THERASENSE INC
Form 10-Q
August 14, 2003
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

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 JUNE 30, 2003

OR

o **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	**94-3267373**
(State or other jurisdiction of incorporation or organization)	**(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.

YesNo
x o

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Securities Exchange Act of 1934).

YesNo
x o

As of August 1, 2003, Registrant had outstanding 41,317,153 shares of Common Stock, $0.001 par value.

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THERASENSE, INC.
QUARTERLY REPORT ON FORM 10-Q

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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 June 30,		Six Months Ended June 30,	
	2003	2002	2003	2002
Total revenues	$ 50,930	$ 59,227	$ 91,834	$ 92,506
Cost of revenues	22,494	34,428	41,608	52,836
Gross profit	28,436	24,799	50,226	39,670
Operating expenses:				
Research and development	5,677	6,046	10,843	10,487
Selling, general and administrative	26,455	22,159	51,735	44,064
Total operating expenses	32,132	28,205	62,578	54,551
Loss from operations	(3,696)	(3,406)	(12,352)	(14,881)
Interest income, net	220	310	337	800
Net loss	$ (3,476)	$ (3,096)	$ (12,015)	$ (14,081)
Net loss per share, basic and diluted	$ (0.08)	$ (0.08)	$ (0.29)	$ (0.36)
Weighted-average shares used in computing net loss per share, basic and diluted	41,078	39,838	40,956	39,634

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)

	June 30, 2003	December 31, 2002 (1)
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 14,313	$ 32,158
Available-for-sale investments	56,756	34,135
Accounts receivable, net	37,196	36,319
Inventories	14,442	21,060
Prepaid expenses and other current assets	3,540	6,358
Total current assets	126,247	130,030
Available-for-sale investments	7,769	11,217
Property and equipment, net	17,004	14,340
Other assets	4,699	5,216
Total assets	$ 155,719	$ 160,803
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 10,402	$ 17,034
Accrued liabilities	18,048	16,109
Deferred revenue	3,856	1,000
Current portion of long-term debt	908	5,149
Total current liabilities	33,214	39,292
Long-term debt, net of current	1,589	3,161
Deferred revenue	12,684	2,261
Other liabilities		500
Total liabilities	47,487	45,214
Stockholders equity:		
Common stock	41	41
Additional paid-in capital	272,771	271,782
Notes receivable from stockholders	(8)	(156)
Deferred stock-based compensation, net	(8,084)	(11,642)
Accumulated other comprehensive income	279	316
Accumulated deficit	(156,767)	(144,752)
Total stockholders equity	108,232	115,589
Total liabilities and stockholders equity	$ 155,719	$ 160,803

(1) The balance sheet at December 31, 2002 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)

	Six Months Ended June 30,	
	2003	**2002**
Cash flows from operating activities:		
Net loss	$ (12,015)	$ (14,081)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	2,102	1,372
Amortization of deferred stock-based compensation	2,761	3,107
Changes in operating assets and liabilities:		
Accounts receivable	(877)	(14,726)
Inventories	6,618	(8,476)
Deferred cost of products sold		16,359
Prepaid expenses and other current assets	2,818	4,888
Other assets	517	(386)
Accounts payable	(6,632)	(2,351)
Accrued and other liabilities	1,439	(3,420)
Deferred revenue	13,279	(23,210)
Net cash provided by (used in) operating activities	10,010	(40,924)
Cash flows from investing activities:		
Proceeds from maturities of investments	61,398	3,000
Purchases of investments	(80,796)	(49,612)
Purchases of property and equipment	(4,766)	(4,840)
Net cash used in investing activities	(24,164)	(51,452)
Cash flows from financing activities:		
Proceeds from exercise of stock options	1,786	3,263
Principal payments on lines of credit	(35,358)	
Principal payments on long-term debt	(2,324)	(3,336)
Proceeds from lines of credit	31,870	1,658
Repayment of notes receivable from stockholders	147	26
Net cash provided by (used in) financing activities	(3,879)	1,611
Effect of foreign exchange rate changes on cash and cash equivalents	188	(26)
Net change in cash and cash equivalents	(17,845)	(90,791)
Cash and cash equivalents, beginning of period	32,158	143,187
Cash and cash equivalents, end of period	$ 14,313	$ 52,396

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 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 only of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the six month period ended June 30, 2003 are not necessarily indicative of the results that may be expected for the year ending December 31, 2003, or for any future period. These condensed consolidated financial statements and notes should be read in conjunction with the consolidated financial statements and notes thereto for the year ended December 31, 2002 included in the Company s Form 10-K for the year ended December 31, 2002.

