

DIACRIN INC /DE/  
 Form 10-Q  
 July 30, 2003

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

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2003

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. 000-20139

Diacrin, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES  NO

--- ---

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

--- ---

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

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As of July 17, 2003, 18,082,449 shares of the registrant's Common Stock were outstanding.

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Diacrin, Inc.  
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Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 concerning our business, operations and financial condition, including statements with respect to planned timetables for the initiation and completion of clinical trials and the expected closing of our merger into GenVec, Inc. All statements, other than statements of historical facts included

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in this Quarterly Report on Form 10-Q regarding our strategy, future operations, timetables for product testing, financial position, costs, prospects, plans and objectives of management are forward-looking statements. When used in this Quarterly Report on Form 10-Q, the words "expect," "anticipate," "intend," "plan," "believe," "seek," "estimate" and similar expressions are intended to identify forward looking statements, although not all forward-looking statements contain these identifying words. Because these forward-looking statements involve risks and uncertainties, actual results could differ materially from those expressed or implied by these forward-looking statements for a number of important reasons, including those discussed under "Certain Factors That May Affect Future Results," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Quarterly Report on Form 10-Q.

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 Quarterly Report on Form 10-Q could substantially harm our business, results of operations and financial condition and that upon the occurrence of any of these events, the trading price of our common stock could decline.

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

Diacrin, Inc.  
Balance Sheets  
(Unaudited)

December 31,  
2002

ASSETS

Current assets:

|  |              |
|--|--------------|
| Cash and cash equivalents                    | \$ 4,189,700 |
| Short-term investments                       | 33,484,274   |
| Interest receivable and other current assets | 683,473      |
|  | -----        |
| Total current assets                         | 38,357,447   |
|  | -----        |

Property and equipment, at cost:

|  |           |
|--|-----------|
| Laboratory and manufacturing equipment | 1,679,436 |
|--|-----------|

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|  |               |
|--|---------------|
| Furniture and office equipment   | 327,382       |
| Leasehold improvements   | 86,597        |
|  | -----         |
|  | 2,093,415     |
| Less- Accumulated depreciation and amortization  | 1,985,364     |
|  | -----         |
|  | 108,051       |
|  | -----         |
| Long-term investments  | 7,282,169     |
|  | -----         |
| Total assets   | \$ 45,747,667 |
|  | =====         |
| LIABILITIES AND STOCKHOLDERS' EQUITY   |               |
| Current liabilities:   |               |
| Accounts payable   | 147,633       |
| Accrued expenses   | 726,168       |
| Deferred revenue - related party   | 32,483        |
| Deferred revenue - other   | 1,755,000     |
|  | -----         |
| Total current liabilities  | 2,661,284     |
|  | -----         |
| Stockholders' equity:  |               |
| Preferred stock, \$.01 par value, authorized--<br>5,000,000 shares; none issued and outstanding  | -             |
| Common stock, \$.01 par value; authorized-- 30,000,000<br>shares; issued and outstanding-- 17,937,204<br>and 18,082,449 shares at December 31, 2002<br>and June 30, 2003, respectively | 179,372       |
| Additional paid-in capital   | 101,401,822   |
| Accumulated deficit  | (58,494,811)  |
|  | -----         |
| Total stockholders' equity   | 43,086,383    |
|  | -----         |
| Total liabilities and stockholders' equity   | \$ 45,747,667 |
|  | =====         |

The accompanying notes are an integral part of these financial statements

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Diacrin, Inc.  
Statements of Operations  
(Unaudited)

|  | Three Months   |          | Six Months     |       |
|--|----------------|----------|----------------|-------|
|  | Ended June 30, |          | Ended June 30, |       |
|  | 2002           | 2003     | 2002           | 2003  |
| REVENUES:                                |                |          |                |       |
| Research and development - related party | \$ 46,853      | \$ 9,600 | \$ 79,441      | \$ 16 |
| Research and development - other         | -              | 73,250   | -              | 146   |

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|  |                |                |                |                |
|--|----------------|----------------|----------------|----------------|
| Total research and development revenue                                     | 46,853         | 82,850         | 79,441         | 163            |
| OPERATING EXPENSES:  |                |                |                |                |
| Research and development   | 1,699,769      | 1,153,716      | 3,322,105      | 2,256          |
| General and administrative   | 433,603        | 1,298,412      | 790,798        | 1,852          |
| Total operating expenses   | 2,133,372      | 2,452,128      | 4,112,903      | 4,108          |
| OTHER INCOME (EXPENSE):  |                |                |                |                |
| Equity in operations of joint venture                                      | (39,175)       | (12,174)       | (70,585)       | (53)           |
| Investment income  | 346,126        | 201,962        | 802,739        | 446            |
| Interest expense   | (866)          | -              | (2,130)        | -              |
| Gain on sale of fixed assets   | -              | 41,803         | -              | 41             |
| Total other income   | 306,085        | 231,590        | 730,024        | 434            |
| NET LOSS   | \$ (1,780,434) | \$ (2,137,687) | \$ (3,303,438) | \$ (3,510,981) |
| BASIC AND DILUTED NET LOSS<br>PER COMMON SHARE                             | \$ (.10)       | \$ (.12)       | \$ (.18)       | \$ (.21)       |
| SHARES USED IN COMPUTING BASIC<br>AND DILUTED NET LOSS PER<br>COMMON SHARE | 17,937,204     | 17,995,653     | 17,937,204     | 17,966,800     |

