

Edgar Filing: DIACRIN INC /DE/ - Form 10-K

DIACRIN INC /DE/  
Form 10-K  
March 26, 2003

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

Form 10-K  
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2002

Commission File No. 0-20139

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

Delaware  
(State or other jurisdiction of  
incorporation or organization)

22-3016912  
(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)

Securities registered pursuant to Section 12 (b) of the Act:  
Title of each class          Name of each exchange on which registered  
None                                  None

Securities registered pursuant to Section 12 (g) of the Act:  
Title of each class  
Common Stock, \$.01 par value

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                          .  
-----                          -----

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). YES                          NO    X                          .  
-----                          -----

The approximate aggregate market value of the voting stock held by non-affiliates of the registrant (based on the closing price of the Common Stock on June 28, 2002) was \$15,472,000.

As of March 17, 2003, 17,937,204 shares of the registrant's Common Stock were outstanding.

# Edgar Filing: DIACRIN INC /DE/ - Form 10-K

Documents Incorporated by Reference

The Registrant's definitive Proxy Statement for the 2003 Annual Meeting of Stockholder's to be filed with the Commission no later than 120 days after the close of the Registrant's fiscal year, has been incorporated by reference in whole or in part, into Part III of this Annual Report on Form 10-K.

## Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K 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 planned timetables for the initiation and completion of clinical trials. All statements, other than statements of historical facts included in this Annual Report on Form 10-K 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 Annual Report on Form 10-K, 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," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Annual Report on Form 10-K.

You should read these statements carefully because they discuss our expectations about our future performance, contain projections of our future operating results or our future financial condition, or state other "forward-looking" information. You should be aware that the occurrence of any of the events described in these risk factors and elsewhere in this Annual Report on Form 10-K 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 Annual Report on Form 10-K represent our expectations as of the date this Annual Report on Form 10-K 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.

## PART I

Item 1. Business

### Overview

We are developing 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. We believe cell transplantation products will address important unmet medical needs and that we will play a leading role in developing these products. We

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

continue to be world leaders in the area of cell transplantation research. We have transplanted cells into approximately 67 patients in FDA approved clinical trials. We are currently focusing most of our efforts towards the development of our cell transplantation technology for the treatment of cardiac disease.

We were incorporated in October 1989. Our principal executive offices are located at Building 96, 13th Street, Charlestown Navy Yard, Charlestown, MA 02129, and our telephone number at that location is (617) 242-9100.

Diacrin is our trademark. All other trademarks and service marks used in this Annual Report are the property of their respective owners.

### Human Muscle Cells for Cardiac Disease

Coronary heart disease is the leading cause of death in the United States, responsible for approximately 1 of every 5 deaths, or approximately 500,000 deaths each year. According to the American Heart Association, approximately 1 million heart attacks occur annually in the United States. Of the 800,000 patients who survive, approximately 200,000 will die within a year. The disease is caused by the accumulation of plaque, consisting of lipid deposits, macrophages and fibrous tissue, on the walls of vessels supplying blood to the heart muscle. Rupture of unstable plaques exposes substances that promote platelet aggregation and clot formation. The clot is composed of platelets, blood cells and fibrin that can block one or more of the coronary vessels, resulting in an inadequate supply of oxygen to the heart muscle. This highly active muscle is quickly damaged and the lesions are irreversible because heart muscle cells are not capable of cell division. The end result is an infarct, a damaged area of heart muscle in which scar tissue and fibrosis replace dead heart muscles, lowering the ability of the heart to contract and function.

Treatments to prevent tissue damage after a heart attack include drugs that break down fibrin clots and open up blocked arteries. These drugs have greatly influenced morbidity and mortality, but must be administered within a short interval after a heart attack to be effective. Even with current medical management, over one third of acute heart attacks are fatal. Cardiac catheterization and angioplasty to dislodge the clot and open the blocked vessel have proved effective in restoring blood flow, but cannot reverse preexisting tissue damage.

Our scientists have isolated and expanded muscle cells from human tissue and are studying the use of these cells for transplantation into damaged heart muscle. We believe that patients suffering from heart attacks would benefit if these muscle cells could repair their damaged hearts. These cells would be isolated from a muscle biopsy of a patient who had suffered a heart attack, thereby allowing transplantation of a patient's own muscle cells into his or her heart, which would avoid any rejection. In April 2001, we and our collaborators published the results of a muscle cell transplantation preclinical 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've completed patient recruitment in two Phase 1 clinical trials treating patients with damaged heart muscle. One of these trials involved transplanting muscle cells into a patient's heart at the same time that the patient received a left ventricular assist device (LVAD). The LVAD is implanted in these patients as a bridge to heart transplant. Our clinical trial

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

involved the implantation of 300 million myoblasts in six patients. This clinical trial was conducted at Temple University, University of Michigan and the Bryant LGH Heart Institute. Once a patient receives a new heart in this trial, we are able to histologically examine their old heart. This allows us to evaluate cell survival and new blood vessel formation after transplantation. In March 2003, we and our collaborators published the results from the review of four explanted hearts in the Journal of American College of Cardiology. Upon examination we noted skeletal muscle cells survived and differentiated into mature myofibers in three of the four hearts and in one heart we noticed an increase in small vessel formation at the site of surviving myotubes.

A second Phase 1 clinical trial involved transplanting muscle cells into the heart at the same time that a patient underwent coronary artery bypass surgery (CABG). This was a 12-patient dose escalation trial with safety being evaluated at doses ranging from 10 million to 300 million cells. This clinical trial was conducted at Arizona Heart Institute, UCLA, The Cleveland Clinic and Ohio State University. In September 2002, we entered into a development and license agreement with Terumo Corporation. Under the terms of the agreement, we licensed to Terumo our human muscle cell transplantation technology for cardiac disease in Japan. Terumo will fund all development in Japan while we continue to independently develop our cardiac repair technology for commercialization in the U.S. and elsewhere. The agreement includes an upfront non-refundable license fee of \$2.0 million which we received in October 2002, milestone payments and a royalty on product sales. The FDA recently cleared our IND for an additional clinical trial involving the transplantation of human muscle cells into the heart at the same time that a patient undergoes CABG. Through this trial, with the involvement of imaging specialists, we plan to define the primary endpoint for a pivotal clinical trial.

### Other Development Efforts

When we began operations thirteen years ago we focused most of our effort on developing porcine (pig) cells for transplantation. In 1995, the United States Food and Drug Administration cleared our IND for the first ever clinical trial to evaluate porcine cells in humans. Since then we've evaluated in human clinical trials the ability of porcine cells to treat many different diseases including Parkinson's disease, stroke, spinal cord injury, focal epilepsy and Huntington's disease. As part of our development of porcine cells we obtained an exclusive, worldwide license from MGH for immunomodulation technology. This technology involved the treatment of isolated cell populations prior to transplantation with antibody fragments directed against MHC class I antigens in order to obviate the need for generalized immunosuppression using agents such as cyclosporin. For years we were encouraged by the results of preclinical and clinical data that showed the cells were safe and could provide a clinical benefit.

Unfortunately, the development of our porcine cell product candidates has experienced clinical and regulatory setbacks. In March 2001, we announced the results of an 18-patient, pivotal, randomized, double-blinded, placebo-controlled Phase 2 clinical trial involving the use of fetal porcine neural cells for the treatment of Parkinson's disease. 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. Additionally, in April 2000, our Phase 1 trial using porcine neural cells for the treatment of stroke was suspended by the FDA to allow the investigation of two serious adverse events. We and an independent group of experts convened by us feel the adverse events were most likely caused by the procedure to implant the cells and not the cells themselves. However, we were not able to obtain approval from the FDA to continue recruiting patients into the trial.

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

While we continue to believe that porcine cells could be developed as viable products, it is clear that the path to product approval 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. As a result, we have suspended the development of products involving the use of porcine cells. We plan to focus our resources in areas that we believe are more likely to add shareholder value while we continue to monitor the environment surrounding xenotransplantation.

### Manufacturing

We isolate and prepare cell populations in our own clinical production facilities in Charlestown, Massachusetts. Our long-range plan is to expand our internal manufacturing capabilities, including the facilities necessary to test, isolate and package an adequate supply of finished cell products in order to meet our long-term clinical manufacturing needs.

### Patents and Licenses

We intend to aggressively seek patent protection for any products we develop. We also intend to seek patent protection or rely upon trade secrets to protect certain of our technologies which will be used in discovering and evaluating new products. We have 19 issued U.S. patents and 18 patent applications pending with the United States Patent and Trademark Office. We have also filed foreign counterparts in the European Union and other selected countries. These applications seek composition-of-matter and use protection for the various products we have in development.

To protect our trade secrets and other proprietary information, we require all employees, consultants, advisors and collaborators to enter into confidentiality agreements with us.

### Sales and Marketing

We have not yet developed sales and marketing capabilities for our product candidates. We may form strategic alliances with established pharmaceutical or biotechnology companies in order to finance the development of certain of our products and, assuming successful development, to market such products. These alliances may enable us to expand or accelerate our product development efforts and also may provide us with access to established marketing organizations. Alternatively, we may decide to market some of our products on our own.

### Government Regulation

Regulation by governmental authorities in the United States, the European Union member states and other foreign countries is a significant factor in the development, manufacture and marketing of our product candidates and in our ongoing research and product development activities. All of our products will require regulatory approval by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous testing and approval procedures by the FDA and similar authorities in foreign countries. Various statutes and regulations govern the preclinical and clinical testing, manufacturing, labeling, distribution, advertising and sale of these products. The process of obtaining these approvals and the subsequent compliance with applicable statutes and regulations require the expenditure of substantial time and financial and other resources.

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

Preclinical testing is generally conducted in the laboratory on animals to evaluate the potential efficacy and the safety of a product. In the United States, the results of these studies are submitted to the FDA as part of an IND application, which must receive FDA clearance before human clinical testing can begin. Clinical trials are typically conducted in three phases which may overlap. Generally, in Phase 1, clinical trials are conducted with a small number of human subjects to determine the early safety profile. In Phase 2, clinical trials are conducted with groups of patients afflicted with the specific disease in order to determine preliminary efficacy, optimal treatment regimens and expanded evidence of safety. Where a product candidate is found to have an effect at an optimal dose and to have an acceptable safety profile in Phase 2, larger scale, multi-center, randomized and blinded Phase 3 clinical trials are conducted with patients afflicted with the target disease to further test for safety, to further evaluate clinical effectiveness and to obtain additional information for labeling. In addition, the FDA may request post-marketing (Phase 4) monitoring of the approved product, during which clinical data are collected on selected groups of patients to monitor longer-term safety.

Upon completion of Phase 3, for products regulated by the FDA's Center for Biologic Evaluation and Research, commonly referred to as CBER, the results of preclinical and clinical testing are submitted to the FDA in the form of a Biologics License Application, commonly referred to as BLA, for approval to manufacture and commence commercial sales. In responding to these applications, the FDA may grant marketing approval, request additional information or deny the application if it determined that the application does not satisfy the agency's regulatory approval criteria. We expect that CBER will regulate all of our product candidates.

The nature of the marketing claims we will be permitted to use for labeling and advertising will be limited to those allowed in the FDA's approval. Claims beyond those approved would constitute a violation of the Food, Drug & Cosmetic Act or the FD&C Act. Noncompliance with the provisions of the FD&C Act or Public Health Service Act can result in, among other things, loss of approval, voluntary or mandatory product recall, seizure of products, fines, injunctions and civil or criminal penalties. Our advertising is also subject to regulation by the Federal Trade Commission under the FTC Act, which prohibits unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce. Violation can result in a variety of enforcement actions including fines, injunctions and other remedies.

In the European member states and other foreign countries, our ability to market a product is contingent upon receiving marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. Generally, we intend to apply for foreign marketing authorizations at a national level. However, within the European Union, procedures are available to companies wishing to market a product in one or all European Union member states. This centralized process is conducted through the European Medicines Evaluation Agency, known as the EMEA. The EMEA coordinates the regulatory process, while a body of experts drawn from member states undertakes the scientific assessment of the product and recommends whether a product satisfies the criteria of safety, quality and efficacy for approval. If the authorities are satisfied that adequate evidence of safety, quality and efficacy has been presented, a marketing authorization will be granted. This foreign regulatory approval process includes all of the risks associated with FDA approval set forth above. We may rely on licensees to obtain regulatory approval for marketing certain of our products in certain European Union member states or other foreign countries.