NOTE 2 Summary of Significant Accounting Policies*:*

The Company s significant accounting policies are disclosed in the Company s Annual Report on Form 10-K for the year ended December 31, 2002 that was filed with the Securities and Exchange Commission on March 27, 2003. The Company s significant accounting policies have not materially changed since December 31, 2002.

NOTE 3 - Recent Accounting Pronouncements:

In November 2002, the Emerging Issues Task Force (EITF) reached a consensus on Issue No. 00-21, Revenue Arrangements with Multiple Deliverables. EITF Issue No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The Company believes that the adoption of EITF No. 00-21 will not have a material impact on its consolidated financial statements.

In January 2003, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 46 (FIN 46), Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. The Company believes that the adoption of FIN 46 will not have a material impact on its consolidated financial statements.

In May 2003, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity (SFAS 150). SFAS No**.** 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS No. 150 requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. SFAS No. 150 is to be implemented by reporting the cumulative effect of a change in an accounting principle for financial instruments created before the issuance date of SFAS No. 150 and still existing at the beginning of the interim period of adoption. Restatement is not permitted. The Company does not expect the adoption of SFAS No. 150 to have a material impact upon its financial position, cash flows or results of operations.

NOTE 4 - Net Loss Per Share:

Basic net loss per share is computed by dividing net loss 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 and warrants. Options, warrants and common stock subject to repurchase were not included in the computation of diluted net loss per share because the effect would be antidilutive.

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2003	2002	2003	2002
Numerator:				
Net loss	$ (3,476)	$ (3,096)	$ (12,015)	$ (14,081)
Denominator:				
Weighted-average common stock outstanding	41,082	39,895	40,960	39,720
Less: Weighted-average shares subject to repurchase	(4)	(57)	(4)	(86)
Weighted-average shares used in computing basic and diluted net loss per share	41,078	39,838	40,956	39,634

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

	June 30,	
	2003	2002
Options to purchase common stock	7,684	6,766
Common stock subject to repurchase	4	47

NOTE 5 - Inventories:

At June 30, 2003 and December 31, 2002, inventories consisted of the following (in thousands):

	June 30, 2003	December 31, 2002
Raw materials	$ 3,303	$ 5,059
Work-in-process	2,475	3,807
Finished goods	8,664	12,194
	$ 14,442	$ 21,060

NOTE 6 - Accrued product warranties:

The Company s condensed consolidated financial statements include accruals for product warranty claims. The Company provides a five-year warranty on its FreeStyle meters. For proper matching of these costs in the period that revenues are recognized, an estimated warranty expense accrual rate is determined based on historical experience. Such costs are accrued at the time revenue is recognized. At June 30, 2003 and December 31, 2002, accrued product warranties totaled $1,787,590 and $1,931,935, respectively, and are included in accrued liabilities in the accompanying condensed consolidated balance sheets.

A tabular reconciliation of the changes in the Company s product warranty liability for the six months ended June 30, 2003 is as follows (in thousands):

Balance at January 1, 2003	$	1,932
Accruals for warranties issued during the period		690
Settlements made during the period		(834)
Balance at June 30, 2003	$	1,788

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

NOTE 7 Revolving Line of Credit Agreement:

In May 2002, the Company entered into a revolving line of credit agreement with a lending company, which was amended and restated in December 2002. Under the terms of the credit agreement, amounts the Company borrows from the lending company are repaid to the lending company directly by the Company s accounts receivable debtors. Outstanding amounts owed to the lending company under the credit agreement are collateralized by all of the Company s assets excluding the Company s intellectual property assets. The maximum amount the Company may borrow from the lending company is based on its eligible accounts receivable and cannot exceed $15,000,000. All outstanding amounts bear interest at the prime rate plus 0.5%. The amended and restated credit agreement includes certain covenants requiring minimum liquidity and minimum net income over time. As of June 30, 2003, the Company was not in compliance with certain of these covenants. In August 2003, the Company and the lending company entered into an amendment to the amended and restated credit and security agreement that brought the Company into compliance with these covenants. As of June 30, 2003, there were no borrowings outstanding under the credit agreement.

