

THERASENSE INC  
Form 10-Q  
May 15, 2002  
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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**Form 10-Q**

(Mark One)

**( X ) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934  
FOR THE PERIOD ENDED MARCH 31, 2002**

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 Number: 000-33139**

**THERASENSE, INC.**

(Exact name of Registrant issuer as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**94-3267373**  
(I.R.S. Employer  
Identification No.)

**1360 South Loop Road, Alameda, California**  
(Address of principal executive offices)

**94502**  
(Zip code)

**(510) 749-5400**  
(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 X No     

As of May 1, 2002, Registrant had outstanding 39,719,189 shares of Common Stock, \$0.001 par value.

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QUARTERLY REPORT ON FORM 10-Q***

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**Table of Contents****PART I: FINANCIAL INFORMATION****ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**THERASENSE, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except per share amounts)  
(unaudited)

|  | Three Months Ended<br>March 31, |             |
|--|---------------------------------|-------------|
|  | 2002                            | 2001        |
| Total revenues   | \$ 33,279                       | \$ 7,677    |
| Cost of revenues   | 18,408                          | 6,225       |
| Gross profit   | 14,871                          | 1,452       |
| Operating expenses:  |                                 |             |
| Research and development   | 4,441                           | 2,798       |
| Selling, general and administrative  | 21,905                          | 11,033      |
| Total operating expenses   | 26,346                          | 13,831      |
| Loss from operations   | (11,475)                        | (12,379)    |
| Interest income, net   | 490                             | 199         |
| Net loss   | (10,985)                        | (12,180)    |
| Deemed dividend related to beneficial conversion feature of preferred stock.           |                                 | (23,303)    |
| Net loss attributable to common stockholders   | \$ (10,985)                     | \$ (35,483) |
| Net loss per common share, basic and diluted   | \$ (0.28)                       | \$ (7.62)   |
| Weighted-average shares used in computing net loss per common share, basic and diluted | 39,429                          | 4,659       |

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

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**THERASENSE, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(in thousands)

|  | <b>March 31,<br/>2002</b> | <b>December 31,<br/>2001</b> |
|--|---------------------------|------------------------------|
|  | <b>(unaudited)</b>        | <b>(Note 1)</b>              |
| <b>Assets</b>                              |                           |                              |
| Current assets:                            |                           |                              |
| Cash and cash equivalents                  | \$ 69,599                 | \$ 143,187                   |
| Available-for-sale investments             | 6,970                     |                              |
| Accounts receivable, net                   | 26,464                    | 21,260                       |
| Inventories                                | 9,770                     | 6,649                        |
| Deferred cost of products sold             | 16,192                    | 16,359                       |
| Prepaid expenses and other current assets  | 6,263                     | 8,239                        |
|  | <b>_____</b>              | <b>_____</b>                 |
| Total current assets                       | 135,258                   | 195,694                      |
| Available-for-sale investments             | 40,753                    | 4,278                        |
| Property and equipment, net                | 7,671                     | 6,539                        |
| Other assets                               | 3,473                     | 2,830                        |
|  | <b>_____</b>              | <b>_____</b>                 |
| Total assets                               | <b>\$ 187,155</b>         | <b>\$ 209,341</b>            |
|  | <b>_____</b>              | <b>_____</b>                 |
| <b>Liabilities and stockholders equity</b> |                           |                              |
| Current liabilities:                       |                           |                              |
| Accounts payable                           | \$ 13,633                 | \$ 20,223                    |
| Accrued liabilities                        | 16,527                    | 19,363                       |
| Deferred revenue                           | 22,180                    | 23,709                       |
| Current portion of long-term debt          | 3,749                     | 3,990                        |
|  | <b>_____</b>              | <b>_____</b>                 |
| Total current liabilities                  | 56,089                    | 67,285                       |
| Long-term debt                             | 3,669                     | 4,255                        |
| Other liabilities                          | 3,511                     | 4,262                        |
|  | <b>_____</b>              | <b>_____</b>                 |
| Total liabilities                          | 63,269                    | 75,802                       |
|  | <b>_____</b>              | <b>_____</b>                 |
| Stockholders equity:                       |                           |                              |
| Common stock                               | 39                        | 39                           |
| Additional paid-in capital                 | 268,746                   | 270,376                      |
| Notes receivable from stockholders         | (291)                     | (292)                        |
| Deferred stock-based compensation, net     | (17,721)                  | (20,995)                     |
| Accumulated deficit                        | (126,574)                 | (115,589)                    |
| Accumulated other comprehensive loss       | (313)                     |                              |
|  | <b>_____</b>              | <b>_____</b>                 |
| Total stockholders equity                  | 123,886                   | 133,539                      |
|  | <b>_____</b>              | <b>_____</b>                 |
| Total liabilities and stockholders equity  | <b>\$ 187,155</b>         | <b>\$ 209,341</b>            |
|  | <b>_____</b>              | <b>_____</b>                 |

(1) The balance sheet at December 31, 2001 has been derived from the audited financial statement at that date but does not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements.

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



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**THERASENSE, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)  
(unaudited)

|   | Three Months Ended<br>March 31, |                   |
|---|---------------------------------|-------------------|
|   | 2002                            | 2001              |
| <b>Cash flows from operating activities:</b>                                |                                 |                   |
| Net loss  | \$ (10,985)                     | \$ (12,180)       |
| Adjustments to reconcile net loss to net cash used in operating activities: |                                 |                   |
| Depreciation and amortization   | 645                             | 422               |
| Amortization of deferred stock-based compensation                           | 1,508                           | 915               |
| Other   | 67                              | 142               |
| Changes in operating assets and liabilities:                                |                                 |                   |
| Accounts receivable   | (5,204)                         | (610)             |
| Inventories   | (3,121)                         | (299)             |
| Deferred cost of products sold  | 168                             | (2,291)           |
| Prepaid expenses and other current assets                                   | 1,973                           | (1,845)           |
| Other assets  | (710)                           | (413)             |
| Accounts payable  | (6,591)                         | (1,253)           |
| Accrued and other liabilities   | (2,837)                         | 2,033             |
| Deferred revenue  | (1,779)                         | 2,978             |
| Other liabilities   | (500)                           |                   |
|   | <u>          </u>               | <u>          </u> |
| Net cash used in operating activities                                       | (27,366)                        | (12,401)          |
|   | <u>          </u>               | <u>          </u> |
| <b>Cash flows from investing activities:</b>                                |                                 |                   |
| Purchase of investments   | (43,757)                        | (613)             |
| Purchase of property and equipment  | (1,777)                         |                   |
|   | <u>          </u>               | <u>          </u> |
| Net cash used in investing activities                                       | (45,534)                        | (613)             |
|   | <u>          </u>               | <u>          </u> |
| <b>Cash flows from financing activities:</b>                                |                                 |                   |
| Proceeds from issuance of convertible preferred stock, net                  |                                 | 48,618            |
| Proceeds from exercise of stock options                                     | 138                             | 32                |
| Principal payments on long-term debt  | (826)                           | (645)             |
|   | <u>          </u>               | <u>          </u> |
| Net cash provided by (used in) financing activities                         | (688)                           | 48,005            |
|   | <u>          </u>               | <u>          </u> |
| Net change in cash and cash equivalents                                     | (73,588)                        | 34,991            |
| Cash and cash equivalents, beginning of period                              | 143,187                         | 12,533            |
|   | <u>          </u>               | <u>          </u> |
| Cash and cash equivalents, end of period                                    | \$ 69,599                       | \$ 47,524         |
|   | <u>          </u>               | <u>          </u> |

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

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**THERASENSE, INC.  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(unaudited)**

**NOTE 1 Summary of Significant Accounting Policies:**

**Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements of TheraSense, Inc. and its subsidiaries ( TheraSense or the Company ) have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three month period ended March 31, 2002 are not necessarily indicative of the results that may be expected for the year ending December 31, 2002, or for any future period. These financial statements and notes should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2001 included in the Company's Form 10-K for the year ended December 31, 2001.

**Basis of Consolidation and Foreign Currency Translation**

The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All material intercompany balances and transactions have been eliminated.

The Company's international subsidiaries use the local currency as their functional currency. Assets and liabilities are translated at exchange rates in effect at the balance sheet date and revenue and expense accounts at average exchange rates during the period. Resulting translation adjustments are recorded directly to a separate component of stockholders' equity.