The accompanying notes are an integral part of these financial statements

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Diacrin, Inc.  
Statements of Cash Flows  
(Unaudited)

|  | Six Months<br>Ended June 30, |                |
|--|------------------------------|----------------|
|  | 2002                         | 2003           |
| CASH FLOWS FROM OPERATING ACTIVITIES:  |                              |                |
| Net loss   | \$ (3,303,438)               | \$ (3,510,981) |
| Adjustments to reconcile net loss to net<br>cash used in operating activities- |                              |                |
| Depreciation and amortization  | 96,443                       | 22,238         |
| Equity in operations of joint venture  | 70,585                       | 53,794         |
| Gain on sale of fixed assets   | -                            | (41,803)       |
| Stock option compensation expense  | -                            | 17,804         |
| Changes in assets and liabilities-   |                              |                |
| Interest receivable and other current assets                                   | (55,343)                     | (1,015)        |
| Accounts payable   | (5,500)                      | (64,036)       |

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|  |              |              |
|--|--------------|--------------|
| Accrued expenses   | (200,279)    | 998,428      |
| Deferred revenue   | 4,079        | (174,475)    |
|  | -----        | -----        |
| Net cash used in operating activities                              | (3,393,453)  | (2,700,046)  |
|  | -----        | -----        |
| CASH FLOWS FROM INVESTING ACTIVITIES:                              |              |              |
| Purchases of investments   | (10,278,651) | (19,422,782) |
| Maturities of investments  | 21,719,253   | 21,838,918   |
| Purchases of property and equipment                                | (12,810)     | (3,900)      |
| Proceeds from the sale of fixed assets                             | -            | 35,000       |
| Return of capital for services provided on behalf of joint venture | 26,480       | 5,653        |
|  | -----        | -----        |
| Net cash provided by investing activities                          | 11,454,272   | 2,452,889    |
|  | -----        | -----        |
| CASH FLOWS FROM FINANCING ACTIVITIES:                              |              |              |
| Principal payments on long-term debt                               | (65,000)     | -            |
| Proceeds from the exercise of stock options                        | -            | 267,719      |
|  | -----        | -----        |
| Net cash (used in) provided by financing activities                | (65,000)     | 267,719      |
|  | -----        | -----        |
| NET INCREASE IN CASH<br>AND CASH EQUIVALENTS                       | 7,995,819    | 20,562       |
| CASH AND CASH EQUIVALENTS, beginning of period                     | 8,534,426    | 4,189,700    |
|  | -----        | -----        |
| CASH AND CASH EQUIVALENTS, end of period                           | \$16,530,245 | \$ 4,210,262 |
|  | =====        | =====        |
| SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:                  |              |              |
| Cash paid for interest during the period                           | \$ 2,130     | \$ -         |
|  | =====        | =====        |

The accompanying notes are an integral part of these financial statements

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Diacrin, Inc.  
Notes to Financial Statements  
(Unaudited)

1. Operations and Basis of Presentation

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

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

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

### 2. Summary of Significant Accounting Policies

#### (a) Terumo Agreement

In September 2002, the Company entered into a development and license agreement with Terumo Corporation ("Terumo"). Under the terms of the agreement, Diacrin licensed to Terumo its human muscle cell transplantation technology for cardiac disease in Japan. Terumo will fund all development in Japan while Diacrin continues to independently develop its cardiac repair technology for commercialization in the U.S. and elsewhere. On October 1, 2002, the Company received an upfront non-refundable license fee of \$2.0 million. The agreement also includes payments by Terumo to Diacrin for development milestones and a royalty on product sales. The Company recorded this fee as deferred revenue and recognizes revenue over the development period of the agreement in accordance with SEC Staff Accounting Bulletin No. 101, "Revenue Recognition" ("SAB 101"). SAB 101 requires companies to recognize certain upfront non-refundable fees over the period in which the Company completes its performance obligations under the related agreement when such fees are received in conjunction with an agreement which includes performance obligations. Determination of the length of the development period requires management's judgment. Any significant changes in the assumptions underlying our estimates used while applying SAB 101 could impact our revenue recognition. Included in research and development revenue for the three and six months ended June 30, 2003 is \$73,000 and \$146,000, respectively, in revenue related to this collaboration.

Diacrin, Inc.  
Notes to Financial Statements  
(Unaudited)

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

#### (b) Joint Venture Agreement

In September 1996, the Company and Genzyme Corporation ("Genzyme") formed a joint venture to develop and commercialize two product candidates. The joint venture is funded by Genzyme and the Company in accordance with the terms of the joint venture agreement. Collaborative revenue under the joint venture agreement with Genzyme is recognized as revenue to the extent that the Company's research and development costs are funded by Genzyme through the joint venture. The

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Company receives non-refundable advances from the joint venture. A portion of deferred revenue at period end represents amounts received prior to recognition of revenue. Research and development costs are expensed as incurred.

