DIACRIN INC /DE/
Form 8-K
July 25, 2002

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):
July 25, 2002

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 July 25, 2002, the Company began mailing its 2001 Annual Report to shareholders. Included in the 2001 Annual Report is a letter to our shareholders. The text of the letter is as follows:

To Our Shareholders:

At Diacrin, we continue to believe that cell transplantation products will successfully address important unmet medical needs and that Diacrin will play a leading role in developing these products. In order to meet this challenge, we are continually evaluating our own and others' cell transplantation technologies to help ensure that we are on the leading edge of technology and are focusing our resources appropriately.

When Diacrin began operations over twelve years ago we focused most of our attention on developing porcine cells for transplantation, although we also initiated a project to transplant human muscle cells. The development of our porcine cell product candidates has recently experienced clinical and regulatory setbacks. While we continue to believe that porcine cells can be developed as viable products, it is clear that the road will be longer than any of us originally anticipated. There are currently no signs that the challenging regulatory environment surrounding porcine cells is going to ease. We believe that the underlying regulatory concern stems from the possibility that porcine endogenous retrovirus (PERV) could theoretically infect humans, despite the fact that no human has ever been infected. We are currently focusing most of our porcine cell development efforts on evaluating the ability of porcine hepatocytes to ameliorate life-threatening liver failure. In this case, the extremely low theoretical risk of PERV infection is far outweighed by the potential benefit. We have also recently completed patient accrual in a Phase 1 clinical trial using porcine spinal cord cells to treat spinal cord injury. Several patients have shown significant improvement in sensory and motor function, and we are continuing to follow the patients in this trial. In addition, several patients in our Phase 1 stroke trial have shown sustained improvement, but the trial remains on clinical hold.

We are now conducting clinical trials to evaluate the ability of human muscle cells to repair damaged heart muscle. In April 2001, we and our collaborators published the results of a muscle cell transplantation study in the journal Circulation. This study showed that transplantation of muscle cells after myocardial infarction in an animal model attenuated deleterious cardiac remodeling and improved cardiac function. We are currently conducting two Phase 1 human clinical trials using autologous human muscle cells.

One of these trials involves transplanting muscle cells into a patient's heart at the same time that they receive a left ventricular assist device (LVAD). The LVAD is implanted in these patients as a bridge to heart transplant. Once a patient receives a new heart, we are able to histologically examine their old heart. This allows us to evaluate cell survival and new blood vessel formation after transplantation. With five out of a planned six patients transplanted and three hearts examined, results to date have been encouraging. We are planning to add six more patients with an increase in dose from 300 million to 900 million cells. This clinical trial is being conducted at Temple University, University of Michigan, and University of Nebraska.

A second Phase 1 clinical trial involves transplanting muscle cells into the heart at the same time that a patient undergoes coronary artery bypass surgery (CABG). This is a 12-patient dose escalation trial with safety being evaluated at doses ranging from 10 million to 300 million cells. To date, we have transplanted ten patients and plan to extend the trial to include two more doses at 600 and 900 million cells. This clinical trial is being conducted at Arizona Heart Institute, UCLA, The Cleveland Clinic, and Ohio State University.

Our net loss for the year was $4.6 million and we ended 2001 with cash and investments of $49.7 million. Our focused approach to the development of cell transplantation products should allow us to continue with our currently planned clinical trials to determine safety and preliminary efficacy. As we move forward into more advanced clinical trials, our plan is to form partnerships with other companies to accelerate development. I look forward to keeping you informed of our progress.

/s/ Thomas H. Fraser

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

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 products 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, 2002 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 July 25, 2002. 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: July 25, 2002 DIACRIN INC.

By: /s/ Thomas H. Fraser

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