**Comprehensive Loss**

Comprehensive loss generally represents all changes in stockholders' equity except those resulting from investments or contributions by stockholders. The Company's unrealized gains on available-for-sale investments and cumulative translation adjustment represent the components of comprehensive loss that are excluded from the net loss.

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**THERASENSE, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(unaudited)**

**NOTE 2 Net Loss Per Share:**

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of vested common shares outstanding for the period. Diluted net loss per share is computed giving effect to all potential dilutive common stock, including options, warrants and convertible preferred stock. Options, warrants, common stock subject to repurchase and convertible preferred stock were not included in the computation of diluted net loss per common share because the effect would be antidilutive.

A reconciliation of the numerator and denominator used in the calculation of basic and diluted net loss per common share follows (in thousands):

|   | <b>Three Months Ended<br/>March 31,</b> |                    |
|---|---|--------------------|
|   | <b>2002</b>                             | <b>2001</b>        |
|   | <b>(unaudited)</b>                      |                    |
| <b>Numerator:</b>   |   |                    |
| Net loss  | \$ (10,985)                             | \$ (12,180)        |
| Deemed dividend related to beneficial conversion feature of preferred stock |   | (23,303)           |
|   | <b>\$ (10,985)</b>                      | <b>\$ (35,483)</b> |
| <b>Denominator:</b>   |   |                    |
| Weighted-average common stock outstanding                                   | 39,544                                  | 5,164              |
| Less: Weighted-average shares subject to repurchase                         | (115)                                   | (505)              |
|   | <b>39,429</b>                           | <b>4,659</b>       |

The following outstanding options, common stock subject to repurchase, convertible preferred stock and warrants were excluded from the computation of diluted net loss per common share attributable to common stockholders as they had an antidilutive effect (in thousands):

|                                    | <b>March 31,</b>   |             |
|------------------------------------|--------------------|-------------|
|                                    | <b>2002</b>        | <b>2001</b> |
|                                    | <b>(unaudited)</b> |             |
| Options to purchase common stock   | 7,325              | 4,713       |
| Common stock subject to repurchase | 67                 | 398         |
| Convertible preferred stock        |                    | 26,101      |
| Warrants                           |                    | 521         |



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**THERASENSE, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(unaudited)**

**NOTE 3 Pro Forma Net Loss Per Common Share:**

Pro forma basic and diluted net loss per common share have been computed to give effect to convertible preferred stock that converted to common stock upon the closing of the Company's initial public offering (using the as-if-converted method) in October 2001. A reconciliation of the numerator and denominator used in the calculation of pro forma basic and diluted net loss per common share follows (in thousands, except for per share amounts):

|  | <b>Three Months Ended<br/>March 31, 2001</b> |
|--|--|
|  | <b>(unaudited)</b>                           |
| Pro forma net loss per common share, basic and diluted:  |  |
| Net loss attributable to common stockholders   | \$ (35,483)                                  |
| Deemed dividend related to beneficial conversion feature of preferred stock                                  | 23,303                                       |
|  | (12,180)                                     |
| Net loss   | \$ (12,180)                                  |
|  |  |
| Weighted-average shares used in computing basic and diluted net loss per common share                        | 4,659  |
| Adjustments to reflect the effect of the assumed conversion of the preferred stock from the date of issuance | 24,300                                       |
|  | 28,959                                       |
| Weighted-average shares used in computing pro forma net loss per common share, basic and diluted             | 28,959                                       |
|  |  |
| Pro forma net loss per common share, basic and diluted   | \$ (0.42)                                    |

**NOTE 4 Inventories:**

At March 31, 2002 and December 31, 2001, inventories consisted of the following (in thousands):

|                 | <b>March 31, 2002</b> | <b>December 31, 2001</b> |
|-----------------|-----------------------|--------------------------|
|                 | <b>(unaudited)</b>    |                          |
| Raw materials   | \$ 2,274              | \$ 2,090                 |
| Work-in-process | 3,280                 | 2,673                    |
| Finished goods  | 4,216                 | 1,886                    |
|                 | \$ 9,770              | \$ 6,649                 |

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**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

This Management's Discussion and Analysis of Financial Condition and Results of Operations and other parts of this Form 10-Q contain forward-looking statements that involve risks and uncertainties. These statements typically may be identified by the use of forward-looking words or phrases such as believe, expect, intend, anticipate, should, planned, estimated, and potential, among others. All forward-looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a safe harbor for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experience to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our businesses include but are not limited to: (1) our limited operating experience and history of losses; (2) our dependence on FreeStyle for future revenues; (3) substantial competition; (4) risks related to failure to protect our intellectual property and litigation in which we may become involved; (5) limited manufacturing experience and sole source suppliers; (6) our limited sales and marketing experience; (7) risks related to noncompliance with FDA regulations; and (8) other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission, including those set forth in this filing as Risk Factors Affecting Operations and Future Results.

All percentage amounts and ratios were calculated using the underlying data in thousands. Operating results for the three period ended March 31, 2002, are not necessarily indicative of the results that may be expected for the full fiscal year or any future period.

**Overview and Critical Accounting Policies**

We develop, manufacture and sell easy to use glucose self-monitoring systems that dramatically reduce the pain of testing for people with diabetes. Our first product, FreeStyle, received FDA clearance in January 2000, and we commenced commercial shipments in the United States in June 2000. We sell FreeStyle in the United States and Canada through national retailers and wholesalers, and directly to consumers over the telephone and through our website. In March 2001, we obtained the CE Mark for FreeStyle, and our European distributor commenced sales of FreeStyle in Germany and Sweden in May 2001 and commenced sales of FreeStyle in Finland, Austria, Norway, the Netherlands, Denmark and Switzerland since that time. In January 2002, we obtained regulatory approval to market FreeStyle in Japan, and our Japanese distributor launched FreeStyle in Japan in February 2002.

We incurred significant operating losses and negative cash flows from operations in each full fiscal year since inception. We incurred net losses of \$13.1 million in 1999, \$43.6 million in 2000, \$52.9 million in 2001 and \$ 11.0 million for the three months ended March 31, 2002. As of March 31, 2002, we had an accumulated deficit of \$126.6 million. We expect to incur significant additional losses as we expand our sales and marketing efforts and continue to develop new products.

Revenues are generated from sales of our FreeStyle System kit and from the recurring sales of disposable FreeStyle test strips and lancets. Our return policy allows end users in the United States and Canada to return FreeStyle System kits to us for a full cash refund within 30 days of purchase. There are no end-user return rights on sales of FreeStyle test strips and lancets. In addition, our FreeStyle System kit and FreeStyle test strips currently have an 18 month shelf life, and retailers and wholesalers in the United States and Canada can return these products to us up to six months beyond this expiration date. As a result of these rights of return and the current unavailability of historical trends in sales and product returns, we have deferred recognition of revenue on sales of FreeStyle test strips until resold by the retailers and wholesalers to end users, and we deferred recognition of revenue on FreeStyle System kits until 30 days after purchase by the end user. Because we lacked a sufficient historical basis from which we could estimate return rates, we were required to rely on data estimates provided to us by third-party data providers in order to recognize revenue from sales to end users by retailers and wholesalers. These data estimates may cause imprecise revenue recognition, as these third-party data providers may not provide consistent, reliable data. We believe that we will have a sufficient historical basis from which we can estimate return rates beginning with the quarter ending June 30, 2002. For this quarter in which we use our own estimates for return rates, we anticipate that our deferred revenue from product sales will decrease and we will experience a corresponding increase in our recognized revenue from product sales. This one-time event could cause a significant increase in our reported net revenues for the second quarter of 2002. In addition, it is expected that reported gross margin for the

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second quarter of 2002 will be reduced compared to the first quarter of 2002 since a large portion of deferred product revenues are from prior sales of system kits which have a lower gross margin than test strip revenues.

Domestic sales to durable medical equipment suppliers do not have a return right so we recognize revenue from these sales upon shipment. Similarly, products distributed internationally, with the exception of shipments to Canada, have no right of return, and we recognize revenue on these products upon shipment. We recognize revenue on direct product sales over the telephone or through our website to end users upon shipment for FreeStyle test strips and lancets and 30 days after purchase on sales of FreeStyle System kits. Our current sales terms to retailers and wholesalers provide for customer payment within 60 days of shipment on initial orders and payment within 30 days for subsequent orders. We perform ongoing credit evaluations of our customers' financial condition and, generally, require no collateral from our customers. We believe our terms to retailers, wholesalers and end users, including their rights to return, are similar to our competitors' terms.