The detail of the Company's investment in the joint venture for the six months ended June 30, 2003 is as follows:

|  | 2003        |
|--|-------------|
|  | -----       |
| Balance, December 31, 2002             | \$ (12,857) |
| Contributions to joint venture         | -           |
| Return of capital                      | (5,653)     |
| Funding of operations of joint venture | (53,794)    |
|  | -----       |
| Balance, June 30, 2003                 | \$ (72,304) |
|  | =====       |

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 the Company is obligated to fund.

Diacrin, Inc.  
Notes to Financial Statements  
(Unaudited)

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

|                                       | 2002      | Six months ended June 30,<br>2003 |
|---------------------------------------|-----------|-----------------------------------|
| Revenue recognized                    | \$79,441  | \$16,959                          |
| Research and development expense      | \$105,921 | \$22,612                          |
| Equity in operations of joint venture | \$70,585  | \$53,794                          |

(b) Net Loss per Common Share

In accordance with Statement of Financial Accounting Standards ("SFAS") No. 128, Earnings per Share, basic and diluted net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for all periods presented. Diluted weighted average shares outstanding for all periods presented exclude the potential common shares from stock options of 1,540,622 and 1,354,187 at June 30, 2002 and 2003, respectively, because to include such shares would be antidilutive.

(c) Stock Options

The Company has several stock-based compensation plans. The Company applies APB Opinion No. 25 "Accounting for Stock Issued to Employees" in accounting for qualifying options granted to its employees under its plans and applies Statement of Financial Accounting Standards No. 123 "Accounting for Stock Issued to Employees" ("SFAS 123") for disclosure purposes only. The SFAS 123 disclosures include pro forma net



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income and earnings per share as if the fair value-based method of accounting had been used. Stock issued to non-employees is accounted for in accordance with SFAS 123 and related interpretations.

### Diacrin, Inc. Notes to Financial Statements (Unaudited)

The following are the pro forma net income and income per share, as if compensation expense for the option plans had been determined based on the fair value at the date of grant:

|   | Three months ended June 30,<br>2002 | 2003        | Six months ended June 30,<br>2002 | 2003        |
|---|-------------------------------------|-------------|-----------------------------------|-------------|
| Net loss, as reported   | (1,780,434)                         | (2,137,687) | (3,303,438)                       | (3,510,981) |
| Less: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects | (152,733)                           | (124,783)   | (305,465)                         | (249,556)   |
| Pro forma net loss  | (1,933,167)                         | (2,262,470) | (3,608,903)                       | (3,760,537) |
| <br>Earnings per share:   |                                     |             |                                   |             |
| Basic and diluted-as reported   | (\$ .10)                            | (\$ .12)    | (\$ .18)                          | (\$ .20)    |
| Basic and diluted-pro forma   | (\$ .11)                            | (\$ .13)    | (\$ .20)                          | (\$ .21)    |

The fair value of options at the date of grant were estimated using the Black-Scholes option pricing model with the following assumptions:

|                            | Three months ended June 30,<br>2002 | 2003 | Six months ended June 30,<br>2002 | 2003 |
|----------------------------|-------------------------------------|------|-----------------------------------|------|
| Volatility                 | 95%                                 | 95%  | 95%                               | 95%  |
| Expected option life-years | 7.5                                 | 7.5  | 7.5                               | 7.5  |
| Interest rate (risk free)  | 3.0                                 | 2.5  | 3.0                               | 2.5  |
| Dividends                  | 0                                   | 0    | 0                                 | 0    |

The effects on the three and six months ended June 30, 2002 and

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2003 pro forma net income and net income per share of the estimated fair value of stock options and shares are not necessarily representative of the effects on results of operations in the future. In addition, the estimates made utilize a pricing model developed for traded options with relatively short lives; our option grants typically have a life of up to ten years and are not transferable. Therefore, the actual fair value of a stock option grant may be different from our estimates. We believe that our estimates incorporate all relevant information and represent a reasonable approximation in light of the difficulties involved in valuing non-traded stock options.

### (d) Comprehensive Income

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

### Diacrin, Inc. Notes to Financial Statements (Unaudited)

### 3. Cash Equivalents and Investments

The Company's cash equivalents and investments are classified as held-to-maturity and are carried at amortized cost, which approximates fair market value. Cash equivalents, short-term investments and long-term investments have maturities of less than three months, less than one year and greater than one year, respectively. Cash equivalents, short-term investments and long-term investments at December 31, 2002 and June 30, 2003 consisted of the following:

|   | December 31,<br>2002 | June<br>2003 |
|---|----------------------|--------------|
| Cash and cash equivalents-  |                      |              |
| Cash  | \$ 400               | \$           |
| Money market mutual fund  | 4,189,300            | 4,2          |
|   | -----                | -----        |
|   | \$ 4,189,700         | \$ 4,2       |
|   | =====                | =====        |
| Short-term investments-   |                      |              |
| Corporate notes (remaining avg. maturity of 4 mos. at June 30, 2003)  | \$29,981,389         | \$ 34,8      |
| U.S. gov't oblig. & agencies  | 3,502,885            |              |
|   | -----                | -----        |
|   | \$ 33,484,274        | \$ 34,8      |
|   | =====                | =====        |
| Long-term investments-  |                      |              |
| Corporate notes (remaining avg. maturity of 13 mos. at June 30, 2003) | \$7,282,169          | \$ 3,4       |
|   | =====                | =====        |

