DIACRIN INC /DE/
Form 10-Q
August 13, 2001

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

Form 10-Q

(Mark One)

x --- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2001

OR

--- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File No. 000-20139

Diacrin, Inc.
(Exact name of registrant as specified in its charter)

Delaware	22-3016912
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

Building 96 13th Street, Charlestown Navy Yard,
Charlestown, MA 02129 (Address of principal executive offices, including zip code)

(617) 242-9100
(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 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

YES X NO
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Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

As of August 13, 2001, 17,914,704 shares of the registrant's Common Stock were outstanding.

Diacrin, Inc.
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Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 concerning our business, operations and financial condition, including statements with respect to development funding expected to be received in connection with our joint venture, the importance of cell transplantation and the availability of sufficient funds to continue our research and development efforts. All statements, other than statements of historical facts included in this Quarterly Report on Form 10-Q regarding our strategy, future operations, timetables for product testing, financial position, costs, prospects, plans and objectives of management are forward-looking statements. When used in this Quarterly Report on Form 10-Q, the words "expect," "anticipate," "intend," "plan," "believe," "seek," "estimate" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Because these forward-looking statements involve risks and uncertainties, actual results could differ materially from those expressed or implied by these forward-looking statements for a number of important reasons, including those discussed under "Certain Factors That May Affect Future Results" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." You should be aware that the occurrence of any of the events described in the risk factors and elsewhere in this Quarterly Report on Form 10-Q could substantially harm our business, results of operations and financial condition and that upon the occurrence of any of these events, the trading price of our common stock could decline.

We cannot guarantee any future results, levels of activity, performance or achievements. The forward-looking statements contained in this Quarterly Report on Form 10-Q represent our expectations as of the date this Quarterly Report on Form 10-Q was first filed with the Securities and Exchange Commission and should not be relied upon as representing our expectation as of any other date. Subsequent events and developments will cause our expectations to change. However, while we may elect to update these forward-looking statements, we specifically disclaim any obligation to do so even if our expectations change.

Diacrin, Inc.
Balance Sheets
(Unaudited)

	December 31, 2000
ASSETS	
Current assets:	
Cash and cash equivalents	$ 11,143,116
Short-term investments	22,485,675
Interest receivable and other current assets	780,406
Total current assets	34,409,197
Property and equipment, at cost:	
Laboratory and manufacturing equipment	1,655,064
Furniture and office equipment	320,106
Leasehold improvements	77,529
	2,052,699
Less- Accumulated depreciation and amortization	1,651,618
	401,081
Long-term investments	20,977,940
Investment in joint venture	4,785
Total other assets	20,982,725
Total assets	$ 55,793,003
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current liabilities:	
Current portion of long-term debt	$ 130,000
Accounts payable	109,307
Accrued expenses	1,323,786
Deferred revenue from joint venture	344,468

Total current liabilities	1,907,561
Long-term debt, net of current portion	119,167
Stockholders' equity:	
Preferred stock, $.01 par value, authorized-- 5,000,000 shares; none issued and outstanding	-
Common stock, $.01 par value; authorized-- 30,000,000 shares; issued and outstanding--17,914,704 shares at December 31, 2000 and June 30, 2001	179,147
Additional paid-in capital	101,373,922
Accumulated deficit	(47,786,794)
Total stockholders' equity	53,766,275
Total liabilities and stockholders' equity	$ 55,793,003

The accompanying notes are an integral part of these financial statements.

Diacrin, Inc.
Statements of Operations
(Unaudited)

	Three Months Ended June 30, 2000	2001	Si End 2000
REVENUES:			
Research and development	$ 506,587	$ 157,545	$ 1,042,626
Interest income	897,207	832,875	1,223,984
Total revenues	1,403,794	990,420	2,266,610
OPERATING EXPENSES:			
Research and development	1,560,868	1,698,341	2,943,461
General and administrative	310,316	461,811	676,789
Interest expense	8,155	3,859	16,697
Total operating expenses	1,879,339	2,164,011	3,636,947

EQUITY IN OPERATIONS OF JOINT VENTURE	(332,038)	(160,210)	(686,225
NET LOSS	$ (807,583)	$ (1,333,801)	$ (2,056,562
BASIC AND DILUTED NET LOSS PER COMMON SHARE	$ (.05)	$ (.07)	$ (.13)
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS PER COMMON SHARE	17,907,890	17,914,704	16,225,528

The accompanying notes are an integral part of these financial statements.

Diacrin, Inc.
Statements of Cash Flows
(Unaudited)

	Six Mont Ended June 2000	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (2,056,562)	$ (
Adjustments to reconcile net loss to net cash used in operating activities-		
Depreciation and amortization	106,090	
Equity in operations of joint venture	686,225	
Changes in assets and liabilities-		
Interest receivable and other current assets	(129,223)	
Accounts payable	5,967	
Accrued expenses	(219,180)	
Deferred revenue	(422,800)	
Net cash used in operating activities	(2,029,483)	(

CASH FLOWS FROM INVESTING ACTIVITIES:		
Decrease (increase) in short-term investments	3,507,207	(1
Purchases of property and equipment, net	(79,112)	
(Increase) decrease in long-term investments	(13,755,768)	1
Investment in joint venture	(789,645)	
Return of capital for services provided on behalf of joint venture	347,542	
Net cash used in investing activities	(10,769,776)	(
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from sale of common stock	37,137,247	
Principal payments on long-term debt	(77,525)	
Net cash provided by (used in) financing activities	37,059,722	
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	24,260,463	(
CASH AND CASH EQUIVALENTS, beginning of period	2,194,001	1
CASH AND CASH EQUIVALENTS, end of period	$ 26,454,464	$
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for interest during the period	$ 16,697	$

The accompanying notes are an integral part of these financial statements.