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

We are also subject to various federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds, infectious disease agents and recombinant DNA materials used in connection with our research work.

We may take advantage of the regulatory pathways which may provide expedited review of our cell transplantation products and allow limited cost recovery during the clinical research phase. These include: (1) expedited review for more effective or better tolerated therapies for serious conditions, commonly referred to as fast track designation, and (2) seeking approval for limited cost recovery during clinical testing under treatment IND status.

**Fast Track Designation.** In 1997, Congress enacted the Food and Drug Administration Modernization Act, in part, to ensure the availability of safe and effective drugs by expediting the FDA review process for new products. This act establishes a statutory program for the approval of fast track products. A fast track product is defined as a new drug intended for the treatment of a serious or life-threatening condition, which demonstrates the potential to address unmet medical needs. Under the fast track program, the sponsor of a new drug may request the FDA to designate the drug as a fast track product at the time of the IND submission or after. If a preliminary review of the clinical data suggests that a fast track product may be effective, the FDA may initiate review of sections of a marketing application for a fast track product before the sponsor completes the application.

**Treatment IND.** Treatment IND is a mechanism established by the FDA in 1987 which allows a company to distribute promising investigational therapies to patients outside of the established clinical trials and to charge a reasonable fee for such therapy. The disease must be serious or life-threatening and there must not be satisfactory alternative treatments. Treatment IND status has been applied to a variety of diseases including cancer, AIDS, Parkinson's disease, Alzheimer's disease and multiple sclerosis and to several anti-infectives for renal transplant patients. We may pursue this designation, where appropriate.

### Competition

We believe that our ability to compete successfully will be based on our ability to create and maintain scientifically advanced technology, develop proprietary products and attract and retain qualified scientific personnel. In addition, we have to obtain adequate financing, patents, orphan drug designation or other protection for our products, and required regulatory approvals, and to manufacture and successfully market our products both independently and through collaborators.

The biopharmaceutical and pharmaceutical industries are characterized by intense competition. We compete against numerous companies, many of which have substantially greater financial and other resources than we do. Private and public academic and research institutions also compete with us in the research and development of human therapeutic products. In addition, many of our competitors have significantly greater experience than we do in the testing of pharmaceutical and other therapeutic products and obtaining FDA and other regulatory approvals of products for use in health care. Accordingly, our competitors may succeed in obtaining FDA approval for products more rapidly than we do. If we commence significant commercial sales of our products, we will also be competing with respect to manufacturing efficiency and marketing capabilities, areas in which we

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

have limited or no experience.

Our products under development will compete with products and therapies which are either currently available or currently under development. Competition will be based, among other things, on efficacy, safety, reliability, price, availability of reimbursement and patent position. We are aware of other companies which are pursuing research and development of alternative products or technologies addressing the same disease categories as our development programs.

### Employees

As of February 15, 2003, we had 29 full-time employees, 21 of whom were engaged in research, development, clinical and quality assurance/quality control activities. None of our employees are represented by a labor union or covered by a collective bargaining agreement.

### Item 2. Properties

We lease a facility which contains approximately 25,000 square feet of space in Charlestown, Massachusetts. The current lease has a five-year term ending in 2006, providing for a base rental rate of approximately \$76,000 per month, plus applicable property taxes and insurance. We have the right to extend the lease an additional five years commencing in 2006. Our facilities are equipped with laboratory and cell culture capabilities sufficient to satisfy our research and development requirements for the foreseeable future and cell isolation capabilities sufficient to satisfy our current clinical production requirements. To the extent that additional similar facilities may be required, we may be required to secure additional facilities or seek outside contractors to provide such capabilities.

### Item 3. Legal Proceedings

We are currently not a party to any material legal proceedings.

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

No matters were submitted to a vote of our security holders, through solicitation of proxies or otherwise, during the last quarter of the fiscal year ended December 31, 2002.

### Executive Officers of the Registrant

The following table sets forth the names, ages and positions of the directors, executive officers and other key employees of the Company:

Name	Age	Position
Thomas H. Fraser, Ph.D.	55	President and Chief Executive Officer; Director
E. Michael Egan	49	Chief Operating Officer
Kevin Kerrigan	32	Controller
Jonathan H. Dinsmore, Ph.D.	41	Senior Director of Cell Transplantation
Roger J. Gay, Ph.D.	49	Senior Director of Process Development
Abdellah Sentissi, Ph.D.	53	Senior Director of Quality Control and Quality Assurance



## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

Douglas B. Jacoby, Ph.D.	42	Director of Research
Zola P. Horovitz, Ph.D. (1)	68	Director
John W. Littlechild (2)	51	Director
Stelios Papadopoulos, Ph.D. (1) (2)	54	Director
Joshua Ruch (1)	53	Director

(1) Member of Audit Committee

(2) Member of Compensation Committee

Thomas H. Fraser, Ph.D., has served as our President and Chief Executive Officer and as a Director since 1990. Dr. Fraser was previously Executive Vice President, Corporate Development, for Repligen Corporation, a biopharmaceutical company. Dr. Fraser was the founding Vice President for Research and Development at Repligen in 1981 and served as Executive Vice President from 1982 through 1990 as well as Chief Technical Officer from 1982 through 1988. Prior to joining Repligen, Dr. Fraser headed the recombinant DNA research group in Pharmaceutical Research and Development at The Upjohn Company, a pharmaceutical company. Dr. Fraser received his Ph.D. in Biochemistry from the Massachusetts Institute of Technology and was a Damon Runyon-Walter Winchell Cancer Fund Postdoctoral Fellow at The University of Colorado.

E. Michael Egan was promoted to Chief Operating Officer in January 2001. Prior to that, Mr. Egan had served as our Senior Vice President, Corporate Development, since 1993. Mr. Egan joined us from Repligen, where he was employed from 1983 to 1993, and since 1989 had been Vice President of Business Development. He was also a member of the Board of Directors of Repligen Clinical Partners, L.P., and the Secretary/Treasurer of Repligen Sandoz Research Corporation. Mr. Egan's previous positions at Repligen include Director of Business Development and Manager of Business Development. Prior to joining Repligen in 1983, Mr. Egan was a laboratory supervisor at Dana-Farber Cancer Institute, Division of Medicine. He received a B.S. in biology from Boston College and a Certificate of Special Studies in Administration and Management from Harvard University in 1986.

Kevin Kerrigan has served as our Controller since November 1998. Mr. Kerrigan joined us in 1997 as Accounting Manager. From 1993 to 1997 Mr. Kerrigan was a member of the professional staff of Price Waterhouse LLP, an accounting firm. Mr. Kerrigan received a B.S. degree in accounting from Merrimack College and was awarded a CPA certificate from the Commonwealth of Massachusetts in 1996.

Jonathan H. Dinsmore, Ph.D., has been Senior Director of Cell Transplantation Research since April 1999. He joined Diacrin in 1992 as a Research Scientist and was subsequently promoted to Principal Investigator and then Director of Cell Transplantation Research. Dr. Dinsmore was previously a Postdoctoral Fellow of the American Cancer Society in the Biology department at the Massachusetts Institute of Technology from 1988 to 1992. He received a Ph.D. in biology from Dartmouth College, where he was a Presidential Scholar and recipient of a Kramer Fellowship. Dr. Dinsmore has worked on National Science Foundation-sponsored research projects at the Marine Biological Laboratories in Woods Hole, Massachusetts and at a United States research base in Antarctica.

Roger J. Gay, Ph.D., has been Senior Director of Process Development

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

since February 2000. Dr. Gay was hired by Diacrin in 1993 as Director of Process Development. From 1986 through 1993, he was Director of Product Development at Organogenesis, Inc. Dr. Gay's previous positions were Manager of a Contract Research and Cytotoxicity Testing Laboratory and Director of Product Development at Bioassay Systems Research Corporation from 1982 to 1986. He received a B.A. in chemistry from the College of the Holy Cross in 1975 and a Ph.D. in biochemistry from the University of Rochester in 1981. From 1981 through 1983, he was a postdoctoral research fellow in the Department of Microbiology and Molecular Genetics at Harvard Medical School.

Abdellah Sentissi, Ph.D., has been Senior Director of Quality Control and Quality Assurance since February 2000. Dr. Sentissi came to Diacrin in 1995 as Director of Quality Control and Quality Assurance. Prior to joining Diacrin, from 1992 to 1995, he served as the Director of QC/QA and Technical Affairs at Endocon, Inc. From 1985 through 1992, he was the Chief of Quality Control at Massachusetts Biologics Laboratories. He received a pharmacy degree in 1973 and a biology degree in 1976 from the University of Paul Sabatier, Toulouse, France, and a Ph.D. in biomedical sciences from Northeastern University in 1984. From 1984 through 1985, he was a postdoctoral research fellow in the Department of Clinical Chemistry at Northeastern University. He has been a lecturer in pharmaceutical biotechnology at the School of Pharmacy at Northeastern University since 1990.

Douglas B. Jacoby, Ph.D., was appointed Director of Research in April 1999. He joined Diacrin in 1993 as a Research Scientist and was subsequently promoted to Principal Investigator. While a postdoctoral fellow in the Biochemistry department at Brandeis University, Dr. Jacoby was awarded a fellowship from the NIH. He received his Ph.D. in Biochemistry from the University of Minnesota with awards from the NIH and a Doctoral Dissertation Fellowship. He was graduated with an A.B. in Biology from Kenyon College.

Zola P. Horovitz, Ph.D., has served as a Director of Diacrin since 1994. Dr. Horovitz was Vice President, Business Development and Planning at Bristol-Myers Squibb Pharmaceutical Group from 1991 until 1994 and was Vice President, Licensing from 1989 to 1991. Prior to 1989, Dr. Horovitz spent 30 years as a member of the Squibb Institute for Medical Research, most recently as Vice President, Research Planning. Dr. Horovitz is also a director of 3-Dimensional Pharmaceuticals, Inc., Avigen, Inc., BioCryst Pharmaceuticals, Genaera Pharmaceuticals, Paligent, Synaptic Pharmaceuticals, Inc. and Palatin Technologies. Dr. Horovitz received his Ph.D. from the University of Pittsburgh.

John W. Littlechild has been a Director of Diacrin since 1992. Mr. Littlechild is associated with several venture capital partnerships managed by HealthCare Ventures LLC, including HealthCare Ventures II, L.P., HealthCare Ventures III, L.P., and HealthCare Ventures IV, L.P. Mr. Littlechild currently serves as Vice Chairman of HealthCare Ventures LLC. From 1984 to 1991, Mr. Littlechild was a Senior Vice President of Advent International Corporation, a venture capital company in Boston and London. Prior to working at Advent in Boston, Mr. Littlechild was involved in establishing Advent in the United Kingdom. From 1980 to 1982, Mr. Littlechild served as Assistant Vice President for Citicorp Venture Corporation, a venture capital company, in London, prior to which he worked with ICI Ltd., an agro-chemical company, and Rank Xerox, an office equipment company, in marketing and financial management. Mr. Littlechild holds a B.Sc. (1st class honors) from the University of Manchester and an MBA from Manchester Business School. Mr. Littlechild serves on the board of directors of various health care and biotechnology companies, including Dyax, a biotechnology company, and Orthofix

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

International N.V., a medical device company. Mr. Littlechild also serves on several Boards for the Harvard Medical School including the Executive Committee of the Board of Fellows, the Science and Technology Committee, and is Chairman of the Microbiology Department Advisory Board.