Manufacturers typically sell their glucose monitoring devices at substantial discounts to list prices, offer customer rebates or provide free product samples to expand their installed base of monitoring devices and thus increase the market for their disposable test strips and lancets. We have been offering and expect to continue to offer similar discounts and rebates on, and free samples of, our FreeStyle System kits to establish an installed base of systems from which we expect to generate recurring revenues from our disposable FreeStyle test strips and lancets. Due to the recent commencement of our sales, we did not have significant historical trends in rebates claimed by end users. As a result, we recorded an allowance for 100% of the allowable rebate as a reduction of revenues reported. We believe that we will have sufficient rebate data to estimate rebate redemptions for the quarter ending June 30, 2002. For this quarter in which we estimate rebate redemptions, we anticipate that our experience on rebate redemptions will approximate the industry norm and the reduction in the rebate accrual rate should not have material impact on our financial results.

The initial product mix of FreeStyle System kits when compared to disposable FreeStyle test strips and lancets will negatively impact our gross margins until we have established a sufficiently large installed base of users, as we currently distribute the FreeStyle System kit at a financial loss due in part to samples, discounts and rebates. In the event we establish a large installed base of systems, we expect to generate an increasing portion of our revenues through recurring sales of our FreeStyle test strips.

Cost of revenues consists primarily of:

- payments to our manufacturing and distribution partners;
- expenses relating to our disposable test strip manufacturing;
- expenses relating to our internal operations;
- expenses relating to our five-year warranty on our FreeStyle meter;
- royalties payable under technology licenses;
- amortization of deferred stock-based compensation; and
- adjustment of FreeStyle System kit inventories to estimated net realizable value.

We provide for the estimated cost of product warranties at the time revenue is recognized. While we engage in extensive product quality programs and processes, including actively monitoring and evaluating the quality of our components suppliers, our warranty obligation is affected by product failure rates, material usage, and service delivery costs incurred in correcting a product failure. We also make estimates to reduce our FreeStyle System kit inventories to estimated fair net realizable value. In doing so, the historical costs of our FreeStyle System kit inventories are compared to realized product revenues, reduced by rebates and estimated direct selling costs.

We manufacture our disposable test strips ourselves at our facility in Alameda, California. We outsource the manufacturing, packaging and testing of our FreeStyle meters to Flextronics International Ltd., an electronics contract manufacturer. Our FreeStyle lancing device and disposable lancets are manufactured by Facet Technologies LLC, a wholly-owned subsidiary of Matria Healthcare, Inc. Our distribution services are performed by Livingston Health Care Systems Inc., a division of UPS Global Logistics.



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Research and development expenses include costs associated with the design, development and testing of our products. These costs consist primarily of:

- salaries and related personnel expenses;
- fees paid to outside service providers;
- expenditures for purchases of laboratory supplies and clinical trials;
- overhead allocated to product development; and
- amortization of deferred stock-based compensation.

All research and development costs are expensed as incurred. Our research and development efforts are periodically subject to significant non-recurring costs and fees that can cause significant variability in our quarterly research and development expenses.

Selling, general and administrative expenses primarily consist of:

- salaries, commissions and related expenses for personnel engaged in sales, marketing, customer service and administrative functions;
- costs associated with advertising, product sampling, trade shows, promotional and other marketing activities;
- general corporate expenses;
- legal and regulatory expenses; and
- amortization of deferred stock-based compensation.

We estimate the uncollectability of our accounts receivable. In doing so, we analyze historical bad debts, customer concentrations, customer credit-worthiness, current economic trends and changes in customer payment terms.

We have recorded deferred stock-based compensation in connection with stock option grants and sales of restricted stock to employees at exercise or sales prices below the deemed fair market value of our common stock. Deferred stock-based compensation for options granted to non-employees has been determined as the fair value of the equity instruments issued. Deferred stock-based compensation for options granted to non-employees is periodically remeasured as the underlying options vest. As of March 31, 2002 we have recorded aggregate deferred stock-based compensation of \$26.7 million, of which \$17.7 million will be amortized to expense on a straight line basis through 2006. This amount is being amortized over the respective vesting periods of these equity instruments, which is typically four years. Stock-based compensation expense has been allocated according to employees and their respective departments and by function for non-employees.

In September 2000, we entered into an exclusive distribution agreement with Disetronic Group relating to the distribution of FreeStyle in Germany, Switzerland, Denmark, Austria, Sweden, Finland, Norway and the Netherlands. In February 2002, this agreement was amended to, among other things, extend the term through December 31, 2006 and to add France, Italy and Belgium to Disetronic's distribution territory. Disetronic commenced sales in Germany and Sweden in May 2001 and since that time has commenced sales in Norway, Finland, Austria, The Netherlands, Denmark and Switzerland. In connection with this agreement, we received an advance payment on a purchase order from Disetronic of \$1.5 million, which we recognized in the second quarter of 2001 as we shipped products.

In April 2001, we entered into a five-year exclusive distribution agreement with Nipro Corporation relating to the distribution of FreeStyle in Japan. Nipro launched FreeStyle in Japan in February 2002. In connection with this agreement, we received a \$5.0 million payment from Nipro, which is being recognized as revenue ratably over the term of the agreement.



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**Table of Contents****Results of Operations***Three Months Ended March 31, 2002 and March 31, 2001*

**Revenues.** Total revenues were \$33.3 million for the three months ended March 31, 2002 as compared to \$7.7 million for the comparable period in 2001. The increase was due primarily to greater sales of FreeStyle System kits and FreeStyle test strips. As of March 31, 2002, deferred revenue was \$22.2 million, of which \$21.2 million is attributable to product shipments awaiting sale through to end users and for the 30-day cash refund period on FreeStyle System kit sales to lapse. Deferred revenue on product shipments decreased by \$1.5 million during the current quarter principally due to increased purchases by end users at retail and reduced inventories by wholesalers and retailers. Only our European distributor, Disetronic, individually accounted for more than 10% of our total revenues for the three months ended March 31, 2002. Two of our customers, McKesson and Walgreens, individually accounted for more than 10% and collectively 35% of our revenues for the three months ended March 31, 2001.

**Cost of revenues.** Cost of revenues increased to \$18.4 million for the three months ended March 31, 2002 from \$6.2 million for the three months ended March 31, 2001, representing an increase of \$12.2 million or 196%. This increase is attributable to higher recognized revenues which grew 333% versus the comparable period in 2001. Amortization of stock-based compensation expense reported in cost of revenues for the three months ended March 31, 2002 was \$0.2 million, as compared to an insignificant amount in the same prior year period.

**Gross Profit.** Gross profit increased to \$14.9 million for the three months ended March 31, 2002 from \$1.5 million for the three months ended March 31, 2001, representing an increase of \$13.4 million or 924%. Our gross margin for three months ended March 31, 2002 improved to 45% from a gross margin of 19% for the three months ended March 31, 2001. Our improved gross margin and gross profit resulted from test strip revenue composing a greater proportion of total revenue, fixed costs being spread over larger sales volumes and reduced test strip and system kit manufacturing costs.

**Research and development expenses.** Research and development expenses increased to \$4.4 million for the three months ended March 31, 2002 from \$2.8 million for the three months ended March 31, 2001, representing an increase of \$1.6 million, or 59%. This increase was primarily attributable to hiring additional personnel and increased spending on product development efforts. Amortization of deferred stock-based compensation was \$0.3 million for the three months ended March 31, 2002 as compared to \$0.2 million in the same prior year period. We expect research and development spending to increase over the next several years as we increase clinical trials for our Continuous Glucose Monitoring System and expand our research and development activities to support our current and future products.

**Selling, general and administrative expenses.** Selling, general and administrative expenses increased to \$21.9 million for the three months ended March 31, 2002 from \$11.0 million for the three months ended March 31, 2001, representing an increase of \$10.9 million, or 99%. This increase was primarily attributable to increases of \$4.7 million spent on product sampling, \$3.4 million for personnel costs largely related to expanding our U.S. direct sales force as well as marketing and business support functions, \$1.0 million for overhead costs and \$0.7 million for travel costs, largely related to our sales force. Amortization of deferred stock-based compensation was \$1.0 million for the three months ended March 31, 2002, as compared to \$0.6 million in the same prior year period. We expect our selling, general and administrative expenses to increase as we increase product sampling, expand our sales force, increase our marketing and promotional activities, and operate as a public company.

