

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

DIACRIN INC /DE/  
Form 10-K  
March 09, 2001

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, 2000

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. []

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 February 28, 2001) was \$48,008,297.

As of February 28, 2001, 17,914,704 shares of the registrant's Common Stock were outstanding.

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

Documents incorporated by reference: Proxy Statement for the 2001 Annual meeting of Stockholders - Part III.

### 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 various clinical trials, development funding expected to be received in connection with our joint venture and the expected sources of porcine cells used in our products. 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. Our products under development include:

- NeuroCell-PD for Parkinson's disease
- Porcine neural cells for stroke
- Porcine neural cells for focal epilepsy

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

- Porcine neural cells for chronic intractable pain
- Porcine spinal cord cells for spinal cord injury
- NeuroCell-HD for Huntington's disease
- Human liver cells for cirrhosis
- Porcine liver cells for acute liver failure
- Human muscle cells for cardiac disease
- Porcine retinal pigment epithelial cells,  
or porcine RPE cells, for macular degeneration.

Although scientists have demonstrated the feasibility of cell transplantation, an inadequate supply of human donor cells has hampered widespread use of cell transplantation in clinical applications. To overcome this constraint, we have pioneered the use of porcine (pig) cells for clinical transplantation. Because porcine cells are functionally similar to human cells, we believe that pigs will be a reliable source of a wide range of cell types suitable for transplantation into humans. We have shown in preclinical studies and clinical trials that transplanted porcine cells appear capable of integrating into the surrounding tissue and addressing the functional deficits caused by cell damage or cell death.

After receiving clearance from the United States Food and Drug Administration, commonly referred to as the FDA, to conduct the first ever clinical trial of transplanted porcine neural cells in humans, we completed a three-year, twelve-patient, Phase 1 clinical trial to evaluate NeuroCell-PD for the treatment of Parkinson's disease in 1999. Based on encouraging results from this Phase 1 clinical trial, we initiated an 18-patient, pivotal, randomized, double-blinded, placebo-controlled Phase 2/3 clinical trial of NeuroCell-PD in 1998. Treatment of patients in this Phase 2/3 clinical trial has been completed, and the trial is expected to be unblinded in March 2001.

In recognition of its potential to address an important unmet medical need, the FDA has designated NeuroCell-PD as a fast track product. Fast track status expedites the regulatory review of new drugs which are intended for the treatment of serious or life-threatening conditions and which demonstrate the potential to address unmet medical needs. The FDA has also granted orphan drug designation for NeuroCell-PD for advanced Parkinson's disease, which is an incentive provided to manufacturers to undertake development and marketing of products to treat relatively rare diseases. Under current law, the first developer to receive FDA marketing approval for a designated orphan drug is generally entitled to a seven-year exclusive marketing period in the United States.

We are developing our lead product candidate, NeuroCell-PD, as well as our NeuroCell-HD product candidate, in a joint venture with Genzyme Corporation, which is called Diacrin/Genzyme LLC. As of December 31, 2000, Genzyme has contributed \$29.7 million and we have contributed \$6.5 million to the joint venture which has been used to develop these product candidates.

We are also conducting four separate six-patient, Phase 1 clinical trials to evaluate fetal porcine neural cells for stroke recovery, fetal porcine neural cells for the treatment of focal epilepsy, human liver cells for cirrhosis and human muscle cells for cardiac disease. We have received FDA clearance to initiate three six-patient Phase 1 clinical trials to evaluate fetal porcine neural cells for chronic intractable pain, porcine spinal cord cells for spinal cord injury

and porcine liver cells for the treatment of acute liver failure. We are

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

conducting preclinical studies to evaluate the use of fetal porcine RPE cells for the treatment of macular degeneration.

We are also developing a proprietary technology designed to modulate the human immune system in order to prevent rejection of transplanted cells without the use of immunosuppressive drugs. This technology, which we refer to as our immunomodulation technology, involves the selective treatment of cell populations prior to transplantation to prevent the patient's immune system from rejecting the transplanted cells. Our approach would eliminate the need for long-term immunosuppressive drugs, which may leave the patient vulnerable to a wide range of undesirable side effects, including increasing the patient's susceptibility to infections and cancer. We have shown in preclinical and clinical studies the ability of our immunomodulation technology to prevent rejection of transplanted porcine cells without compromising the immune system or causing undesirable side effects. We published scientific evidence in *The Journal of Immunology* in June 1999 that describes how this technology might work to allow survival of transplanted cells.

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. Neurocell is a trademark of our joint venture, Diacrin/Genzyme LLC. All other trademarks and service marks used in this Annual Report are the property of their respective owners.

### Diacrin's Transplantation Technology

We have pioneered the use of fetal porcine cells for clinical transplantation for the treatment of human disease. In March 1995, we received the first FDA clearance to transplant porcine cells into humans. We have developed critical technology relating to the production process for obtaining and screening porcine cells. We are also developing technology to modulate the human immune system to enable porcine cell transplantation into the body without the use of immunosuppressive drugs.

Each step of our production process has been designed based on proposed FDA guidelines and is controlled in order to obtain cells suitable for human transplantation. We have developed procedures to screen pigs for infectious agents and then quarantine qualified donor pigs at our biomedical animal facilities. We harvest cells of appropriate age and type under current good manufacturing procedures, commonly referred to as cGMP, at either our facilities or those of our joint venture with Genzyme.

We perform our screening procedures in accordance with FDA guidelines covering xenotransplantation. These guidelines have been designed to prevent contamination of transplanted cellular products with infectious agents that have the potential to affect human cells. The FDA requires all sponsors of human clinical trials involving porcine tissue, including us, to test for the presence of porcine endogenous retroviruses, commonly known as PERV, in patient blood samples. To date, none of our patients have shown any sign of PERV.

Current transplantation technology generally requires that the patient's immune system be suppressed in order to avoid rejection of transplanted cells. T cells, the main cells involved in directing the body's immune response, recognize and bind to cell surface proteins known as MHC class I proteins. When T cells recognize foreign MHC class I proteins, a cascade of events is triggered which ultimately results in destruction of the transplanted cells that display these foreign proteins. Cyclosporine, a standard immunosuppressive drug,

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

prevents this rejection process. Using cyclosporine, we have demonstrated survival of transplanted porcine cells in a variety of preclinical animal models and have histologically documented survival of transplanted porcine fetal neural cells in a deceased patient who had received NeuroCell-PD.

We are also developing proprietary technology to modulate the immune system to avoid rejection of transplanted cells. We treat isolated cell populations prior to transplantation with antibody fragments directed against MHC class I proteins. This technology is designed to eliminate the need for long-term immunosuppressive drugs. To date the use of our immunomodulation technology in clinical trials has not resulted in any undesirable side effects. Our scientists and academic collaborators have performed preclinical studies which show that cells that have been pretreated using our immunomodulation technology prior to transplantation survived in several animal models without immunosuppression. The long-term survival of the transplanted cells seen in these studies suggests that the recipient's immune system has "learned" to accept the transplant. Thus, we believe that treatment of cells with antibody fragments prior to transplantation will induce a state of graft-specific immunological tolerance, which would allow continued survival of the transplanted cells.

In connection with our Phase 1 clinical trials, six Parkinson's disease patients, six Huntington's disease patients, three focal epilepsy patients and five stroke patients have been transplanted with antibody-pretreated porcine neural cells, using no immunosuppressive drugs. Preliminary indications from the Phase 1 NeuroCell-PD clinical trial suggest that the improvement in Parkinson's disease symptoms that has occurred in patients transplanted with antibody-treated NeuroCell-PD is comparable to the improvement shown in patients transplanted with NeuroCell-PD with immunosuppressive drugs.

### Product Development Programs

We are developing products to address human diseases characterized by cell dysfunction or cell death which represent a broad-based application of our technologies for cell production and transplantation. The following table summarizes our product development programs in cell transplantation and each product's stage of development:

Diacrin Product Development Programs			
Product Candidate	Disease Indication	U.S. Targeted Patient Population	St
NeuroCell-PD *	Parkinson's disease	130,000	Pha (accrual
Porcine neural cells	Stroke	3,100,000	Pha
Porcine neural cells	Focal epilepsy	200,000	Pha
Porcine neural cells	Chronic intractable pain	2,100,000	IND
Porcine spinal cord cells	Spinal cord injury	200,000	IND
NeuroCell-HD *	Huntington's disease	25,000	Pha (accrual

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

Human liver cells	Cirrhosis	1,100,000	Pha
Porcine liver cells	Acute liver failure	45,000	IND
Human muscle cells	Cardiac disease	200,000	Pha
Porcine RPE cells	Macular degeneration	1,400,000	Pre

\* Being developed by our joint venture with Genzyme.

### NeuroCell-PD for Parkinson's Disease

Parkinson's disease is a neurodegenerative disease that results from the loss of dopamine-producing neural cells within an area of the brain called the substantia nigra, causing the loss of coordinated muscular activity. The disease is generally characterized by progressively worsening physical conditions, including difficulty in movement, muscular rigidity, tremors and postural instability. In addition to a decreased quality of life, Parkinson's disease may also result in premature death. In the United States, there are approximately 500,000 people afflicted with Parkinson's disease. The majority of Parkinson's disease patients are first diagnosed between the ages of 45 and 65. NeuroCell-PD will be directed to the treatment of patients with advanced Parkinson's disease, which we estimate to be approximately 130,000 patients in the United States. We expect the prevalence of Parkinson's disease to increase with the increasing average age of the population.

Current therapies consist of administration of levodopa, commonly known as L-dopa, a precursor of dopamine, and dopamine analogues. However, L-dopa is only effective for a limited period of time, with most patients experiencing a progressive reduction in drug efficacy over a 10 to 15 year period, due to the cumulative loss of viable neural cells and tolerance to L-dopa. In addition, L-dopa therapy can result in severe side-effects, including uncontrolled movements, also known as dyskinesia, and hallucinations. No currently available therapy prevents progression of the neurological deficits caused by Parkinson's disease.

Clinical researchers have shown that transplantation of human fetal neural cells into Parkinson's disease patients is effective in treating the disease. For example, Swedish researchers have demonstrated survival and function of transplanted human fetal neural cells in Parkinson's

disease patients in an ongoing study which commenced in 1989. This study has shown long-term survival of cells and improvements in patients' conditions. However, the lack of availability of human fetal neural cells and ethical concerns regarding the use of human fetal tissue limit its widespread clinical application. Moreover, even when available, the quality of human fetal neural cells is variable, which may limit the clinical effectiveness of this treatment.

Our approach to the treatment of Parkinson's disease is to produce and transplant NeuroCell-PD to replace the function of those neural cells damaged by the disease. We and our collaborators have shown in animal models that transplanted porcine fetal neural cells become integrated into the surrounding brain tissue and correct functional deficits. While NeuroCell-PD is not a cure for Parkinson's disease, the goal of this treatment is to significantly improve the clinical condition of patients with severe Parkinson's disease in order to allow them to function independently.

