previous agreements and resolving its dispute with NeuroSpheres. The pending action in the United State District Court and its counterpart actions in Calgary, Alberta, Canada, as well as all arbitration proceedings, have been discontinued. Under the terms of the settlement, the Company has an exclusive royalty-bearing license to growth-factor responsive stem cells for transplantation. NeuroSpheres had an option to acquire co-exclusive rights, but failed to exercise the option by the April 1998 deadline. Accordingly, the NeuroSpheres' option to acquire co-

exclusive rights has lapsed and CytoTherapeutics retains exclusive rights for transplantation. The parties have no further research obligations to each other.

In February 1997, CytoTherapeutics and Cognetix, Inc. entered into a Collaboration and Development Agreement to screen selected peptides isolated by Cognetix for possible development into therapeutic products aimed at a broad range of human disease states using CytoTherapeutics' cell-based delivery technology. The Company and Cognetix have also entered into an option agreement giving CytoTherapeutics the right to option up to three of Cognetix's compounds for use in treating eye diseases. CytoTherapeutics has exercised its right as to one protein. The Company and Cognetix are presently discussing proposed revisions to their relationship under the agreements.

In November 1996, the Company signed collaborative development and licensing agreements with Genentech, Inc. relating to the development of products using the Company's technology to deliver certain of Genentech's proprietary growth factors to treat Parkinson's disease, Huntington's disease and amyotrophic lateral sclerosis ("ALS").

Under the terms of the agreement for Parkinson's disease, Genentech purchased 829,171 shares of common stock for \$8,300,000 to fund development of products to treat Parkinson's disease. Additional equity purchases and other funding by Genentech is available for future clinical development as determined by the parties. Genentech has the right, in its discretion, to terminate the Parkinson's program at specified milestones in the program. If the Parkinson's program is terminated and the funds the Company received from the sale of stock to Genentech pursuant to the Parkinson's agreement exceed the expenses incurred by the Company in connection with such studies by more than \$1 million, Genentech has the right to require the Company to repurchase from Genentech shares of Company Common Stock having a value equal to the amount of the overfunding, based upon the share price paid by Genentech. As such, the Common Stock purchased by Genentech is classified as Redeemable Common Stock until such time as the related funds are expended on the program. On May 21, 1998, Genentech exercised its right to terminate the collaboration and negotiations are currently underway to determine the balance of Redeemable Common Stock to be redeemed in accordance with the agreement.

The Company also licensed certain growth factors for the treatment of Huntington's disease and amyotrophic lateral sclerosis ("ALS"). Under the terms of the agreements, the Company is responsible for conducting and funding all preclinical and clinical development, subject to specified rights

of Genentech to participate in the development and marketing of the proposed products. Should Genentech share in the development cost of the proposed products, the companies will share profits at a negotiated percentage upon commercialization. Should Genentech elect not to participate in the development, upon commercialization, the Company will pay Genentech an agreed upon royalty based upon sales. These agreements supersede the Development Collaboration and License Agreement between the Company and Genentech entered into in March 1994.

In March 1995, the Company signed a collaborative research and development agreement with Astra AB for the development and marketing of certain encapsulated-cell products to treat pain. Astra made an initial, nonrefundable payment of \$5,000,000, a milestone payment of \$3,000,000 in the first quarter of 1997 which was recognized as revenue in the second quarter of 1997 and may make up to \$13,000,000 in additional payments subject to the achievement of certain development milestones. Under the agreement, the Company is obligated to conduct certain research and development pursuant to a four-year research plan agreed upon by the parties. Over the term of the research plan, the Company expects to receive annual research payments from Astra of \$5 million to \$7 million. Subject to the successful development of such products and obtaining necessary regulatory approvals, Astra is obligated to conduct all clinical trials of products arising from the collaboration and to seek approval for their sale and use. Astra has the exclusive worldwide right to market products covered by the agreement. Until the later of either the last to expire of all patents included in the licensed technology or a specified fixed term, the Company is entitled to a royalty on the worldwide net sales of such products in return for the license granted to Astra and the Company's obligation to manufacture and supply such products. Astra has the right to terminate the original agreement beginning April 1, 1998. In May 1998, Astra AB agreed to increase the annual research and development payments from \$7 million to \$8.5 million for the calendar year 1998. This increase in funding will be recognized as revenue in the 3rd and 4th quarters of 1998.

Substantial additional funds will be required to support the Company's research and development programs, for acquisition of technologies and intellectual property rights, for preclinical and clinical testing of its anticipated products, pursuit of regulatory approvals, acquisition of capital equipment, expansion of laboratory and office facilities, establishment of production capabilities and for general and administrative expenses. Until the Company's operations generate significant revenues from product sales, cash reserves and proceeds from equity and debt offerings, and funding from collaborative arrangements will be used to fund operations.