Diacrin, Inc.
Notes to Financial Statements
(Unaudited)

1. Operations and Basis of Presentation

Diacrin, Inc. (the "Company") was incorporated on October 10, 1989 and is developing transplantable cells for the treatment of human diseases which are characterized by cell dysfunction or cell death and for which current therapies are either inadequate or nonexistent.

The financial statements included herein have been prepared by the Company, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission and include, in the opinion of management, all adjustments, consisting of normal, recurring adjustments, necessary for a fair presentation of interim period results. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. The Company believes, however, that its disclosures are adequate to make the information presented not misleading. The results for the interim periods presented are not necessarily indicative of

results to be expected for the full fiscal year or any future periods. These financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's latest Annual Report on Form 10-K filed with the Securities and Exchange Commission.

2. Summary of Significant Accounting Policies

(a) Joint Venture Agreement

In September 1996, the Company and Genzyme Corporation ("Genzyme") formed a joint venture (the "Joint Venture") to develop and commercialize NeuroCell(TM)-PD for Parkinson's disease and NeuroCell(TM)-HD for Huntington's disease (the "Joint Venture Products"). The Joint Venture is funded by Genzyme and the Company in accordance with the terms of the joint venture agreement. Collaborative revenue under the joint venture agreement with Genzyme is recognized as revenue to the extent that the Company's research and development costs are funded by Genzyme through the Joint Venture. The Company receives non-refundable monthly advances from the Joint Venture. Deferred revenue represents amounts received prior to recognition of revenue. Research and development costs are expensed as incurred.

The detail of the Company's investment in the Joint Venture for the six months ended June 30, 2001 is as follows:

	2001
Balance, December 31, 2000	$ 4,785
Contributions to joint venture	691,841
Return of capital	(180,202)
Funding of operations of joint venture	(490,500)
Balance, June 30, 2001	$ 25,924

Contributions to the joint venture represent cash contributions. The return of capital represents cash payments made to the Company by the Joint Venture for research and development costs that are funded by the Company. Funding of operations of the Joint Venture represents costs incurred by Genzyme on behalf of the Joint Venture, which are funded by the Company.

A summary of the revenue and expenses from the joint venture are as follows:

	Six months ended June 30,	
	2000	2001
Revenue recognized	$1,042,626	$540,067
Research and development expense	$1,390,168	$720,089
Equity in operations of joint venture	$686,225	$382,639

(b) Net Loss per Common Share

In accordance with Statement of Financial Accounting Standards ("SFAS") No. 128, Earnings per Share, basic and diluted net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for all periods presented. Diluted weighted average shares outstanding for all periods presented exclude the potential common shares from stock options and warrants of 4,038,047 and 1,258,247 at June 30, 2000 and 2001, respectively, because to include such shares would be antidilutive.

(c) New Accounting Standards

In June 2001, the Financial Accounting Standards Board (FASB) issued SFAS 141, Business Combinations. This statement addresses financial accounting and reporting for business combinations and supercedes APB Opinion No. 16, Business Combinations and SFAS 38, Accounting for Preacquisition Contingencies of Purchased Enterprises. All business combinations in the scope of this Statement are to be accounted for using one method, the purchase method. The provisions of this Statement apply to all business combinations initiated after June 30, 2001.

Also in June 2001, the FASB issued SFAS 142, Goodwill and Other Intangible Assets. This Statement addresses financial accounting and reporting for acquired goodwill and other intangible assets and supercedes APB Opinion No. 17, Intangible Assets. It addresses how intangible assets that are acquired individually or with a group of other assets (but not those acquired in a business combination) should be accounted for in financial statements upon their acquisition. This Statement also addresses how goodwill and other intangible assets should be accounted for after they have been initially recognized in the financial statements. The Company does not expect adoption of this Statement to have a material impact on the Company's financial statements.