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

We harvest porcine fetal neural cells under cGMP for transplantation. We have developed a specially qualified porcine fetal cell source in collaboration with Tufts University School of Veterinary Medicine. The porcine fetal neural cells, which are isolated from a specific region of the developing brain, function the same as human fetal neural cells. These cells are isolated and vialled in a suite of clean rooms designed to prevent contamination of the cells. The vialled cells are then transported to a hospital where a neurosurgeon injects them into a precise area of the patient's brain. This is accomplished using standard stereotactic surgical equipment and techniques.

Our twelve-patient Phase 1 clinical trial of NeuroCell-PD, which completed enrollment in October 1996, was the first FDA-authorized trial involving transplantation of porcine cells into humans. Although the study was designed to evaluate the safety of NeuroCell-PD, we also evaluated its effects on the Parkinson's disease symptoms of the transplant recipients. Each of the twelve patients in the study received approximately 12 million cells transplanted unilaterally (one side of the brain). A histological study of one of the patients, who died of causes unrelated to the transplant, published in the March 1997 issue of Nature Medicine, demonstrated that porcine fetal neural cells survived and matured in his brain. This study marked the first published documentation of the survival of cells transplanted from another species into the human brain and the appropriate growth of the non-human neural cells in the brain of a Parkinson's disease patient.

Our clinical evaluators observed clinical improvement in the Parkinson's disease patients beginning approximately three months after transplantation. The patients who have been followed demonstrated statistically significant clinical improvement at one year, two years and three years post transplantation as measured by the Unified Parkinson's Disease Rating Scale.

In 1999, our joint venture with Genzyme completed accrual of patients in an 18-patient pivotal, randomized, double-blinded, placebo-controlled Phase 2/3 clinical trial involving the transplantation of NeuroCell-PD in conjunction with cyclosporine immunosuppression versus a control group. Each of the treated patients in this trial received approximately 48 million cells transplanted bilaterally (both sides of the brain). Treatment of patients in this Phase 2/3 clinical trial has been completed and the trial is expected to be unblinded in March 2001.

In recognition of its potential to address an important unmet medical need, the FDA has designated NeuroCell-PD a fast track product. The FDA has also granted orphan drug designation for NeuroCell-PD for advanced Parkinson's disease.

### Porcine Neural Cells for Stroke

Stroke is the third leading cause of death in the United States, ranking behind coronary artery disease and cancer. It is also the leading cause of long-term disability in the United States. Approximately 600,000 people suffer a stroke each year and there are 4.4 million people that have been disabled by stroke in the United States. A stroke occurs when the blood supply to a part of the brain is suddenly interrupted. When blood flow to the brain is interrupted, some brain cells die immediately, while others will die days or weeks after the stroke. The death of these brain cells creates a void which becomes a fluid filled cavity in the brain.

Current therapies for stroke target the early events that occur at the time of the stroke. Timely intervention with surgery or with non-invasive therapies that restore blood flow can limit the cell death that occurs. Therapies include

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

surgical intervention to remove a clearly defined clot or anticoagulant therapy to "break up" the clot formation. All current therapies are most effective when administered as quickly as possible after the stroke, and there is a time post-stroke (12-24 hours) after which therapeutic intervention is useless in limiting brain cell death.

Our approach of using porcine fetal neural cell transplantation is based on the premise that many patients who have survived but not fully recovered from a stroke may benefit from the introduction of cells that may repair or replace the damaged neural circuitry. We and others have demonstrated in numerous animal studies the feasibility of repairing and restoring function to a stroke-damaged brain. In an animal model of stroke, we have shown that transplanted porcine fetal neural cells survive at high frequency. These cells not only survived in the brain cavity, but formed solid grafts that integrated appropriately with the normal brain tissue surrounding the cavity. We have observed extensive neural outgrowth from the graft to the surrounding brain and behavioral improvements in a rat model of stroke after transplantation of porcine fetal neural cells. The transplanted cells have the capacity to form billions of new synaptic connections as well as to release other chemicals that promote neural cell growth.

We initiated a six-patient, Phase 1 clinical trial using porcine fetal neural cells in stroke patients in Boston, Massachusetts at Beth Israel Deaconess Medical Center and Brigham and Women's Hospital. In April 2000, this Phase 1 clinical trial was suspended by the FDA to allow investigation of the cause of two serious adverse events. At the time the trial was suspended we had treated 5 patients. Both patients who suffered adverse events have recovered from their adverse event. We have reviewed the scientific and clinical information relating to these adverse events and concluded that they were most likely associated with the surgical procedure used to implant the cells. This conclusion has been supported by an independent group of experts convened by Diacrin. We are now working with the FDA to obtain clearance to continue recruiting patients in this trial, although there is no assurance that the FDA will agree with our conclusions and allow us to resume the trial.

### Porcine Neural Cells for Focal Epilepsy

Epilepsy is a chronic, recurrent disorder characterized by excessive neuronal discharge in the brain, causing muscle spasms or convulsions. Epileptic seizures are usually associated with some alteration of consciousness. Epilepsy is one of the most common neurological disorders and is estimated to affect 1.8 million people in the United States. The only currently available treatments for epilepsy are drug therapy and surgery. A number of anti-epileptic drugs are available to treat seizures. However, these drugs fail to control seizure activity in a significant number of patients and frequently cause side effects that range in severity from minimal impairment of the central nervous system to death from liver failure. By several estimates, approximately 200,000 patients with complex partial epilepsy have seizures that are not well-controlled with currently available drug therapy. The seizures are of many different types and arise as a result of diverse pathologies. Other therapies available to these patients are surgical removal of portions of the temporal or frontal lobe and vagal nerve stimulation through an implantable device. We believe that transplantation of porcine fetal neural cells will be preferable to removal of brain tissue if the transplantation is shown to be safe and efficacious.

Our initial therapeutic focus in this area is in the treatment of patients with complex partial seizures, which are characterized by a focal onset and a loss of consciousness. Because focal epilepsy is characterized by excessive electrical activity in a localized area of the brain and the spread of this activity through the brain, our approach to therapy is to transplant porcine



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

fetal neural cells in order to exert an inhibitory effect on the hyperexcitable brain region.

We have initiated a six-patient, Phase 1 clinical trial of porcine fetal neural cells at Beth Israel Deaconess Medical Center and Brigham and Women's Hospital in Boston. As of February 28, 2001, we had treated three patients in this trial.

### Porcine Neural Cells for Chronic Intractable Pain

Chronic intractable pain can be caused by neuropathologic processes in tissues and organs, or by prolonged dysfunction of peripheral or central nervous system pathways. Chronic intractable pain is characterized by the death of inhibitory neural cells in the spinal cord and cannot be relieved even with pain killers such as morphine. It is estimated that 500,000 individuals in the United States suffer from unrelieved chronic pain as a result of these peripheral neuropathies. Peripheral neuropathies can also be associated with diseases such as HIV, diabetes and cancer. Many patients with malignant disease develop chronic intractable pain, and the prevalence of severe pain in cancer patients increases as the disease progresses to the advanced stages. There are an estimated 1.6 million cancer patients who experience chronic intractable pain in the United States.

We intend to use porcine fetal neural cells to alleviate chronic pain by repopulating inhibitory neural cells to recover appropriate neurotransmission in the spinal cord. We have demonstrated in animal studies a favorable safety profile and survival of porcine fetal inhibitory neural cells transplanted into the dorsal horn of the spinal cord. Our Investigational New Drug Application, commonly referred to as IND, has been cleared by the FDA and we plan to initiate a six-patient, Phase 1 clinical trial in 2001 at New England Medical Center in Boston and at Washington University Medical Center in St. Louis, Missouri.

### Porcine Spinal Cord Cells for Spinal Cord Injury

The prevalence of spinal cord injury, commonly known as SCI, in the United States is approximately 200,000, with 13,000 additional SCIs annually. Nearly 80% of the injured patients are males in their late 20s to early 30s. Greater than 95% of these SCIs are compression injuries, the remainder are cases in which the cord is severed. The spinal cord in the neck is vulnerable to injury because of its extreme mobility, and approximately 80% of SCIs occur in this region. Loss of sensorimotor neuron function due to injury requires lengthy hospitalization after the initial incident as well as extensive rehabilitative care. Furthermore, all victims of SCI face a lifelong series of acute and chronic non-neurological complications that can be life-threatening.

The primary objective of current therapies available for SCIs is to prevent further injury by physically stabilizing the spine and by inhibiting the inflammatory response that results from the injury. These strategies attempt to establish optimal conditions for functional recovery and improve patients' rehabilitative potential. Surgery is designed to protect the patient from further injury through immobilization, spinal cord realignment and stabilization, and decompression. To date, there is no drug therapy available for SCIs except palliative therapies using the corticosteroid, methylprednisolone, to reduce inflammation of the injured area, and standard medical practice for complications arising from chronic denervation.

We believe that the transplantation of porcine fetal spinal cord cells into the site of injury of a damaged human spinal cord may partially reestablish neural pathways. The transplantation of these cells into a recently injured cord

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

may prevent secondary neural and muscular atrophy known to occur in these patients. Partial or full recovery of limb movement, and other motor neural pathways may reduce the overall time spent in the hospital, decrease the secondary equipment required for care, and reduce severe and life threatening complications arising from the injury.

The FDA has cleared our IND to conduct a six-patient Phase 1 clinical trial. We hope to determine from this trial whether porcine fetal spinal cord cells transplanted into the damaged spinal cord region will engraft and repair the damage, leading to improved mobility and function. We plan to begin recruitment of patients at Albany Medical Center in Albany, New York and at Washington University Medical Center in St. Louis.

### NeuroCell-HD for Huntington's Disease

Huntington's disease is a genetically transmitted disease caused by a loss of neural cells in the striatum, a specific region of the brain. The loss of these neural cells results in a progressive deterioration marked by discordant movement, intellectual impairment and a spectrum of psychiatric and behavioral disturbances. The clinical symptoms of Huntington's disease generally become apparent between 40 and 50 years of age. There are approximately 25,000 people diagnosed with Huntington's disease in the United States. Currently there is no effective therapy for Huntington's disease. Treatment is palliative with tranquilizers and anti-psychotic drugs being the only options.

Our approach to treating this disease consists of producing and transplanting NeuroCell-HD to replace the function of neural cells damaged by Huntington's disease. Porcine fetal neural cells are isolated from the area of the pig's brain which develops into the striatum for transplantation into the striatum of the human transplant recipient's brain.

We have treated twelve patients in a Phase 1 clinical trial in which NeuroCell-HD was transplanted unilaterally. The Huntington's disease patients in the clinical trial tolerated the procedure well and the preliminary clinical data suggest that the product is safe. Of the twelve patients in this trial, the Huntington's disease in some patients has not progressed, while the disease in most of the patients has progressed as measured by total functional capacity scores. Two of the patients have died from the continued progression of the disease. Because Huntington's disease progresses over an extended period of time, we intend to follow these patients for at least the next twelve months. We currently have no plans to conduct a Phase 2 clinical trial until we gather additional data.