**Interest income, net.** Net interest income increased to \$0.5 million for the three months ended March 31, 2002 from \$0.2 million for the three months ended March 31, 2001. This increase was primarily attributable to higher cash, cash equivalents, and investment balances, resulting from the net proceeds of our initial public offering in October 2001. Interest expense remained comparable between the two periods.

**Dividends related to beneficial conversion feature of preferred stock.** Dividends relating to the beneficial conversion of our preferred stock of \$23.3 million were recorded in the three months ended March 31, 2001. These dividends arose due to the issuance of 6,021,842 shares of Series D preferred stock in January and February 2001 for net proceeds of \$51.1 million.

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**Table of Contents****Liquidity and Capital Resources**

In October 2001, we consummated our initial public offering of common stock in which we received net proceeds of \$120.9 million. Previously, we have financed our operations primarily through private placements of convertible preferred stock resulting in net proceeds of \$119.2 million. We have also financed our operations through equipment financing arrangements and other loans with \$7.4 million in principal outstanding at March 31, 2002. Our current principal debt arrangements include both a \$5.0 million subordinated debt agreement at an effective interest rate of 22.3% per annum and a \$2.5 million equipment line of credit at effective interest rates between 8.5% and 9.5% per annum with Comdisco Ventures, a \$3.0 million equipment line of credit at an effective rate 7.3% with GE Healthcare Financial Services, and a \$2.0 million senior loan and security agreement at an effective interest rate of 13.1% per annum with Phoenix Capital. These effective annual interest rates include the amortization of the fair value of warrants issued to Comdisco Ventures and Phoenix Capital. We may no longer borrow capital under these debt arrangements. As of March 31, 2002, we had cash, cash equivalents, and investments of \$117.3 million.

**Cash used in operations.** Net cash used in operating activities was approximately \$27.4 million and \$12.4 million for the three months ended March 31, 2002 and 2001, respectively. For the three months ended March 31, 2002, the difference between our net loss and our net cash used in operating activities reflected increases in accounts receivable and inventories as well as decreases in accounts payable and accrued liabilities. The increase in accounts receivable principally related to the experienced growth in revenues as compared to the previous quarter. The increase in inventories occurred to support planned revenue growth for upcoming quarters, including international expansion into Canada via our wholly-owned subsidiary. The decrease in accounts payable reflected a return to a more normalized balance, based on current business operations, from a balance at December 31, 2001 that was substantially higher than previous levels. The balance in accounts payable at December 31, 2001 included amounts due for the manufacture of a large number system kits manufactured in December 2001. There were no significant changes in vendor payment terms and practices during the current quarter. The decrease in accrued liabilities during the current quarter reflected semiannual royalty payments under our principal licensing agreements and bonus payments to our employees under the 2001 incentive plan.

**Cash used in investing activities.** Net cash used in investing activities was approximately \$45.5 million and \$0.6 million for the three months ended March 31, 2002 and 2001, respectively. During the current quarter, some of the proceeds from the initial public offering in October 2001 were invested in corporate bonds, municipal securities, and governmental securities. All investments are classified as available-for-sale securities. Capital expenditures for the current quarter include manufacturing equipment used in the production of our disposable test strips, as we increased production capacity to meet planned growth.

**Cash provided by (used in) financing activities.** Net cash used in financing activities for the current quarter was approximately \$0.7 million, primarily attributable to principal payments on long-term debt. Net cash provided by financing activities was \$48.0 million for the three months ended March 31, 2001, primarily attributable to the net proceeds from private placements of equity securities, partially offset by principal payment on long-term debt.

We may have negative cash flows from operations for the next 12 months. We also expect increased sales and marketing expenses related to the promotion of FreeStyle, increased research and development expenses, as well as expenses for additional personnel and product enhancement efforts. Our future capital requirements will depend on a number of factors, including market acceptance of FreeStyle, the resources we devote to developing and supporting our products, continued progress of our research and development of potential products, the need to acquire licenses to technology and the availability of other financing. Our capital expenditures for the three months ended March 31, 2002 were \$1.8 million, and we believe that our capital requirements for the next 12 months will increase as a result of expanding our facilities. We believe that our current cash, cash equivalents and investment balances, together with the revenue to be derived from sales of FreeStyle, will be sufficient to fund our operations for at least the next 18 months. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to raise additional capital or incur additional indebtedness to fund our operations. Additional equity or debt financing, if required, may not be available on acceptable terms, or at all. If we are unable to obtain additional capital, we may be required to reduce our selling and marketing activities for FreeStyle, delay, reduce the scope of or eliminate our research and development programs, or relinquish rights to technologies or products that we might otherwise seek to develop or commercialize. In the event that we do raise additional equity financing, investors will be further diluted. In the event we incur additional indebtedness to fund our operations, we may have to grant the lender a security

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interest in our assets.

**Inflation**

The impact of inflation on our business has not been material to date.

**Risk Factors Affecting Operations and Future Results**

**We have limited operating experience and a history of net losses and may never achieve or maintain profitability.**

We have a limited history of operations and have focused primarily on research and development, product engineering, clinical trials and seeking FDA regulatory clearance to market our products. We received FDA clearance for FreeStyle, our first commercial product, in January 2000, and we commenced commercial shipments in June 2000. We have generated only limited revenues from the sale of our products to date and have incurred losses every year since 1997. We incurred losses of \$13.1 million in 1999, \$43.6 million in 2000, \$52.9 million in 2001 and \$11.0 million in the three months ended March 31, 2002. As of March 31, 2002, we had an accumulated deficit of approximately \$126.6 million. It is possible that we will never generate sufficient revenues from product sales to achieve profitability. Even if we do achieve significant revenues from our product sales, we expect that increased operating expenses will result in significant operating losses over the next several quarters as we, among other things:

- expand our domestic and international selling and marketing activities as we attempt to gain market share for FreeStyle;

- increase our research and development efforts to improve our existing products and develop new products such as our Continuous Glucose Monitoring System;

- perform clinical research and trials in an effort to obtain governmental clearance and approval for the commercial sale of our Continuous Glucose Monitoring System; and

- expand our facilities in Alameda, California.

We will need to significantly increase the revenues we receive from sales of our products. We may be unable to do so, and therefore, may never achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

**We expect to derive substantially all of our future revenue from sales of FreeStyle, a product we recently introduced, and this product could fail to generate significant revenues and achieve market acceptance.**

Currently, the primary products we market are the FreeStyle System kit, FreeStyle lancets and FreeStyle test strips, all of which we commercially introduced in June 2000. Our FreeStyle products are expected to account for substantially all of our revenues for at least the next several years. Accordingly, our success depends upon the acceptance by people with diabetes, as well as health care providers and third-party payors of FreeStyle as a preferred blood glucose self-monitoring device. As a relatively new company in the area of glucose self-monitoring, we may have difficulty raising the brand awareness necessary to generate interest in FreeStyle.

To date, only a limited number of people have used FreeStyle, and people with diabetes or the medical community may not endorse FreeStyle as a preferred blood glucose self-monitoring device. In addition, FreeStyle may not achieve market acceptance on a timely basis, if at all, due to:

- the significant influence of established glucose monitoring products;

- the ability of some of our competitors to price products below a price at which we can competitively manufacture and sell our products;

- the introduction or acceptance of competing products or technologies; and

- cost constraints.

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Furthermore, FreeStyle may not encourage more active testing, and participants in the glucose self-monitoring market may gravitate toward more established brands. If we are unable to successfully market and sell our FreeStyle products, we may not be able to generate significant revenues or achieve profitability because we do not have alternative products.

In addition, to encourage market acceptance of our products, we currently distribute the FreeStyle System kit at a financial loss through samples, discounts and rebates. In order to generate sufficient revenues in the future, we will therefore have to rely on recurring revenue from the repeated purchase of our FreeStyle test strips. If FreeStyle does not gain sufficient market share to generate significant recurring revenue from the sale of our test strips, we may not achieve profitability.