Stelios Papadopoulos, Ph.D., has been a Director of Diacrin since 1991. Dr. Papadopoulos is a Managing Director in the investment banking division at SG Cowen Securities Corporation focusing on the biotechnology and pharmaceutical sectors. Prior to joining SG Cowen Securities Corporation in February 2000, he spent 13 years as an investment banker at PaineWebber, where he was most recently Chairman of PaineWebber Development Corp., a PaineWebber subsidiary. Prior to becoming an investment banker he spent two years as a biotechnology analyst, first at Donaldson, Lufkin & Jenrette and subsequently at Drexel Burnham Lambert, where he was elected to the Institutional Investor 1987 All-American Research Team. Before coming to Wall Street in 1985, Dr. Papadopoulos was on the faculty of the Department of Cell Biology at New York University Medical Center. He continues his affiliation with NYU Medical Center as an Adjunct Associate Professor of Cell Biology. Dr. Papadopoulos holds a Ph.D. in biophysics and an MBA in finance, both from New York University. He is a founder and Chairman of the Board of Exelixis, Inc., and sits on the board of several private companies in the biotechnology sector.

Joshua Ruch has been a Director of Diacrin since March 1998. Mr. Ruch is the Chairman and Chief Executive Officer of Rho Capital Partners, Inc., an international investment management firm which he co-founded in 1981. Prior to founding Rho, Mr. Ruch was employed in investment banking at Salomon Brothers and Bache Halsey Stuart, Inc. Mr. Ruch received a B.S. degree in electrical engineering from the Israel Institute of Technology (Technion) and an MBA from the Harvard Business School. Mr. Ruch also serves on the board of directors of 3-Dimensional Pharmaceuticals, Inc. as well as several private companies in the technology sector.

Directors are elected annually by our stockholders and hold office until the next annual meeting of stockholders or until their resignation or removal. Each executive officer serves at the discretion of the board of directors and holds office until his or her successor is elected and qualified or until his or her earlier resignation or removal. There are no family relationships among any of our directors or executive officers.

### PART II

#### Item 5. Market for Registrant's Common Stock and Related Stockholder Matters

Our common stock is traded on the NASDAQ National Market under the symbol DCRN. The following table sets forth for the periods indicated the high and low sale prices for the common stock during 2001 and 2002 as reported on the Nasdaq National Market:

High

Low

Fiscal Year 2001

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

First Quarter	6.5000	1.1250
Second Quarter	2.9700	1.0500
Third Quarter	2.2000	1.5000
Fourth Quarter	2.1500	1.5000
Fiscal Year 2002		
First Quarter	2.3100	1.7500
Second Quarter	1.9500	1.3100
Third Quarter	1.6100	1.0000
Fourth Quarter	1.4500	.9900

As of March 10, 2003 there were approximately 90 record holders of our common stock and approximately 3,000 beneficial owners of our common stock.

We have never declared or paid cash dividends on our capital stock. We intend to retain earnings, if any, for use in our business and do not anticipate declaring or paying any cash dividends in the foreseeable future.

We did not sell any equity securities during the quarter ended December 31, 2002 that were not registered under the Securities Act.

### Item 6. Selected Financial Data

The selected financial data set forth below as of December 31, 2002 and for the year ended December 31, 2002 are derived from our financial statements which have been audited by PricewaterhouseCoopers LLP, independent accountants, and which are included elsewhere in this Annual Report on Form 10-K. The selected financial data set forth below as of December 31, 2001 and for the years ended December 31, 2000 and 2001 are derived from our financial statements which have been audited by Arthur Andersen LLP also included elsewhere in this Annual Report on Form 10-K. The selected financial data set forth below as of December 31, 1998, 1999 and 2000 and for the years ended December 31, 1998 and 1999 are derived from our financial statements audited by Arthur Andersen LLP and are not included herein. The data set forth below should be read in conjunction with our financial statements, related notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report on Form 10-K.

Year Ended December 31,				
-----	-----	-----	-----	-----
1998	1999	2000	2001	2002
----	----	----	----	----

Statement of Operations Data:

(in thousands, except share and per share data)

Edgar Filing: DIACRIN INC /DE/ - Form 10-K

REVENUES:					
Research and development	\$ 3,623	\$ 2,971	\$ 2,082	\$ 737	\$ 346
OPERATING EXPENSES:					
Research and development	7,372	5,921	5,997	6,350	6,124
General and administrative	1,484	1,398	1,348	1,624	1,535
Total operating expenses	8,856	7,319	7,345	7,974	7,659
OPERATING INCOME (EXPENSE):					
Equity in operations of joint venture	(1,084)	(1,688)	(1,369)	(547)	(103)
Investment income	1,576	1,323	3,125	3,150	1,359
Interest expense	(89)	(47)	(30)	(14)	(3)
Total other income (expense)	403	(412)	1,726	2,589	1,253
Net loss	\$ (4,830)	\$ (4,760)	\$ (3,537)	\$ (4,648)	\$ (6,060)
Net loss per common share:					
Basic and diluted	\$ (.34)	\$ (.33)	\$ (.21)	\$ (.26)	\$ (.34)
Weighted average shares outstanding(1):					
Basic and diluted	14,156,179	14,364,154	17,073,194	17,914,889	17,937,200

	At December 31,				
Balance Sheet Data:	1998	1999	2000	2001	2002
Cash, cash equivalents and investments	\$ 26,270	\$ 21,420	\$ 54,607	\$ 49,727	\$ 44,956
Working capital	21,812	17,133	32,502	41,078	35,696
Total assets	27,484	22,366	55,793	50,681	45,748
Long-term debt	392	249	119	-	-
Stockholders' equity	24,845	20,145	53,766	49,146	43,086

(1) Computed as described in Note 2 (e) of Notes to Financial Statements.

Item 7. 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 we have received funding from our collaboration with Terumo Corporation ("Terumo") and our joint venture with Genzyme. We do not expect to

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

derive a material amount of revenues from our joint venture with Genzyme in the future. 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 December 31, 2002, we had an accumulated deficit of \$58.5 million.

In September 2002, we entered into a development and license agreement with Terumo. Under the terms of the agreement, we licensed to Terumo our human muscle cell transplantation technology for cardiac disease in Japan. Terumo will fund all development in Japan while we continue to independently develop our cardiac repair technology for commercialization in the U.S. and elsewhere. The agreement includes an upfront non-refundable license fee of \$2.0 million, milestone payments and a royalty on product sales.

### Critical Accounting Policies

We believe our most critical accounting policies are those that dictate how we account for our development and license agreement with Terumo and joint venture with Genzyme. On October 1, 2002 we received an upfront non-refundable license fee of \$2.0 million from Terumo. We recorded this fee as deferred revenue and recognize revenue over the development period of the agreement in accordance with SEC Staff Accounting Bulletin No. 101, "Revenue Recognition" ("SAB 101"). SAB 101 requires companies to recognize certain upfront non-refundable fees over the period in which the Company completes its performance obligations under the related agreement when such fees are received in conjunction with an agreement which includes performance obligations. Determination of the length of the development period requires management's judgment. Any significant changes in the assumptions underlying our estimates used while applying the percentage of completion method could impact our revenue recognition. Revenue from milestone payments under which we have continuing performance obligations are recognized as revenue upon the achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved in achieving the milestone; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as we complete our performance obligations. Payments received under these arrangements prior to the completion of the related work are recorded as deferred revenue.

In 1996, we formed a joint venture with Genzyme to develop and commercialize two product candidates. We record as research and development expense all costs related to the joint venture's product candidates 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

Year Ended December 31, 2002 Versus Year Ended December 31, 2001

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

Research and development revenues were \$346,000 for the year ended December 31, 2002 and \$737,000 for the year ended December 31, 2001. The decrease in revenues was primarily a result of a decrease in revenue from our joint venture with Genzyme offset in part by an increase in revenue of \$245,000 related to our collaboration with Terumo. The decrease in revenues from our joint venture with Genzyme is due to efforts by us to decrease the costs associated with the joint venture's product candidates. We do not expect to derive a material amount of revenues from our joint venture with Genzyme in the future.

Research and development expenses were \$6.1 million and \$6.4 million for the years ended December 31, 2002 and 2001, respectively. The decrease in research and development expenses was primarily due to a decrease in costs related to the development of several xenotransplantation related product candidates offset in part by an increase in costs related to the development of our cell transplantation technology for cardiac repair.

General and administrative expenses of \$1.5 million and \$1.6 million for the year ended December 31, 2002 and 2001, respectively, remained relatively unchanged.

For the year ended December 31, 2002 and 2001, the Company recorded an expense of \$103,000 and \$547,000, 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.

Investment income was \$1.4 million and \$3.2 million for the year ended December 31, 2002 and 2001, respectively. The decrease in investment income was due to lower cash balances available for investment in the current year period and a lower return on investment due to the decline in interest rates.

Interest expense was \$3,000 for the year ended December 31, 2002 and \$14,000 for the year ended December 31, 2001. The decrease in 2002 was due to the scheduled pay down of loan debt outstanding.

The Company incurred a net loss of approximately \$6.1 million for the year ended December 31, 2002 versus a net loss of approximately \$4.6 million for the year ended December 31, 2001.

### Year Ended December 31, 2001 Versus Year Ended December 31, 2000

Research and development revenues were approximately \$737,000 for the year ended December 31, 2001 and \$2.1 million for the year ended December 31, 2000. Revenues for both years were comprised entirely of revenue from the joint venture. The decrease in revenues was primarily a result of a decrease in clinical production activity related to our joint venture with Genzyme.

Research and development expenses were \$6.4 million for the year ended December 31, 2001 versus \$6.0 million for the year ended December 31, 2000. The increase in research and development expenses was primarily due to an increase in the costs associated with sponsoring and managing our clinical trials.

General and administrative expenses were \$1.6 million for the year ended December 31, 2001 versus \$1.3 million for the year ended December

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

31, 2000. The increase in general and administrative expenses was primarily due to an increase in personnel costs related to an executive retention plan and an increase in professional fees incurred as we evaluated strategic relationships.

For the year ended December 31, 2001, we recorded a \$547,000 charge related to our equity in the operations of the joint venture compared to a \$1.4 million charge for the year ended December 31, 2000. This expense related to funds contributed by us to the joint venture that were used to fund expenses incurred by Genzyme on behalf of the joint venture. The decreased charge in 2001 was primarily due to a decrease in clinical activity performed by Genzyme on behalf of the joint venture.

Investment income of approximately \$3.2 million for the years ended December 31, 2001 and 2000 remained relatively unchanged.

Interest expense was \$14,000 for the year ended December 31, 2001 and \$30,000 for the year ended December 31, 2000. The decrease in 2001 was due to the scheduled pay down of lease and loan debt outstanding.

We incurred a net loss of approximately \$4.6 million for the year ended December 31, 2001 versus a net loss of approximately \$3.5 million for the year ended December 31, 2000.

### Liquidity and Capital Resources

We have financed our activities primarily with the net proceeds from the sale of equity and debt securities aggregating \$102.0 million and with interest earned thereon. In addition, we have recorded approximately \$15.3 million in revenue from our joint venture since it commenced on October 1, 1996. At December 31, 2002, we had cash and cash equivalents, short-term investments and long-term investments aggregating approximately \$45.0 million.

We believe that our existing funds 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, 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.

Net cash used in operating activities was \$4.6 million for the year ended December 31, 2002, \$3.9 million for the year ended December 31, 2001 and \$2.5 million for the year ended December 31, 2000. Cash used in operations for the year ended December 31, 2002 was primarily attributable to our net loss, offset in part by an increase in deferred revenue of \$1.8 million related primarily to an upfront payment by Terumo. Cash used in operations for the years ended December 31, 2001 and 2000 was primarily attributable to our net loss, offset in part by our equity in operations of the joint venture.



## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

Net cash provided by investing activities was \$390,000 and \$1.4 million for the years ended December 31, 2002 and 2001, respectively. Net cash used in investing activities was \$25.6 million for the year ended December 31, 2000. Net cash provided by investing activities for the years ended December 31, 2002 and 2001 was primarily attributable to a decrease in long-term investments offset by an increase in short-term investments. Net cash used in investing activities for the year ended December 31, 2000 was primarily attributable to an increase in short-term investments and long-term investments. The increase in investments was due to our public offering of Common Stock in March 2000.

Net cash used in financing activities was \$119,000 and \$102,000 for the years ended December 31, 2002 and 2001, respectively. Net cash provided by financing activities was \$37.0 million for the year ended December 31, 2000. Net cash used in financing activities for the years ended December 31, 2002 and 2001 was primarily attributable to principal payments made on our long-term debt. Net cash provided by financing activities for the year ended December 31, 2000 was primarily attributable to net proceeds from the sale of common stock in a public offering in March 2000.