### Human Liver Cells for Cirrhosis

Cirrhosis of the liver is a common affliction in the United States, affecting an estimated 1.5 million individuals and leading to approximately 50,000 deaths annually. In cirrhosis, liver tissue is progressively lost due to accumulation of fibrous tissue and scarring, and liver function is compromised due to the degenerative changes. The most common causes of cirrhosis are viral hepatitis B and C infections and alcoholic liver disease. In the initial stages of the disease, the patient may experience jaundice and disorientation as liver function decreases. As the disease progresses, the patient will be hospitalized with increasing central nervous system effects, known as encephalopathy, which may lead to coma. The tremendous reserve of liver tissue allows the continued function of the organ, despite loss of up to 90% of the normal complement of liver cells. In advanced cirrhosis, little normal liver tissue remains.

The only effective therapy for advanced cirrhosis is liver transplantation.

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

However, the United Network of Organ Sharing has documented a national lack of donor livers for transplantation, resulting in a waiting period of over two years for the average patient. Over 5,000 individuals await liver transplants in the United States and about 4,000 liver transplants are performed per year for all indications. Recently, artificial extra-corporeal liver assist devices, commonly known as ELAD, containing porcine or human liver cells attached to a dialysis cartridge have been used in an attempt to treat liver failure in advanced cirrhosis. Studies to date suggest that ELAD may improve some biochemical parameters such as ammonia levels but the devices have not resulted in increased survival. Human whole liver transplantation has also been used in both acute and chronic liver failure. In pilot clinical trials by others, transplantation of liver cells into either the liver or the spleen has been shown to be both safe and potentially effective in humans as a bridge to whole liver transplantation.

For chronic liver disease, we and others have shown in animal models that liver cell integration is possible when liver cells are injected into the liver or into the spleen. The spleen appears to be the preferred site due to the fibrosis and loss of blood supply to the cirrhotic liver. In animal models, transplantation of liver cells into the spleen is well described, and results in populating parts of the spleen with functioning liver cells that perform normal liver functions.

We have initiated a six-patient, Phase 1 clinical trial of human liver cell transplantation for the treatment of cirrhosis in patients that have been listed for organ transplantation but are likely to wait at least one year before receiving a transplant. We believe these patients may benefit from the growth of transplanted liver cells in their liver or spleen leading to an increase in liver function. In addition, expansion of the cells may allow sufficient improvement to render a liver transplant unnecessary, unlike the case with ELAD which are used only as a bridge to

transplantation. As part of the clinical trial, conventional immunosuppression will be compared to the use of our immunomodulation technology to determine whether graft protection is achieved by this technique. We are conducting this study in collaboration with Massachusetts General Hospital and New England Medical Center and at the University of Nebraska Medical Center in Omaha, Nebraska.

### Porcine Liver Cells for Acute Liver Failure

Acute liver failure is a severe life-threatening disease that can result from alcohol consumption, viral infections, such as hepatitis B and C, and drugs or toxins that damage the liver. The clinical spectrum of acute liver disease can vary from patients with severe liver failure to patients without symptoms. The mortality from acute liver failure can be as high as 70%, with patients dying from associated complications. Acute liver failure results in approximately 63,000 deaths annually in the United States.

There is currently no therapy that is beneficial for all patients with acute liver failure. The best available therapy is liver transplantation. However, many patients are unable to qualify as candidates for liver transplantation due to multi-organ failure or active alcohol consumption. Current therapies attempt to treat complications arising from the acute condition, such as swelling of the brain, infections, and circulatory collapse.

Our approach to the treatment of acute liver failure is to support the patient by liver cell transplantation in order to provide liver function while allowing the patient's own liver to recover. In extensive studies in animal models, our scientists have shown that porcine liver cells can be isolated and

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

infused into the recipient liver where they continue to function. Long-term survival and function of these cells has been demonstrated in these animal models. We believe liver cell transplantation could become a viable alternative to whole liver transplantation for the treatment of acute liver disease. We believe this approach would be preferable to transplantation of a whole liver, due to the difficulty of obtaining livers for transplantation as well as the expense and invasiveness of the procedure.

Porcine liver cells will be infused into the spleen or liver of these patients by minimally invasive procedures, thus avoiding a surgical procedure for these critically ill patients. In addition to the high level of quality control that can be maintained over the production of porcine liver cells, these cells also have the advantage of being resistant to infection by human hepatitis B and C viruses. Since many of the patients enrolled in this study are likely to carry these viruses, we believe the resistance of the porcine liver cells to infection may provide a further advantage over human liver transplantation in which hepatitis B and C reinfect donor livers.

The FDA has cleared our IND application for a six-patient, Phase 1 clinical trial to test transplantation of porcine liver cells for the treatment of acute liver failure. Patients enrolled in this trial will not be candidates for liver transplantation. We are currently recruiting patients for this clinical trial which will be conducted at Massachusetts General Hospital, New England Medical Center and University of Nebraska Medical Center.

### Additional Liver Cell Applications

Successful delivery of liver cells to patients with alcoholic hepatitis or cirrhosis may provide the possibility of applying this technology to a variety of other diseases. The preparation of the cells and their delivery by minimally invasive procedures should be the same in most of these applications, thus providing a platform that may be used in multiple applications.

Additional applications include the use of liver cells for the treatment of metabolic diseases resulting from genetic mutations. Familial hypercholesterolemia is a disease caused by a defective receptor gene for low density lipoprotein, commonly referred to as LDL, that leads to elevated levels of LDL cholesterol and coronary disease at an early age. Familial hypercholesterolemia afflicts approximately 500,000 patients in the United States. Currently available drugs do not sufficiently lower circulating LDL cholesterol levels in approximately 20% of these patients, who may thus benefit from liver cell transplantation. Our scientists have shown through transplantation of liver cells into a rabbit model of this disease that porcine liver cells provide the animal with functional receptors that reduce serum LDL levels. There is a range of additional metabolic disorders that may be candidates for treatment by liver cell transplantation. Approximately 30,000 patients in the United States suffer from these metabolic disorders.

### 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,

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

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 preclinical studies, we have demonstrated that muscle cells integrate into rodent heart muscle. The cells form stable grafts in a damaged heart.

In August 2000, we initiated a six-patient, Phase 1 clinical trial for patients with damaged heart muscle at Temple University Hospital.

### Porcine RPE Cells for Macular Degeneration

Age related macular degeneration, commonly referred to as AMD, is a disease of the retina characterized by the loss of vision due to the atrophy of photoreceptors in the central part of the retina. This is the most important part of the eye for high resolution vision, such as that used in reading and driving. Macular degeneration is a common disease, affecting 13 million people in the United States. It is primarily a disease of the elderly, with approximately 19% of 65-74 year olds and approximately 37% of individuals over 75 having vision loss. Approximately 85-90% of AMD patients have the "dry" form of the disease in which the RPE cell layer degenerates without new blood vessel growth and 10-15% have the "wet" form.

While laser surgery is available to treat the "wet" form of AMD, there are currently no effective therapies for the "dry" form of AMD. In AMD, abnormal accumulation of metabolic debris results from reduced activity of the RPE cells and leads to gradual loss of photoreceptors. The RPE cells become dysfunctional and metabolic by-products damage photoreceptors, thus compromising visual acuity. As this layer of cells does not readily replicate in the adult, damage to the RPE cells can be irreversible and lead to loss of photoreceptors with associated decreased visual acuity.

RPE cells lie beneath the light-sensing cells responsible for vision and provide support for the retinal photoreceptors. Our approach is to repopulate the dysfunctional RPE cell layer by transplanting porcine RPE cells below the retinal photoreceptors. This therapeutic approach has the potential to reestablish function in the central part of the retina, prevent further loss of vision and to improve visual acuity in patients with the "dry" form of the disease. In patients with the "wet" form of AMD, this therapy could be used in conjunction with surgery.

The idea of replacing defective RPE cells by transplantation is attractive

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

because of the key role RPE cells play in maintaining the integrity of the photoreceptors and their lack of regenerative capacity. Human fetal RPE cells have been successfully tested by others in preclinical studies and are currently being evaluated in clinical trials. Our approach is to use porcine fetal RPE cells. Our preclinical studies have demonstrated the efficacy of porcine fetal RPE cells in rescuing the photoreceptor layer of the retina from damage that results from experimental disruption of the RPE cell layer. We will also test our proprietary immunomodulation technology to prevent rejection of the transplant. Assuming successful completion of preclinical studies, we plan to file an IND for a six-patient Phase 1 clinical trial in late 2001.

### Genzyme Joint Venture

In September 1996, we formed Diacrin/Genzyme LLC with Genzyme, a joint venture to develop and commercialize NeuroCell-PD and NeuroCell-HD. Under the terms of the agreement, Genzyme has provided 100% of the first \$10 million in funding for the development and commercialization of these product candidates incurred after October 1, 1996, and has agreed to provide 75% of the following \$40 million in funding. We agreed to provide the

remaining 25% of the following \$40 million in funding. We will share all costs incurred in excess of \$50 million equally with Genzyme. We will also share any profits of the joint venture equally with Genzyme. The joint venture agreement provides that we and Genzyme will jointly develop NeuroCell-PD and NeuroCell-HD and that Genzyme will market and sell these products on a cost reimbursement basis on behalf of the joint venture. As of December 31, 2000, Genzyme had provided \$29.7 million to the joint venture and we had provided \$6.5 million.

In connection with the joint venture agreement with Genzyme, we granted to the joint venture the exclusive, worldwide, irrevocable (during the term of the joint venture agreement), royalty-free right and license to develop and commercialize NeuroCell-PD and NeuroCell-HD under our existing patent rights and technology. The license we granted is limited to the treatment of Parkinson's disease and Huntington's disease in humans using porcine fetal cells. In the event that either we or Genzyme develop or acquire additional technology or patent rights that are useful in this field, the party owning such technology or patent rights is obligated to offer a license to the joint venture to such technology or patent rights.

The joint venture is governed by a six-member steering committee comprised of three persons from Genzyme and three persons from Diacrin. The steering committee meets regularly and makes all of the decisions with respect to the joint venture's work plans and budgets. The steering committee has appointed a program manager from each organization to execute the agreed upon product development work plans.

### Manufacturing

The manufacture of most of our products will require the continuous availability of porcine tissue harvested under cGMP from pigs tested to be free of infectious agents. Our current source of pig facilities and services is obtained under contracts from Tufts University School of Veterinary Medicine and PharmServices, Inc., a division of Charles River Laboratories, Inc. We have also qualified several pig producers to provide pigs for our production processes.

For the Phase 1 clinical trials of our products, we isolate and prepare cell populations in our own clinical production facilities in Charlestown, Massachusetts. We expanded our manufacturing capacity to include approximately 12,000 square feet of clinical production and support space in Framingham,

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

Massachusetts dedicated to the production of our joint venture products needed in conjunction with planned clinical trials. We believe that the Framingham facility is capable of satisfying projected initial demand for commercial quantities of NeuroCell-PD. This will enable us to utilize our Charlestown facility for the clinical supply of other product candidates and to postpone the need for significant additional investment in such facilities.

We currently obtain the antibody fragments used in our immunomodulation technology from a contract manufacturer. We will evaluate on an ongoing basis the cost effectiveness and other relevant factors necessary to determine whether we should continue to obtain the antibody fragment from a contract manufacturer or produce them ourselves.

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 and commercial 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 11 issued U.S. patents and 24 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.