Diacrin, Inc.
Notes to Financial Statements
(Unaudited)

3. Cash Equivalents and Investments

The Company's cash equivalents and investments are classified as held-to-maturity and are carried at amortized cost, which approximates fair market value. Cash equivalents, short-term investments and long-term investments have maturities of less than ninety days, less than one year and greater than one year, respectively. Cash equivalents, short-term investments and long-term investments at December 31, 2000 and June 30, 2001 consisted of the following:

	December 31,
Cash and cash equivalents-	
Cash	$ 806
Corporate note	1,006,519
Money market mutual fund	10,135,791
	$ 11,143,116

Short-term investments-	
Corporate notes (remaining avg. mat. of 5 mos. at June 30, 2001)	22,485,675
Commercial paper (remaining mat. of 1 month at June 30, 2001)	-
	$ 22,485,675
Long-term investments-	
Corporate notes (remaining avg. mat. of 14 mos. at June 30, 2001)	$ 20,977,940

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

Since our inception, we have principally focused our efforts and resources on research and development of cell transplantation technology for treating human diseases that are characterized by cell dysfunction or cell death and for which current therapies are either inadequate or nonexistent. Our primary source of working capital to fund those activities has been proceeds from the sale of equity and debt securities. In addition, commencing October 1, 1996, we have received funding from our joint venture with Genzyme in support of the NeuroCell(TM)-PD and NeuroCell(TM)-HD product development programs. We have not received any revenues from the sale of products to date and do not expect to generate product revenues for the next several years. We have experienced fluctuating operating losses since inception and expect that the additional activities required to develop and commercialize our products will result in increasing operating losses for the next several years. At June 30, 2001, we had an accumulated deficit of $49.9 million.

In September 1996, we formed a joint venture with Genzyme to develop and commercialize NeuroCell(TM)-PD and NeuroCell(TM)-HD. Under the joint venture agreement, Genzyme agreed to fund 100% of the first $10 million of development and commercialization costs incurred after October 1, 1996, 75% of the next $40 million and 50% of all development and commercialization costs in excess of $50 million. After Genzyme funds the first $10 million, we are responsible for funding 25% of the next $40 million and 50% of all development and commercialization costs in excess of $50 million.

Through December 31, 1997, Genzyme made 100% of the total cash contributions to the joint venture. During the first quarter of 1998, we began making cash contributions to the joint venture equal to 25% of the Joint Venture's funding requirements. As of June 30, 2001, Genzyme had contributed approximately $31.8 million to the joint venture and we had contributed approximately $7.2 million.

We record as research and development expense all costs related to the joint venture incurred by us on behalf of the Joint Venture. We then recognize

research and development revenue equal to the amount of reimbursement received by us from the joint venture out of funds contributed by Genzyme. We do not recognize research and development revenue for amounts we receive from the Joint Venture out of funds contributed by us. As Genzyme incurs costs on behalf of the Joint Venture that we are obligated to fund, we recognize an expense in our statement of operations captioned "Equity in operations of joint venture."

Results of Operations

Three Months Ended June 30, 2001 Versus Three Months Ended June 30, 2000

Research and development revenues of approximately $158,000 for the three months ended June 30, 2001 and $507,000 for the three months ended June 30, 2000 were derived exclusively from the Joint Venture. The decrease in revenues was primarily a result of a decrease in clinical production activity related to the Joint Venture Products.

Interest income was $833,000 and $897,000 for the three months ended June 30, 2001 and 2000, respectively. The decrease in interest income was due to lower average cash balances available for investment in the current year period.

Research and development expenses were $1.7 million and $1.6 million for the three months ended June 30, 2001 and 2000, respectively. The increase in research and development expenses is primarily due to an increase in costs associated with sponsoring and managing the Company's clinical trials.

General and administrative expenses were $462,000 and $310,000 for the three months ended June 30, 2001 and 2000, respectively. The increase in general and administrative expenses is primarily due to an increase in professional fees incurred as the Company evaluated strategic relationships.

For the three months ended June 30, 2001 and 2000, the Company recorded an expense of $160,000 and $332,000, respectively, related to its equity in operations of the joint venture. This expense was due to funds contributed by the Company to the Joint Venture that were used to fund expenses incurred by Genzyme on behalf of the Joint Venture. The decreased charge in the current year period was primarily due to a decrease in clinical activity performed by Genzyme on behalf of the Joint Venture.

The Company incurred a net loss of approximately $1.3 million for the three months ended June 30, 2001 versus approximately $808,000 for the three months ended June 30, 2000.

Six Months Ended June 30, 2001 Versus Six Months Ended June 30, 2000

Research and development revenues were approximately $541,000 for the six months ended June 30, 2001 versus $1.0 million for the six months ended June 30, 2000 and were derived exclusively from the Joint Venture. The decrease in revenues was primarily a result of a decrease in clinical production activity related to the Joint Venture Products.

Interest income was $1.7 million and $1.2 million for the six months ended June 30, 2001 and 2000, respectively. The increase in interest income was due to greater average cash balances available for investment in the current year period as a result of the Company's public stock offering completed in March 2000.

Research and development expenses were $3.1 million for the six months

ended June 30, 2001 and $2.9 million for the six months ended June 30, 2000. The increase in research and development costs is primarily due to an increase in costs associated with sponsoring and managing the Company's clinical trials.

General and administrative expenses were $887,000 and $677,000 for the six months ended June 30, 2001 and 2000, respectively. The increase in general and administrative expenses is primarily due to an increase in professional fees incurred as the Company evaluated strategic relationsips.

For the six months ended June 30, 2001 and 2000, the Company recorded an expense of $383,000 and $686,000, respectively, related to its equity in operations of the joint venture. This expense was due to funds contributed by the Company to the Joint Venture that were used to fund expenses incurred by Genzyme on behalf of the Joint Venture. The decreased charge in the current year period was primarily due to a decrease in clinical activity performed by Genzyme on behalf of the Joint Venture

The Company incurred a net loss of approximately $2.1 million for the six months ended June 30, 2001 and for the six months ended June 30, 2000.