Our only material commitment at December 31, 2002 was a lease for a facility. In October 2000, we exercised the first of two options we have to extend this lease an additional five years. Minimum rental payments under the lease are as follows:

	Rental Commitment
2003	\$ 908,000
2004	908,000
2005	908,000
2006	681,000
	-----
Total	\$ 3,405,000 =====

### Diacrin/Genzyme LLC Financial Statements

For the year ended December 31, 2000, our equity in operations of the joint venture exceeded 20% of our net loss. Accordingly, pursuant to the rules of the Securities and Exchange Commission, our prior year Annual Report on Form 10-K included separate audited financial statements for the joint venture. For the years ended December 31, 2001 and 2002, our equity in operations of the joint venture did not exceed 20% of our net loss. As a result, the financial information with respect to the joint venture presented in this Annual Report on Form 10-K is unaudited.

### Recently Issued Accounting Pronouncements

In July 2002, the FASB issued SFAS 146, Accounting for Costs Associated with Exit or Disposal Activities. SFAS 146 requires that a liability for a cost associated with an exit or disposal activity be recognized at its fair market value when the liability is incurred, rather than at the date of an entity's commitment to an exit plan. The provisions of SFAS 146 are effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of SFAS 146 has not had a material effect on our financial statements.

In November 2002, the FASB issued Interpretation No. 45 (FIN 45), Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, an interpretation

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

of FASB Statements No. 5, 57, and 107 and Rescission of FASB Interpretation No. 34. FIN 45 elaborates on the existing disclosure requirements for most guarantees, including loan guarantees such as standby letters of credit and warranty obligations. It also clarifies that at the time a company issues a guarantee, a company must recognize an initial liability for the fair value of the obligations it assumes under the guarantee and must disclose that information in its interim and annual financial statements. The provisions of FIN 45 relating to initial recognition and measurement must be applied on a prospective basis to guarantees issued or modified after December 31, 2002. We do not expect the adoption of the initial recognition and measurement provisions in the first quarter of 2003 to have a significant impact on our financial condition or results of operations. The disclosure requirements of FIN 45, which are effective for both interim and annual periods that end after December 15, 2002, were adopted by us for the year ended December 31, 2002.

In December 2002, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation - Transition and Disclosure. SFAS 148 provides alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation as originally provided by SFAS No. 123, Accounting for Stock-Based Compensation. Additionally, SFAS 148 amends the disclosure requirements of SFAS 123 to require prominent disclosure in both the annual and interim financial statements about the method of accounting for stock-based compensation and the effect of the method used on reported results. The transitional requirements of SFAS 148 will be effective for all financial statements for fiscal years ending after December 15, 2002. The disclosure requirements shall be effective for financial reports containing condensed financial statements for interim periods beginning after December 15, 2002. The transitional disclosure requirements were adopted by us for the year ended December 31, 2002. We expect to adopt the disclosure portion of this statement for the quarter ending March 31, 2003. The application of this standard will have no impact on our financial position or results of operations.

In January 2003, the FASB issued FASB Interpretation No. 46 (FIN 46), Consolidation of Variable Interest Entities. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the entity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is required to be applied to preexisting entities of the Company as of the beginning of the first quarter after June 15, 2003. FIN 46 is required to be applied to all new entities with which the Company becomes involved beginning February 1, 2003. Based upon the accounting guidance and other information available, we do not believe our joint venture meets the definition of a variable interest entity. We currently believe adoption of FIN 46 will not have a significant impact on the Company. We believe the interpretive accounting guidance necessary for FIN 46 will continue to evolve. Additional interpretive guidance could affect the accounting for our joint venture.

### 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 Annual Report on Form 10-K or presented elsewhere by management from time to time. The forward-looking statements contained in this Annual Report on Form 10-K represent our expectations as of March 26, 2003, the date our Annual Report on Form 10-K was filed with the SEC. Subsequent events will cause our expectations to

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

change. However, while we may elect to update these forward-looking statements, we specifically disclaim any obligation to do so. 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.

We are focusing our resources on cell transplantation technology which 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. Currently, we are focusing most of our resources on the development of our cell transplantation technology for cardiac disease.

Our technological approaches may not enable us to successfully develop and commercialize any products. Our decision to focus on one technology as opposed to multiple increases the risk associated with our stock. 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.

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.

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

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;
- 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 clinical trials could be 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.

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

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

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 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 December 31, 2002, we had an accumulated deficit of \$58.5 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 develop our research and development programs, expand our clinical trials, apply for regulatory approvals and begin commercialization activities.

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

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

- 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;

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

- 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.

The 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

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

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. 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 development and license agreement with Terumo, we have granted to Terumo sales and marketing rights to our human muscle cell transplantation technology for cardiac disease in Japan. We may have limited or no control over the sales, marketing and distribution activities of Terumo in Japan or other collaborative partners. Our future revenues may be materially dependent upon the success 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.

Disruptions in our manufacturing process may delay or disrupt our development efforts

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 replace quickly or inexpensively 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



## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

sales. Our present manufacturing process may not meet our initial expectations as to scheduling, reproducibility, yield, purity, cost, potency or quality.

### 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 any insurance we subsequently obtain will not provide adequate coverage against all potential claims.

Our success 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 growth or 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

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

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 41% 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.

Our common stock may be delisted from The Nasdaq National Market, which could cause the price to fall further and decrease its liquidity

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

Our common stock trades on The Nasdaq National Market. In order to continue trading on Nasdaq, we must comply with The Nasdaq National Market's continued listing requirements, which require that we either maintain a minimum stockholder's equity of \$10 million and a minimum closing bid price of \$1.00 per share or, if we fall below the minimum stockholder's equity requirement, maintain a minimum closing bid price of \$3.00 per share. At December 31, 2002, we had stockholder's equity of approximately \$19.6 million. However, our stockholder's equity may decline. If our stockholder's equity falls below \$10.0 million, we will need to maintain a minimum closing bid price of \$3.00 rather than \$1.00.

If we do not satisfy Nasdaq's continued listing requirements, our common stock may be delisted from The Nasdaq National Market. The delisting of our common stock may result in the trading of the stock on the Nasdaq Small Cap Market, the over-the-counter markets in the so-called "pink sheets" or the NASD's electronic bulletin board. Consequently, a delisting of our common stock from The Nasdaq National Market would materially reduce the liquidity of our common stock, not only in the number of shares that could be bought and sold, but also through delays in the timing of the transaction and reductions in securities analysts and media coverage. This may reduce the demand for our stock and significantly destabilize the price of our stock. In addition, a delisting would materially adversely affect our ability to raise additional necessary capital.

### Item 7A. 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 it is 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. Our investment portfolio contains instruments that are subject to the risk of a decline in interest rates. For example, if the annualized interest rate on our interest bearing investments were to change 1%, investment income would have hypothetically increased or decreased by approximately \$473,000 during the year ended December 31, 2002. This hypothetical analysis does not take into consideration the effects of the economic conditions that would give rise to such an interest rate change or our response to such hypothetical conditions.

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 it has a material exposure to interest rate risk.

### Item 8. Financial Statements

The financial statements required to be filed hereunder are filed as an exhibit hereto, are listed under item 14(a)(1) and are incorporated herein by reference.

### Item 9. Changes in and Disagreements on Accounting and Financial Disclosure

There have been no disagreements on accounting and financial disclosure matters.

# Edgar Filing: DIACRIN INC /DE/ - Form 10-K

## PART III

Item 10 - 13.

The information required for Part III of this Annual Report on Form 10-K is hereby incorporated by reference from portions of our definitive proxy statement relating to the 2003 annual meeting of stockholders, which statement will be filed with the Commission not later than 120 days after the end of our 2002 fiscal year. Such information will be contained in the sections of such proxy statement captioned "Election of Directors," "Meetings of Board of Directors and Committees," "Executive Compensation," "Certain Relationships and Related Transactions," "Section 16(a) Beneficial Ownership Reporting Compliance," "Compensation Committee Interlocks and Insider Participation," and "Principal Stockholders." Information regarding executive officers of the Company is furnished in Part I of this Annual Report on Form 10-K under the heading, "Executive Officers of the Registrant."

Item 14. Controls and Procedures

1. Evaluation of disclosure controls and procedures. Based on their evaluation of the Company's disclosure controls and procedures (as defined in Rules 13a-14(c) and 15d-14(c) under the Securities and Exchange Act of 1934) as of a date within 90 days of the filing date of this Annual Report on Form 10-K, the Company's Chief Executive Officer and Controller have concluded that the Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and are operating in an effective manner.

2. Changes in internal controls. There were no significant changes in the Company's internal controls or in other factors that could significantly affect these controls subsequent to the date of their most recent evaluation.

## PART IV

Item 15. Exhibits, Financial Statements and Reports on Form 8-K

(a) (1) Index to Financial Statements

The following Financial Statements are included in this Annual Report on Form 10-K.

Financial Statements:	Page
(a.) Diacrin, Inc.	
1. Report of Independent Public Accountants	F-1
2. Balance Sheets as of December 31, 2001 and 2002	F-3
3. Statements of Operations for each of the three years in the period ended December 31, 2002	F-4

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

4.	Statements of Stockholders' Equity (Deficit) for each of the three years in the period ended December 31, 2002	F-5
5.	Statements of Cash Flow for each of the three years in the period ended December 31, 2002	F-6
6.	Notes to Financial Statements	F-7
(b.) Diacrin/Genzyme LLC (A Development Stage Enterprise)		
1.	Balance Sheets as of December 31, 2001 and 2002	F-18
2.	Statements of Operations for the years ended December 31, 2001 and 2002 and for the period from October 1, 1996 (date of inception) to December 31, 2002	F-19
3.	Statements of Cash Flows for the years ended December 31, 2001 and 2002 and for the period from October 1, 1996 (date of inception) to December 31, 2002	F-20
4.	Statements of Change in Venturers' Capital (Deficit) for the period from October 1, 1996 (date of inception) to December 31, 2002	F-21
5.	Notes to Financial Statements	F-22

### (2) Exhibits

The following is a list of exhibits filed as part of this Annual Report on Form 10-K:

Exhibit No.	Title	Page
-----	-----	----
3.1	- Amended and Restated Certificate of Incorporation of Diacrin as amended to date	(5)
3.2	- Amended and Restated By-laws of Diacrin	(4)
+10.1	- Employment Agreement dated February 6, 1990 by and between Diacrin and Dr. Thomas H. Fraser	(2)
10.2	- Rights Agreement dated July 29, 1991 by and among Diacrin and the holders of the preferred stock as amended on September 27, 1991	(2)
10.2(a)	- Consent and Agreement to Amend dated April 26, 1995 by and among Diacrin and certain investors named therein	(1)
10.2(b)	- Consent and Agreement to Amend dated as of January 4, 1996 by and among Diacrin and certain investors named therein	(4)
+10.3	- 1990 Stock Option Plan, as amended	(3)
10.4	- Sublease dated January 24, 1991 by and among Diacrin and Building 79 Associated Limited Partnership and Building 96 Associates Limited	

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

	Partnership	(2)
10.4(a)	- Amendment to Sublease dated April 30, 2002	*
+10.5	- 1994 Directors' Stock Option Plan, as amended	(7)
10.6	- Registration Rights Agreements dated May 31, 1995 by and among Diacrin and the investors listed on Schedules I and II attached thereto	(1)
10.6(a)	- Amendment No. 1 to Registration Rights Agreement dated as of January 4, 1996 by and among Diacrin and certain investors named therein	(4)
10.7	- Collaboration Agreement among Diacrin, Inc., Genzyme Corporation and Diacrin/Genzyme LLC dated as of October 1, 1996	(6)
10.8	- Operating Agreement of Diacrin/Genzyme LLC	(6)

Exhibit No.	Title	Page
-----	-----	----
+10.9	- 1997 Stock Option Plan	(8)
10.10	- \$650,000 Promissory Note dated November 25, 1997 made by Diacrin to the order of Fleet National Bank	(9)
10.10(a)	- Letter Agreement dated November 25, 1997 by and between Diacrin and Fleet National Bank	(9)
21	- Subsidiaries	*
23.1	- Consent of PricewaterhouseCoopers LLP	*
99.1	- Chief Executive Officer - Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	*
99.2	- Controller - Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	*

-----

\* Filed herewith

(1) Filed as an exhibit to our Quarterly Report on Form 10-Q (File No. 0-20139) for the quarter ended June 30, 1995 and incorporated herein by reference.