Massachusetts General Hospital has been awarded two patents in the United States covering the basic immunomodulation technology we use. Foreign counterparts of these patents have been filed in the European Union and other selected countries. Under an agreement with MGH, we have an exclusive, worldwide license to the technology and the inventions described in the patents, and all foreign counterparts, including any continuations, reissues or substitutions as well as any patents and equivalents which may mature from such patents, subject to the payment of royalties. Unless sooner terminated, our rights will continue, on a country by country basis, until the last to expire of the patents. We or MGH may terminate the agreement, upon notice, in the event the other party defaults in its material obligations and has failed to cure this default within 60 days of receipt of this notice.

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

Our joint venture agreement with Genzyme authorizes Genzyme, which has an established sales force experienced in the sales and marketing of biopharmaceutical and surgical products, to market and sell NeuroCell-PD and NeuroCell-HD on an exclusive basis as agent of the joint venture on a cost reimbursement basis.

We have not yet developed sales and marketing capabilities for our other 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

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

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.

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 NeuroCell-PD and all of our other products.

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



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

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.

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 intend to 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. We also intend to seek marketing exclusivity for products which qualify for orphan drug status, where appropriate.

**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. NeuroCell-PD was granted fast track designation in 1999.

**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 intend to pursue this designation, where appropriate.

**Orphan Drug Status.** The Orphan Drug Act generally provides incentives to manufacturers to undertake development and marketing of products to treat

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

relatively rare diseases or diseases where fewer than 200,000 persons in the United States would be likely to receive the treatment. A drug that receives orphan drug designation by the FDA and is the first product to receive FDA marketing approval for its product claim is entitled to a seven-year exclusive marketing period in the United States for that product claim. The FDA may terminate an orphan drug designation for many reasons, including if the manufacturer of the orphan drug product cannot provide an adequate supply of the product. Furthermore, a drug that the FDA considers to be different from a particular orphan drug is not barred from sale in the United States during such seven-year exclusive marketing period. Legislation to limit the marketing exclusivity provided for certain orphan drugs has occasionally been introduced in Congress. Although the outcome of that legislation is uncertain, future legislation may limit the incentives currently afforded to the developers of orphan drugs.

We have assigned to the joint venture the orphan drug designation we received from the FDA for NeuroCell-PD and for NeuroCell-HD. Our porcine fetal spinal cord cells for spinal cord injury product is also targeted to a population of less than 200,000 and, therefore, we will pursue orphan drug designation for this product candidate.

### 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 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 28, 2001, we had 38 full-time employees, 30 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

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

We lease a facility which contains approximately 28,000 square feet of space in Charlestown, Massachusetts. The lease had a ten-year term ending in 2001, providing for a base rental rate of approximately \$60,000 per month, plus applicable property taxes and insurance. In October 2000, we exercised the first of two options we have, each to extend the lease an additional five years. As a result, our lease currently expires in 2006. The new base rental rate which will begin in October 2001 will be determined in accordance with our lease agreement which calls for us to pay 90% of the market value rate for similar space. 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 the clinical production requirements of several of our product candidates. To the extent that additional similar facilities may be required, we will 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, 2000.

### 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. (1)	52	President and Chief Executive Officer
E. Michael Egan	47	Chief Operating Officer
Kevin Kerrigan	29	Controller
Albert S. B. Edge, Ph.D.	47	Senior Director of Molecular and Cellular Biology
Jonathan H. Dinsmore, Ph.D.	39	Senior Director of Cell Transplantation
Roger J. Gay, Ph.D.	47	Senior Director of Process Development
Abdellah Sentissi, Ph.D.	51	Senior Director of Quality Control
Douglas B. Jacoby, Ph.D.	40	Director of Research and Development
Zola P. Horovitz, Ph.D. (1)	66	Director

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

John W. Littlechild (2)	49	Director
Stelios Papadopoulos, Ph.D. (1) (2)	52	Director
Joshua Ruch	51	Director
Henri A. Termeer (2)	54	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. Mr. Kerrigan received a B.S. degree in accounting from Merrimack College and was awarded a CPA certificate from the Commonwealth of Massachusetts in 1993.

Albert S. B. Edge, Ph.D., has been Senior Director of Molecular and Cellular Biology since October 1994. He joined Diacrin in 1992 as Director of Protein Chemistry and in 1993 became Director of Molecular and Cellular Biology. Dr. Edge was previously Assistant Professor of Medicine at Harvard Medical School and Investigator at the Joslin Diabetes Center. He has been Principal Investigator on several grants from the NIH and was the recipient of a Career Development Award from the Juvenile Diabetes Foundation from 1987 to 1990. He was Mary K. Iacocca Fellow of the Joslin Diabetes Center in 1984 and after appointment to the faculty was selected as Capps Scholar in Diabetes of Harvard Medical School from 1985 to 1987. While a Postdoctoral Fellow in the Department of Biological Chemistry at Harvard Medical School, Dr. Edge was awarded Fellowships from the American Cancer Society and the NIH. He received his Ph.D. in biochemistry from Albany Medical College where he was a Predoctoral Research

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

Fellow of the United States Public Health Service.

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 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 Avigen, Inc., BioCryst Pharmaceuticals, Magainin Pharmaceuticals, Paligent, Shire Pharmaceuticals, 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.

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

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. 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 Orthofix International N.V., a medical device company, and AVANT Immunotherapeutics and Dyax, biotechnology companies. 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. He is also a member of the Board of Visitors of the Beth Israel Deaconess Center for Research and Education.

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 Management Company, 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.

Henri A. Termeer has been a Director of Diacrin since December 1996. Mr. Termeer has served as President and Director of Genzyme Corporation since 1983, as Chief Executive Officer since 1985 and as Chairman of the Board since 1988. For ten years prior to joining Genzyme, Mr. Termeer held various management positions at Baxter Travenol Laboratories, Inc., a manufacturer of human health care products. Mr. Termeer also serves on the boards of directors of Abiomed, Inc., AutoImmune, Inc., Genzyme Transgenics Corporation and is a trustee of Hambrecht & Quist Healthcare Investors and Hambrecht & Quist Life Sciences Investors.

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.

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

### Scientific Advisory Board

Our scientific advisory board is a multi-disciplinary assemblage of scientists and physicians in the fields of transplantation, immunology, endocrinology, neurophysiology and neuromuscular physiology, transplantation biology and surgery. The scientific advisory board meets regularly to review and evaluate our research programs and advise us with respect to technical matters. The members of the scientific advisory board are as follows:

Name	Member Since	Position
Hugh Auchincloss, Jr., M.D.	1992	Professor of Surgery, Harvard Medical School; Director, Kidney Transplantation, Brigham and Women's Hospital; Surgical Director, Pancreas Transplantation and Visiting Surgeon, Massachusetts General Hospital
Jay A. Berzofsky, M.D., Ph.D.	1992	Chief, Molecular Immunogenetics and Vaccine Research Section, Metabolism Branch, National Cancer Institute, National Institutes of Health
Robert H. Brown, Jr., M.D., D.Phil.	1992	Director of Cecil B. Day Laboratory for Neuromuscular Research, Associate in Neurology, Massachusetts General Hospital; Professor of Neurology, Harvard Medical School
Laurie H. Glimcher, M.D.	1993	Professor of Immunology, Department of Immunology and Infectious Diseases, Harvard School of Public Health; Professor of Medicine, Harvard Medical School
Ronald D. McKay, Ph.D.	1998	Chief, Laboratory of Molecular Biology, National Institute of Neurological Disorders and Stroke, National Institutes of Health
David H. Sachs, M.D.	1990	Director, Transplantation Biology Research Center, Massachusetts General Hospital; Paul S. Russell/Warner-Lambert Professor of Surgery (Immunology), Harvard Medical School

PART II

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

### 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 1999 and 2000 as reported on the Nasdaq National Market:

	High	Low
Fiscal Year 1999		
First Quarter	6 3/4	4
Second Quarter	6 3/16	5
Third Quarter	6 1/8	4 1/2
Fourth Quarter	8 1/4	3 3/4
Fiscal Year 2000		
First Quarter	19 11/16	5 3/4
Second Quarter	13 1/2	6 5/16
Third Quarter	9 5/8	6 1/4
Fourth Quarter	7 5/8	3 7/8

In connection with our initial public offering in February 1996, we issued 2,875,000 redeemable warrants to purchase our common stock at an exercise price of \$16 per share, subject to certain adjustments. The warrants were traded on the NASDAQ National Market under the symbol DCRNW. On December 31, 2000, all unexercised warrants expired.

As of February 20, 2001 there were approximately 110 record holders of our common stock and approximately 3,900 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, 2000 that were not registered under the Securities Act.

The following information updates and supplements the information regarding use of proceeds originally filed by Diacrin on Form SR for the period ended May 12, 1996, as amended to date and relates to securities sold by the Company pursuant to the Registration Statement on Form S-2 (Registration No: 33-80773) which was declared effective on February 12, 1996: Through December 31, 2000, we have used approximately \$18,400,000 of the total net proceeds from our initial public offering of \$20,911,755. Of the \$18,400,000 used, approximately \$394,000 was used for the purchase of machinery and equipment; approximately \$1.0 million was used for repayment of indebtedness; and approximately \$17,006,000 was used for working capital. The unused proceeds of approximately \$2,512,000 are in temporary investments consisting of corporate notes and a money market mutual fund. All proceeds used or invested were direct or indirect payments to others.

### Item 6. Selected Financial Data



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

The selected financial data set forth below as of December 31, 1999 and 2000 and for each of the three years in the period ended December 31, 2000 are derived from our financial statements which have been audited by Arthur Andersen LLP, independent public 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, 1996, 1997 and 1998 and for the years ended December 31, 1996 and 1997 are derived from our financial statements which have been 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,				
	1996	1997	1998	1999	
	-----	-----	-----	-----	
Statement of Operations Data:	(in thousands, except share and per share data)				
REVENUES:					
Research and development	\$ 1,144	\$ 4,763	\$ 3,623	\$ 2,971	\$
Interest income	1,100	1,302	1,576	1,323	
	-----	-----	-----	-----	-----
Total revenues	2,244	6,065	5,199	4,294	
	-----	-----	-----	-----	-----
OPERATING EXPENSES:					
Research and development	5,767	6,863	7,372	5,921	
General and administrative	1,304	1,460	1,484	1,398	
Interest expense	158	93	89	47	
	-----	-----	-----	-----	-----
Total operating expenses	7,229	8,416	8,945	7,366	
	-----	-----	-----	-----	-----
Equity in operations of joint venture	-	-	(1,084)	(1,688)	
	-----	-----	-----	-----	-----
Net loss	\$ (4,985)	\$ (2,351)	\$ (4,830)	\$ (4,760)	\$
	=====	=====	=====	=====	=====
Net loss per common share					
Basic and diluted	\$ (.44)	\$ (.18)	\$ (.34)	\$ (.33)	\$
	=====	=====	=====	=====	=====
Weighted average shares					
Basic and diluted	11,389,823	13,235,286	14,156,179	14,364,154	1
	=====	=====	=====	=====	=====
	At December 31,				
Balance Sheet Data:	1996	1997	1998	1999	
	-----	-----	-----	-----	
Cash, cash equivalents and investments	\$ 23,482	\$ 21,347	\$ 26,270	\$ 21,420	\$
Working capital	12,413	9,551	21,812	17,133	
Total assets	24,275	22,780	27,484	22,366	
Long-term debt	370	672	392	249	

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

Stockholders' equity	22,437	20,204	24,845	20,145
----------------------	--------	--------	--------	--------

-----  
(1) Computed as described in Note 2 (d) 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, since October 1, 1996, we have received funding from our joint venture with Genzyme in support of the NeuroCell-PD and NeuroCell-HD product development programs. We have not received any revenues from the sale of products to date and do not expect to generate product revenues for the next several years. We have experienced fluctuating operating losses since inception and expect that the additional activities required to develop and commercialize our products will result in increasing operating losses for the next several years. At December 31, 2000, we had an accumulated deficit of \$47.8 million.