Liquidity and Capital Resources

We have financed our activities primarily with the net proceeds from the sale of equity and debt securities aggregating $102 million and with the interest earned thereon. In addition, we have recorded approximately $15.0 million in revenue from our joint venture since it commenced on October 1, 1996. At June 30, 2001, we had cash and cash equivalents, short-term investments and long-term investments aggregating approximately $52.3 million.

We have purchased approximately $2.4 million of capital equipment since inception. In November 1997, we borrowed $650,000 at the prime rate plus 0.5% (7.25% at June 30, 2001) under an unsecured five-year term loan with a bank to finance our biomedical animal facility acquired during 1997. At June 30, 2001, we had $184,167 outstanding under the borrowing. We had no material commitments for capital expenditures as of June 30, 2001.

We believe that our existing funds, together with expected future funding under the joint venture agreement with Genzyme, will be sufficient to fund our operating expenses and capital requirements as currently planned for the foreseeable future. However, our cash requirements may vary materially from those now planned because of results of research and development, the scope and results of preclinical and clinical testing, any termination of the joint venture, relationships with future strategic partners, changes in the focus and direction of our research and development programs, competitive and technological advances, the FDA's regulatory process, the market acceptance of any approved products and other factors.

We expect to incur substantial additional costs, including costs related to ongoing research and development activities, preclinical studies, clinical trials, expanding our cell production capabilities and the expansion of our laboratory and administrative activities. Therefore, in order to achieve commercialization of our potential products, we may need substantial additional funds. We cannot assure you that we will be able to obtain the additional funding that we may require on acceptable terms, if at all.

Certain Factors That May Affect Future Results

The following important factors, among others, could cause actual results to differ materially from those contained in forward-looking statements made in this Quarterly Report on Form 10-Q or presented elsewhere by management from time to time. See "Cautionary Note Regarding Forward-Looking Statements."

Risks Related to Our Business, Industry and Strategy

We have not successfully commercialized any products to date and, if we do not successfully commercialize any products, we will not be profitable

Neither we nor any other company has received regulatory approval to market the types of products we are developing. The products that we are developing will require additional research and development, clinical trials and regulatory approval prior to any commercial sale. Our product candidates are currently in early phase clinical trials or in the preclinical stage of development. Our products may not be effective in treating any of our targeted disorders or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may prevent or limit their commercial use.

We currently have no products for sale and do not expect to have any products available for sale for several years. If we are not successful in developing and commercializing any products, we will never become profitable.

The evaluation of the unblinded data from our recently completed Phase 2/3 clinical trial of NeuroCell-PD may not support further development

In March 2001, we unblinded our Phase 2/3 clinical trial of NeuroCell-PD and announced a preliminary analysis of the results. We did not see a statistically significant difference between the treated patients and the patients in the control group and, therefore, did not meet the primary endpoint in the trial. While we are still evaluating the data from this clinical trial, it is possible that further clinical development of NeuroCell-PD will not be supported by Genzyme, or that we may choose to discontinue development or modify the clinical trial protocols, which could result in the termination of or significant delay in the progress of the NeuroCell-PD development program.

We are dependent on Genzyme Corporation to fund, develop and market NeuroCell-PD, and if our joint venture with Genzyme terminates, we may not be able to complete development or commercialization of NeuroCell-PD

We have entered into a joint venture agreement with Genzyme relating to the development and commercialization of NeuroCell-PD to treat Parkinson's disease. This agreement also covers our NeuroCell-HD product candidate. Under this agreement, Genzyme has agreed to provide significant funding toward the development and commercialization of these products and to market and sell the products on behalf of the joint venture. Genzyme has the right to terminate the agreement at any time upon 180 days notice to us. We cannot assure you that Genzyme will not terminate this agreement because of the results of the Phase 2/3 clinical trial or for any other reason. In addition, there can be no assurance that our economic and other interests will coincide with those of Genzyme during the term of the agreement. If Genzyme were to terminate this agreement, we:

- would lose a significant source of funding for the NeuroCell-PD and NeuroCell-HD product development programs;

- would lose access to Genzyme's experienced development, sales and marketing organizations and manufacturing facilities;

- would need to establish clinical production facilities for the production of NeuroCell-PD and NeuroCell-HD; and

- may be unable to complete development or commercialization of NeuroCell-PD and NeuroCell-HD.

In addition, Genzyme has the right to terminate the joint venture agreement following an unremedied breach of any material term of the agreement by us. If Genzyme terminates the agreement, Genzyme has the option to obtain an exclusive, worldwide, royalty bearing license to some of our technology which is required to manufacture and market NeuroCell-PD and NeuroCell-HD. If Genzyme exercises this option, we would only be entitled to receive a royalty on the net sales of NeuroCell-PD and NeuroCell-HD and this royalty would be significantly less than the amounts we would be entitled to receive under the joint venture agreement.