4. GenVec, Inc. Business Combination Transaction

On April 14, 2003, the Company entered into an Agreement and Plan of Reorganization and related Agreement and Plan Merger with GenVec, Inc., a publicly-traded company, providing for the Company to merge into GenVec. Upon completion of the merger, each outstanding share of the Company's common stock would be exchanged for 1.5292 shares of GenVec common stock. The merger is expected to close in the third quarter of 2003, subject to the satisfaction of closing conditions, including receipt of Diacrin and GenVec stockholder approval.

5. New Accounting Pronouncements

In May 2003, the FASB issued SFAS 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity."

SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. This Statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS 150 is not expected to have a material effect on the Company's financial statements.

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

Overview

Since our inception, we have principally focused our efforts and resources on research and development of cell transplantation technology for treating human diseases that are characterized by cell dysfunction or cell death and for which current therapies are either inadequate or nonexistent. Our primary source of working capital to fund those activities has been proceeds from the sale of equity and debt securities. In addition, we have received funding from our collaboration with Terumo and our joint venture with Genzyme. We do not expect to derive a material amount of revenues from our joint venture with Genzyme in the future. We have not received any revenues from the sale of products to date and do not expect to generate product revenues for the next several years. We have experienced fluctuating operating losses since inception and expect that the additional activities required to develop and commercialize our products will result in increasing operating losses for the next several years. At June 30, 2003, we had an accumulated deficit of \$62.0 million.

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

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sales.

On April 14, 2003, we entered into an Agreement and Plan of Reorganization and related Agreement and Plan Merger with GenVec, Inc., a publicly-traded company, providing for us to merge into GenVec. Upon completion of the merger, each outstanding share of our common stock would be exchanged for 1.5292 shares of GenVec common stock. The merger is expected to close in the third quarter of 2003, subject to the satisfaction of closing conditions, including receipt of Diacrin and GenVec stockholder approval.

### Critical Accounting Policies

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

In 1996, we formed a joint venture with Genzyme to develop and commercialize two product candidates. Each of Diacrin and Genzyme owns 50% of the joint venture. We record as research and development expense all costs related to the joint venture's product candidates incurred by us on behalf of the joint venture. We then recognize research and development revenue equal to the amount of reimbursement received by us from the joint venture out of funds contributed by Genzyme. We do not recognize research and development revenue for amounts we receive from the joint venture out of funds contributed by us. As Genzyme incurs costs on behalf of the joint venture that we are obligated to fund, we recognize an expense in our statement of operations captioned "Equity in operations of joint venture."

We are currently focused on the development of one product candidate, human muscle cells for cardiac disease. The expenditures that will be necessary to execute our product development plan are subject to numerous uncertainties, which may adversely affect our liquidity and capital resources. Completion of clinical trials may take several years or more, but the length of time generally varies substantially according to the type, complexity, novelty and intended use of a product candidate.

We estimate that clinical trials of the type we generally conduct are typically completed over the following timelines:

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| CLINICAL PHASE | ESTIMATED<br>COMPLETION<br>PERIOD |
|----------------|-----------------------------------|
| Phase I        | 1-2 Years                         |
| Phase II       | 1-3 Years                         |
| Phase III      | 2-4 Years                         |

The duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during the clinical trial protocol, including, among others, the following:

- the number of patients that ultimately participate in the trial;
- the duration of patient follow-up that seems appropriate in view of the results;
- the number of clinical sites included in the trials; and
- the length of time required to enroll suitable patient subjects.

We test potential product candidates in numerous pre-clinical studies to identify indications for which they may be product candidates. As we obtain results from trials, we may elect to discontinue clinical trials for certain product candidates or for certain indications in order to focus our resources on more promising product candidates or indications.

An element of a company's business strategy is to pursue the research and development of a range of product candidates for a variety of indications. This is intended to allow the company to diversify the risks associated with its research and development expenditures. We are currently focusing our efforts towards the development of one product candidate. As a result, our future capital requirements and our future financial success are substantially dependent on this product candidate.

Our product candidate has not yet received FDA regulatory approval, which is required before we can market it as a therapeutic product. In order to proceed to subsequent clinical trial stages and to ultimately achieve regulatory approval, the FDA must conclude that our clinical data establish safety and efficacy. Historically, the results from pre-clinical testing and early clinical trials have often not been predictive of results obtained in later clinical trials. A number of new drugs and biologics have shown promising results in early clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

Furthermore, our product development strategy includes the option of entering into collaborative arrangements with third parties to complete the development and commercialization of our product candidates. In the event that third parties take over the clinical trial process for our product candidate, the estimated completion date would largely be under the control of that third party rather than us. We cannot forecast with any degree of certainty which proprietary products or indications, if any, will be subject to future collaborative arrangements, in whole or in part, and how such arrangements would affect our development plan or capital requirements. Our programs may also benefit from subsidies, grants or government or agency-sponsored studies that could reduce our development costs.