(2) Filed as an exhibit to our Form 10, as amended (File No. 0-20139), on April 29, 1992, and incorporated herein by reference.

(3) Filed as an exhibit to our Quarterly Report on Form 10-Q (File No. 0-20139) for the quarter ended September 30, 1994 and incorporated herein by reference.

(4) Filed as an exhibit to our Registration Statement on Form S-2, as amended

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

(Registration No. 33-80773) on December 22, 1995, and incorporated herein by reference.

(5) Filed as an exhibit to our Annual Report on Form 10-K (File No. 0-20139) for the fiscal year ended December 31, 1995 and incorporated herein by reference.

(6) Filed as an exhibit to our Quarterly Report on Form 10-Q, as amended on Form 10-Q/A (File No. 0-20139) for the quarter ended September 30, 1996 and incorporated herein by reference.

(7) Filed as an exhibit to our Annual Report on Form 10-K (File No. 0-20139) for the fiscal year ended December 31, 1996 and incorporated herein by reference.

(8) Filed as an exhibit to our Quarterly Report on Form 10-Q (File No. 0-20139) for the quarter ended June 30, 1997 and incorporated herein by reference.

(9) Filed as an exhibit to our Annual Report on Form 10-K (File No. 0-20139) for the fiscal year ended December 31, 1997 and incorporated herein by reference.

+ Management contract or compensatory plan or arrangement filed as an exhibit to this Form pursuant to Items 14(a) and 14(c) of Form 10-K.

(b) Reports on Form 8-K.

We did not file any current reports on Form 8-K during the last quarter of the period covered by this report.

(c) Description of Exhibits.

See Item 14 (a)

(d) Description of Financial Statement Schedules.

None.

### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

DIACRIN, INC.

By: /s/ Thomas H. Fraser

-----  
Thomas H. Fraser  
President and Chief Executive Officer

Date: March 26, 2002

Pursuant to the requirement of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Edgar Filing: DIACRIN INC /DE/ - Form 10-K

Signature	Date	Title
/s/ Thomas H. Fraser ----- Thomas H. Fraser	March 26, 2003	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ Kevin Kerrigan ----- Kevin Kerrigan	March 26, 2003	Controller (Principal Financial and Accounting Officer)
/s/ Zola P. Horovitz ----- Zola P. Horovitz	March 26, 2003	Director
/s/ John W. Littlechild ----- John W. Littlechild	March 26, 2003	Director
/s/ Stelios Papadopoulos ----- Stelios Papadopoulos	March 26, 2003	Director
/s/ Joshua Ruch ----- Joshua Ruch	March 26, 2003	Director

CERTIFICATIONS

I, Thomas H. Fraser, President and Chief Executive Officer certify that:

1. I have reviewed this annual report on Form 10-K of Diacrin, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant is made known to us by others,



## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

particularly during the period in which this annual report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) presented in this Annual Report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the Audit Committee of the registrant's Board of Directors:

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls;

6. The registrant's other certifying officer and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 26, 2003

/s/ Thomas H. Fraser

-----

Thomas H. Fraser  
President and Chief Executive Officer  
(Principal Executive Officer)

### CERTIFICATIONS

I, Kevin Kerrigan, Controller, certify that:

1. I have reviewed this annual report on Form 10-K of Diacrin, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant is made known to us by others, particularly during the period in which this annual report is being prepared;

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) presented in this Annual Report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the Audit Committee of the registrant's Board of Directors:

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls;

6. The registrant's other certifying officer and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 26, 2003

/s/ Kevin Kerrigan

-----  
Kevin Kerrigan  
Controller  
(Principal Financial Officer)

Report of Independent Public Accountants

To the Board of Directors and Stockholders of  
Diacrin, Inc.

In our opinion, the accompanying balance sheet and the related statements of operations, stockholders' equity and cash flows present fairly, in all material respects, the financial position of Diacrin, Inc. at December 31, 2002, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit of these statements in accordance with auditing standards generally accepted in the United States of America which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion. The financial statements of Diacrin, Inc. as of December 31, 2001, and for each of the two years in the period ended December 31, 2001 were audited by

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

other independent accountants who have ceased operations. Those independent accountants expressed an unqualified opinion on those financial statements in their report dated February 21, 2002.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts  
January 21, 2003

F-1

The following report is a copy of a report issued by Arthur Andersen LLP and has not been reissued by Arthur Andersen LLP.

### Report of Independent Public Accountants

To the Board of Directors of  
Diacrin, Inc.:

We have audited the accompanying balance sheets of Diacrin, Inc. (a Delaware corporation) as of December 31, 2000 and 2001 and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of Diacrin, Inc.'s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Diacrin, Inc. as of December 31, 2000 and 2001 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

/s/ Arthur Andersen LLP

Boston, Massachusetts  
February 21, 2002

F-2

Edgar Filing: DIACRIN INC /DE/ - Form 10-K

DIACRIN, INC.  
Balance Sheets

	At December 31,	
	2001	2002
	----	----
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 8,534,426	\$ 4,189,700
Short-term investments	33,410,736	33,484,274
Interest receivable and other current assets	668,020	683,473
	-----	-----
Total current assets	42,613,182	38,357,447
	-----	-----
Property and equipment, at cost:		
Laboratory and manufacturing equipment	1,660,963	1,679,436
Furniture and office equipment	324,913	327,382
Leasehold improvements	77,529	86,597
	-----	-----
	2,063,405	2,093,415
Less - Accumulated depreciation and amortization	1,861,110	1,985,364
	-----	-----
	202,295	108,051
	-----	-----
Long-term investments	7,782,035	7,282,169
Investment in joint venture	83,984	-
	-----	-----
Total other assets	7,866,019	7,282,169
	-----	-----
Total assets	\$ 50,681,496	\$ 45,747,667
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 117,663	\$ 147,633
Accrued expenses	1,269,278	726,168
Deferred revenue	29,238	1,787,483
Current portion of long-term debt	119,167	-
	-----	-----
Total current liabilities	1,535,346	2,661,284
	-----	-----
Commitments (Notes 4 and 10)		
Stockholders' equity:		
Preferred stock, \$0.01 par value; authorized--5,000,000 shares; none issued and outstanding	-	-
Common stock, \$0.01 par value; authorized--30,000,000 shares; issued and outstanding--17,937,204 shares at December 31, 2001 and 2002	179,372	179,372
Additional paid-in capital	101,401,822	101,401,822
Accumulated deficit	(52,435,044)	(58,494,811)

Edgar Filing: DIACRIN INC /DE/ - Form 10-K

Total stockholders' equity	----- 49,146,150 -----	----- 43,086,383 -----
Total liabilities and stockholders' equity	\$ 50,681,496 =====	\$ 45,747,667 =====

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

F-3

DIACRIN, INC.  
Statements of Operations

	Year Ended December 31,		
	----- 2000 -----	----- 2001 -----	----- 2002 -----
REVENUES:			
Research and development	\$ 2,081,795 -----	\$ 737,290 -----	\$ 346,316 -----
OPERATING EXPENSES:			
Research and development	5,996,550	6,350,190	6,123,580
General and administrative	1,348,072 -----	1,624,470 -----	1,535,507 -----
Total operating expenses	7,344,622 -----	7,974,660 -----	7,659,087 -----
OTHER INCOME (EXPENSE):			
Equity in operations of joint venture	(1,368,945)	(546,562)	(103,069)
Investment income	3,124,929	3,149,543	1,358,692
Interest expense	(29,898) -----	(13,861) -----	(2,619) -----
Total other income (expense)	1,726,086 -----	2,589,120 -----	1,253,004 -----
NET LOSS	\$ (3,536,741) =====	\$ (4,648,250) =====	\$ (6,059,767) =====
NET LOSS PER COMMON SHARE:			
Basic and diluted	\$ (.21) =====	\$ (.26) =====	\$ (.34) =====
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:			
Basic and diluted	17,073,194 =====	17,914,889 =====	17,937,204 =====

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

Edgar Filing: DIACRIN INC /DE/ - Form 10-K

F-4

DIACRIN, INC.  
Statements of Stockholders' Equity

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Sto
	Number of Shares	\$.01 Par Value			
BALANCE, December 31, 1999	14,386,183	143,862	64,250,741	(44,250,053)	20
Proceeds from public offering of common stock, net of \$2,765,500 financing costs	3,450,000	34,500	36,875,000	-	36
Exercise of stock options and warrants	78,521	785	248,181	-	
Net loss	-	-	-	(3,536,741)	(3
BALANCE, December 31, 2000	17,914,704	179,147	101,373,922	(47,786,794)	53
Exercise of stock options	22,500	225	27,900	-	
Net loss	-	-	-	(4,648,250)	(4
BALANCE, December 31, 2001	17,937,204	179,372	101,401,822	(52,435,044)	49
Net loss	-	-	-	(6,059,767)	(6
BALANCE, December 31, 2001	17,937,204	179,372	101,401,822	(58,494,811)	43

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

F-5

DIACRIN, INC.

# Edgar Filing: DIACRIN INC /DE/ - Form 10-K

## Statements of Cash Flows

	Year Ended December 31,		
	2000	2001	2002
	----	----	----
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (3,536,741)	\$ (4,648,250)	\$ (6,000,000)
Adjustments to reconcile net loss to net cash used in operating activities-			
Depreciation and amortization	213,969	209,492	1,000,000
Equity in operations of joint venture	1,368,945	546,562	1,000,000
Changes in current assets and liabilities-			
Interest receivable and other current assets	(451,041)	112,386	(1,000,000)
Accounts payable	(29,461)	8,356	(1,000,000)
Accrued expenses	55,866	160,687	(5,000,000)
Deferred revenue from joint venture	(94,259)	(315,230)	1,700,000
	-----	-----	-----
Net cash used in operating activities	(2,472,722)	(3,925,997)	(4,600,000)
	-----	-----	-----
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Increase in short-term investments	(5,903,423)	(10,925,061)	(1,000,000)
Purchases of property and equipment, net	(102,510)	(10,706)	(1,000,000)
(Increase) decrease in long-term investments	(18,333,856)	13,195,905	4,000,000
Investment in joint venture	(1,947,422)	(1,086,545)	(1,000,000)
Return of capital for services provided on behalf of joint venture	693,932	245,589	(1,000,000)
	-----	-----	-----
Net cash (used in) provided by investing activities	(25,593,279)	1,419,182	3,000,000
	-----	-----	-----
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Net proceeds from sale of common stock	36,909,500	-	(1,000,000)
Net proceeds from the exercise of stock options and warrants	248,966	28,125	(1,000,000)
Principal payments on long-term debt	(143,350)	(130,000)	(1,000,000)
	-----	-----	-----
Net cash provided by (used in) financing	37,015,116	(101,875)	(1,000,000)
	-----	-----	-----
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	8,949,115	(2,608,690)	(4,300,000)
CASH AND CASH EQUIVALENTS, beginning of year	2,194,001	11,143,116	8,500,000
	-----	-----	-----
CASH AND CASH EQUIVALENTS, end of year	\$11,143,116	\$ 8,534,426	\$ 4,100,000
	=====	=====	=====
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:</b>			
Cash paid for interest	\$ 30,946	\$ 15,547	\$ 1,000,000
	=====	=====	=====

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

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

F-6

Diacrin, Inc.

### Notes to Financial Statements

#### (1) Operations and Basis of Presentation

Diacrin, Inc. (the "Company") was incorporated on October 10, 1989 and is developing cell transplantation technology for the treatment of human diseases that are characterized by cell dysfunction or cell death and for which current therapies are either inadequate or nonexistent. The Company operates in a single segment.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, reliance on corporate partners to successfully research, develop and commercialize products based on the Company's technologies, and compliance with FDA government regulations and approval requirements as well as the ability to grow the Company's business and obtain adequate financing to fund this growth.