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

Through December 31, 1997, Genzyme made 100% of the total cash contributions to the joint venture. During the first quarter of 1998, we began making cash contributions to the joint venture equal to 25% of the joint venture's funding requirements. As of December 31, 2000, approximately \$29.7 million had been contributed to the joint venture by Genzyme and approximately \$6.5 million had been contributed by us. The joint venture's 2001 product development plans, together with our continued funding of the joint venture, are expected to significantly increase our net loss and our use of cash and investments to fund the joint venture in 2001 as compared with 2000.

We record as research and development expense all costs related to NeuroCell-PD and NeuroCell-HD 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, 2000 Versus Year Ended December 31, 1999

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

Research and development revenues were approximately \$2.1 million for the year ended December 31, 2000 and \$3.0 million for the year ended December 31, 1999. 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. The joint venture completed accruing patients into its Phase 2/3 clinical trial for NeuroCell-PD in 1999.

Interest income was \$3.1 million for the year ended December 31, 2000 versus \$1.3 million for the year ended December 31, 1999. The increase in 2000 was due to greater cash balances available for investment in the current year period as a result of our public stock offering completed in March 2000.

Research and development expenses of \$6.0 million for the year ended December 31, 2000 and \$5.9 million for the year ended December 31, 1999, remained relatively unchanged between the periods.

General and administrative expenses of \$1.3 million for the year ended December 31, 2000 and \$1.4 million for the year ended December 31, 1999, remained relatively unchanged between the periods.

Interest expense was \$30,000 for the year ended December 31, 2000 and \$47,000 for the year ended December 31, 1999. The decrease in 2000 was due to the scheduled pay down of lease and loan debt outstanding.

For the year ended December 31, 2000, we recorded a \$1.4 million charge related to our equity in the operations of the joint venture compared to a \$1.7 million charge for the year ended December 31, 1999. 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 the current year period was primarily due to a decrease in clinical activity performed by Genzyme on behalf of the joint venture as the joint venture completed recruiting patients into its Phase 2/3 clinical trial in 1999.

We incurred a net loss of approximately \$3.5 million for the year ended December 31, 2000 versus a net loss of approximately \$4.8 million for the year ended December 31, 1999.

### Year Ended December 31, 1999 Versus Year Ended December 31, 1998

Research and development revenues were approximately \$3.0 million for the year ended December 31, 1999 versus \$3.6 million for the year ended December 31, 1998. Revenues for both years were comprised entirely of revenue received from Genzyme for reimbursement of our expenses for the joint venture. The reduction in research and development revenues in 1999 was primarily attributable to the reduction from 100% to 75% of the percentage of funding for the joint venture provided by Genzyme. This reduction took effect in the first quarter of 1998.

Interest income was \$1.3 million for the year ended December 31, 1999 versus \$1.6 million for the year ended December 31, 1998. The 16% decrease in 1999 was primarily due to reduced interest income realized on lower cash balances available for investment.

Research and development expenses were \$5.9 million for the year ended December 31, 1999 versus \$7.4 million for the year ended December 31, 1998. The 20% decrease in 1999 was primarily due to a reduction in preclinical research as several of our product candidates had begun clinical testing. The decrease was, to a lesser extent, due to the additional production costs of clinical grade antibody incurred during 1998 for use in our clinical trials and preclinical

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

research.

General and administrative expenses were \$1.4 million for the year ended December 31, 1999 and \$1.5 million for the year ended December 31, 1998.

Interest expense was \$47,000 for the year ended December 31, 1999 and \$89,000 for the year ended December 31, 1998. The decrease in 1999 was due to the scheduled pay down of lease and loan debt outstanding.

We recorded a charge of \$1.7 million for the year ended December 31, 1999 and \$1.1 million for the year ended December 31, 1998 related to our equity in the operations of the joint venture. The increased charge was primarily due to the timing of the reduction in the percentage of funding from Genzyme from 100% to 75% in accordance with the joint venture agreement.

We incurred a net loss of approximately \$4.8 million for each of the two years in the period ended December 31, 1999.

### 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 \$14.5 million in revenue from our joint venture since it commenced on October 1, 1996. At December 31, 2000, we had cash and cash equivalents, short-term investments and long-term investments aggregating approximately \$54.6 million.

Net cash used in operating activities was \$2.5 million for the year ended December 31, 2000, \$2.9 million for the year ended December 31, 1999 and \$3.1 million for the year ended December 31, 1998. Cash used in operations for the years ended December 31, 2000, 1999 and 1998 was primarily attributable to our net loss, offset in part by our equity in operations of the joint venture.

Net cash used in investing activities was \$25.6 million for the year ended December 31, 2000. Net cash provided by investing activities was \$344,000 for the year ended December 31, 1999. Net cash used in investment activities was \$6.0 million for the year ended December 31, 1998. 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 provided by investing activities for the year ended December 31, 1999 was primarily attributable to a decrease in short-term investments and the return of capital for services provided on behalf of our joint venture, offset in part by our investment in our joint venture. Net cash used by investing activities for the year ended December 31, 1998 was primarily attributable to an increase in short-term investments and our investment in our joint venture, offset in part by a decrease in long-term investments and to a lesser extent the return of capital for services provided on behalf of our joint venture.

Net cash provided by financing activities was \$37.0 million for the year ended December 31, 2000. Net cash used in financing activities was \$220,000 for the year ended December 31, 1999. Net cash provided by financing activities was \$9.1 million for the year ended December 31, 1998. 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. Net cash used in financing activities for the year ended December 31, 1999 was primarily attributable to principal payments made towards long-term debt. Net cash provided by financing activities for the year ended December 31, 1998 was primarily attributable to net proceeds from the sale of common stock in a private placement in February 1998.

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

We have purchased approximately \$2.4 million of capital equipment since inception. In November 1997, we borrowed \$650,000 at the prime rate plus 0.5% (10.00% at December 31, 2000) under an unsecured five-year term loan with a bank to finance our biomedical animal facility acquired during 1997. As of December 31, 2000, we owed \$249,000 under this term loan. We had no material commitments for capital expenditures as of December 31, 2000.

In accordance with the joint venture agreement, Genzyme agreed to make financing available to us from and after the date that Genzyme provides the initial \$10 million of funding to the joint venture. Genzyme agreed to make available an unsecured, subordinated line of credit of up to an aggregate amount of \$10 million. We may draw on this facility only in the event that our cash and cash equivalents are insufficient to fund our budgeted operations for a specified period of time, and we may use the funds only to fund capital contributions to the joint venture. The facility will be available through the date five years after the date we first draw on the facility, and all outstanding principal and interest will be due on that fifth anniversary. Advances will be interest-bearing, evidenced by a promissory note and subject to other customary conditions. The aggregate amount of draws under the facility in any calendar year may not exceed \$5 million. We have not made any draws on the facility as of December 31, 2000, and do not anticipate drawing on the facility for the foreseeable future.

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

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

### Diacrin/Genzyme LLC Financial Statements

For the years ended December 31, 2000 and 1999, 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, this Annual Report on Form 10-K includes separate financial statements for the joint venture.

### Recently Issued Accounting Pronouncements

In June 1998, the FASB issued SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. The statement (as amended by SFAS No. 137) is effective for all fiscal quarters of all fiscal years beginning after June 15, 2000. SFAS No. 133 (as amended by SFAS No. 138) establishes accounting and reporting standards for derivative instruments including certain derivative instruments embedded in other contracts (collectively referred to as

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

derivatives) and for hedging activities. The Company does not expect adoption of this statement to have a material impact on the Company's financial statements.

In December 1999, the Securities and Exchange Commission issued Staff Accounting Bulletin (SAB) No. 101, Revenue Recognition in Financial Statements. SAB No. 101, as amended, is effective for the fourth quarter of all fiscal periods beginning after December 15, 1999. Adoption of SAB No. 101 did not have a material impact on the Company's financial position or results of operations.

### 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 the date this Annual Report on Form 10-K was first filed with the SEC. Subsequent events 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. 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. Other than our NeuroCell-PD product candidate for the treatment of Parkinson's disease which is in Phase 2/3 clinical trials, the remainder of 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 dependent on Genzyme Corporation to fund, develop and market our lead product candidate, NeuroCell-PD, and if our joint venture with Genzyme terminates, we may not be able to complete development or commercialization of NeuroCell-PD

We have entered into a joint venture agreement with Genzyme relating to the development and commercialization of NeuroCell-PD, our most advanced product candidate. This agreement also covers our NeuroCell-HD product candidate. Under this agreement, Genzyme has agreed to provide significant funding toward the development and commercialization of these products and to market and sell the products on behalf of the joint venture. Genzyme has the right to terminate the agreement at any time upon 180 days notice to us. We cannot assure you that Genzyme will not terminate this agreement, or that our economic and other interests will coincide with those of Genzyme during the term of the agreement. If Genzyme were to terminate this agreement, we:

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

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

- would lose access to Genzyme's experienced development, sales and marketing organizations and manufacturing facilities;
- would need to establish clinical production facilities for the production of NeuroCell-PD and NeuroCell-HD; and
- may be unable to complete development or commercialization of NeuroCell-PD and NeuroCell-HD.

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

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

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

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

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

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

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

In January 2001, the FDA issued definitive regulatory guidelines for xenotransplantation titled "PHS Guideline on Infectious Disease Issues in

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

Xenotransplantation." We cannot assure you that we will be able to comply with these guidelines.

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

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

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

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

- the timing of receipt of marketing approvals and the countries in which those approvals are obtained;
- the safety and efficacy of our products;
- the need for surgical administration of our products;
- problems encountered in the field of xenotransplantation;
  
- the success of physician education programs;
- the cost of our products which may be higher than conventional therapeutic products because our products involve surgical transplantation of living cells; and
- the availability of government and third-party payor reimbursement of our products.

### Risks Relating to Clinical and Regulatory Matters

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

We have completed treatment of patients in a Phase 2/3 trial for our NeuroCell-PD product candidate, and the final patient in the trial reached the eighteen-month post-transplantation endpoint in February 2001. The trial is expected to be unblinded in March 2001. As is the case with the results of any clinical trial, the results of the Phase 2/3 clinical trial may not show a statistically significant difference between the treated patients and the patients in the control group. If such an outcome were to occur, it is possible that further clinical development of NeuroCell-PD would not be supported by Genzyme, or that we may choose to discontinue development or modify the clinical trial protocols, which could result in the termination of or significantly delay



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

the progress of the NeuroCell-PD development program.