Our cell transplantation technology is complex and novel and there are uncertainties as to its effectiveness

We have concentrated our efforts and therapeutic product research on cell transplantation technology, and our future success depends on the successful development of this technology. Our principal approach is based upon xenotransplantation, or the transplantation of cells, tissues or organs from one species to another. Our product candidates generally involve the transplantation of porcine (pig) neural cells into humans. Xenotransplantation is an emerging technology with limited clinical experience. Neither the FDA nor any foreign regulatory body has approved any xenotransplantation-based therapeutic product for humans.

Our technological approaches may not enable us to successfully develop and commercialize any products. If our approaches are not successful, we may be required to change the scope and direction of our product development activities. In that case, we may not be able to identify and implement successfully an alternative product development strategy.

Xenotransplantation involves risks which have resulted in additional FDA oversight and which in the future may result in additional regulation

Xenotransplantation poses a risk that viruses or other animal pathogens may be unintentionally transmitted to a human patient. The FDA requires us to perform tests to determine whether infectious agents, including porcine endogenous retroviruses, referred to as PERV, are present in patients who have received porcine cells. While PERV has not been shown to cause any disease in pigs, it is not known what effect, if any, PERV may have on humans. We have performed tests on patients who have received our porcine cells. No PERV has been detected to date, but we cannot assure you that we will not detect PERV or another infectious agent in the future.

The FDA requires lifelong monitoring of porcine cell transplant recipients. If PERV or any other virus or infectious agent is detected in tests or samples, the FDA may require us to halt our clinical trials and perform additional tests to assess the risk to patients of infection. This could result in additional costs to us and delays in the trials of our porcine cell products. Furthermore, even if patients who have received our porcine cells remain PERV-free, we could be adversely affected if PERV is detected in patients who receive porcine cells

provided by others.

In January 2001, the FDA issued definitive regulatory guidelines for xenotransplantation titled "PHS Guideline on Infectious Disease Issues in Xenotransplantation." We cannot assure you that we will be able to comply with these guidelines.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do

The products we are developing compete with existing and new products being developed by pharmaceutical, biopharmaceutical and biotechnology companies, as well as universities and other research institutions. Many of our competitors are substantially larger than we are and have substantially greater capital resources, research and development staffs and facilities than we have. Efforts by other biotechnology or pharmaceutical companies could render our products uneconomical or result in therapies for the disorders we are targeting that are superior to any therapy we develop. Furthermore, many of our competitors are more experienced in product development and commercialization, obtaining regulatory approvals and product manufacturing. As a result, they may develop competing products more rapidly and at a lower cost. These competitors may discover, develop and commercialize products which render non-competitive or obsolete the products that we are seeking to develop and commercialize.

If the market is not receptive to our products upon introduction, our products may not achieve commercial success

The commercial success of any of our products will depend upon their acceptance by patients, the medical community and third-party payors. Among the factors that we believe will materially affect acceptance of our products are:

- the timing of receipt of marketing approvals and the countries in which those approvals are obtained;

- the safety and efficacy of our products;

- the need for surgical administration of our products;

- problems encountered in the field of xenotransplantation;

- the success of physician education programs;

- the cost of our products which may be higher than conventional therapeutic products because our products involve surgical transplantation of living cells; and

- the availability of government and third-party payor reimbursement of our products.

Risks Relating to Clinical and Regulatory Matters

If our clinical trials are not successful for any reason, we will not be able to develop and commercialize any related products

In order to obtain regulatory approvals for the commercial sale of our product candidates, we will be required to complete extensive clinical trials in humans to demonstrate the safety and efficacy of the products. We have limited experience in conducting clinical trials.

The submission of an investigational new drug application, or IND, may not result in FDA authorization to commence clinical trials. If clinical trials begin, we may not complete testing successfully within any specific time period, if at all, with respect to any of our product candidates. Furthermore, we or the FDA may suspend clinical trials at any time on various grounds, including a finding that the patients are being exposed to unacceptable health risks. Clinical trials, if completed, may not show any potential product to be safe or effective. Thus, the FDA and other regulatory authorities may not approve any of our product candidates for any disease indication.

The rate of completion of clinical trials depends in part upon the rate of enrollment of patients. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the existence of competitive clinical trials and the availability of alternative treatments. In particular, the patient population for some of our potential products is small. Delays in planned patient enrollment may result in increased costs and program delays.

We rely on third-party clinical investigators to conduct our clinical trials. As a result, we may encounter delays outside of our control.

We may not be able to reinitiate a clinical trial that has been suspended by the FDA

Clinical trials are subject to ongoing review by the FDA. The FDA has the authority to suspend a clinical trial for various reasons, as they did in April 2000 with respect to our clinical trial using porcine neural cells to treat stroke patients. Because our products are novel and complex, getting the FDA to lift a suspension could result in significant program delays and additional costs to us. It is possible that we may not be able to obtain permission from the FDA to continue a clinical trial that has been suspended. Cost increases and ongoing delays as a result of an FDA suspension could result in our decision to postpone pursuing certain product candidates.

The regulatory approval process is costly and lengthy and we may not be able to successfully obtain all required regulatory approvals

We must obtain regulatory approval for each of our product candidates before we can market or sell it. We may not receive regulatory approvals to conduct clinical trials of our products or to manufacture or market our products. In addition, regulatory agencies may not grant approvals on a timely basis or may revoke previously granted approvals. Any delay in obtaining, or failure to obtain, approvals could adversely affect the marketing of our products and our ability to generate product revenue.