#### (2) Summary of Significant Accounting Policies

##### (a) Depreciation and Amortization

The Company provides for depreciation using the straight-line method by charges to operations in amounts estimated to allocate the cost of these assets over a five-year life. Amortization of leasehold improvements is computed using the straight-line method over the shorter of the estimated useful life of the asset or the lease term.

##### (b) Cash and Cash Equivalents

All highly liquid investments with original maturities of three months or less are considered cash equivalents. Cash and cash equivalent balances consist of deposits, commercial paper and investments in a money market mutual fund. At December 31, 2002 and 2001, the Company has classified as cash equivalent approximately \$4.2 million and \$8.5 million, respectively. These investments are stated at amortized cost, which approximates fair value.

##### (c) Revenue Recognition

Revenues under the collaboration agreement with Terumo Corporation (see Note 4) and the joint venture agreement with Genzyme Corporation ("Genzyme") (see Note 5) are recognized as work is performed. Revenues related to the Terumo collaboration are recognized as the Company completes its performance obligations under the related agreement. Revenues under the joint venture agreement are 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



## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

the joint venture. Deferred revenue represents amounts received prior to recognition of revenue. Research and development costs are expensed as incurred.

Revenue from milestone payments under which we have continuing performance obligations are recognized as revenue upon the achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved in achieving the milestone; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as we complete our performance obligations. Payments received under these arrangements prior to the completion of the related work are recorded as deferred revenue.

F-7

Diacrin, Inc.

### Notes to Financial Statements (Continued)

#### (d) Income Taxes

The Company records income taxes using the asset and liability method. Deferred income tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases, and operating loss and tax credit carry forwards. Deferred income tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences, operating losses, or tax credit carry forwards are expected to be recovered or settled. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Statement of Financial Accounting Standards No. 109, Accounting for Income Taxes, requires the establishment of a valuation allowance to reflect the likelihood of realization of deferred tax assets. Significant management judgment is required in determining the Company's provision for income taxes, its deferred tax assets and liabilities and any valuation allowance recorded against its net deferred tax assets. The Company evaluates the weight of all available evidence to determine whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. See Note 11.

#### (e) Net Loss per Common Share

In accordance with 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 of 1,258,247, 1,263,872 and 1,461,557 at December 31, 2000, 2001, and 2002, respectively, because to include such shares would have been antidilutive.

#### (f) Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

(g) Comprehensive Income

SFAS No. 130, Reporting Comprehensive Income ("SFAS 130") establishes standards for reporting and display of comprehensive income and its components, including net loss and equity from non-shareholder sources, in a full set of general-purpose financial statements. There are no differences between the Company's reported income and comprehensive income for all periods presented.

(h) Fair Value of Financial Instruments

Financial instruments consist mainly of cash and cash equivalents, short-term investments, long-term investments, accounts payable and current portion of long-term debt. The carrying amounts of these instruments approximate their fair value.

(i) Stock-Based Compensation

Stock options issued to employees under the Company's stock option and employee stock purchase plans are accounted for under APB Opinion No. 25, Accounting for Stock Issued to Employees and related interpretations, including FASB Interpretation No. 44 (see Note 10). All stock-based awards to non-employees are accounted for at their fair value in accordance with SFAS No. 123, Accounting for Stock-Based Compensation, and Emerging Issues Task Force (EITF) Issue No. 96-18, Accounting for Equity Instruments that are Issued to Other than Employees.

F-8

Diacrin, Inc.

Notes to Financial Statements (Continued)

Statement of Financial Accounting Standards No. 123 (SFAS 123), Accounting for Stock-Based Compensation, requires that companies either recognize compensation expense for grants of stock options and other equity instruments based on fair value, or provide pro forma disclosure of net loss and net loss per share in the notes to the financial statements. At December 31, 2002, the Company has three stock-based compensation plans, which are described more fully in Note 10. The Company accounts for those plans under the recognition and measurement principles of Account Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations. Accordingly, no compensation cost has been recognized under SFAS 123 for the Company's employee stock option plans. Had compensation cost for the awards under those plans been determined based on the grant date fair values, consistent with the method required under SFAS 123, the Company's net loss and net loss per share would have been reduced to the pro forma amounts indicated below:

	For the year ended December 31,		
	2000	2001	2002
	-----	-----	-----
Net loss applicable to common stockholders as reported	(3,536,741)	(4,648,250)	(6,059,767)

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

Deduct: Stock-based compensation expense determined under fair value based method for all award	(1,178,182)	(964,544)	(646,554)
	-----	-----	-----
Net loss applicable to common stockholders, pro forma	(4,714,923)	(5,612,794)	(6,706,321)
	=====	=====	=====
Basic and diluted net loss per share:			
As reported	\$ (.21)	\$ (.26)	\$ (.34)
	=====	=====	=====
Pro forma	\$ (.28)	\$ (.31)	\$ (.37)
	=====	=====	=====

(j) Reclassification

Investment income has been reclassified in the prior period financial statements into Other Income / (Expense) to conform with the current period presentation.

(k) New Accounting Standards

In July 2002, the FASB issued SFAS 146, Accounting for Costs Associated with Exit or Disposal Activities. SFAS 146 requires that a liability for a cost associated with an exit or disposal activity be recognized at its fair market value when the liability is incurred, rather than at the date of an entity's commitment to an exit plan. The provisions of SFAS 146 are effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of SFAS 146 has not had a material effect on our financial statements.

In November 2002, the FASB issued Interpretation No. 45 (FIN 45), Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, an interpretation of FASB Statements No. 5, 57, and 107 and Rescission of FASB Interpretation No. 34. FIN 45 elaborates on the existing disclosure requirements for most guarantees, including loan guarantees such as standby letters of credit and warranty obligations. It also clarifies that at the time a company issues a guarantee, a company must recognize an initial liability for the fair value of the obligations it assumes under the guarantee and must disclose that information in its interim and annual financial statements. The provisions of FIN 45 relating to initial recognition and measurement must be applied on a prospective basis to guarantees issued or modified after December 31, 2002. We do not expect the adoption of the initial recognition and measurement provisions in the first quarter of 2003 to have a significant impact on our financial condition or results of operations. The disclosure requirements of FIN 45, which are effective for both interim and annual periods that end after December 15, 2002, were adopted by us for the year ended December 31, 2002.

F-9

Diacrin, Inc.

Notes to Financial Statements (Continued)

In December 2002, the Financial Accounting Standards Board issued

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation - Transition and Disclosure. SFAS 148 provides alternative methods of transition for a voluntary change to the fair value method of accounting for stock-based employee compensation as originally provided by SFAS No. 123, Accounting for Stock-Based Compensation. Additionally, SFAS 148 amends the disclosure requirements of SFAS 123 to require prominent disclosure in both the annual and interim financial statements about the method of accounting for stock-based compensation and the effect of the method used on reported results. The transitional requirements of SFAS 148 will be effective for all financial statements for fiscal years ending after December 15, 2002. The disclosure requirements shall be effective for financial reports containing condensed financial statements for interim periods beginning after December 15, 2002. The transitional disclosure requirements were adopted by us for the year ended December 31, 2002. We expect to adopt the disclosure portion of this statement for the quarter ending March 31, 2003. The application of this standard will have no impact on our financial position or results of operations.

In January 2003, the FASB issued FASB Interpretation No. 46 (FIN 46), Consolidation of Variable Interest Entities. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the entity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is required to be applied to preexisting entities of the Company as of the beginning of the first quarter after June 15, 2003. FIN 46 is required to be applied to all new entities with which the Company becomes involved beginning February 1, 2003. Based upon the accounting guidance and other information available, we do not believe our joint venture meets the definition of a variable interest entity. We currently believe adoption of FIN 46 will not have a significant impact on the Company. We believe the interpretive accounting guidance necessary for FIN 46 will continue to evolve. Additional interpretive guidance could affect the accounting for our joint venture.

### (3) Sale of Common Stock

In March 2000, the Company completed a public offering of 3,450,000 shares of its common stock for \$11.50 per share for net proceeds of approximately \$36.9 million.

### (4) Terumo Agreement

In September 2002, the Company entered into a development and license agreement with Terumo Corporation ("Terumo"). Under the terms of the agreement, Diacrin licensed to Terumo its human muscle cell transplantation technology for cardiac disease in Japan. Terumo will fund all development in Japan while Diacrin continues to independently develop its cardiac repair technology for commercialization in the U.S. and elsewhere. On October 1, 2002, the Company received an upfront non-refundable license fee of \$2.0 million. The agreement also includes payments by Terumo to Diacrin for development milestones and a royalty on product sales. The Company recorded the upfront license fee as deferred revenue and recognizes revenue over the development period of the agreement in accordance with SEC Staff Accounting Bulletin No. 101, "Revenue Recognition" ("SAB 101"). SAB 101 requires companies to recognize certain upfront non-refundable fees over the period in which the Company completes its performance obligations under the related agreement when such fees are received in conjunction with an agreement which includes performance obligations. Determination of the length of the development period requires management's judgment. Any significant changes in the assumptions underlying our estimates used while applying the percentage

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

of completion method could impact our revenue recognition. Included in research and development revenue for the year ended December 31, 2002 is \$245,000 in revenue related to performance obligations completed by December 31, 2002.

F-10

Diacrin, Inc.

### Notes to Financial Statements (Continued)

Revenue from milestone payments under which we have continuing performance obligations are recognized as revenue upon the achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved in achieving the milestone; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as we complete our performance obligations. Payments received under these arrangements prior to the completion of the related work are recorded as deferred revenue. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as we complete our performance obligations.

#### (5) Joint Venture Agreement

In September 1996, the Company and Genzyme Corporation formed a joint venture to develop and commercialize two product candidates. Under the terms of the joint venture agreement, which was effective October 1, 1996, Genzyme agreed to provide 100% of the first \$10 million in funding and 75% of the following \$40 million in funding for the two products. All costs incurred in excess of \$50 million will be shared equally between Genzyme and the Company in accordance with the terms of the agreement. Any profits of the joint venture will be shared equally by the two parties. As of December 31, 2002, Genzyme had provided \$33.0 million to the joint venture and the Company had provided \$7.6 million.

The Company records as research and development expense all costs related to developing the joint venture's product candidates incurred by it on behalf of the joint venture. The Company recognizes research and development revenue equal to the amount of reimbursement received by it from the joint venture out of funds contributed by Genzyme. The Company does not recognize research and development revenue for amounts received from the joint venture out of funds it contributed. As Genzyme incurs costs on behalf of the joint venture that the Company is obligated to fund, it recognizes an expense in its statement of operations captioned "Equity in operations of joint venture."

Genzyme agreed to make financing available to Diacrin from and after the date that Genzyme provides the initial \$10 million of funding to the joint venture. Genzyme agreed to make available to Diacrin an unsecured, subordinated line of credit of up to an aggregate amount of \$10 million. Diacrin may draw on the line only in the event that Diacrin's cash and cash equivalents are insufficient to fund Diacrin's budgeted operations for a specified period of time, and the funds may be used by Diacrin only to fund capital contributions to the joint venture. The line will be available through the date five years after the date Diacrin first draws on the line, and all outstanding principal and interest will be due on that fifth anniversary. Advances will be interest-bearing, evidenced by a promissory note and

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

subject to other considerations and the aggregate amount of draws in any calendar year may not exceed \$5 million. Diacrin did not make any draws on the line through December 31, 2002.

The Company accounts for its investment in the joint venture on the equity method. The detail of the Company's investment in the joint venture is as follows:

	2000	2001	2002
	----	----	----
Balance, beginning of year	\$103,730	\$ 4,785	\$ 83,984
Contributions to joint venture	1,947,422	1,086,545	40,000
Return of capital	(693,932)	(245,589)	(33,772)
Funding of operations of joint venture	(1,352,435)	(761,757)	(103,069)
	-----	-----	-----
Balance, end of year	\$4,785	\$83,984	\$(12,857)
	=====	=====	=====

F-11

Diacrin, Inc.