As a result of the uncertainties discussed above, among others, we are unable to estimate the duration and completion costs of our research and development projects or when, if ever, and to what extent we will receive

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cash inflows from the commercialization and sale of a product. Our inability to complete our research and development projects in a timely manner or our failure to enter into collaborative agreements, when appropriate, could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time to time in order to continue with our business strategy. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

Our one product candidate, human muscle cells for cardiac disease, is currently in Phase I clinical testing. We estimate that, since 1990, we have spent between \$15 million and \$20 million on the development of this product candidate, primarily in research and development expenses, including an allocation of corporate general and administrative expenses. We expect to continue to expend substantial additional amounts for the development of this product. We cannot reasonably estimate costs to complete development of this product due to the uncertainties of the development process and the requirements of the FDA, which could necessitate additional and unexpected clinical trials or other development, testing and analysis. Until we obtain further relevant clinical data, we will not be able to estimate our future expenses related to this program or when, if ever, and to what extent we will receive cash inflows from it. Results of any testing could result in a decision to alter or terminate development of this product, in which case estimated future costs could change substantially. Furthermore, this program may benefit from subsidies, grants, partners or government or agency sponsored studies that could reduce our development costs.

### Results of Operations

#### Three Months Ended June 30, 2003 Versus Three Months Ended June 30, 2002

Research and development revenues were \$83,000 for the three months ended June 30, 2003 and \$47,000 for the three months ended June 30, 2002. The increase in revenues was primarily a result of an increase in revenue of \$73,000 related to our collaboration with Terumo offset in part by a decrease in revenue from our joint venture with Genzyme. We and Genzyme have suspended the development of the product candidates being developed by the joint venture. As a result, we are focusing on reducing or eliminating activity we perform related to the joint venture's product candidates. Because our revenue in connection with the joint venture is determined by how much activity we perform on behalf of the joint venture, the successful reduction or elimination of this activity by us has resulted in a decrease in revenue. We do not expect to derive a material amount of revenues from our joint venture with Genzyme in the future.

Research and development expenses were \$1.2 million and \$1.7 million for the three months ended June 30, 2003 and 2002, respectively. The decrease in research and development expenses is primarily due to a decrease in clinical and production costs related to several product candidates of \$274,000 and a decrease in personnel costs of \$73,000.

General and administrative expenses were \$1.3 million and \$434,000 for the three months ended June 30, 2003 and 2002, respectively. The increase in general and administrative expenses was primarily due to an increase in professional fees of \$963,000 due to our business combination transaction with GenVec, Inc.

For the three months ended June 30, 2003 and 2002, we recorded an

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expense of \$12,000 and \$39,000, respectively, related to our equity in operations of the joint venture. This expense was due 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 expense amount remained relatively unchanged between the periods.

Investment income was \$202,000 and \$346,000 for the three months ended June 30, 2003 and 2002, respectively. The decrease in investment income was due to lower cash balances available for investment in the current year period and a lower return on investment due to the decline in interest rates.

We incurred a net loss of approximately \$2.1 million for the three months ended June 30, 2003 versus approximately \$1.8 million for the three months ended June 30, 2002.

### Six Months Ended June 30, 2003 Versus Six Months Ended June 30, 2002

Research and development revenues were \$163,000 for the six months ended June 30, 2003 and \$79,000 for the six months ended June 30, 2002. The increase in revenues was primarily a result of an increase in revenue of \$146,000 related to our collaboration with Terumo offset in part by a decrease in revenue from our joint venture with Genzyme. We and Genzyme have suspended the development of the product candidates being developed by the joint venture. As a result, we are focusing on reducing or eliminating activity we perform related to the joint venture's product candidates. Because our revenue in connection with the joint venture is determined by how much activity we perform on behalf of the joint venture, the successful reduction or elimination of this activity by us has resulted in a decrease in revenue. We do not expect to derive a material amount of revenues from our joint venture with Genzyme in the future.

Research and development expenses were \$2.3 million and \$3.3 million for the six months ended June 30, 2003 and 2002, respectively. The decrease in research and development expenses is primarily due to a decrease in clinical and production costs related to several product candidates of \$470,000 and a decrease in personnel costs of \$123,000.

General and administrative expenses were \$1.9 million and \$791,000 for the six months ended June 30, 2003 and 2002, respectively. The increase in general and administrative expenses was primarily due to an increase in professional fees of \$1.2 million due to our business combination transaction with GenVec, Inc.

For the six months ended June 30, 2003 and 2002, we recorded an expense of \$54,000 and \$71,000, respectively, related to our equity in operations of the joint venture. This expense was due 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 expense amount remained relatively unchanged between the periods.

Investment income was \$446,000 and \$803,000 for the three months ended June 30, 2003 and 2002, respectively. The decrease in investment income was due to lower cash balances available for investment in the current year period and a lower return on investment due to the decline in interest rates.

We incurred a net loss of approximately \$3.5 million for the six months ended June 30, 2003 versus approximately \$3.3 million for the six months ended June 30, 2002.

