

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:  
JUNE 30, 1997

0-19871  
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  
-----

(I.R.S. Employer  
identification No.)

TWO RICHMOND SQUARE  
PROVIDENCE, RI 02906  
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(Address of principal executive offices including zip code)

(401) 272-3310  
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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, 1997 there were 16,536,172 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, 1997 (unaudited)	December 31, 1996 (audited)
	-----	-----
Assets		
Current assets:		
Cash and cash equivalents	\$ 12,434,980	\$ 19,921,584
Marketable securities	18,821,289	22,685,855
Receivables from collaborative agreement	162,967	70,681
Other current assets	1,167,613	1,074,091
	-----	-----
Total current assets	32,586,849	43,752,211
Property, plant and equipment, net	14,329,002	10,732,102
Other assets	4,385,865	3,912,430
	-----	-----
Total assets	\$ 51,301,716	\$ 58,396,743
	=====	=====
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,125,335	\$ 4,159,769
Deferred revenue	20,371	1,859,092
Current maturities of capitalized lease obligations	519,418	553,557
Current maturities of long term debt	647,613	695,570
	-----	-----
Total current liabilities	5,312,737	7,267,988
Capitalized lease obligations, less current maturities	3,710,000	3,971,594
Long term debt, less current maturities	3,921,342	4,251,008
Redeemable common stock	6,667,681	8,158,798
Stockholders' equity		
Common stock	158,401	156,144
Additional paid in capital	109,486,998	107,649,659
Accumulated deficit	(77,802,237)	(72,922,674)
Deferred compensation	(35,359)	(90,118)
Unrealized currency loss	(100,765)	(60,416)
Unrealized gain (loss) on marketable securities	(17,082)	14,760
	-----	-----
Total stockholders' equity	31,689,956	34,747,355
	-----	-----
Total liabilities and stockholders' equity	\$ 51,301,716	\$ 58,396,743
	=====	=====

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,	
	1997	1996	1997	1996
Revenue from collaborative arrangements	\$ 5,084,864	\$ 1,850,632	\$ 6,941,486	\$ 3,514,849
Operating expenses:				
Research and development	4,449,727	4,175,341	9,099,227	8,080,500
General and administrative	1,684,917	1,173,221	3,481,347	2,407,269
	6,134,644	5,348,562	12,580,574	10,487,769
Loss from operations	(1,049,780)	(3,497,930)	(5,639,088)	(6,972,920)
Other income (expense):				
Investment income	467,769	572,744	1,116,399	1,207,269
Interest expense	(70,583)	(149,145)	(246,094)	(304,740)
Other income (expense)	(15,360)	342,500	(110,780)	342,500
	381,826	766,099	759,525	1,245,029
Net loss	(\$ 667,954)	(\$ 2,731,831)	(\$ 4,879,563)	(\$ 5,727,891)
Net loss per share	(\$ 0.04)	(\$ 0.18)	(\$ 0.30)	(\$ 0.37)
Shares used in calculation	16,498,374	15,368,009	16,484,864	15,320,989

See accompanying notes to condensed consolidated financial statements.

## PART I - ITEM 1 - FINANCIAL STATEMENTS

CYTOTHERAPEUTICS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Six Months Ended June 30,	
	1997	1996
	-----	
Cash flows from operating activities:		
Net loss	(\$ 4,879,563)	(\$ 5,727,891)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	967,350	794,645
Compensation expense relating to the grant of stock options	27,413	31,061
Loss on sale of fixed assets	825	--
Changes in operating assets and liabilities	(1,963,479)	(639,653)
	-----	-----
Net cash used in operating activities	(5,847,454)	(5,541,838)
	-----	-----
Cash flows from investing activities:		
Proceeds from sale of marketable securities	9,936,929	6,207,051
Purchases of marketable securities	(6,104,205)	(3,083,620)
Purchase of property, plant and equipment	(4,504,373)	(1,149,202)
Proceeds from the sale of fixed assets	1,941	--
Acquisition of other assets	(572,576)	(305,791)
	-----	-----
Net cash provided by (used in) investing activities	(1,242,284)	1,668,438
	-----	-----
Cash flows from financing activities:		
Proceeds from the exercise of stock options	375,825	1,085,138
Proceeds from financing transactions	--	821,172
Principal payments under capitalized lease obligations and mortgage payable	(538,485)	(497,425)
	-----	-----
Net cash provided by (used in) financing activities	(162,660)	1,408,885
Effect of exchange rate on cash and cash equivalents	(234,206)	--
	-----	-----
Decrease in cash and cash equivalents	(7,486,604)	(2,464,515)
Cash and cash equivalents, January 1	19,921,584	9,548,579
	-----	-----
Cash and cash equivalents, June 30	\$ 12,434,980	\$ 7,084,064
	=====	=====

See accompanying notes to condensed consolidated financial statements.