The process of obtaining FDA and other required regulatory approvals is lengthy and expensive. The time required for FDA and other clearances or approvals is uncertain and typically takes a number of years, depending on the complexity and novelty of the product. We have only limited experience in filing and prosecuting applications necessary to gain regulatory approvals.

Our analysis of data obtained from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities which could delay, limit or prevent regulatory approval. Any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may

market the product. These limitations may limit the size of the market for the product.

We also are subject to numerous foreign regulatory requirements governing the design and conduct of the clinical trials and the manufacturing and marketing of our future products. The approval procedure varies among countries. The time required to obtain foreign approvals often differs from that required to obtain FDA approvals. Moreover, approval by the FDA does not ensure approval by regulatory authorities in other countries.

Even if we obtain marketing approval, our products will be subject to ongoing regulatory oversight which may affect the success of our products

Any regulatory approvals that we receive for a product may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing follow-up studies. After we obtain marketing approval for any product, the manufacturer and the manufacturing facilities for that product will be subject to continual review and periodic inspections by the FDA and other regulatory authorities. The subsequent discovery of previously unknown problems with the product, such as the presence of PERV, or with the manufacturer or facility, may result in restrictions on the product or manufacturer, including withdrawal of the product from the market.

If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

Risks Relating to Financing Our Business

We have incurred substantial losses, we expect to continue to incur losses and we may never achieve profitability

We have incurred losses in each year since our founding in 1989. At June 30, 2001, we had an accumulated deficit of $49.9 million. We expect to incur substantial operating losses for the foreseeable future. We have no material sources of revenue from product sales or license fees. We anticipate that it will be a number of years, if ever, before we develop significant revenue sources or become profitable, even if we are able to commercialize products.

We expect to increase our spending significantly as we continue to expand our research and development programs, expand our clinical trials, apply for regulatory approvals and begin commercialization activities. In particular, we may devote significant economic resources to funding our joint venture with Genzyme and to its product development plans. Under the joint venture agreement, we are currently required to provide 25% of the funding required for the development and commercialization of NeuroCell-PD and NeuroCell-HD and in the future will be required to provide 50% of the required funding.

We may require additional financing, which may be difficult to obtain and may dilute your ownership interest

We will require substantial funds to conduct research and development, including clinical trials of our product candidates, and to manufacture and market any products that are approved for commercial sale. We believe that our existing funds, together with expected future funding under the joint venture agreement with Genzyme will be sufficient to fund our operating expenses and capital requirements as currently planned for the foreseeable future. However,

our future capital requirements will depend on many factors, including the following:

- the analysis of the data from the Phase 2/3 clinical trial of NeuroCell-PD which could result in the termination of our joint venture with Genzyme;

- continued progress in our research and development programs, as well as the magnitude of these programs;

- the resources required to successfully complete our clinical trials;

- the time and costs involved in obtaining regulatory approvals;

- the cost of manufacturing and commercialization activities;

- the cost of any additional facilities requirements;

- the timing, receipt and amount of milestone and other payments from future collaborative partners;

- the timing, receipt and amount of sales and royalties from our potential products in the market; and

- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and the costs of obtaining any required licenses to technologies.

We may seek additional funding through collaborative arrangements and public or private financings. Additional financing may not be available to us on acceptable terms or at all.

If we raise additional funds by issuing equity securities further dilution to our then existing stockholders may result. In addition, the terms of the financing may adversely affect the holdings or the rights of our stockholders. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs.

We also could be required to seek funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, product candidates, or products which we would otherwise pursue independently.

Risks Relating to Intellectual Property

We may not be able to obtain patent protection for our discoveries and we may infringe patent rights of others

The patent positions of pharmaceutical and biotechnology companies, including us, are generally uncertain and involve complex legal, scientific and factual issues.

Our success depends significantly on our ability to:

- obtain patents;

- protect trade secrets;

- operate without infringing upon the proprietary rights of others; and

- prevent others from infringing on our proprietary rights.

Patents may not issue from any patent applications that we own or license. If patents do issue, the claims allowed may not be sufficiently broad to protect our technology. In addition, issued patents that we own or license may be challenged, invalidated or circumvented. Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States may be maintained in secrecy until patents issue, others may have filed or maintained patent applications for technology used by us or covered by our pending patent applications without our being aware of these applications.

We may not hold proprietary rights to some patents related to our proposed products. In some cases, others may own or control these patents. As a result, we or our collaborative partners may be required to obtain licenses under third-party patents to market some of our proposed products. If licenses are not available to us on acceptable terms, we will not be able to market these affected products.

If we are not able to keep our trade secrets confidential, our technology and information may be used by others to compete against us

We rely significantly upon unpatented proprietary technology, information, processes and know how. We seek to protect this information by confidentiality agreements with our employees, consultants and other third-party contractors as well as through other security measures. These confidentiality agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors.