The Company intends to pursue opportunities to obtain additional financing in the future through equity and debt financings, lease agreements related to capital equipment, grants and collaborative research arrangements. The source, timing

and availability of any future financing will depend principally upon equity market conditions, interest rates and, more specifically, on the Company's continued progress in its exploratory, preclinical and clinical development programs. There can be no assurance that such funds will be available on favorable terms, if at all.

The Company expects that its existing capital resources, revenues from collaborative agreements and income earned on invested capital will be sufficient to fund its operations through 1999. The Company's cash requirements may vary, however, depending on numerous factors. Lack of necessary funds may require the Company to: delay, scale back or eliminate some or all of its research and product development programs; and/or reduce its capital expenditures; and/or license its potential products or technologies to third parties.

PART II - ITEM 1

LEGAL PROCEEDINGS

None.

PART II - ITEM 4

SUBMISSION OF MATTERS TO A VOTE OF SECURITY-HOLDERS

- (a) On May 5, 1998 the 1998 Annual Meeting of Stockholders was held in Lincoln, Rhode Island.
- (b) Not applicable
- (c) The following is a brief description of each matter voted upon at the meeting and a breakdown of the votes cast for, against or withheld, as well as the number of abstentions voted for each proposal.

1. Proposal to elect the following nominees as Directors of the Company: Mark J. Levin, Irving L. Weissman, M.D.

Mr. Levin -	13,727,774 votes in favor 107,272 votes withheld
Dr. Weissman -	13,727,423 votes in favor 107,623 votes withheld

PART II - ITEM 6

EXHIBITS AND REPORTS ON FORM 8-K

- (a) Exhibits  
Exhibit 99 - Cautionary Factors Relevant to Forward-Looking-Information.
- (b) Reports on Form 8-K  
None.

SIGNATURE

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

CYTOTHERAPEUTICS, INC.  
-----  
(Name of Registrant)

August 14, 1998  
-----  
(Date)

/s/ John S. McBride  
-----  
Executive Vice President and Chief  
Financial Officer  
(principal financial officer and  
principal accounting officer)



## 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 Annual 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 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, by regulatory restrictions, 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 for a sufficiently long time to be efficacious and commercially viable; (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. While clinicians have generally had little difficulty in retrieving the Company's implants, there have been cases where the implant broke on attempted explant. The Company has changed its implantation procedure and is continuing a program of developing stronger implants. In addition, the viability of implanted encapsulated cells varies depending of the cell type, the implantation location and other factors. Lack of viability could restrict certain of the Company's programs to indications where long-term delivery of the therapeutics substances is not required. There can also be no assurance that the products that may be generated in the Company's stem cell programs will: (i) survive and persist in the desired locations, (ii) provide the therapeutic benefits intended, (iii) properly differentiate and integrate into existing tissue in the desired manner, or (iv) not cause tumors or other side effects.

There has been increasing regulatory concern about the risks of cell transplantation. Concern has focused on the use of 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; 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 the type of cells used in the Company's pain program). In addition, the FDA has proposed guidelines which impose significant constraints on the conduct of clinical trials utilizing xenotransplantation and are likely to significantly affect the cost of producing the Company's products using nonhuman cells; such costs could make the Company's products cost more to produce than the Company receives for their production. Furthermore, the FDA has published a "Proposed Approach to Regulation of Cellular and Tissue-Based Products" which relates to the use of human cells. The Company cannot presently determine the effects of such actions nor what other actions might be taken. Restrictions on the testing or use of cells, whether human or nonhuman, as human therapeutics could 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 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. Moreover, the Company is particularly dependent on its pain program partner, Astra AB, because changes in the development of this particular program may significantly affect the Company's stock price. In addition, because of the Company's obligation to repurchase certain of the stock it sold to Genentech in connection with certain termination's of the Parkinson's Agreement, any such termination could have an adverse effect on the Company's liquidity.

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 that a number of entities have filed applications relating to stem and/or progenitor cells. The Company is also 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 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 encapsulated products and expects that it may wish to genetically modify its stem/progenitor cells. 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" in the Company's Annual Report on Form 10-K.

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"

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. In addition, many suppliers of materials used by the Company in its media, implants, and other components have restricted the use of such materials for implantation into humans; if the Company cannot obtain the necessary materials for its implants, the Company would be adversely affected.

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 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. 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. 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. See "Reimbursement and Health Cost Control."



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