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

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

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

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

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

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

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

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

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

and prosecuting applications necessary to gain regulatory approvals.

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

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

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

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

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

### Risks Relating to Financing Our Business

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

We have incurred losses in each year since our founding in 1989. At December 31, 2000, we had an accumulated deficit of \$47.8 million. We expect to incur substantial operating losses for the foreseeable future. We have no material sources of revenue from product sales or license fees. We anticipate that it will be a number of years, if ever, before we develop significant revenue sources or become profitable, even if we are able to commercialize products.

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

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

We will require substantial funds to conduct research and development,

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

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

- 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 are maintained in secrecy until patents issue, others may have filed or maintained patent applications for technology used by us or covered by our pending patent applications without our being aware of these applications.

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

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

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

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

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

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

- we may initiate litigation or other proceedings against third parties to enforce our patent rights;
- we may initiate litigation or other proceedings against third parties to seek to invalidate the patents held by these third parties or to obtain a judgment that our products or services do not infringe the third parties' patents;
- if our competitors file patent applications that claim technology also claimed by us, we may participate in interference or opposition proceedings to determine the priority of invention; and
- if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we will need to defend against such claims.

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

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

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

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

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

### Risks Relating to Product Manufacturing, Marketing and Sales

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

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

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

- we may not be able to attract and build a significant marketing or sales force;
- the cost of establishing a marketing or sales force may not be justifiable in light of any product revenues; and
- our direct sales and marketing efforts may not be successful.

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

Before we can begin commercially manufacturing our product candidates, we must obtain regulatory approval of our manufacturing facility and process.

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

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

We and our joint venture 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 and at the joint venture's facility in Framingham, Massachusetts. If these facilities or the equipment in these facilities is significantly damaged or destroyed, we will not be able to quickly or inexpensively replace our manufacturing capacity.

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

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

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

### Risks Related to Ongoing Operations

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

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

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

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

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

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

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

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

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

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

### Risks Relating to our Common Stock

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

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

- the election of directors;
- the amendment of our organizational documents; or
- the approval of a merger, sale of assets or other major corporate transaction.

Our stock price could be volatile, which could cause you to lost 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

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

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

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

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

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

### Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We own financial instruments that are sensitive to market risks as part of its 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. The investment portfolio contains instruments that are subject to the risk of a decline in interest rates.

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



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

matters.

### 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 2001 annual meeting of stockholders, which statement will be filed with the Commission not later than 120 days after the end of our 2000 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."

### PART IV

Item 14. 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, 1999 and 2000	F-2
3. Statements of Operations for each of the three years in the period ended December 31, 2000	F-3
4. Statements of Stockholders' Equity (Deficit) for each of the three years in the period ended December 31, 2000	F-4
5. Statements of Cash Flow for each of the three years in the period ended December 31, 2000	F-5
6. Notes to Financial Statements	F-6
(b.) Diacrin/Genzyme LLC (A Development Stage Enterprise)	
1. Report of Independent Public Accountants	F-17
2. Balance Sheets as of December 31, 1999 and 2000	F-18

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

3.	Statements of Operations for the years ended December 31, 1999 and 2000 and for the period from October 1, 1996 (date of inception) to December 31, 2000	F-19
4.	Statements of Cash Flows for the years ended December 31, 1999 and 2000 and for the period from October 1, 1996 (date of inception) to December 31, 2000	F-20
5.	Statements of Change in Venturers' Capital (Deficit) for the period from October 1, 1996 (date of inception) to December 31, 2000	F-21
6.	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
3.1	- Amended and Restated Certificate of Incorporation of Diacrin as amended to date
3.2	- Amended and Restated By-laws of Diacrin
+10.1	- Employment Agreement dated February 6, 1990 by and between Diacrin and Dr. Thomas H. Fraser
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
10.2(a)	- Consent and Agreement to Amend dated April 26, 1995 by and among Diacrin and certain investors named herein
10.2(b)	- Consent and Agreement to Amend dated as of January 4, 1996 by and among Diacrin and certain investors named herein
+10.3	- 1990 Stock Option Plan, as amended
10.4	- Sublease dated January 24, 1991 by and among Diacrin and Building 79 Associated Limited Partnership and Building 96 Associated Limited Partnership
+10.5	- 1994 Directors' Stock Option Plan, as amended
10.6	- Registration Rights Agreements dated May 31, 1995 by and among Diacrin and the investors listed on Schedule I and II attached thereto
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
10.7	- Collaboration Agreement among Diacrin, Inc., Genzyme Corporation and Diacrin/Genzyme LLC dated as of October 1, 1996
10.8	- Operating Agreement of Diacrin/Genzyme LLC

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

Exhibit No.	Title
+10.9	- 1997 Stock Option Plan
10.10	- \$650,000 Promissory Note dated November 25, 1997 made by Diacrin to the order of Fleet National Bank
10.10(a)	- Letter Agreement dated November 25, 1997 by and between Diacrin and Fleet National Bank
21	- Subsidiaries
23.1	- Consent of Arthur Andersen LLP
23.2	Consent of PricewaterhouseCoopers LLP

(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.

\* 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 (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)

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

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.

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:

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:

Signature	Date	Title
/s/ Thomas H. Fraser ----- Thomas H. Fraser	March 9, 2001	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ Kevin Kerrigan ----- Kevin Kerrigan	March 9, 2001	Controller (Principal Financial and Accounting Officer)
/s/ Zola P. Horovitz ----- Zola P. Horovitz	March 9, 2001	Director

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

/s/ John W. Littlechild                      March 9, 2001                      Director

-----  
John W. Littlechild

/s/ Stelios Papadopoulos                      March 9, 2001                      Director

-----  
Stelios Papadopoulos

/s/ Henri A. Termeer                      March 9, 2001                      Director

-----  
Henri A. Termeer

Director

-----  
Joshua Ruch

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, 1999 and 2000 and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2000. These financial statements are the responsibility of the 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, 1999 and 2000 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2000, in conformity with accounting principles generally accepted in the United States.

/s/                      Arthur Andersen LLP

Boston, Massachusetts

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

January 26, 2001

F-1

DIACRIN, INC.  
Balance Sheets

	At December 31,	
	1999	1998
	-----	-----
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 2,194,001	\$ 11,000
Short-term investments	16,582,252	22,000
Interest receivable and other current assets	329,365	---
	-----	-----
Total current assets	19,105,618	34,000
Property and equipment, at cost:		
Laboratory and manufacturing equipment	1,569,224	1,000
Furniture and office equipment	303,436	---
Leasehold improvements	77,529	---
	-----	-----
	1,950,189	2,000
Less - Accumulated depreciation and amortization	1,437,649	1,000
	-----	-----
	512,540	---
Long-term investments		
Long-term investments	2,644,084	20,000
Investment in joint venture	103,730	---
	-----	-----
Total other assets	2,747,814	20,000
	-----	-----
Total assets	\$ 22,365,972	\$ 55,000
	=====	=====
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Current portion of long-term debt	\$ 143,350	\$ ---
Accounts payable	138,768	---
Accrued expenses	1,251,410	1,000
Deferred revenue from joint venture	438,727	---
	-----	-----
Total current liabilities	1,972,255	1,000
	-----	-----
Long-term debt, net of current portion	249,167	---
	-----	-----
Commitments (Notes 4 and 10)		

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

Stockholders' equity:		
Preferred stock, \$0.01 par value; authorized--5,000,000 none issued and outstanding	-	
Common stock, \$0.01 par value; authorized--30,000,000 issued and outstanding-- 14,386,183 and 17,914,704 shares at December 31, 1999 and 2000, respectively	143,862	
Additional paid-in capital	64,250,741	101,
Accumulated deficit	(44,250,053)	(47,
	-----	-----
Total stockholders' equity	20,144,550	53,
	-----	-----
Total liabilities and stockholders' equity	\$ 22,365,972	\$ 55,
	=====	=====

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

F-2

DIACRIN, INC.  
Statements of Operations

	1998	Year Ended December 31, 1999	2000
REVENUES:			
Research and development	\$ 3,623,249	\$ 2,970,846	\$ 2,970,846
Interest income	1,575,998	1,323,520	3,323,520
	-----	-----	-----
Total revenues	5,199,247	4,294,366	5,199,247
	-----	-----	-----
OPERATING EXPENSES:			
Research and development	7,371,385	5,921,141	5,921,141
General and administrative	1,484,319	1,398,151	1,398,151
Interest expense	89,135	47,318	47,318
	-----	-----	-----
Total operating expenses	8,944,839	7,366,610	7,366,610
	-----	-----	-----
EQUITY IN OPERATIONS OF JOINT VENTURE	(1,084,358)	(1,688,071)	(1,688,071)
	-----	-----	-----
NET LOSS	\$ (4,829,950)	\$ (4,760,315)	\$ (4,760,315)
	=====	=====	=====
NET LOSS PER COMMON SHARE:			
Basic and diluted	\$ (.34)	\$ (.33)	\$ (.33)
	=====	=====	=====
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:			
Basic and diluted	14,156,179	14,364,154	17,914,704
	=====	=====	=====

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

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

F-3

DIACRIN, INC.  
Statements of Stockholders' Equity

	Common Stock			Additional Paid-in Capital	A D
	Number of Shares	\$.01 Par Value			
BALANCE, December 31, 1997	13,268,256	\$132,683		\$54,730,773	\$ (
Proceeds from private placement of stock, net of \$58,080 financing costs	1,027,027	10,270		9,431,650	
Exercise of stock options	31,935	319		28,652	
Net loss	-	-		-	
BALANCE, December 31, 1998	14,327,218	143,272		64,191,075	(
Exercise of stock options	58,965	590		59,666	
Net loss	-	-		-	
BALANCE, December 31, 1999	14,386,183	143,862		64,250,741	(
Proceeds from public offering of common stock, net of \$2,765,500 financing costs	3,450,000	34,500		36,875,000	
Exercise of stock options and warrants	78,521	785		248,181	
Net loss	-	-		-	
BALANCE, December 31, 2000	17,914,704	\$179,147		\$101,373,922	\$ (

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

F-4



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

DIACRIN, INC.  
Statements of Cash Flows

	1998 -----	Year Ended December 1999 -----
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (4,829,950)	\$ (4,760,315)
Adjustments to reconcile net loss to net cash used in operating activities-		
Depreciation and amortization	345,762	237,976
Equity in operations of joint venture	1,084,358	1,688,071
Changes in current assets and liabilities-		
Interest receivable and other current assets	44,343	65,048
Accounts payable	82,696	(129,234)
Accrued expenses	185,322	(126,762)
Deferred revenue from joint venture	(48,201)	99,872
	-----	-----
Net cash used in operating activities	(3,135,670)	(2,925,344)
	-----	-----
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
(Increase) decrease in short-term investments	(12,670,294)	2,088,140
Purchases of property and equipment, net	(76,386)	(26,019)
Decrease (increase) in long-term investments	7,726,279	(39,074)
Investment in joint venture	(1,911,216)	(2,669,384)
Return of capital for services provided on behalf of joint venture	912,843	990,282
	-----	-----
Net cash (used in) provided by investing	(6,018,774)	343,945
	-----	-----
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Net proceeds from sale of common stock	9,441,920	-
Net proceeds from the exercise of stock options warrants	28,971	60,256
Principal payments on long-term debt	(337,170)	(279,910)
	-----	-----
Net cash provided by (used in) financing	9,133,721	(219,654)
	-----	-----
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(20,723)</b>	<b>(2,801,053)</b>
CASH AND CASH EQUIVALENTS, beginning of year	5,015,777	4,995,054
	-----	-----
CASH AND CASH EQUIVALENTS, end of year	\$ 4,995,054	\$ 2,194,001
	=====	=====
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:</b>		
Cash paid for interest	\$ 111,405	\$ 49,743

The accompanying notes are integral part of these financial statements.