### Liquidity and Capital Resources

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We have financed our activities primarily with the net proceeds from the sale of equity and debt securities aggregating \$102 million and with the interest earned thereon. In addition, we have recorded approximately \$15.3 million in revenue from our joint venture since it commenced on October 1, 1996. At June 30, 2003, we had cash and cash equivalents, short-term investments and long-term investments aggregating approximately \$42.6 million.

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

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

Net cash used in operating activities was \$2.7 million for the six months ended June 30, 2003 and \$3.4 million for the six months ended June 30, 2002. Cash used in operations for the six months ended June 30, 2003 was primarily attributable to our net loss, offset in part by an increase in accrued expenses. The increase in accrued expenses was due to costs incurred related to our business combination transaction with GenVec. Cash used in operations for the six months ended June 30, 2002 was primarily attributable to our net loss.

Net cash provided by investing activities was \$2.5 million for the six months ended June 30, 2003 and \$11.5 million for the six months ended June 30, 2002. Net cash provided by investing activities for the six months ended June 30, 2003 and 2002 was primarily attributable to maturities of investments, offset in part by purchases of investments.

Net cash provided by financing activities of \$268,000 for the six months ended June 30, 2003 was due to proceeds from the exercise of stock options. Net cash used in financing activities of \$65,000 for the six months ended June 30, 2002 was attributable to principal payments on long-term debt.

At June 30, 2003, we had a lease for a facility which is considered a material commitment. In October 2000, we exercised the first of two options we have to extend this lease an additional five years. Minimum rental payments under the lease are as follows:

|      | Rental<br>Commitment |
|------|----------------------|
| 2003 | \$ 908,000           |
| 2004 | 908,000              |
| 2005 | 908,000              |



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|      |              |
|------|--------------|
| 2006 | 681,000      |
|      | -----        |
|      | \$ 3,405,000 |
|      | =====        |

We are obligated to fund 25% of the joint venture's expenditures. Due to the curtailment of development spending by the joint venture, we do not expect to pay more than \$150,000 in 2003 or any future year to the Diacrin/Genzyme LLC to fund operations. Upon the closing of our business combination transaction with GenVec we will be obligated to pay our financial advisors \$400,000.

### Certain Factors That May Affect Future Results

The following important factors, among others, could cause actual results to differ materially from those contained in forward-looking statements made in this Quarterly Report on Form 10-Q or presented elsewhere by management from time to time. The forward-looking statements contained in this Quarterly Report on Form 10-Q represent our expectations as of July 30, 2003, the date our Quarterly Report on Form 10-Q was 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

Failure to complete the merger with GenVec could negatively impact the market price of our common stock and our future business and operations.

If the merger with GenVec is not completed for any reason, we will be subject to a number of material risks, including:

- under the circumstances described in the merger agreement, we could be required to pay GenVec a termination fee in the amount of up to \$1.2 million;
- the market price of our common stock may decline to the extent that the current market price of such shares reflects a market assumption that the merger will be completed;
- the costs related to the merger, such as legal and accounting fees and a portion of the investment banking fees, must be paid even if the merger is not completed; and
- the benefits that we expect to realize from the merger would not be realized.

During the pendency of the merger agreement, we may not be able to enter into a merger or business combination with another party at a favorable price because of restrictions in the merger agreement. Covenants in the merger agreement with GenVec also impede our ability to make acquisitions or complete other transactions that are not in the ordinary course of business but that could be favorable to us and our stockholders pending completion of the merger. As a result, if the merger is not consummated, we may be at a disadvantage to our competitors.

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

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developing will require additional research and development, clinical trials and regulatory approval prior to any commercial sale. Our product candidates are currently in early phase clinical trials or in the preclinical stage of development. Our products may not be effective in treating any of our targeted disorders or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may prevent or limit their commercial use.

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

We are focusing our resources on cell transplantation technology which is complex and novel and there are uncertainties as to its effectiveness

We have concentrated our efforts and therapeutic product research on cell transplantation technology, and our future success depends on the successful development of this technology. Currently, we are focusing most of our resources on the development of our cell transplantation technology for cardiac disease.

Our technological approaches may not enable us to successfully develop and commercialize any products. Our decision to focus on one technology as opposed to multiple technologies increases the risk associated with our stock. If our approaches are not successful, we may be required to change the scope and direction of our product development activities. In that case, we may not be able to identify and implement successfully an alternative product development strategy.

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

Cell transplantation products would compete with existing products that are already accepted by the medical community. For example, if successfully developed, our cardiac repair product would compete with already available treatments, such as pharmaceuticals, cardiac catheterization and angioplasty. These products may be more effective and/or less costly than our product under development, which involves the surgical transplantation of living cells. In addition, because these available products are already accepted as effective treatments, to successfully compete with these existing treatments, we may need to demonstrate that our product is not only safe and effective, but safer and/or more effective than existing products.

We will also compete with products currently under development by pharmaceutical, biopharmaceutical and biotechnology companies, as well as universities and other research institutions. We have limited experience in product development and commercialization, obtaining regulatory approvals and product manufacturing. Many of our competitors are more experienced in these areas and, as a result, they may develop competing products more rapidly and at a lower cost. In addition, 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. These competitors may discover, develop and commercialize products which render non-competitive or obsolete the products that we seek to develop.