### **We face competition from competitors with greater resources, which may make it more difficult for us to achieve significant market penetration.**

The market for medical devices is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. We compete directly with Roche Diagnostics Corporation, LifeScan, Inc., a division of Johnson & Johnson, MediSense, a division of Abbott Laboratories, and Bayer AG, which currently account for approximately 90% of the worldwide sales of blood glucose self-monitoring systems. Each of these companies is either publicly traded or a division of a publicly-traded company, and enjoys several competitive advantages, including:

- significantly greater name recognition;

- established relations with health care professionals, customers and third-party payors

- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or incentives to gain a competitive advantage;

- established distribution networks and relationships with retailers; and

- greater resources for product development, sales and marketing and patent litigation.

These companies and others have developed and will continue to develop and acquire new products that compete directly with our products. In addition, our competitors spend significantly greater funds for the research, development, promotion and sale of new and existing products. These resources can allow them to respond more quickly to new or emerging technologies and changes in customer requirements. For all the foregoing reasons, we may not be able to compete successfully against our current and future competitors.

### **Because the medical device industry is litigious, we may be sued for allegedly violating the intellectual property rights of others.**

The medical technology industry has in the past been characterized by a substantial amount of litigation and related administrative proceedings regarding patents and intellectual property rights. In addition, major medical device companies have used litigation against emerging growth companies as a means of gaining a competitive advantage.

Should third parties file patent applications or be issued patents claiming technology also claimed by us in pending applications, we may be required to participate in interference proceedings in the U.S. Patent and Trademark Office to determine the relative priorities of our inventions and the third parties' inventions. We could also be required to participate in interference proceedings involving our issued patents and pending applications of another entity. An adverse outcome in an interference proceeding could require us to cease using the technology or to license rights from prevailing third parties.

Third parties may claim we are using their patented inventions and may go to court to stop us from engaging in our normal operations and activities. These lawsuits are expensive to defend and conduct and would also consume and divert the time and attention of our management. A court may decide that we are infringing a third party's patents and may order us to cease the infringing activity. The court could also order us to pay damages for the infringement. These damages could be substantial and could harm our business, financial condition and operating results. In September 2001, we received a letter from the exclusive licensee of an issued patent alleging that FreeStyle infringes the patent and requesting that we contact the licensee regarding sublicense opportunities. We have evaluated the patent and have made contact with the licensee to discuss a possible sublicense.



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If we were unable to obtain, on reasonable commercial terms, any necessary license following a determination of infringement or an adverse determination in litigation or in interference or other administrative proceedings, we would have to redesign our products to avoid infringing a third party's patent and could temporarily or permanently have to discontinue manufacturing and selling some of our products. If this were to occur, it would negatively impact future sales.

### **If we fail to protect our intellectual property rights, our competitors may take advantage of our ideas and compete directly against us.**

We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality agreements and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. For example, our patents may be challenged, invalidated or circumvented by third parties. Our patent applications may not be issued as patents in a form that will be advantageous to us. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by employees. Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Even if our intellectual property rights are adequately protected, litigation may be necessary to enforce our intellectual property rights, which could result in substantial costs to us and result in a substantial diversion of management attention. If our intellectual property is not adequately protected, our competitors could use our intellectual property to enhance their products. This would harm our competitive position, decrease our market share or otherwise harm our business.

### **The prosecution and enforcement of patents licensed to us by third parties are not within our control, and without these technologies, our products may not be successful and our business would be harmed.**

We rely on licenses to use various technologies that are material to our business. We do not own the patents that underlie these licenses. The licenses from Asulab, SA and Unilever PLC grant us the right under specific patents to make and sell diagnostic devices for diabetes monitoring that contain the inventions claimed in the licensed patents. Our rights to use these technologies and employ the inventions claimed in the licensed patents are subject to our licensors abiding by the terms of those licenses. In addition, we do not control the prosecution of the patents to which we hold licenses, and we do not control the strategy for determining when any patents to which we hold licenses should be enforced. Instead, we rely upon our licensors to determine the appropriate strategy for prosecuting and enforcing those patents.

### **We have limited experience manufacturing our FreeStyle test strips in substantial quantities, and if we are unable to purchase additional equipment or are otherwise unable to meet customer demand, we may not improve our sales growth sufficiently to achieve profitability.**

To be successful, we must manufacture our FreeStyle test strips in substantial quantities at acceptable costs. If we do not succeed in manufacturing sufficient quantities of our test strips to meet customer demand, we could lose customers and fail to acquire new customers, if they choose a competitor's product because our product is not available. We currently manufacture our FreeStyle test strips using a process with which we have limited experience. Increasing demand since the launch of FreeStyle has necessitated an increase in our test strip manufacturing capacity. In response, we are now operating a second manufacturing line at our facilities in Alameda, California. The delay in receiving certain specialized equipment extended the date when we were able to begin operations on the second line. If demand for FreeStyle increases further, we may need to purchase additional specialized equipment with substantial lead times and obtain additional raw materials in order to increase the output volume of our test strips. If we are unable to obtain the necessary equipment or raw materials to effectively manufacture and meet customer demand for our FreeStyle test strips, we may not improve our sales growth sufficiently to achieve profitability.

### **We currently depend on single suppliers and manufacturers for our FreeStyle products, and the loss of any of these suppliers or manufacturers could harm our business.**

Our FreeStyle meters, along with our FreeStyle lancing devices and lancets, are each currently manufactured according to our specifications by single third-party manufacturers. The meters, lancing devices and lancets are manufactured from components purchased from outside suppliers, and some of these components are currently single-sourced. We have recently experienced delays in the delivery of some sole sourced electronic components for our meters. Our FreeStyle test strips, which we manufacture ourselves, are comprised of several components obtained from single-source suppliers. In the event we are unable, for whatever reason, to obtain components from suppliers as

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scheduled, or if our contract manufacturers are unable to meet our manufacturing requirements, we may not be able to obtain components from alternate suppliers or engage an additional manufacturer in a timely manner. Any disruption or delay in shipments of FreeStyle meters, test strips, lancing devices or lancets could result in the loss of customers or the failure to acquire new customers, if they choose a competitor's product because our product is not available. Such a disruption or delay would negatively affect our revenues. In addition, the purchase of components from alternate suppliers or engaging an additional manufacturer in a timely manner could impose increased costs that could negatively impact our gross margins.

### **We have limited sales and marketing experience and any failure to expand sales of FreeStyle will negatively impact future revenues.**

We currently have limited experience in marketing and selling our products. We received regulatory clearance for our initial product in January 2000 and commenced commercial shipments in June 2000. We currently sell our products in the United States directly, using a sales organization that we assembled following regulatory clearance. Our products require a complex marketing and sales effort targeted at health care professionals, diabetes educators, people with diabetes, pharmacists and national retailers. We significantly expanded our sales and marketing teams in 2001, and we are continuing this expansion in 2002. We will face significant challenges and risks in training, managing and retaining these teams, including managing geographically dispersed efforts and adequately training our people in the use and benefits of our products. We may not be able to hire sufficient additional personnel to increase demand for our products. In addition, we have distribution arrangements for the sale of our products internationally and are dependent upon the sales and marketing efforts of our third-party distributors. These distributors may not commit the necessary resources to effectively market and sell our products. Further, they may not be successful in selling our products. Our financial condition would be harmed if our marketing and sales efforts were unsuccessful.

### **If we are unable to continue to develop innovative products in the glucose monitoring market, our business would be harmed.**

The glucose monitoring market is subject to rapid technological change and product innovations. Our products are based on our proprietary technology, but our competitors may succeed in developing or marketing products that will be technologically superior to ours or be more competitive with regard to product features, such as small sample size. In addition, over \$44 billion is spent annually on diabetes treatment and the National Institutes for Health and other supporters of diabetes research are continually seeking ways to prevent or cure diabetes. Therefore, our products may also be rendered obsolete by technological breakthroughs in diabetes prevention, monitoring or treatment.

We are currently developing additional enhancements for FreeStyle, and we are developing new products such as our Continuous Glucose Monitoring System. Marketing of these products will require FDA and other regulatory clearances and approvals. Development of these products will require additional research and development expenditures. We may not be successful in developing, marketing or manufacturing these new products. In addition, several of our competitors are in various stages of development of products similar to our Continuous Glucose Monitoring System, and the FDA has approved two of these products. If any of our competitors succeeds in developing a commercially viable product for continuous glucose monitoring and obtains government approval or successfully commercializes its FDA-approved product, this could negatively affect our future revenues.