F-5

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.

(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) Research and Development

Collaborative revenue under the joint venture agreement with Genzyme Corporation ("Genzyme") (see Note 4) and revenues from research grants are recognized as work is performed. Collaborative revenue under the joint venture agreement is recognized as revenue to the extent that the Company's research and development costs are funded by Genzyme through the joint venture. The Company receives non-refundable monthly advances from the joint venture. Deferred revenue represents amounts received prior to recognition of revenue. Research and development costs are expensed as incurred.

(c) Income Taxes

The Company accounts for income taxes in accordance with Statement of Financial Accounting Standards ("SFAS") No. 109, Accounting for Income Taxes. At December 31, 2000, the Company has a net operating loss carryforward for federal income tax purposes of approximately \$49,750,000. The difference from losses reported for financial reporting purposes relates primarily to expenses reflected in the financial statements not yet deductible for tax purposes. The net operating loss carryforwards expire commencing in the year 2006 and are subject to review and possible adjustment 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 cause a change in ownership, as defined by the Act. The Company does not believe that

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

such ownership changes will significantly impact the Company's ability to utilize the net operating loss and tax credit carryforwards as of the date of such ownership changes. Ownership changes in future periods may limit the Company's ability to utilize net operating loss and tax credit carryforwards.

F-6

Diacrin, Inc.

### Notes to Financial Statements - (Continued)

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

	1999 ----	2000 ----
Loss carryforwards	\$ 16,403,000	\$ 19,900,000
Credit carryforwards	3,815,000	4,900,000
Other temporary differences	10,000	13,500
	-----	-----
Total deferred tax assets	20,228,000	24,813,500
Less - valuation allowance	(20,228,000)	(24,813,500)
	-----	-----
Net deferred tax asset	\$ -	\$ -
	=====	=====

A valuation allowance has been provided as it is uncertain if the Company will realize the deferred tax assets. The change in the total valuation allowance during the year ended December 31, 2000 was an increase of approximately \$4,585,500 and relates to the increase in the deferred tax asset which is primarily due to the net operating loss and tax credits generated during 2000.

(d) 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 and warrants of 4,000,738, 4,111,523 and 1,258,247 at December 31, 1998, 1999, and 2000, respectively, because to include such shares would have been antidilutive.

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

(f) Reclassifications

Certain prior year amounts have been reclassified to conform to the current year presentation.

(g) Comprehensive Income

In June 1997, the Financial Accounting Standards Board ("FASB") issued SFAS No. 130, Reporting Comprehensive Income ("SFAS 130"). SFAS 130 establishes

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

standards for reporting and display of comprehensive income and its components (revenues, expenses, gains and losses) in a full set of general-purpose financial statements. This statement is effective for fiscal years beginning after December 15, 1997. The Company adopted this statement for the year ended December 31, 1998 with no impact on the Company's financial statements as there are no material differences between the Company's reported income and comprehensive income for all periods presented.

F-7

Diacrin, Inc.

Notes to Financial Statements - (Continued)

(h) Segment Reporting

In June 1997, the FASB issued SFAS No. 131, Disclosure about Segments of an Enterprise and Related Information ("SFAS 131"). SFAS 131 establishes standards for the way that public business enterprises report information about operating segments in annual financial statements and requires that enterprises report selected information about operating segments in interim financial reports issued to stockholders. The Company adopted this statement for the year ended December 31, 1998. In accordance with SFAS 131, the Company believes that it operates in one operating segment.

(i) Fair Value of Financial Instruments

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

(j) New Accounting Standards

In June 1998, the FASB issued SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. The statement (as amended by SFAS No. 137) is effective for all fiscal quarters of all fiscal years beginning after June 15, 2000. SFAS No. 133 (as amended by SFAS No. 138) establishes accounting and reporting standards for derivative instruments including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities. The Company does not expect adoption of this statement to have a material impact on the Company's financial statements.

F-8

Diacrin, Inc.

Notes to Financial Statements - (Continued)

In December 1999, the Securities and Exchange Commission issued Staff Accounting Bulletin (SAB) No. 101, Revenue Recognition in Financial Statements. SAB No. 101, as amended, is effective for the fourth quarter of all fiscal periods beginning after December 15, 1999. Adoption of SAB No. 101 did not have a material impact on the Company's financial position or results of operations.

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

### (3) Sales of Common Stock

In February 1998, the Company completed a private placement of 1,027,027 shares of its common stock for \$9.25 per share for net proceeds of approximately \$9.4 million.

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) Joint Venture Agreement

In September 1996, the Company and Genzyme Corporation formed a joint venture to develop and commercialize the Company's NeuroCell-PD and NeuroCell-HD products for transplantation into people with advanced Parkinson's disease and Huntington's disease, respectively. 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, 2000, Genzyme had provided \$29.7 million to the joint venture and the Company had provided \$6.5 million.

The Company records as research and development expense all costs related to NeuroCell-PD and NeuroCell-HD 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."

F-9

Diacrin, Inc.

### Notes to Financial Statements - (Continued)

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 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, 2000.

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

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:

	1998	1999	2000
Balance, beginning of year	\$ -	\$ 94,508	\$ 103,730
Contributions to joint venture	1,911,216	2,669,384	1,947,422
Return of capital	(912,843)	(990,282)	(693,932)
Funding of operations of joint venture	(903,865)	(1,669,880)	(1,352,435)
	-----	-----	-----
Balance, end of year	\$ 94,508	\$ 103,730	\$ 4,785
	=====	=====	=====

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:

	1998	1999	2000
Revenue recognized (see note 2b)	\$3,623,249	\$2,970,846	\$2,081,795
Research and development expense (see note 2b)	\$4,536,089	\$3,961,128	\$2,775,727
Equity in operations of joint venture	\$1,084,358	\$1,688,071	\$1,368,945

Genzyme's President and Chief Executive Officer is a director of the Company.

F-10

Diacrin, Inc.

Notes to Financial Statements - (Continued)

(5) 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, short-term investments and long-term investments have maturities of less than three months, less than one year and greater than one year, respectively. Cash and cash equivalents, short-term investments and long-term investments at December 31, 1999 and 2000 consisted of the following:

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

1999

Cash and cash equivalents-

Cash	\$	738	\$
Corporate note		-	
Money market mutual fund		2,193,263	
		-----	
	\$	2,194,001	\$
		=====	

Short-term investments-

Corporate notes (remaining avg. maturity of 6 mos. at December 31, 2000)	\$	11,826,917	\$
Commercial paper		4,755,335	
		-----	
	\$	16,582,252	\$
		=====	

Long-term investments-

Corporate notes (remaining avg. maturity of 16 mos. at December 31, 2000)	\$	2,644,084	\$
		=====	

(6) Accrued Expenses

Accrued expenses consisted of the following at December 31, 1999 and 2000:

	1999	2000
	----	----
Accrued clinical trials costs	\$ 607,561	\$ 812,384
Accrued professional fees	298,891	159,999
Accrued payroll	158,584	114,899
Accrued contract research costs	43,244	54,862
Accrued other	143,130	181,642
	-----	-----
Total	\$ 1,251,410	\$ 1,323,786
	=====	=====

(7) Long-term Debt and Obligations Under Capital Leases

(a) Term Loan

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. Interest accrues at the prime rate plus one-half of one percent (10.00% at December 31, 2000) and is payable monthly in arrears. The loan is payable in 60 principal installments of \$10,833 commencing December 1, 1997 and may be prepaid without penalty. The Company is required to maintain certain covenants, including certain financial ratios and unencumbered cash balances of not less than \$1 million. As of December 31, 2000, the Company was in compliance with all covenants. Principal payments on the loan for each of the next two years will be \$130,000 and \$119,167, respectively.

F-11

Diacrin, Inc.

Notes to Financial Statements - (Continued)

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

### (b) Capital Leases

The Company had entered into a capital lease for certain laboratory and manufacturing equipment. As of December 31, 2000, all amounts under the capital lease had been repaid.

### (8) Stockholders' Equity

#### (a) 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.

#### (b) Warrants

In February 1996, the Company issued redeemable warrants in connection with the Company's initial public offering to purchase 2,875,000 shares of common stock at an exercise price of \$16 per share, subject to certain adjustments. During 2000, 2,995 shares were issued upon exercise of warrants. All unexercised warrants expired on December 31, 2000.

### (9) Common Stock Options

The Company has adopted the 1990 Stock Option Plan (the "1990 Plan") under which the Board of Directors is authorized 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. As of December 31, 2000, there were options to purchase 98,545 shares of common stock available for future grant under the 1990 Plan.

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, 2000, 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, 2000, there were

F-12

Diacrin, Inc.

Notes to Financial Statements - (Continued)



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

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, 2000, options to purchase 601,000 shares of common stock were available for future grant under the 1997 Plan.

The following table summarizes incentive and non-qualified stock option activity, exclusive of the warrants discussed in Note 8(b):

	Number of options	Weighted average Exercise price
Balance, December 31, 1997	1,026,798	\$ 4.69
Options granted	189,250	6.43
Options exercised	(31,935)	.91
Options canceled	(58,375)	9.18
	-----	-----
Balance, December 31, 1998	1,125,738	4.87
Options granted	183,500	5.97
Options exercised	(58,965)	1.02
Options canceled	(13,750)	11.20
	-----	-----
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
	=====	=====
Exercisable, December 31, 2000	860,869	\$ 4.68
	=====	=====
Exercisable, December 31, 1999	822,332	\$ 4.15
	=====	=====
Exercisable, December 31, 1998	735,609	\$ 3.31
	=====	=====

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

F-13

Diacrin, Inc.