### Notes to Financial Statements (Continued)

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:

	2000	2001	2002
	----	----	----
Revenue recognized (see note 2c)	\$2,081,795	\$737,290	\$101,316
Research and development expense (see note 2c)	\$2,775,727	\$983,054	\$135,087
Equity in operations of joint venture	\$1,368,945	\$546,562	\$103,069

#### (6) Cash, 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 market value. Cash equivalents test is done at purchase date. Investments classification is determined at balance sheet date. Short-term investments and long-term investments have maturities of less than one year and greater than one year, respectively. Cash and cash equivalents, short-term investments and long-term investments at December 31, 2001 and 2002 consisted of the following:

Edgar Filing: DIACRIN INC /DE/ - Form 10-K

	2001 ----
Cash and cash equivalents-	
Cash	\$ 1,003
Money market mutual fund	8,533,423
	-----
	\$ 8,534,426
	=====
Short-term investments-	
Corporate notes (remaining avg. maturity of 6 mos. at Dec. 31, 2002)	\$26,651,221
US Gov't Obligations (remaining maturity of 1 mos. at Dec. 31, 2002)	6,510,826
Commercial paper	248,689
	-----
	\$33,410,736
	=====
Long-term investments-	
Corporate notes (remaining avg. maturity of 13 mos. at Dec. 31, 2002)	\$ 4,198,142
US Gov't Obligations	3,583,893
	-----
	\$ 7,782,035
	=====

During the year ended December 31, 2001 the Company sold two of its held-to-maturity investments due to significant evidence of deterioration in the issuers' creditworthiness. The cost of the two investments was approximately \$5.5 million and the sale resulted in a realized gain of approximately \$96,000, which is included in Investment income on the statement of operations for the year ended December 31, 2001. This sale represents a change in circumstances as defined in SFAS No. 115 Accounting for Certain Investments in Debt and Equity Securities and does not impact the classification of the remaining portfolio as held-to-maturity investments as the Company continues to have the intent and ability to hold its investments to maturity.

F-12

Diacrin, Inc.

Notes to Financial Statements (Continued)

(7) Accrued Expenses

Accrued expenses consisted of the following at December 31, 2001 and 2002:

	2001 ----	2002 ----
Accrued clinical trials costs	\$ 499,341	\$ 223,145
Accrued professional fees	138,364	137,879
Accrued payroll	288,813	163,000
Accrued contract research costs	98,934	72,590
Accrued other	243,826	129,554

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

	-----	-----
Total	\$1,269,278	\$ 726,168
	=====	=====

(8) Long-term Debt

In November 1997, the Company entered into an unsecured term loan agreement with a bank whereby the bank loaned the Company \$650,000 to construct a pilot manufacturing facility. The loan was paid in 60 principal installments of \$10,833 commencing December 1, 1997 and ending November 1, 2002.

(9) Preferred Stock

The Company has authorized 5,000,000 shares of undesignated preferred stock. The Company's Board of Directors is authorized, subject to any limitations prescribed by law and without further stockholder approval, to issue from time to time up to 5,000,000 shares of preferred stock in one or more series. Each such series of preferred stock shall have such number of shares, designations, preferences, voting powers, qualifications and rights or privileges as shall be determined by the Board of Directors. There have been no shares of preferred stock issued by the Company.

(10) Common Stock Options

In 1990, the Company established the 1990 Stock Option Plan (the "1990 Plan") which authorized the Board of Directors to grant incentive stock options, non-qualified stock options and stock appreciation rights to employees, directors and consultants of the Company for up to 800,000 shares of the Company's common stock. All options granted have 10-year terms, and the majority vest in equal annual installments of 25% over four years of continued service from the date of hire or grant. In 2000, the 1990 Plan expired and no further grants have been made. All options outstanding on the expiration date remain in effect.

In July 1994, the stockholders approved the 1994 Directors' Stock Option Plan (the "Director Plan") which automatically grants an option to each eligible outside director of the Company for the purchase of 7,500 shares of common stock at an exercise price of the then fair market value. Each option granted under the Director Plan has a 10-year term and may be exercised on a cumulative basis as to 25% of the shares on the first anniversary of the date of grant and an additional 25% at the end of each one-year period thereafter. In December 1996, the Board of Directors amended the Director Plan to automatically grant 15,000 options to each new eligible outside director. The Company has reserved 30,000 shares for issuance under this plan. As of December 31, 2002, there were 15,000 options outstanding under the Director Plan at a weighted average exercise price of \$9.50 per share. As of December 31, 2002, there were options to purchase 13,125 shares of common stock available for future grant under the Director Plan.

In June 1997, the stockholders approved the 1997 Stock Option Plan (the "1997 Plan") under which the Board of Directors is authorized to grant incentive stock options and non-qualified stock options to employees, directors and consultants of the Company for up to 1,200,000 shares of the Company's common stock. All options granted have 10-year terms, and vest in equal annual installments of 25% over four years of continued service from the date of hire or grant. As of December 31, 2002, options to purchase 336,000 shares of common stock were available for future grant under the 1997 Plan.



Edgar Filing: DIACRIN INC /DE/ - Form 10-K

Diacrin, Inc.

Notes to Financial Statements (Continued)

The following table summarizes incentive and non-qualified stock option activity:

	Number of options	Weighted average Exercise price
Balance, December 31, 1999	1,236,523	5.14
Options granted	154,750	5.56
Options exercised	(75,526)	2.66
Options canceled	(57,500)	8.91
	-----	----
Balance, December 31, 2000	1,258,247	5.15
Options granted	32,000	2.18
Options exercised	(22,500)	1.25
Options canceled	(3,875)	6.27
	-----	----
Balance, December 31, 2001	1,263,872	\$ 5.14
Options granted	302,000	2.00
Options exercised	-	-
Options canceled	(104,315)	5.20
	-----	----
Balance, December 31, 2002	1,461,557	\$ 4.49
	=====	=====
Exercisable, December 31, 2002	1,046,557	\$ 5.12
	=====	=====
Exercisable, December 31, 2001	988,996	\$ 5.08
	=====	=====
Exercisable, December 31, 2000	860,869	\$ 4.68
	=====	=====

All options have been granted at the fair market value of the Company's common stock on the date of grant.

The following table summarizes certain information about options outstanding and exercisable at December 31, 2002:

Options outstanding			
Range of exercise prices	Number of options outstanding at December 31, 2002	Weighted average remaining contractual life	Weighted average exercise price
\$1.22 to \$2.50	787,057	4.12	\$2.09
\$4.63 to \$7.50	435,250	6.67	\$5.76
\$7.88 to \$12.00	239,250	4.79	\$10.06
	-----	-----	-----
	1,461,557		\$4.49
	=====		=====

Edgar Filing: DIACRIN INC /DE/ - Form 10-K

Diacrin, Inc.

Notes to Financial Statements (Continued)

Options exercisable

Range of exercise prices	Number exercisable At December 31, 2002	Weighted average exercise price
\$1.25 to \$2.50	478,057	\$2.15
\$4.63 to \$7.50	341,250	\$5.91
\$7.88 to \$12.00	227,250	\$10.18
	-----	-----
	1,046,557	\$5.12
	=====	=====

The Company has adopted SFAS No. 123, Accounting for Stock-Based Compensation. As permitted by SFAS No. 123, the Company has continued to account for employee stock options in accordance with Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and has included the pro forma disclosure required by SFAS No. 123 for all periods presented.

Pro forma information regarding net income (loss) and earnings (loss) per share is required by SFAS No. 123, and has been determined as if the Company had accounted for its employee and director stock options under the fair value method of SFAS No. 123. The fair-value for these options was estimated at the date of grant using a Black-Scholes option pricing model with the following assumptions for 2000, 2001 and 2002: risk-free interest rates of 6.0%, 6.0% and 3.0% for 2000, 2001 and 2002; dividend yield of 0% for all years; volatility factor of the expected market price of the Company's common stock of 95% for all years; and a weighted-average expected life of the options of 7.5 years for all years. The weighted average fair value of options granted in 2000, 2001 and 2002 was \$4.71, \$1.85 and \$1.66, respectively.

For purposes of pro forma disclosure, the estimated fair value of the options is amortized to expense over the options' vesting period. The aggregate fair value of options granted in 2000, 2001 and 2002 was approximately \$729,000, \$59,000 and \$500,000, respectively. See Note 2(i).

F-15

Diacrin, Inc.

Notes to Financial Statements (Continued)

(11) Income Taxes

The Company accounts for income taxes in accordance with Statement of Financial Accounting Standards ("SFAS") No. 109, Accounting for Income Taxes. The Company has recorded no provision for federal and state income taxes. As of December 31, 2002 the Company has federal and state tax NOL carryforwards of \$57,748,000 and \$25,029,000, respectively. These NOL carryforwards begin to expire in 2005 and 2003, respectively. The net operating loss carryforwards are subject to review and possible adjustment

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

by the Internal Revenue Service.

Net operating loss and tax credit carryforwards may be limited in the event of certain changes in the ownership interests of significant shareholders. The Company believes the issuance of the convertible notes payable in May 1995, as well as the initial public offering in February 1996, caused a change in ownership, as defined by the Tax Reform Act of 1986 (the "Act"). Additionally, the Company's private placement in 1998 and secondary offering in 2000 may have caused a change in ownership, as defined by the Act. Ownership changes in future periods may further limit the Company's ability to utilize net operating loss and tax credit carryforwards.

The components of the net deferred tax assets are approximately as follows:

	2001 ----	2002 ----
Loss carryforwards	\$21,360,000	\$21,204,000
Credit carryforwards	4,250,000	6,062,000
Other temporary differences	43,500	(3,000)
	-----	-----
Total deferred tax assets	25,653,500	27,263,000
Less - valuation allowance	(25,653,500)	(27,263,000)
	-----	-----
Net deferred tax asset	\$ -	\$ -
	=====	=====

The Company has determined that it is more likely than not that the deferred tax assets will not be realized, therefore, a valuation allowance has reduced all of the deferred tax assets to zero. The change in the total valuation allowance during the year ended December 31, 2002 was an increase of approximately \$1,609,500 and relates to the increase in the deferred tax asset which is primarily due to the net operating loss generated during 2002.

### (12) Facility Lease

During 1991, the Company entered into a 10-year operating lease for a facility. In October 2000, the Company exercised the first of two options to extend the lease an additional five years commencing October 2001. Minimum rental payments under the lease are as follows:

	Rental Commitment -----
2003	\$ 908,000
2004	908,000
2005	908,000
2006	681,000
	-----
	\$3,405,000
	=====

Total rent expense for the years ended December 31, 2000, 2001 and 2002 was approximately \$751,000, \$758,000 and \$981,000, respectively.

# Edgar Filing: DIACRIN INC /DE/ - Form 10-K

## Notes to Financial Statements (Continued)

### (13) Employment Retirement / Savings Plan

The Company maintains an employee retirement / savings plan (the "Plan") which permits participants to make tax deferred contributions by salary reduction pursuant to section 401(k) of the Internal Revenue Code. All active employees, 21 years of age or older, who have completed a calendar quarter of service are eligible to participate in the Plan. The Company pays all administrative costs of the Plan. During 2000, 2001 and 2002 the Company made discretionary contributions of \$28,500, \$54,700 and \$57,600, respectively, to the Plan.