### **If we fail to obtain or maintain necessary FDA clearances or approvals for products, or if approvals are delayed, we will be unable to commercially distribute and market our products in the United States.**

Our products are medical devices that are subject to extensive regulation in the United States and in foreign countries where we do business. Unless an exemption applies, each medical device that we wish to market in the United States must first receive either 510(k) clearance or premarket approval from the FDA. Either process can be lengthy and expensive. The FDA's 510(k) clearance process usually takes from four to twelve months from the date the application is complete, but may take longer. Although we have obtained 510(k) clearance for our initial product, FreeStyle, our 510(k) clearance can be revoked if safety or effectiveness problems develop. The premarket approval process is much more costly, lengthy and uncertain. It generally takes from one to three years from the date the application is complete or even longer. However, achieving a completed application is a process that may take numerous clinical trials and require the filing of amendments over time. Our Continuous Glucose Monitoring System under development will require premarket approval. Therefore, even if the product is successfully developed, it may not be commercially available for a number of years. We may not be able to obtain additional clearances or approvals in a timely fashion, or at all. Delays in obtaining clearance or approval could adversely affect our revenues and profitability.

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### **Modification to our marketed devices may require new 510(k) clearances or premarket approvals or require us to cease marketing or recall the modified devices until these clearances are obtained.**

Any modification to an FDA cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new FDA 510(k) clearance or possibly premarket approval. The FDA requires every manufacturer to make this determination in the first instance, but the FDA can review any such decision. We have modified aspects of FreeStyle since receiving regulatory approval, but we believe that new 510(k) clearances are not required. In the case of certain labeling changes for FreeStyle, the FDA required a new 510(k) clearance which was obtained in December 2001. We may make additional modifications to FreeStyle and future products after they have received clearance or approval, and in appropriate circumstances, determine that new clearance or approval is unnecessary. The FDA may not agree with any of our decisions not to seek new clearance or approval. If the FDA requires us to seek 510(k) clearance or premarket approval for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. Also, in these circumstances, we may be subject to significant regulatory fines or penalties.

### **If our suppliers or we fail to comply with the FDA's Quality System Regulation, our manufacturing operations could be delayed, and our product sales and profitability could suffer.**

Our manufacturing processes for our FreeStyle test strips, as well as the manufacturing processes utilized by our suppliers of FreeStyle meters, lancing devices, lancets and control solution, are required to comply with the FDA's Quality System Regulation, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. The FDA enforces the Quality System Regulation through unannounced inspections. The manufacturing line for our FreeStyle meters at Flextronics International USA Inc. has not been inspected to date. If we or one of our suppliers fail a Quality System Regulation inspection, our operations could be disrupted and our manufacturing delayed. If we fail to take adequate corrective action in response to any FDA observations, we could face various enforcement actions, which could include a shut-down of our manufacturing operations and a recall of our products, which would cause our product sales and profitability to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements.

### **Our products are subject to product recalls even after receiving FDA clearance or approval, which would harm our reputation.**

The FDA and similar governmental authorities in other countries have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design defects. Any recall of product would divert managerial and financial resources and harm our reputation with customers.

### **We outsource several key parts of our operations and any interruption in the services provided could prevent us from expanding our business.**

We currently outsource several aspects of our business, including the manufacture of FreeStyle meters, lancing devices and lancets, the functioning of our procurement systems, and the operation of our customer service function. Since outsourcing leaves us without direct control over these business functions, interruptions in the services of our third-party providers may be difficult or impossible to remedy in a timely fashion. In addition, we may be unable to obtain the necessary resources from our third-party providers to meet realized growth in our business.

### **Any adverse changes in reimbursement procedures by Medicare or other third-party payors may limit our ability to market and sell our products.**

In the United States, glucose self-monitoring devices and test strips are generally covered by Medicare and other third-party payors, which provide for reimbursement of all or part of the cost of the product. Medicare and other third-party payors are increasingly scrutinizing whether to cover new products and the level of reimbursement for covered products. FreeStyle is currently being reimbursed through Medicare, Medicaid, open formulary plans and certain preferred provider organizations.

International market acceptance of our products will depend, in part, upon the availability of reimbursement within prevailing health care payment systems. Reimbursement and health care payment systems in international markets vary significantly by country, and include both government sponsored health care and private insurance. We may not obtain international reimbursement approvals in a timely manner, if at all. Our failure to receive

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international reimbursement approvals may negatively impact market acceptance of our products in the international markets in which those approvals are sought.

We believe that in the future, reimbursement will be subject to increased restrictions both in the United States and in international markets. Third-party reimbursement and coverage may not be available or adequate in either the United States or international markets. Future legislation, regulation or reimbursement policies of third-party payors may adversely affect the demand for our existing products or our products currently under development or our ability to sell our products on a profitable basis. The lack of third-party payor coverage or the inadequacy of reimbursement could have a material adverse effect on our business, financial condition and results of operations.

### **We may have difficulty managing our growth.**

We expect to continue to experience significant growth in the scope of our operations and the number of our employees. This growth may continue to place a significant strain on our management and operations. Our ability to manage this growth will depend upon our ability to attract, hire and retain skilled employees. Our success will also depend on the ability of our officers and key employees to continue to implement and improve our operational and other systems, to manage multiple, concurrent development projects and to hire, train and manage our employees. Our future success is heavily dependent upon growth and acceptance of new products. If we cannot scale our business appropriately or otherwise adapt to anticipated growth and new product introduction, our business, financial condition and results of operations will be adversely affected.

### **Our success will depend on our ability to attract and retain key personnel and scientific staff.**

We believe our future success will depend upon our ability to successfully manage our growth, including attracting and retaining scientists, engineers and other highly skilled personnel. Our employees may terminate their employment with us at any time and are not subject to employment contracts. Hiring qualified management and technical personnel will be difficult due to the limited number of qualified professionals. Competition for these types of employees is intense in the field of diabetes monitoring and management. We have in the past experienced difficulty in recruiting qualified personnel. If we fail to attract and retain personnel, particularly management and technical personnel, we may not be able to execute on our business plan.

### **Our products carry return policies that do not permit us to recognize revenue from sales to retailers and wholesalers prior to resale to end users.**

Our return policy allows end users in the United States and Canada to return FreeStyle System kits to us for any reason for a full refund within 30 days of purchase. In addition, our FreeStyle System kits and FreeStyle test strips currently have an 18 month shelf life. Retailers and wholesalers in the United States and Canada can return these products to us within six months after this expiration date. If we experience significant returns from retailers, wholesalers or end users, this could seriously harm our business and results of operations. As a result of these rights to return and the unavailability of historical return rates, we defer revenue recognition on sales of test strips until resold by the retailers and wholesalers to end users, and we defer revenue recognition on FreeStyle System kits until 30 days after purchase by the end user.

Because we lack a sufficient historical basis from which we could estimate return rates, we are required to rely on data estimates provided to us by third-party data providers in order to recognize revenue from sales to end users by retailers and wholesalers. These data estimates may cause imprecise revenue recognition, as these third-party data providers may not provide consistent, reliable data. Further, we do not know how long we will be required to rely on these estimates, although we believe that we will have a sufficient historical basis from which we can estimate return rates beginning with the quarter ending June 30, 2002.

### **If we do not provide quality customer service, we would lose customers and our operating results would suffer.**

Our ability to provide superior customer service to our customers, health care professionals and educators is critical. To effectively compete, we must build strong brand awareness among our customers, much of which is based upon personal referrals. In order to gain these referrals, we must provide customer service representatives who are able and available to provide our customers with answers to questions regarding our products. This will require us to continue to build and maintain customer service operations, for which we currently rely on a single third-party provider. We will require increased staff at our third-party provider to further support growth in new customers. Any

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failures or disruption to our customer services operations, or the termination of our contract with our only third-party provider, could cause us to lose customers.

**We currently have only one distributor in Europe and one distributor in Japan, and if these distributors are not successful or we are unable to attract additional distributors, we may never realize significant international revenues.**

In September 2000, we entered into an agreement for the exclusive marketing and sale of FreeStyle in several European countries, subject to regulatory approval. In May 2001, our third-party distributor commercially introduced FreeStyle in Germany and Sweden and has commercially introduced FreeStyle in Finland, Austria, Norway, The Netherlands, Denmark and Switzerland since that time. In February 2002, this agreement was expanded to include France, Italy and Belgium. In April 2001, we entered into an agreement for the exclusive marketing and sale of FreeStyle in Japan.