Notes to Financial Statements - (Continued)

The following table summarizes certain information about options

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

outstanding and exercisable at December 31, 2000:

Options outstanding				
Range of exercise prices	Number outstanding at December 31, 2000	Weighted average remaining contractual life	Weighted average exercise price	
\$ 1.22 to \$ 2.50	520,997	3.36	\$ 2.08	
\$ 4.50 to \$ 7.50	471,500	8.67	\$ 5.75	
\$ 7.88 to \$15.75	265,750	6.81	\$ 10.12	
	----- 1,258,247 =====			

Options exercisable				
Range of exercise prices	Number exercisable at December 31, 2000	Weighted average exercise price		
\$ 1.22 to \$ 2.50	520,997	\$ 2.08		
\$ 4.50 to \$ 7.50	135,625	\$ 6.18		
\$ 7.88 to \$ 15.75	204,247	\$ 10.33		
	----- 860,869 =====			

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 proforma 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 1998, 1999 and 2000: risk-free interest rates of 5.5%, 6.0% and 6.0%, respectively; dividend yield of 0% for all years; volatility factor of the expected market price of the Company's common stock of 70%, 95% and 95%, respectively; 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 1998, 1999 and 2000 was \$4.68, \$4.97 and \$4.71, respectively.

F-14

Diacrin, Inc.

Notes to Financial Statements - (Continued)

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 1998, 1999 and 2000 was approximately \$886,000, \$912,000 and \$729,000, respectively. The Company's pro forma information

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

follows:

		1998 ----	1999 ----	2000 ----
Net loss	As reported	\$(4,829,950) =====	\$(4,760,315) =====	\$(3,536,741) =====
	Pro forma	(5,644,899) =====	(5,796,810) =====	(4,714,923) =====
Basic and diluted net loss per share:	As reported	(.34) =====	(.33) =====	(.21) =====
	Pro forma	(.40) =====	(.40) =====	(.27) =====

(10) Facility Lease

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

	Rental Commitment
2001	\$ 710,000
2002	710,000
2003	710,000
2004	710,000
2005	533,000
	-----
	\$ 3,373,000 =====

Total rent expense for the years ended December 31, 1998, 1999 and 2000 was approximately \$771,000, \$761,000 and \$751,000, respectively.

(11) 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. There were no contributions made to the plan by the Company in 1998 and 1999. During 2000, the Company made discretionary contributions of \$28,500 to the plan.

F-15

Diacrin, Inc.

Notes to Financial Statements - (Continued)

(12) Quarterly Results of Operations (Unaudited)

The following table presents a condensed summary of quarterly results of operations for the years ended December 31, 2000 and 1999.

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

	Year Ended December 31, 2000			
	First	Second	Third	Fourth
Total revenue	\$ 863	\$ 1,404	\$ 1,543	\$ 1,397
Net loss	\$ (1,249)	\$ (808)	\$ (820)	\$ (660)
Basic and diluted net loss per	\$ (.09)	\$ (.05)	\$ (.05)	\$ (.04)

	Year Ended December 31, 1999			
	First	Second	Third	Fourth
Total revenue	\$ 1,156	\$ 1,214	\$ 1,032	\$ 892
Net loss	\$ (1,265)	\$ (1,083)	\$ (1,174)	\$ (1,238)
Basic and diluted net loss per	\$ (.09)	\$ (.08)	\$ (.08)	\$ (.09)

F-16

Report of Independent Accountants

To the Steering Committee of Diacrin/Genzyme LLC:

In our opinion, the accompanying balance sheets and the related statements of operations, of cash flows and of changes in Venturers' capital (deficit) present fairly, in all material respects, the financial position of Diacrin/Genzyme LLC (a development stage enterprise) at December 31, 1999 and 2000, and the results of its operations and its cash flows for the years then ended and for the period from October 1, 1996 (date of inception) to December 31, 2000, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Steering Committee of the Joint Venture; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits 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 audits provide a reasonable basis for our opinion.

As more fully discussed in Note A, either Venturer may terminate the Collaboration Agreement of the Joint Venture for any reason upon 180 days notice

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

to the other Venturer and such termination could lead to the discontinuation of the Joint Venture.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts  
January 26, 2001

F-17

Diacrin/Genzyme LLC  
(A Development Stage Enterprise)

Balance Sheets  
December 31, 1999 and 2000

	1999	2000
Assets		
Current assets:		
Cash	\$ 9,531	\$ 1,032,170
Prepaid to Diacrin, Inc. (Note C)	433,712	365,245
Other current assets	-	11,266
	-----	-----
Total current assets	443,243	1,408,681
Property and equipment, net (Note D)	192,054	156,176
	-----	-----
Total assets	\$ 635,297	\$ 1,564,857
	=====	=====
Liabilities and Venturers' Capital (Deficit)		
Payable to Genzyme Corporation (Note C)	\$ 948,088	\$2,150,488
Accrued expenses	24,353	23,900
	-----	-----
Total liabilities	972,441	2,174,388
Commitments and contingencies (Note C)		
Venturers' capital (deficit) (including deficit accumulated during the development stage of \$36,872,217):		
Venturer's capital - Genzyme Corporation	513,949	444,140
Venturer's capital - Diacrin, Inc.	111,817	88,548
Unpaid Venturer's capital - Genzyme Corporation	(764,682)	(861,664)
Unpaid Venturer's capital - Diacrin, Inc.	(198,228)	(280,555)
	-----	-----
Total Venturers' capital (deficit)	(337,144)	(609,531)
	-----	-----
Total liabilities and Venturers' capital (deficit)	\$635,297	\$ 1,564,857
	=====	=====

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

The accompanying notes are an integral part of these financial statements

F-18

Diacrin/Genzyme LLC  
(A Development Stage Enterprise)

Statements of Operations

	For the year ended December 31,		For the period from October 1, 1996 (date of inception) to December 31,
	1999	2000	2000
Operating costs and expenses:			
Research and development-Genzyme Corporation	\$ 6,677,683	\$ 5,394,335	\$ 19,561,089
Research and development-Diacrin, Inc.	3,961,129	2,736,293	17,046,820
General and administrative	79,377	90,113	277,753
	-----	-----	-----
Total operating costs and expenses	10,718,189	8,220,741	36,885,662
Interest income	4,778	8,667	13,445
	-----	-----	-----
Net loss	\$ (10,713,411)	\$ (8,212,074)	\$ (36,872,217)
	=====	=====	=====

The accompanying notes are an integral part of these financial statements

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

F-19

Diacrin/Genzyme LLC  
(A Development Stage Enterprise)

Statements of Cash Flows

	For the Year Ended December 31,		For the period from October 1, 1996 (date of inception) to December 31, 2000
	----- 1999	2000 -----	
Cash flows from operating activities:			
Net loss	\$ (10,713,411)	\$ (8,212,074)	\$ (36,872,217)
Reconciliation of net loss to net cash used by operating activities:			
Depreciation	48,221	49,146	156,585
Increase (decrease) in cash from working capital changes:			
Prepaid to Diacrin, Inc.	(86,787)	68,467	(365,245)
Payable to Genzyme Corporation	62,927	1,202,400	2,150,488
Other current assets	11,899	(11,266)	(11,266)
Accrued expenses	24,353	(453)	23,900
	-----	-----	-----
Net cash used by operating activities	(10,652,798)	(6,903,780)	(34,917,755)
Cash flows from investing activities:			
Acquisition of property and equipment	(20,111)	(13,268)	(312,761)
Cash flows from financing activities:			
Capital contributed by Genzyme Corporation	8,008,148	5,992,265	29,736,639
Capital contributed by Diacrin, Inc.	2,669,384	1,947,422	6,526,047
	-----	-----	-----
Net cash provided by financing activities	10,677,532	7,939,687	36,262,686
	-----	-----	-----
Increase in cash	4,623	1,022,639	1,032,170
Cash at beginning of period	4,908	9,531	-
	-----	-----	-----
Cash at end of period	\$ 9,531	\$ 1,032,170	\$ 1,032,170
	=====	=====	=====

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

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, 2000

			Unpaid Venturers' capital		
	Genzyme Corporation	Diacrin, Inc.	Genzyme Corporation	Diacrin, Inc.	
1996 capital contributions	\$ 1,911,968	\$ -	\$ -	\$ -	\$ 1,911,968
1996 net loss	(1,542,374)	-	-	-	(1,542,374)
	-----	-----	-----	-----	-----
Balance at December 31, 1996	369,594	-	-	-	-
1997 capital contributions	6,819,536	-	-	-	6,819,536
1997 net loss	(6,809,012)	-	-	-	(6,809,012)
	-----	-----	-----	-----	-----
Balance at December 31, 1997	380,118	-	-	-	-
1998 capital contributions	7,709,137	2,085,079	(704,415)	(175,838)	8,014,063
1998 net loss	(7,608,663)	(1,986,683)	-	-	(9,595,346)
	-----	-----	-----	-----	-----
Balance at December 31, 1998	480,592	98,396	(704,415)	(175,838)	(100,265)
1999 capital contributions	8,068,415	2,691,774	(60,267)	(22,390)	10,777,532
1999 net loss	(8,035,058)	(2,678,353)	-	-	(10,713,411)
	-----	-----	-----	-----	-----
Balance at December 31, 1999	513,949	111,817	(764,682)	(198,228)	(137,144)
2000 capital contributions	6,089,247	2,029,749	(96,982)	(82,327)	7,949,687
2000 net loss	(6,159,056)	(2,053,018)	-	-	(8,212,074)
	-----	-----	-----	-----	-----
Balance at December 31, 2000	\$ 444,140	\$ 88,548	\$ (861,664)	\$ (280,555)	\$ (610,531)
	=====	=====	=====	=====	=====



The accompanying notes are an integral part of these financial statements

F-21

Diacrin/Genzyme LLC  
(A Development Stage Enterprise)

Notes to Financial Statements

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. Funding is provided on a monthly basis. 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.

F-22

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

Diacrin/Genzyme LLC  
(A Development Stage Enterprise)

## Notes to Financial Statements

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 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.

#### 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.

#### Reclassification

Certain prior year data has been reclassified to conform to the 2000 presentation.

Diacrin/Genzyme LLC  
(A Development Stage Enterprise)

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

### Notes to Financial Statements - (Continued)

#### 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 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, 2000, 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, 2000, Genzyme and Diacrin have funded \$29.7 million and \$6.5 million, respectively.

##### 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 month.

At December 31, 1999 and 2000, both Venturers had funded less than their allocated losses which resulted in unpaid Venturer's capital and represents receivables from the Venturers.

Genzyme charges the Joint Venture for use of certain research and development facilities under a three-year agreement which commenced July 1, 1998. These charges amounted to \$364,164 for each of the years ended December 31, 1999 and 2000 and \$1,338,720 from inception through December 31, 2000 and the Joint Venture expects to incur \$182,082 in the year ending December 31, 2001.

F-24

Diacrin/Genzyme LLC  
(A Development Stage Enterprise)

### Notes to Financial Statements - (Continued)

#### D. Property and Equipment

Property and equipment is stated at cost. At December 31, 1999 and 2000, property and equipment consisted of the following:

1999	2000
------	------

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

Lab equipment	\$ 186,931	\$ 200,199
Computer equipment	71,991	71,991
Leasehold improvements	27,608	27,608
Furniture and fixtures	12,963	12,963
	-----	-----
	299,493	312,761
Less: accumulated depreciation	(107,439)	(156,585)
	-----	-----
Property and equipment, net	\$ 192,054	\$ 156,176
	=====	=====

Depreciation expense was \$48,221 and \$49,146 for the years ended December 31, 1999 and 2000, respectively, and \$156,585 from inception through December 31, 2000.

F-25