DIACRIN INC /DE/
Form 8-K
June 29, 2001

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported):
June 25, 2001

Diacrin, Inc.

(Exact name of registrant as specified in its charter)

Delaware	0-20139	22-3016912
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Building 96 13th Street Charlestown Navy Yard Charlestown, MA	02129
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (617) 242-9100

N/A

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

Item 9. Regulation FD Disclosure

On June 29, 2001, the Company began mailing its 2000 Annual Report to shareholders. Included in the 2000 Annual Report is a letter to our shareholders. The text of the letter is as follows:

To Our Shareholders:

We have made good progress in most of our product development programs over the last year. However, we recently reported inconclusive results from a Phase 2/3 clinical trial of NeuroCell(TM)-PD for the treatment of Parkinson's disease. Although treated patients showed significant clinical improvement from baseline after transplantation, there was also improvement in the imitation surgery control patients. Thus, the treatment group was not significantly improved over the control group. Several treatment group patients, however, showed marked improvement as measured by the Unified Parkinson's Disease Rating Scale (UPDRS) which was the primary endpoint in the clinical trial. We are continuing to analyze the clinical data to determine if it would be possible to prospectively identify patients that may show marked improvement after cell transplantation. In addition, we are evaluating the enrolled patients subsequent to being informed whether they received neural cells or imitation surgery.

Our other product development programs have not been affected by the NeuroCell(TM)-PD results, and we are moving forward with clinical trials. As of June, 2001 we had transplanted autologous human muscle cells into the hearts of four patients with heart disease as part of a Phase 1 clinical trial. Two of these patients were transplanted in conjunction with implantation of a ventricular assist device and two were transplanted in conjunction with a coronary artery bypass procedure. Patients with ventricular assist devices are expected to receive a future heart transplant, at which time we plan to histologically examine their hearts and may be able to determine survival and integration of the transplanted muscle cells. This clinical trial is being conducted at leading cardiac research centers including Temple University, University of Michigan, UCLA, and The Cleveland Clinic.

We have recently transplanted fetal porcine spinal cord cells into three patients that were paralyzed due to spinal cord damage. While it is too early to determine whether these patients' sensation and movement have improved, the transplantation appears to have been well-tolerated in all three patients. We plan to transplant three more patients to complete the Phase 1 clinical trial.

In addition, we plan to complete a Phase 1 clinical trial using fetal porcine inhibitory neurons to treat epilepsy and to begin transplanting fetal porcine neurons into the spinal cord of patients suffering from chronic intractable pain.

We are also working to resume our clinical trial to treat chronic stroke patients with fetal porcine neural cells. This trial is currently on hold, but we have reached an understanding with the FDA that should allow us to transplant additional patients and complete our Phase 1 clinical trial. Four of the five transplanted patients continue to show improvement.

Our net loss for the year was $3.5 million and we ended 2000 with cash and investments of $54.6 million. Our controlled rate of spending should allow us to continue with our currently planned clinical trials to determine safety and preliminary efficacy of our product candidates.

We continue to believe that cell transplantation products, even for complex conditions such as Parkinson's disease, will be successfully developed and will significantly improve the quality of life for people suffering from numerous intractable diseases. Inevitably, as we have seen with the NeuroCell(TM)-PD clinical trial, there will be disappointments along the way. We view these situations as learning experiences which will ultimately maximize our chances of success. At Diacrin we will continue to work hard to turn our pioneering cell transplantation research into products. I look forward to keeping you informed

of our progress.

/s/ Thomas H. Fraser

Thomas H. Fraser, Ph.D.
President and CEO

June 25, 2001

This filing contains certain forward-looking statements that involve risks and uncertainties, including statements with respect to the safety, efficacy, potential benefits and successful development of the Company's products under development, the importance of cell transplantation and the Company's plans relating to its products under development. Among the factors that could cause actual results to differ materially from those indicated by such forward-looking statements are: the results of clinical trials with respect to products under development; the submission, acceptance and approval of regulatory filings; the timing of the initiation and completion of clinical trials; the Company's ability to re-initiate a clinical trial that the FDA has put on hold; the continuation and/or success of the Company's joint venture with Genzyme Corporation; the scope of the Company's patent protection with respect to its product under development; the commercial success of the Company's products under development; the ability of the Company to attract and retain qualified personnel; the availability of sufficient funds to continue research and development efforts; and certain other factors. For a more detailed discussion of these and other factors, see the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2001 as filed with the Securities and Exchange Commission. The forward-looking statements contained in this Current Report on Form 8-K represent the expectations of the Company as of June 25, 2001, the date of the letter to the Company's shareholders. Subsequent events will cause the Company's expectations to change. However, while the Company may elect to update these forward-looking statements, it specifically disclaims any obligation to do so.

SIGNATURE

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

Date: June 29, 2001

DIACRIN INC.

By: /s/ Thomas H. Fraser

Thomas H. Fraser, Ph.D.
Chief Executive Officer