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

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acceptance by patients, the medical community and third-party payors. Among the factors that we believe will materially affect acceptance of our products are:

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

### Risks Relating to Clinical and Regulatory Matters

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

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

The submission of an investigational new drug application, or IND, may not result in FDA authorization to commence clinical trials. If clinical trials begin, we may not complete testing successfully within any specific time period, if at all, with respect to any of our product candidates. For example, in March 2001, we announced that we were not conducting a planned Phase III clinical study of NeuroCell-PD because of disappointing Phase II clinical study results. 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. For instance, in April 2000, we put on hold, and later terminated, a Phase I clinical trial using porcine fetal neural cells in stroke patients due to two adverse events.

The FDA recently cleared our IND for an additional clinical trial involving the transplantation of human cells into the heart. We have only performed Phase I clinical trials relating to this product and cannot assure you that we will complete our most recent Phase I trial or that we will complete any Phase II or Phase III clinical trials. Moreover, clinical trials, if completed, may not show this or any other product to be safe or effective. Thus, the FDA and other regulatory authorities may not approve any of our product candidates for any disease indication.

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

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

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

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

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

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

There is limited regulatory precedent for the approval of cell transplantation products. Cell transplantation, especially cell transplantation into the heart, is a relatively new technology that has not been extensively tested in humans. Accordingly, the regulatory requirements governing cell transplantation products may be more rigorous than for conventional products such as drugs and other surgical procedures. As a result, we may experience a longer regulatory process in connection with any cell transplantation products that we seek to develop.

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. We have limited experience with foreign regulatory requirements and approvals.

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. Following commercialization, the discovery of previously unknown problems with the product, the manufacturer or the manufacturing facility may result in restrictions on the product or manufacturer, including withdrawal of the product from the market. Moreover, if we ever market a product and fail to comply with applicable regulatory requirements, we may be subject to fines, suspensions or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecutions. If we are subject to any of these restrictions or penalties, the success of our products could be materially adversely affected. We have never marketed a product and, therefore, have no experience with, and may not be successful at conducting

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post-market studies, manufacturing products and/or complying with post-marketing regulatory requirements.

### Risks Relating to Financing Our Business

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

We have incurred losses in each year since our founding in 1989. At June 30, 2003, we had an accumulated deficit of \$62.0 million. We expect to incur substantial operating losses for the foreseeable future. We have no material sources of revenue from product sales or license fees. We anticipate that it will be a number of years, if ever, before we develop significant revenue sources or become profitable, even if we are able to commercialize products.

We expect to increase our spending significantly as we develop our research and development programs, expand our clinical trials, apply for regulatory approvals and begin commercialization activities.

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

We will require substantial funds to conduct research and development, including clinical trials of our product candidates, and to manufacture and market any products that are approved for commercial sale. Our future capital requirements will depend on many factors, including the following:

- continued progress in our research and development programs, as well as the magnitude of these programs;
- the resources required to successfully complete our clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the cost of manufacturing and commercialization activities;
- the cost of any additional facilities requirements;
- the timing, receipt and amount of milestone and other payments from future collaborative partners;
- the timing, receipt and amount of sales and royalties from our potential products in the market; and
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and the costs of obtaining any required licenses to technologies.

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

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

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

### Risks Relating to Intellectual Property

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

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

Our success depends significantly on our ability to:

- obtain patents;
- protect trade secrets;
- operate without infringing upon the proprietary rights of others; and
- prevent others from infringing on our proprietary rights.

Patents may not issue from any patent applications that we own or license. If patents do issue, the claims allowed may not be sufficiently broad to protect our technology. In addition, the patent positions of pharmaceutical and biotechnology companies have recently been the subject of much investigation and our patents may be challenged, invalidated or circumvented. We have limited experience in bringing and/or defending patent claims and have fewer resources than many of the parties against which we may be forced to defend ourselves or bring action. Any challenge to, or invalidation or circumvention of, our patents or patent applications would be costly, require significant time and attention of our management and could have a materially adverse effect on our business.

We may not hold proprietary rights to some patents related to our proposed products. In some cases, others may own or control these patents. Because patent applications in the United States may be maintained in secrecy until patents issue, others may have filed or maintained patent applications for technology used by us or covered by our pending patent applications without our being aware of these applications. 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.

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

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

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

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

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

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

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

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

We are a party to technology in-licenses that are important to our business and expect to enter into additional licenses in the future. These licenses impose commercialization, sublicensing, royalty, insurance and other obligations on us. If we fail to comply with these requirements, the licensor will have the right to terminate the license.

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

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

We have no sales, marketing and distribution experience or infrastructure. We plan to rely significantly on sales, marketing and distribution arrangements with third parties for the products that we are developing. For example, under our development and license agreement with Terumo, we have granted to Terumo sales and marketing rights to our human muscle cell transplantation technology for cardiac disease in Japan. We may have limited or no control over the sales, marketing and distribution activities of Terumo in Japan or other collaborative partners. Our future revenues may be materially dependent upon the success of these third parties.