**Complying with international regulatory requirements is an expensive, time-consuming process and approval is never certain.**

International sales of our products are subject to strict regulatory requirements. The review process varies from country to country, is typically lengthy and expensive, and approval is never certain. We have the required regulatory approvals to market FreeStyle in Europe, Japan, Canada and certain countries in the Middle East. Failure to maintain current foreign approvals or to receive and maintain approvals in other countries would prevent us from expanding international sales of FreeStyle, which would negatively impact our future revenues.

**If we choose to acquire new and complementary businesses, products or technologies instead of developing them ourselves, we may be unable to complete these acquisitions or to successfully integrate an acquired business or technology in a cost-effective and non-disruptive manner.**

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing technologies, customer demands and competitive pressures. Accordingly, we may, in the future, acquire complementary businesses, products, or technologies instead of developing them ourselves. We do not know if we will be able to complete any acquisitions, or whether we will be able to successfully integrate any acquired business, operate it profitably or retain its key employees. Integrating any business, product or technology we acquire could be expensive and time consuming, disrupt our ongoing business and distract our management. If we are unable to integrate any acquired entities, products or technologies effectively, our business will suffer. In addition, any amortization of goodwill or other assets or charges resulting from the costs of acquisitions could harm our business and operating results.

**If we become subject to product liability claims, we may be required to pay damages that exceed our insurance coverage.**

Our business exposes us to potential product liability claims that are inherent in the testing, production, marketing and sale of human diagnostic products. While we believe that we are reasonably insured against these risks, we may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Currently, we maintain product liability insurance in the amount of \$22 million. A product liability claim in excess of our insurance coverage would have to be paid out of cash reserves and would harm our reputation in the industry.

**We are subject to additional risks associated with international operations.**

We believe that a significant amount of our future revenues may come from international sales, and these sales are subject to a number of risks. For example, foreign regulatory agencies often establish requirements different from those in the United States. Fluctuations in exchange rates of the U.S. dollar against foreign currencies may affect demand for our products overseas. In addition, our international sales may be adversely affected by export license requirements, the imposition of governmental controls, political and economic instability, trade restrictions, changes in tariffs and difficulties in staffing and managing international operations.

**If we require future capital, we may not be able to secure additional funding in order to expand our operations and develop new products.**

We may seek additional funds from public and private stock offerings, borrowings under lease lines of credit or other sources. This additional financing may not be available on a timely basis on terms acceptable to us, or at all.



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This financing may be dilutive to stockholders or may require us to grant a lender a security interest in our assets. The amount of money we will need will depend on many factors, including:

- revenues generated by sales of FreeStyle and our future products, if any;
- expenses we incur in developing and selling our products;
- the commercial success of our research and development efforts; and
- the emergence of competing technological developments.

If adequate funds are not available, we may have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products. Any of these results would harm our financial condition.

### **We may have warranty claims that exceed our reserves.**

FreeStyle meters carry a five-year warranty against defects in materials and workmanship. We have established reserves for the liability associated with product warranties. However, any unforeseen warranty exposure could adversely affect our operating results.

### **Most of our operations are currently conducted at a single location, and a disaster at this facility is possible and could result in a prolonged interruption of our business.**

We currently conduct all our scientific and test strip manufacturing and most of our management activities at a single location in Alameda, California near known earthquake fault zones. In addition, our facilities were built on fill material dredged from the San Francisco Bay in the 1960s. Our sole supplier of FreeStyle meters also currently manufactures these devices at a single facility in San Jose, California near known earthquake fault zones. We have taken precautions to safeguard our facilities, including insurance, health and safety protocols, and off-site storage of computer data. However, a natural disaster, such as an earthquake, fire or flood, could cause substantial delays in our operations, damage or destroy our manufacturing equipment or inventory, and cause us to incur additional expenses. A disaster could seriously harm our business and adversely affect our reputation with customers. The insurance we maintain against fires, floods, and earthquakes may not be adequate to cover our losses in any particular case.

### **Power outages in California may adversely affect us.**

We conduct all of our scientific, test strip manufacturing and management activities in California and rely on a continuous power supply to conduct operations. Our sole-source supplier of FreeStyle meters is currently manufacturing our meters in a single facility that is also in California. California has previously implemented, and may in the future have to implement, rolling blackouts throughout the state. If blackouts interrupt our power supply, we may be temporarily unable to continue operations at our facilities, which includes the manufacture and production of our FreeStyle test strips. Interruptions in our ability to continue operations at our facilities could delay our shipments of FreeStyle test strips, delay the development of our products, and disrupt communications with our customers, suppliers and third-party manufacturing operations. Future interruptions could result in lost revenue and damage our reputation, either of which could harm our business and results of operations. Furthermore, past shortages in wholesale electricity supplies have caused power prices to increase. If similar shortages occur in the future, our operating expenses will likely increase, which will have a negative effect on our operating results.

### **We may be liable for contamination or other harm caused by materials that we use, and changes in environmental regulations could cause us to incur additional expense.**

Our research and development and clinical processes involve the use of potentially harmful biological materials as well as hazardous materials. We are subject to federal, state and local laws and regulations governing the use, handling, storage and disposal of hazardous and biological materials and we incur expenses relating to compliance with these laws and regulations. If violations of environmental, health, and safety laws occur, we could be held liable for damages, penalties and costs of remedial actions. These expenses or this liability could have a significant negative impact on our financial condition. We may violate environmental, health and safety laws in the future as a result of human error, equipment failure, or other causes. Environmental laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We are subject to potentially conflicting and changing regulatory agendas of political, business, and environmental groups. Changes



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to or restrictions on permitting requirements or processes, hazardous or biological material storage or handling might require an unplanned capital investment and/or relocation. Compliance with new laws or regulations could harm our business, financial condition and results of operations.

### **Our common stock has been and will likely continue to be subject to substantial price and volume fluctuations, and the value of our stock could decline.**

The market prices and trading volumes for emerging growth medical device companies have been highly volatile and are likely to continue to be highly volatile in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our stock:

volume and timing of orders for our products;

monthly variations in market data relative to our competitors;

our ability to develop, obtain regulatory clearance for, and market, new and enhanced products on a timely basis;

the announcement of new products or product enhancements by us or our competitors;

announcements of technological or medical innovations in the monitoring or treatment of diabetes;

product liability claims or other litigation;

quarterly variations in our or our competitors' results of operations;

changes in governmental regulations or in the status of our regulatory approvals or applications;

changes in the availability of third-party reimbursement in the United States or other countries;

changes in earnings estimates or recommendations by securities analysts; and

general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

### **The sales of a substantial number of shares of our common stock, including shares that will become eligible for sale in the near future, may adversely affect the market price for our common stock**

Sales of a significant number of shares of our common stock in the public market or the market perception that these sales may occur, could negatively affect the market price for our common stock. As of May 1, 2002, we had 39,719,189 shares of common stock outstanding. Substantially all of these shares are available for sale. Also, many of our employees, consultants and directors may exercise their stock options in order to sell the stock underlying their options in the market under a registration statement we have filed with the SEC. All of these shares are available for sale.

In addition, the holders of approximately 21.3 million shares of common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Furthermore, if we were to include in a company-initiated registration statement shares held by those holders pursuant to the exercise of their registration rights, those sales could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

**Our principal stockholders, executive officers, directors and director nominees own a significant percentage of our stock, and as a result, the trading price for our shares may be depressed and these stockholders can take actions that may be adverse to investors interests.**

Our executive officers, directors, director nominees and entities affiliated with them beneficially own, in the aggregate, approximately 41.9% of our common stock as of May 1, 2002. This significant concentration of share ownership may adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. These stockholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the

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election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. In addition, they could dictate the management of our business and affairs. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control, or impeding a merger or consolidation, takeover or other business combination that could be favorable to our investors.

### **Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable and could also limit the market price of investors stock.**

Our certificate of incorporation and bylaws will contain provisions that could delay or prevent a change in control of our company. Some of these provisions:

authorize the issuance of preferred stock which can be created and issued by the board of directors without prior stockholder approval, commonly referred to as blank check preferred stock, with rights senior to those of common stock;

prohibit stockholder actions by written consent; and

provide for a classified board of directors.

In addition, we are governed by the provisions of Section 203 of Delaware General Corporate Law. These provisions may prohibit stockholders owning 15% or more of our outstanding voting stock from merging or combining with us. These and other provisions in our amended and restated certificate of incorporation and bylaws and under Delaware law could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in the market price being lower than it would be without these provisions.