We may become involved in expensive patent litigation or other intellectual property proceedings which could result in liability for damages or stop our development and commercialization efforts

There has been substantial litigation and other proceedings regarding the complex patent and other intellectual property rights in the pharmaceutical and biotechnology industries. We may become a party to patent litigation or other proceedings regarding intellectual property rights.

Other types of situations in which we may become involved in patent litigation or other intellectual property proceedings include:

- we may initiate litigation or other proceedings against third parties to enforce our patent rights;

- we may initiate litigation or other proceedings against third parties to seek to invalidate the patents held by these third parties or to obtain a judgment that our products or services do not infringe the third parties' patents;

- if our competitors file patent applications that claim technology also claimed by us, we may participate in interference or opposition proceedings to determine the priority of invention; and

- if third parties initiate litigation claiming that our processes or

products infringe their patent or other intellectual property rights, we will need to defend against such claims.

The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. If a patent litigation or other intellectual property proceeding is resolved unfavorably to us, we may be enjoined from manufacturing or selling our products and services without a license from the other party and be held liable for significant damages. We may not be able to obtain any required license on commercially acceptable terms or at all.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

If we breach any of the agreements under which we license technology from others we could lose license rights that are important to our business

We are a party to technology in-licenses that are important to our business and expect to enter into additional licenses in the future. In particular, our immunomodulation technology and some of our product candidates are covered by patents licensed from Massachusetts General Hospital, commonly referred to as MGH. These licenses impose commercialization, sublicensing, royalty, insurance and other obligations on us. If we fail to comply with these requirements, the licensor will have the right to terminate the license.

Risks Relating to Product Manufacturing, Marketing and Sales

Since we have no sales and marketing experience or infrastructure, we must rely on third parties

We have no sales, marketing and distribution experience or infrastructure. We plan to rely significantly on sales, marketing and distribution arrangements with third parties for the products that we are developing. For example, under our joint venture agreement, we have granted to Genzyme (on behalf of the joint venture) exclusive worldwide marketing rights to NeuroCell-PD and NeuroCell-HD. We may have limited or no control over the sales, marketing and distribution activities of Genzyme, the joint venture or any future collaborative partners. Our future revenues will be materially dependent upon the success of the efforts of these third parties.

If in the future we determine to perform sales, marketing and distribution functions ourselves, we would face a number of additional risks, including:

- we may not be able to attract and build a significant marketing or sales force;

- the cost of establishing a marketing or sales force may not be justifiable in light of any product revenues; and

- our direct sales and marketing efforts may not be successful.

Delays in obtaining regulatory approval of our manufacturing facility and disruptions in our manufacturing process may delay or disrupt our commercialization efforts

Before we can begin commercially manufacturing our product candidates, we must obtain regulatory approval of our manufacturing facility and process. Manufacturing of our product candidates must comply with cGMP, and foreign regulatory requirements. The cGMP requirements govern quality control and documentation policies and procedures. In complying with cGMP and foreign regulatory requirements, we will be obligated to expend time, money and effort on production, recordkeeping and quality control to ensure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we would be subject to possible regulatory action and may be limited in the jurisdictions in which we are permitted to sell our product candidates.

We are the only manufacturers of our product candidates. For the next several years, we expect that we will conduct all of our manufacturing in our facility in Charlestown, Massachusetts. If this facility or the equipment in this facility is significantly damaged or destroyed, we will not be able to quickly or inexpensively replace our manufacturing capacity.

We have no experience manufacturing our product candidates in the volumes that will be necessary to support large clinical trials or commercial sales. Our present manufacturing process may not meet our initial expectations as to scheduling, reproducibility, yield, purity, cost, potency or quality.

The manufacture of our products would be delayed by disruptions in our supply of porcine tissue

The manufacture of our products requires the continuous availability of porcine tissue harvested from pigs tested to be free of infectious agents and quarantined in a qualified animal facility. Our main sources of these facilities and services are Tufts University School of Veterinary Medicine and PharmServices, Inc., a division of Charles River Laboratories, Inc. A disease epidemic or other catastrophe in either of these facilities could destroy all or a portion of our pig supply, which would interrupt or significantly delay the research, development and commercialization of our products.

Risks Related to Ongoing Operations

If we fail to obtain an adequate level of reimbursement for our future products by third party payors, there may be no commercially viable markets for our products

Our products may be more expensive than conventional treatments because they involve the surgical transplantation of living cells. The availability of reimbursement by governmental and other third-party payors affects the market for any pharmaceutical product. These third-party payors continually attempt to contain or reduce the costs of health care by challenging the prices charged for medical products. In some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. We may not be able to sell our products profitably if reimbursement is unavailable or limited in scope or amount.

In both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system. Further proposals are likely. The potential for adoption of these proposals may affect our ability to raise capital, obtain additional collaborative partners and market our products.

If we obtain marketing approval for our products, we expect to experience pricing pressure due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals.

We could be exposed to significant liability claims if we are unable to obtain insurance at acceptable costs or otherwise to protect us against potential product liability claims

We may be subjected to product liability claims that are inherent in the testing, manufacturing, marketing and sale of human health care products. These claims could expose us to significant liabilities that could prevent or interfere with the development or commercialization of our products. Product liability claims could require us to spend significant time and money in litigation or to pay significant damages. Product liability insurance is generally expensive for biopharmaceutical companies such as ours. Although we maintain limited product liability insurance coverage for the clinical trials of our products, it is possible that we will not be able to obtain further product liability insurance on acceptable terms, if at all, and that our present insurance levels and insurance subsequently obtained will not provide adequate coverage against all potential claims.