PART I - ITEM 1 - FINANCIAL STATEMENTS  
-----NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)  
JUNE 30, 1997 AND 1996

## 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, 1997 are not necessarily indicative of the results that may be expected for the entire fiscal year ended December 31, 1997.

For further information, refer to the audited financial statements and footnotes thereto as of December 31, 1996 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 PRONOUNCEMENTS

The Company will adopt Statement of Accounting Standards No. 128, Earnings per Share (EPS) which is effective for both interim and annual financial statements for periods ended after December 15, 1997. Under Statement 128, primary EPS computed in accordance with Opinion 15 will be replaced with a simpler calculation called basic EPS. Basic EPS will be calculated by dividing income available to common stockholders by the weighted average common shares outstanding. Fully dilutive EPS will not change significantly, but has been renamed diluted EPS. The adoption of Statement 128 is not expected to have any effect on the Company's financial statements since in the past common equivalent shares from stock options and warrants have been excluded as their effect is antidilutive.

## NOTE 4. LEGAL PROCEEDINGS

The Company has settled its dispute with NeuroSpheres LTD. The pending action in the United States District Court and its counterpart actions in Calgary, 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 has an option to acquire co-exclusive rights in exchange for an up front payment of \$5,000,000. NeuroSpheres' option expires in 1998, if unexercised. The parties have no further research obligations to each other.

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, 1997 and 1996 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, 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 substantially 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 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 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 payments.

#### RESULTS OF OPERATIONS

##### THREE MONTHS ENDED JUNE 30, 1997 AND 1996

For the quarter ended June 30, 1997 and 1996, revenues from collaborative

agreements totaled \$5,085,000 and \$1,851,000, respectively. The revenues were earned primarily from a Development, Marketing, and License Agreement with Astra AB. For the quarter ended June 30, 1997, the Company recognized a \$3,000,000 milestone payment from Astra related to the Phase II clinical program for ACTID (Analgesic Cell Therapy Implantable Device), the Company's cell-containing, pain control implant.

Research and development expenses totaled \$4,450,000 for the three months ended June 30, 1997, compared with \$4,175,000 for the same period in 1996. The increase of \$275,000, or 7%, from 1996 to 1997 is principally due to increases in the number of scientists and the addition of Modex, a 50% owned subsidiary, which contributed \$347,000 to the expense increase, partially offset by a decrease in expenses related to research agreements.

General and administrative expenses were \$1,685,000 for the three months ended June 30, 1997, compared with \$1,173,000 for the same period in 1996. The increase of 512,000 or 44%, from 1996 to 1997 was primarily attributable to legal expenses incurred related to arbitration proceedings with NeuroSpheres, an increase in patent expenses and the addition of Modex, a 50% owned subsidiary, which contributed \$211,000 to the increase.

Other income in the amount of \$343,000 was received in May 1996 for settlement of a legal suit filed on behalf of the Company.

Interest income for the three months ended June 30, 1997 and 1996 was \$468,000 and \$573,000, respectively. The average investment balances were \$34,672,000 and \$38,807,000 in the second quarter of 1997 and 1996, respectively.

Interest expense was \$71,000 for the three months ended June 30, 1997, compared with \$149,000 for the same period in 1996. The decrease from 1997 to 1996 was attributable to the capitalization of interest for the new facility in the amount of \$99,000.

Net loss for the three months ended June 30, 1997 was \$668,000, or \$0.04 per share, as compared to net loss of \$2,732,000, or \$0.18 per share, for the comparable period in 1996.