### **The liquidity of our common stock is uncertain since it has been publicly traded for a short period of time and may have a limited market.**

Prior to our initial public offering in October 2001, there was no public market for our common stock. We cannot predict the extent to which investor interest in our company will lead to the development of an active, liquid trading market. Active trading markets generally result in lower price volatility and more efficient execution of buy and sell orders for investors.

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**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Although we transact our business in U.S. dollars, future fluctuations in the value of the U.S. dollar may affect the price competitiveness of our products. However, we do not believe that we currently have any significant direct foreign currency exchange rate risk and have not hedged exposures denominated in foreign currencies or any other derivative financial instruments.

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. The recorded carrying amounts of cash and cash equivalents approximate fair value due to their short-term maturities. Fixed income securities are subject to interest rate risk. The investment portfolio is diversified and consists of investment grade securities to minimize credit risk. We do not believe that an increase in market rates would have any significant negative impact on the realized value of our investments, but an increase in market rates could negatively impact the interest expense associated with a portion of our long-term debt. Substantially all of our long-term debt obligations have a fixed rate of interest.

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**Table of Contents****PART II: OTHER INFORMATION****ITEM 1. LEGAL PROCEEDINGS**

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

**ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS**

In October 2001, we closed our initial public offering of 6,900,000 shares of our common stock at a per share price of \$19.00 pursuant to a Registration Statement on Form S-1 (Registration No. 333-64456), which was declared effective on October 11, 2001. Of the \$131,100,000 in gross proceeds raised in connection with the offering, (i) \$9,177,000 was paid to the managing underwriters in connection with underwriting discounts and commissions, and (ii) \$1,023,633 was paid by us in connection with expenses, including legal, printing and filing fees, in connection with the offering.

To date, we have spent a portion of the net proceeds as follows (i) approximately \$400,000 for the purchase of machinery we use to manufacture our test strips, (ii) approximately \$3.3 million to sponsor free product samples and accelerate the hiring of additional sales representatives in an effort to expand our installed base of FreeStyle system kits intended to increase our market for disposable test strips and lancets and (iii) additional amounts for general working capital purposes. We are currently investing the remaining net proceeds from the offering for future use as additional working capital. Such remaining net proceeds have been invested in highly liquid instruments, such as commercial paper and U.S. Government obligations, with an average maturity of twelve months or less.

From January 1, 2002 through March 31, 2002, TheraSense did not issue any unregistered securities.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

None

**ITEM 5. OTHER INFORMATION**

None

**ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K**

(a) Exhibits

| Exhibit<br>Number | Description of Document   |
|-------------------|---|
| **3.1             | Certificate of Incorporation of TheraSense, Inc., a Delaware corporation, as currently in effect  |
| ***3.2            | Bylaws of TheraSense, Inc. as currently in effect   |
| *4.1              | Specimen Common Stock Certificate   |
| ***10.1           | 1997 Stock Plan, as amended, and forms of agreements thereunder                                   |
| *10.2             | 2001 Stock Plan and forms of agreements thereunder  |
| *10.3             | 2001 Employee Stock Purchase Plan and forms of agreement thereunder                               |
| *10.4             | Form of Director and Executive Officer Indemnification Agreement                                  |
| *10.5             | Employment Letter from TheraSense, Inc. to W. Mark Lortz, dated as of October 6, 1997             |
| *10.6             | Technology Purchase Agreement between TheraSense and E. Heller & Co. dated as of October 10, 2000 |
| *10.7             | Cooperative Development Agreement between TheraSense, Inc. and Facet Technologies LLC             |

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- (f/k/a Gainor Medical North America LLC), dated as of December 1, 1998
- \*10.7 (a) First Amendment to Cooperative Development Agreement between TheraSense, Inc. and Facet Technologies LLC (f/k/a Gainor Medical North America LLC), effective June 1, 2001
  - \*10.7 (b) Master Purchase Agreement between TheraSense, Inc. and Facet Technologies LLC effective June 1, 2001
  - \*10.8 Standard Industrial/Commercial Single-Tenant Lease between TheraSense, Inc. and PlyProperties, a Partnership, dated as of February 26, 1999, and addendum thereto
  - \*10.9 Master Purchase Agreement between TheraSense and Flextronics International USA, Inc., dated as of November 3, 1999
  - \*10.10 Assignment of Patent Rights and Technology by and among Board of Regents of the University of Texas System, an agency of the State of Texas, Dr. Adam Heller, E. Heller & Company and TheraSense Inc. dated August 1, 1991
  - \*10.11 First Amendment, dated March 19, 1998, to the Agreement entitled Assignment of Patent Rights and Technology by and among Board of Regents of the University of Texas System, an agency of the State of Texas, Dr. Adam Heller, E. Heller & Company and TheraSense Inc. dated August 1, 1991
  - \*10.12 License Agreement between TheraSense, Inc. and Asulab SA., dated February 23, 2000
  - \*10.13 Warehouse Distribution Contract between TheraSense, Inc. and Livingston Healthcare Service, Inc., dated March 15, 2000
  - \*10.14 International Distributor Agreement between TheraSense, Inc. and Nipro Corporation, dated April 1, 2001
  - \*10.15 International Distributor Agreement between TheraSense, Inc. and Disetronic Handels AG, dated September 13, 2000
  - \*\*\*\*10.15(a) Amendment No. 1 to International Distributor Agreement between TheraSense, Inc. and Disetronic Handels AG, dated February 8, 2002
  - \*10.16 Management Services Agreement between TheraSense, Inc. and ICT Group, Inc., dated January 31, 2000
  - \*10.17 License Agreement between TheraSense, Inc. and Unilever PLC dated February 10, 2000
  - \*10.18 Promissory Note dated March 5, 1999 for the principal aggregate amount of \$72,495 issued by W. Mark Lortz to TheraSense
  - \*10.19 Promissory Note dated July 30, 1998 for the principal aggregate amount of \$17,500 issued by Charles T. Liamos to TheraSense
  - \*10.20 Promissory Note dated March 5, 1999 for the principal aggregate amount of \$15,187.50 issued by Charles T. Liamos to TheraSense
  - \*\*\*\*10.20(a) Amendment to Promissory Note dated July 30, 1998 for the principal aggregate amount of \$17,500 issued by Charles T. Liamos to TheraSense, Inc.
  - \*10.21 Promissory Note dated September 1, 1999 for the principal aggregate amount of \$61,250 issued by Charles T. Liamos to TheraSense
  - \*10.22 Promissory Note dated December 1, 1997 for the principal aggregate amount of \$62,650 issued by W. Mark Lortz to TheraSense, Inc.
  - \*\*\*\*10.22(a) Amendment to Promissory Note dated December 1, 1997 for the principal aggregate amount of \$62,650 issued by W. Mark Lortz to TheraSense, Inc.
  - \*10.23 Amended and Restated Investors Rights Agreement by and among holders of TheraSense Preferred Stock and TheraSense, Inc., dated January 23, 2001, as amended
  - \*10.24 First Amendment to the Agreement Entitled Sponsored Research Agreement No. UTA 98-0296 entered into as of October 10, 2000, by and between TheraSense, Inc. and the Board of Regents of the University of Texas System on behalf of the University of Texas at Austin
  - \*10.25 Form of Change of Control Agreement between TheraSense, Inc. and each Vice President of TheraSense, Inc.
- \* Incorporated by reference to the same exhibit filed with our Registration Statement on Form S-1 (Registration No. 333-64456), which was declared effective on October 11, 2001.
- \*\* Incorporated by reference to Exhibit 3.1(b) filed with our Registration Statement on Form S-1 (Registration No. 333-64456), which was declared effective on October 11, 2001.
- \*\*\* Incorporated by reference to Exhibit 3.2(b) filed with our Registration Statement on Form S-1 (Registration No. 333-64456), which was declared effective on October 11, 2001.
- \*\*\*\* Incorporated by reference to the same exhibit filed with our Form 10-K for the year ended December 31, 2001.



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Confidential treatment granted for portions of these exhibits.

- (a) Reports on Forms 8-K.

TheraSense did not file any reports on Form 8-K during the period covered by this report.

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***SIGNATURE***

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

THERASENSE, INC.

/s/ CHARLES T. LIAMOS

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**Charles T. Lamos**  
**Chief Financial Officer and Chief Operating Officer**  
**(Principal Financial and Accounting Officer)**

Date: May 14, 2002

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