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

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

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- 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

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

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

### Risks Related to Ongoing Operations

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

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

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

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

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

We may be subjected to product liability claims that are inherent in the testing, manufacturing, marketing and sale of human health care products. These claims could expose us to significant liabilities that could prevent or interfere with the development or commercialization of our products. Product liability claims could require us to spend significant time and money in litigation or to pay significant damages. Product liability insurance is generally expensive for biopharmaceutical companies such as ours. Although we maintain limited product liability insurance coverage for the clinical



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trials of our products, it is possible that we will not be able to obtain further product liability insurance on acceptable terms, if at all, and that our present insurance levels and any insurance we subsequently obtain will not provide adequate coverage against all potential claims.

### 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 39% of our outstanding common stock. Due to this concentration of ownership, this group may be able to prevail on all matters requiring a stockholder vote, including:

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

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

The market price of our common stock, like that of the common stock of many other development stage biotechnology companies, may be highly volatile. For example, since January 2001, our stock price has fluctuated from a high sale price of \$6.50 to a low sale price of \$0.99. In addition, the stock market has experienced extreme price and volume fluctuations. This volatility has significantly affected the market prices of securities of many biotechnology and pharmaceutical companies for reasons frequently unrelated to or disproportionate to the operating performance of the specific companies. These broad market fluctuations may adversely affect the market price of our common stock. Prices for our common stock will be determined in the market place and may be influenced by many factors, including variations in our financial results and investors' perceptions of us, changes in recommendations by securities analysts as well as their perceptions of general economic, industry and market conditions.

Our board of directors has the authority to designate and issue preferred stock without further stockholder approval. The issuance of such stock could delay or prevent an acquisition and changes in control in our board and management and could adversely affect the price of our common stock

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

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

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Our common stock trades on the NASDAQ National Market. In order to continue trading on the NASDAQ National Market, we must comply with the NASDAQ National Market's continued listing requirements, which require that we either maintain a minimum stockholders' equity of \$10.0 million and a minimum closing bid price of \$1.00 per share or, if we fall below the minimum stockholders' equity requirement, maintain a minimum closing bid price of \$3.00 per share. At June 30, 2003, we had stockholders' equity of approximately \$51.5 million and a closing stock price of \$2.85. However, our stockholders' equity may decline. If our stockholders' equity falls below \$10.0 million, we will need to maintain a minimum closing bid price of \$3.00 rather than \$1.00.

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

### Item 3. Quantitative and Qualitative Disclosures About Market Risk

We own financial instruments that are sensitive to market risks as part of our investment portfolio. The investment portfolio is used to preserve our capital until it is required to fund operations, including our research and development activities. None of these market-risk sensitive instruments are held for trading purposes. We do not own derivative financial instruments in our investment portfolio. Our investment portfolio contains instruments that are subject to the risk of a decline in interest rates. For example, if the annualized interest rate on our interest bearing investments were to change 1%, investment income would have hypothetically increased or decreased by approximately \$219,000 during the six months ended June 30, 2003. This hypothetical analysis does not take into consideration the effects of the economic conditions that would give rise to such an interest rate change or our response to such hypothetical conditions.

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

### Item 4. Controls and Procedures.

The Company's Chief Executive Officer and Controller evaluated the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2003. Based on this evaluation, the Company's Chief Executive Officer and Controller have concluded that, as of June 30, 2003, the Company's disclosure controls and procedures were (1) designed to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to the Company's Chief Executive Officer and Controller by others within those entities, particularly during the period in which this report was being prepared and

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(2) effective, in that they provide reasonable assurance that the information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

No change in the Company's internal control over financial reporting (as defined in 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended June 30, 2003 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

Item 2. Changes in Securities and Use of Proceeds

(c) The Company did not sell any equity securities during the quarter ended June 30, 2003 that were not registered under the Securities Act.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

See the Exhibit Index on the page immediately preceding the exhibits for a list of exhibits filed or furnished as part of this Quarterly Report, which Exhibit Index is incorporated herein by reference.

(b) Reports on Form 8-K

The Company filed the following Report on Form 8-K during the quarter ended June 30, 2003.

(1) On April 18, 2003, the Company filed a Current Report on Form 8-K to report, pursuant to Item 5, that it had entered into a definitive merger agreement with GevVec, Inc.

SIGNATURES

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

Diacrin, Inc.

July 30, 2003

/s/ Thomas H. Fraser  
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Thomas H. Fraser  
President and  
Chief Executive Officer

/s/ Kevin Kerrigan  
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Kevin Kerrigan  
Controller

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## EXHIBIT INDEX

| Exhibit Number | Description   |
|----------------|---|
| 31.1           | Chief Executive Officer<br>- Rule 13a-14(a)/15d-<br>14(a) Certification   |
| 31.2           | Controller - Rule 13a-<br>14(a)/15d - 14(a)<br>Certification  |
| 32.1           | Chief Executive Officer<br>- Certification pursuant<br>to 18 U.S.C. Section<br>1350, as adopted<br>pursuant to Section 906<br>of the Sarbanes-Oxley<br>Act of 2002. |
| 32.2           | Controller -<br>Certification pursuant<br>to 18 U.S.C. Section<br>1350, as adopted<br>pursuant to Section 906<br>of the Sarbanes-Oxley<br>Act of 2002.              |