#### RESULTS OF OPERATIONS

##### SIX MONTHS ENDED JUNE 30, 1997 AND 1996

For the six months ended June 30, 1997 and 1996, revenues from collaborative agreements totaled \$6,941,000 and \$3,515,000. The revenues were earned primarily from a Development, Marketing and License Agreement with Astra AB. Included in the 1997 revenues is a \$3,000,000 milestone payment from Astra



related to the Phase II clinical program for ACTID (Analgesic Cell Therapy Implantable Device), the Company's cell-containing, pain control implant.

Research and development expenses totaled \$9,099,000 for the six months ended June 30, 1997, compared with \$8,081,000 for the same period in 1996. The increase of \$1,018,000 or 13%, from 1996 to 1997 is principally due to increases in the number of scientists and related expenses and the addition of Modex, a 50% owned subsidiary, which contributed \$704,000 to the increase.

General and administrative expenses were \$3,481,000 for the six months ended June 30, 1997, compared with \$2,407,000 for the same period in 1996. The increase of \$1,074,000 or 45%, from 1996 to 1997 was primarily attributable to increased spending for legal fees associated with the NeuroSpheres litigation, patents, recruiting fees and other professional services, as well as, the addition of Modex, a 50% owned subsidiary, which contributed \$286,000 to the increase.

Other income in the amount of \$343,000 was received in May 1996 for settlement of a legal suit filed on behalf of the Company.

Interest income for the six months ended June 30, 1997 and 1996 was \$1,116,000 and \$1,207,000, respectively. The average investment balances were \$37,555,000 and \$40,517,000 for the first six months of 1997 and 1996, respectively.

Interest expense was \$246,000 for the six months ended June 30, 1997, compared with \$305,000 for the same period in 1996. The decrease from 1996 to 1997 was attributable to the capitalization of interest for the new facility in the amount of \$99,000.

Net loss for the six months ended June 30, 1997 was \$4,880,000, or \$0.30 per share, as compared to net loss of \$5,728,000, or \$0.37 per share, for the comparable period in 1996.

#### 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 \$31,256,000 at June 30, 1997. Cash equivalents and marketable securities are invested in agencies of the U.S. government,

investment grade corporate bonds and money market funds.

The Company currently occupies all of its laboratory and administrative office space, other than that at its pilot manufacturing site, under the terms of operating leases subject to termination upon nine months notice by the Company. As a result of an anticipated increase in the number of employees, the Company's current facilities will not be sufficient to accommodate the Company's needs past the end of 1997. The Company has purchased land and a building and began construction of a new headquarters and laboratory facility in the fourth quarter of 1996. The total cost of the project is estimated to be \$7,800,000. The Company has spent \$6,273,000 on the project through June 30, 1997.

In October 1996, the Company obtained financing of \$5,500,000 from a bank, secured by a mortgage on the new facility. The Company had borrowed \$1,450,000 under this agreement as of June 30, 1997. Any unused commitment expires October 31, 1997. Quarterly principal payments of 1/40 of the loan balance commence September 30, 1997 with the balance due at maturity, October 2001. The loan agreement requires the Company provide full cash collateral if the Company's unencumbered cash balance falls below \$18,000,000 and to comply with certain financial covenants.

In May 1996, the Company secured an equipment loan facility with a bank in the amount of \$2,000,000. The Company has borrowed \$741,000 under this agreement as of June 30, 1997. The loan requires interest payments only for the first two years; principal payments are payable over a three-year period beginning May 1998. Any unused commitment expires on May 15, 1998. The loan is secured by equipment purchased with the proceeds of the credit facility.

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, 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 has an option to acquire co-exclusive rights in exchange for an up front payment of \$5,000,000. NeuroSpheres' option expires in 1998, if unexercised. 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. Based on in vitro data, a screening committee comprised of an equal number of representatives from CytoTherapeutics

and Cognetix will determine which compounds to select for in vivo studies and possible clinical trials. The companies will generally share expenses associated with the development of any specific product candidate and any resulting revenues, except as otherwise determined on a product-by-product basis. As part of the agreement with Cognetix, CytoTherapeutics has purchased \$250,000 of Cognetix preferred stock and subject to certain milestones, is obligated to purchase up to a total of \$1,750,000 of Cognetix stock over the next year. In July 1997, the Company loaned \$250,000 to Cognetix. The loan will bear interest and is payable on the earlier of February 20, 1998 or the completion of a financing greater than \$2,000,000 by Cognetix.