Our growth could be limited if we are unable to attract and retain key personnel and consultants

Our success depends substantially on our ability to attract and retain qualified scientific and technical personnel for the research and development activities we conduct or sponsor. If we lose one or more of the members of our senior management or other key employees or consultants, our business and operating results could be seriously harmed.

Our anticipated growth and expansion into areas and activities requiring additional expertise, such as regulatory compliance, manufacturing and marketing, will require the addition of new management personnel. The pool of personnel with the skills that we require is limited. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate such additional personnel.

Risks Relating to our Common Stock

Our officers and directors may be able to control the outcome of most corporate actions requiring stockholder approval

Our directors and officers and entities with which they are affiliated control approximately 40% of our outstanding common stock. Due to this concentration of ownership, this group may be able to prevail on all matters requiring a stockholder vote, including:

- the election of directors;

- the amendment of our organizational documents; or

- the approval of a merger, sale of assets or other major corporate transaction.

Our stock price could be volatile, which could cause you to lose part or all of your investment

The market price of our common stock, like that of the common stock of many other development stage biotechnology companies, may be highly volatile. In addition, the stock market has experienced extreme price and volume fluctuations. This volatility has significantly affected the market prices of

securities of many biotechnology and pharmaceutical companies for reasons frequently unrelated to or disproportionate to the operating performance of the specific companies. These broad market fluctuations may adversely affect the market price of our common stock. Prices for our common stock will be determined in the market place and may be influenced by many factors, including variations in our financial results and investors' perceptions of us, changes in recommendations by securities analysts as well as their perceptions of general economic, industry and market conditions.

We have antitakeover defenses that could delay or prevent an acquisition and could adversely affect the price of our common stock

Provisions of our certificate of incorporation, our bylaws, and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing changes in control of our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interest.

Our certificate of incorporation permits our board of directors to issue preferred stock without shareholder approval upon such terms as the board of directors may determine. The rights of the holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued in the future. The issuance of preferred stock, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from acquiring, a majority of our outstanding common stock. The issuance of a substantial number of preferred shares could adversely affect the price of our common stock.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We own financial instruments that are sensitive to market risks as part of our investment portfolio. The investment portfolio is used to preserve our capital until we are required to fund operations, including our research and development activities. None of these market-risk sensitive instruments are held for trading purposes. We do not own derivative financial instruments in our investment portfolio. The investment portfolio contains instruments that are subject to the risk of decline in interest rates.

Our investment portfolio includes investment grade debt instruments. These bonds are subject to interest rate risk, and could decline in value if interest rates fluctuate. Due to the short duration and conservative nature of these instruments, we do not believe that we have a material exposure to interest rate risk.

PART II. OTHER INFORMATION

Item 2. Changes in Securities and Use of Proceeds

(c) The Company did not sell any equity securities during the quarter ended June 30, 2001 that were not registered under the Securities Act.

(d) The following information updates and supplements the information regarding use of proceeds originally filed by Diacrin on Form SR for the period ended May 12, 1996, as amended to date and relates to securities sold by the Company pursuant to the Registration Statement on Form S-2 (Registration No: 33-80773) which was declared effective on February 12, 1996: Through June 30, 2001, the Company has used approximately $20,818,000 of the total net proceeds from its initial public offering of $20,911,755. Of the $20,818,000 used, approximately $400,000 was used for the purchase of machinery and equipment; approximately $1,070,000 was used for repayment of indebtedness; and approximately $19,348,000 was used for working capital. The unused proceeds of approximately $94,000 are in temporary investments consisting of corporate notes and a money market mutual fund. All proceeds used or invested were direct or indirect payments to others.

Item 4. Submission of Matters to a Vote of Security Holders

At the Company's Annual Meeting of Stockholders held on July 31, 2001, the following proposals were adopted by the vote specified below:

Proposal	For	Against
1. Election of Directors:		
Thomas H. Fraser	15,338,310	144,353
Zola P. Horovitz	15,438,310	44,353
John W. Littlechild	15,438,310	44,353
Stelios Papadopoulos	15,438,310	44,353
Joshua Ruch	15,438,310	44,353
Henri Termeer	12,449,845	3,032,818

	For	Against	Abstain
2. To ratify the selection of Arthur Andersen LLP as the Company's Independent auditors for fiscal 2001:	15,463,485	17,428	1,750

Item 6. Exhibits and Reports on Form 8-K

(b) Reports on Form 8-K

On June 29, 2001, the Company furnished a Current Report on Form 8-K under Item 9 furnishing a copy of the Letter to Shareholders being mailed to all shareholders as part of the Company's Annual Report.

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 thereunto duly authorized.

Diacrin, Inc.

August 13, 2001

/s/ Thomas H. Fraser

Thomas H. Fraser
President and
Chief Executive Officer

/s/ Kevin Kerrigan

Kevin Kerrigan
Controller