### (14) Quarterly Results of Operations (Unaudited)

The following table presents, in thousands, a condensed summary of quarterly results of operations for the years ended December 31, 2002 and 2001:

	Year Ended December 31, 2002			
	First Quarter -----	Second Quarter -----	Third Quarter -----	Fourth Quarter -----
Total revenue	\$ 33 =====	\$ 47 =====	\$ 92 =====	\$ 174 =====
Net loss	\$ (1,523) =====	\$ (1,780) =====	\$ (1,537) =====	\$ (1,220) =====
Basic and diluted net loss per common share	\$ (.08) =====	\$ (.10) =====	\$ (.09) =====	\$ (.07) =====
	Year Ended December 31, 2001			
	First Quarter -----	Second Quarter -----	Third Quarter -----	Fourth Quarter -----
Total revenue	\$ 383 =====	\$ 158 =====	\$ 69 =====	\$ 127 =====
Net loss	\$ (811) =====	\$ (1,334) =====	\$ (1,175) =====	\$ (1,328) =====
Basic and diluted net loss per common share	\$ (.05) =====	\$ (.07) =====	\$ (.07) =====	\$ (.07) =====

F-17

Diacrin/Genzyme LLC  
(A Development Stage Enterprise)

Balance Sheets

Edgar Filing: DIACRIN INC /DE/ - Form 10-K

December 31, 2001 and 2002  
Unaudited

	2001	2002
Assets		
Current assets:		
Cash	\$ 498,093	\$ 91,527
Prepaid to Diacrin, Inc. (Note C)	50,014	53,260
Other current assets	11,267	1,667
	-----	-----
Total current assets	559,374	146,454
Property and equipment, net (Note D)	106,365	-
	-----	-----
Total assets	\$ 665,739	\$ 146,454
	=====	=====
Liabilities and Venturers' Capital (Deficit)		
Payable to Genzyme Corporation (Note C)	\$ 77,699	\$ 8,742
Accrued expenses	-	3,334
	-----	-----
Total liabilities	77,699	12,076
Commitments and contingencies (Note C)		
Venturers' capital (deficit) (including deficit accumulated during the development stage of \$40,655,182);		
Venturers' capital - Genzyme Corporation	485,654	145,408
Venturers' capital - Diacrin, Inc.	102,386	(11,030)
	-----	-----
Total Venturers' capital (deficit)	588,040	134,378
	-----	-----
Total liabilities and Venturers' capital (deficit)	\$ 665,739	\$ 146,454
	=====	=====

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

F-18

Diacrin/Genzyme LLC  
(A Development Stage Enterprise)

Statements of Operations  
(Unaudited)

Edgar Filing: DIACRIN INC /DE/ - Form 10-K

	2001	2002	For the fr October (date of i to Dece 2
Operating costs and expenses:			
Research and development - Genzyme Corporation	\$ 2,178,191	\$ 361,186	\$ 22,
Research and development - Diacrin, Inc.	983,054	135,087	18,
General and administrative	64,959	54,667	
Loss from disposal of fixed assets	-	66,299	
	-----	-----	-----
Total operating costs and expenses	3,226,204	617,239	40,
Interest income	56,902	3,577	
	-----	-----	-----
Net loss	\$ (3,169,302)	\$ (613,662)	\$ (40,
	=====	=====	=====

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

F-19

Diacrin/Genzyme LLC  
(A Development Stage Enterprise)

Statements of Cash Flows  
(Unaudited)

Edgar Filing: DIACRIN INC /DE/ - Form 10-K

	2001	2002	For Oct (date to
Cash flows from operating activities:			
Net loss	\$ (3,169,302)	\$ (613,662)	\$ (4
Reconciliation of net loss to net cash used			
Depreciation	49,811	40,066	
Loss on disposal of fixed assets	-	66,299	
Increase (decrease) in cash from working			
Prepaid to Diacrin, Inc.	315,230	(4,913)	
Payable to Genzyme Corporation	(2,072,790)	(68,957)	
Other current assets	-	11,267	
Accrued expenses	(23,900)	3,334	
	-----	-----	
Net cash used by operating activities	(4,900,951)	(566,566)	(4
Cash flows from investing activities:			
Acquisition of property and equipment	-	-	
Cash flows from financing activities:			
Capital contributed by Genzyme Corporation	3,280,155	120,000	3
Capital contributed by Diacrin, Inc.	1,086,719	40,000	
	-----	-----	
Net cash provided by financing activities	4,366,874	160,000	4
	-----	-----	
(Decrease) increase in cash	(534,077)	(406,566)	
Cash at beginning of period	1,032,170	498,093	
	-----	-----	
Cash at end of period	\$ 498,093	\$ 91,527	\$
	=====	=====	=

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

F-20

Diacrin/Genzyme LLC  
(A Development Stage Enterprise)

Statements of Changes in Venturers' Capital (Deficit)  
For the Period from October 1, 1996 (Date of Inception) to December 31, 2002

Edgar Filing: DIACRIN INC /DE/ - Form 10-K

(Unaudited)

	Genzyme Corporation	Diacrin, Inc.	Unpaid Venture Genzyme Corporation
1996 capital contributions	\$ 1,911,968	\$ -	\$ -
1996 net loss	(1,542,374)	-	-
	-----	-----	-----
Balance at December 31, 1996	369,594	-	-
1997 capital contributions	6,819,536	-	-
1997 net loss	(6,809,012)	-	-
	-----	-----	-----
Balance at December 31, 1997	380,118	-	-
1998 capital contributions	7,709,137	2,085,079	(704,415)
1998 net loss	(7,608,663)	(1,986,683)	-
	-----	-----	-----
Balance at December 31, 1998	480,592	98,396	(704,415)
1999 capital contributions	8,068,415	2,691,774	(60,267)
1999 net loss	(8,035,058)	(2,678,353)	-
	-----	-----	-----
Balance at December 31, 1999	513,949	111,817	(764,682)
2000 capital contributions	6,089,247	2,029,749	(96,982)
2000 net loss	(6,159,056)	(2,053,018)	-
	-----	-----	-----
Balance at December 31, 2000	444,140	88,548	(861,664)
2001 capital contributions	2,418,491	806,164	861,664
2001 net loss	(2,376,977)	(792,326)	-
	-----	-----	-----
Balance at December 31, 2001	\$ 485,654	\$ 102,386	\$ -
2002 capital contributions	120,000	40,000	-
2002 net loss	(460,246)	(153,416)	-
	-----	-----	-----
Balance at December 31, 2002	\$ 145,408	\$ (11,030)	\$ -
	=====	=====	=====

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



Diacrin/Genzyme LLC  
(A Development Stage Enterprise)

Notes to December 31, 2002 Financial Statements  
(Unaudited)

A. Nature of Business and Organization

On October 1, 1996, Diacrin/Genzyme LLC ("the Joint Venture") was established as a joint venture between Genzyme Corporation ("Genzyme") and Diacrin, Inc. ("Diacrin") (collectively, the "Venturers"), to develop and commercialize products and processes for use in the treatment of Parkinson's disease and Huntington's disease in humans using porcine fetal cells. Under the terms of the Collaboration Agreement among Diacrin, Genzyme and the Joint Venture (the "Collaboration Agreement"), all funding is provided by the Venturers, and all payments for work performed are made to the Venturers. Genzyme provided the initial \$10.0 million of the funding requirements, and the next \$40.0 million of the funding requirements are to be provided 75% by Genzyme and 25% by Diacrin. After \$50.0 million has been funded, any additional funding will be provided equally by the Venturers. Profits and losses from the Joint Venture will be shared in proportion to the then current capital contribution ratio of each Venturer. The Joint Venture reimburses the Venturers for costs incurred based upon the dollar amount of work, at a defined cost, that each Venturer performs on behalf of the Joint Venture. All general and administrative expenses recorded on the statements of operations are for costs incurred by and reimbursed to the Venturers. See also Note C.

The Steering Committee of the Joint Venture is comprised of representatives of each Venturer. The Steering Committee is responsible for approving the budget of the Joint Venture, reviewing costs incurred by the Venturers and monitoring the scientific progress of the Joint Venture.

The Joint Venture is subject to risks common to companies in the biotechnology industry, including but not limited to, the results of clinical trials, development by its competitors of new technological innovations, protection of proprietary technology, health care cost containment initiatives, product liability and compliance with government regulations, including those of the United States Department of Health and Human Services and the United States Food and Drug Administration.

In addition, either Venturer may terminate the Collaboration Agreement for any reason upon 180 days notice to the other Venturer. During the 180-day period, the obligations of the Venturers, including without limitation obligations with respect to capital contributions, will continue in full force and effect. A decision by one or both of the Venturers to discontinue the Collaboration Agreement for any reason could lead to the discontinuation of the Joint Venture.

The intangible assets and technological know-how contributed by Diacrin to the Joint Venture are not included as an asset in these financial statements, because generally accepted accounting principles require that the Joint Venture record contributed assets at the book value of the

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

Venturer, at the time of the asset transfer the book value was \$0.

### B. Summary of Significant Accounting Policies

#### Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reported period. Actual results could differ from those estimates.

F-22

Diacrin/Genzyme LLC  
(A Development Stage Enterprise)

Notes to December 31, 2002 Financial Statements (Continued)  
(Unaudited)

#### Cash and Cash Equivalents

Cash and cash equivalents, consisting principally of money market funds and municipal notes purchased with initial maturities of three months or less, are valued at cost plus accrued interest, which approximates market.

#### Property and Equipment

Depreciation expense is computed on a straight-line basis over the useful life of the property and equipment (3 to 10 years), and over the lesser of the life of the lease or the life of the leasehold improvement. When assets are retired or otherwise disposed of, the assets and the related accumulated depreciation are removed from the accounts and any resulting gains or losses are included in the results of operations.

#### Research and Development Expenses

Research and development costs are expensed as incurred. The research and development efforts are being conducted by the Venturers. The costs incurred by these related parties, which are subject to an annual budget approved by the Joint Venture's Steering Committee, are then charged to the Joint Venture, at a defined cost, or at amounts agreed to by the Venturers.

#### Income Taxes

The Joint Venture is organized as a pass-through entity; accordingly, the financial statements do not include a provision for income taxes. Taxes, if any, are the liability of Genzyme and Diacrin, as Venturers.

### C. Agreements with Venturers

#### Funding

Genzyme agreed to make available to Diacrin an unsecured, subordinated line of credit (the "Line") of up to an aggregate amount of \$10.0 million after the date that Genzyme provided the initial \$10.0 million of funding to the Joint Venture. Diacrin may draw on the Line only in the event that Diacrin's cash and cash equivalents are insufficient to fund Diacrin's budgeted operations for a specified period of time, and the funds may be used by Diacrin only to fund capital contributions to the Joint Venture. The Line will be available through the date five years after the date Diacrin first draws on the Line, and all outstanding principal and interest will be due on that fifth anniversary. Advances will be interest

## Edgar Filing: DIACRIN INC /DE/ - Form 10-K

bearing, evidenced by a promissory note and subject to other considerations; and the aggregate amount of draws in any calendar year may not exceed \$5.0 million. As of December 31, 2002, Diacrin had not made any draws on the Line.

During the year ended December 31, 1998, Genzyme provided its initial \$10.0 million of funding to the Joint Venture. After the initial \$10.0 million, Genzyme and Diacrin provide 75% and 25%, respectively, of the next \$40.0 million of funding to the Joint Venture. Thereafter, all funding will be shared equally by the two parties. As of December 31, 2002, Genzyme and Diacrin have funded \$33.0 million and \$7.6 million, respectively.

F-23

### Diacrin/Genzyme LLC (A Development Stage Enterprise)

Notes to December 31, 2002 Financial Statements (Continued)  
(Unaudited)

#### Other Agreements

The payable to Genzyme Corporation will be settled by cash payment and represents costs incurred by Genzyme that are reimbursable under the Collaboration Agreement. The prepaid to Diacrin is an estimate of the reimbursable costs Diacrin expects to incur on behalf of the Joint Venture in the next calendar quarter.

Genzyme charged the Joint Venture for use of certain research and development facilities under a three-year agreement which commenced July 1, 1998. The charges were \$182,082 and \$1,520,820 for the year ended December 31, 2001 and from inception through December 31, 2001, respectively. There were no charges for rent during the year ended December 31, 2002.

#### D. Property and Equipment

Property and equipment is stated at cost. At December 31, 2001, property and equipment consisted of the following:

	2001 (Unaudited)
Lab equipment	\$200,199
Computer equipment	71,991
Leasehold improvements	27,608
Furniture and fixtures	12,963
	-----
	312,761
Less: accumulated depreciation	(206,396)
	-----
Property and equipment, net	\$106,365
	=====

Depreciation expense was \$49,811 and \$40,066 for the years ended December 31, 2001 and 2002, respectively, and \$246,462 from inception

Edgar Filing: DIACRIN INC /DE/ - Form 10-K

through December 31, 2002. During the year ended December 31, 2002, the joint venture disposed of its property and equipment and recorded a loss of \$66,299 related to this disposal.

F-24