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. 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. Upon commercialization, Genentech and the Company will share profits in the U.S. at an agreed upon percentage, and Genentech will pay the Company a royalty based upon deals outside the U.S. The Company retains manufacturing rights and will be paid manufacturing costs for products sold.

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 July 1996, the Company invested \$2 million in Modex, a 50% owned Swiss subsidiary, to pursue extensions of the Company's encapsulated-cell technology for specific applications outside the central nervous system, with a commitment to invest an additional Sfr 2.4 million on the second anniversary of the agreement if Modex has, prior to that time, achieved one or more specified scientific milestones. An investment fund, managed by Swiss private bank, has invested \$2 million in Modex, with a commitment to invest an additional Sfr 1.2 million on the second anniversary of the agreement, in exchange for a 15% stake in the company. The remaining 35% of Modex is owned by the scientific founders of Modex. The Company has granted to Modex an exclusive, royalty-bearing license to the Company's proprietary encapsulated-cell technology for three applications outside the central nervous system: diabetes, obesity and anemia. Modex granted the Company 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, the Company is also obligated to issue to Modex up to 300,000 shares of the Company's 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' founding scientists and other researchers upon achievement of such milestones.

Under the terms of its agreement with the investment fund, during the first two years following closing, the Company has the right to acquire the fund's interest in Modex for the greater of a 30% annual return or Sfr 3.6 million. Following this two-year period, the Company has the right to purchase the fund's interest 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 the Company to purchase the fund's interest in Modex for 90% of the fair market value of such interest. Any purchase made by the Company under any of the circumstances described in this paragraph may be made at the Company's option in cash or shares of the Company's Common Stock valued at the market price at the time of purchase. The Company also has the right to acquire, and the founders have the right to require the Company to acquire, the founders' initial equity interest in Modex in exchange for the issuance of an aggregate of approximately 92,000 shares of the Company's Common Stock.

In March 1995, the Company signed a collaborative research and development agreement with Astra 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, which the Company expects should approximate the research and development costs incurred by the Company under the plan. 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 products. Astra has the right to terminate the agreement after April 1, 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 into the first half of 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 its capital expenditures or to license its potential products or technologies to third parties.

## PART II - ITEM 1

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LEGAL PROCEEDINGS

The Company has settled its dispute with NeuroSpheres LTD. The pending action in the United States District Court and its counterpart actions in Calgary, 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 has an option to acquire co-exclusive rights in exchange for an up front payment of \$5,000,000. NeuroSpheres' option expires in 1998, if unexercised. The parties have no further research obligations to each other.

## PART II - ITEM 4

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SUBMISSION OF MATTERS TO A VOTE OF SECURITY-HOLDERS

- (a) On May 6, 1997 the 1997 Annual Meeting of Stockholders was held in Providence, 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:  
Patrick Aebischer, Peter Simon, Richard Ramsden

Dr. Aebischer -	13,247,349 votes in favor 17,966 votes withheld
Mr. Simon -	13,247,468 votes in favor 17,847 votes withheld
Mr. Ramsden -	13,247,468 votes in favor 16,847 votes withheld

2. Proposal to increase by 100,000 the number of shares of Common Stock available for issuance under the Company's 1992 Employee Stock Purchase Plan.

12,706,879 votes in favor
74,487 votes against
43,980 votes abstaining
439,969 votes delivered - not voted

## PART II - ITEM 5

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OTHER INFORMATION

Effective as of August 4, 1997, Sandra Nusinoff Lehrman, M.D. resigned from the Company. Dr. Lehrman had served as the President, Chief Operating Officer and a Director of the Company. E. Edward Baetge, Ph.D. Vice President, Research, has also resigned from the Company.

## PART II - ITEM 6

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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, 1997  
-----  
(Date)

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

6-MOS  
DEC-31-1997  
JUN-30-1997  
12,434,980  
18,821,289  
0  
0  
0  
32,586,849  
22,170,181  
7,841,179  
51,301,716  
5,312,737  
7,631,342  
0  
0  
158,401  
31,531,555  
51,301,716  
0  
6,941,486  
0  
12,580,574  
0  
246,094  
(4,879,563)  
0  
(4,879,563)  
0  
0  
(4,879,563)  
(.30)  
(.30)

## 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 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 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, 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** - - 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. 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."