In March 2002, the Company entered into an arrangement to finance the purchase of certain equipment the Company uses to manufacture its FreeStyle test strips with its supplier of test strip packaging vials. The purchase price of the equipment is approximately $1,600,000. From March 2002 to March 2003, the Company paid down the equipment purchase price to the supplier through a portion of the purchase price for each packaging vial purchased from the supplier. In April 2003, the Company paid the remaining purchase price of approximately $1,500,000 for the equipment to the supplier and took title to the equipment.

During 1998, the Company entered into an equipment line of credit agreement with a lending company under which the Company could borrow up to $2,500,000 for equipment purchases prior to December 31, 1999. Prior to December 31, 1999, the Company borrowed a total of approximately $580,000 under this arrangement. During 1999, the Company entered into a subordinated debt agreement with this lending company under which the Company could borrow up to $5,000,000 for equipment purchases prior to July 7, 2000. The Company borrowed a total of $5,000,000 under this arrangement. In April 2003, the Company and the lending company entered into an agreement pursuant to which the Company paid $844,451 as a compromised and final payment of all amounts outstanding under these arrangements, and the Company took title to all of the equipment that had been leased pursuant to these arrangements. The gain recorded from the compromised and final payment is not significant. The gain is recorded on the Interest income, net line item of the Company s condensed consolidated statement of operations.

NOTE 8 Accounting for Stock-Based Compensation:

In December 2002, the FASB issued SFAS No. 148 (SFAS No. 148), Accounting for Stock Based Compensation, Transition and Disclosure, an amendment of FASB Statement No. 123 , which amends FASB Statement No. 123, (SFAS No. 123), Accounting for Stock-Based Compensation . SFAS No. 148 requires more prominent disclosures in both annual and interim financial statements about the method of accounting and effects of stock-based compensation on reported results. The Company uses the intrinsic value method of Accounting Principles Board Opinion No. 25 (APB No. 25), Accounting for Stock Issued to Employees, in accounting for its employee stock options, and presents disclosure of pro forma information required under SFAS No. 123, as amended by SFAS No. 148.

The following table provides a reconciliation of net loss to pro forma net loss as if the fair value method has been applied to all employee stock options outstanding as of the dates indicated below (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2003	2002	2003	2002
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Net loss as reported	$ (3,476)	$ (3,096)	$ (12,015)	$ (14,081)
Add: Stock-based employee compensation expense included in reported net loss	1,299	1,485	2,624	2,800
Deduct : Total stock-based employee compensation expense determined under fair value based method for all awards	(5,398)	(4,243)	(8,147)	(7,110)
Pro forma net loss	$ (7,575)	$ (5,854)	$ (17,538)	$ (18,391)

Weighted average shares used in computing net loss per share, basic and diluted	41,078	39,838	40,956	39,634
Net loss per share, basic and diluted				
As reported	$ (0.08)	$ (0.08)	$ (0.29)	$ (0.36)
Pro forma	$ (0.18)	$ (0.15)	$ (0.43)	$ (0.46)

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

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force Issue No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services, which require that these equity instruments are recorded at their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest.

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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 report 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- 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 history of losses and variable quarterly results; (2) our dependence on FreeStyle for future revenues; (3) our limited sales and marketing experience; (4) substantial competition; (5) risks related to failure to protect our intellectual property and litigation in which we may become involved; (6) risks relating to development of innovative products; (7) risks related to noncompliance with FDA regulations;(8) limited manufacturing experience and our reliance on single manufacturers and sole source suppliers; and (9) 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 and six-month periods ended June 30, 2003, are not necessarily indicative of the results that may be expected for any future period.

Overview

We develop, manufacture and sell easy to use glucose self-monitoring systems that dramatically reduce the pain of testing for people with diabetes. We commenced commercial shipments in the United States of our first product, FreeStyle, 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. 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, Switzerland, France, Italy and Belgium since that time. Our Japanese distributor launched FreeStyle in Japan in February 2002. We also sell FreeStyle in the United Kingdom through retailers and wholesalers. Our sales of FreeStyle products in Canada and the United Kingdom are through a wholly-owned subsidiary in each country.

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 UPS Supply Chain Management f/d/b/a Livingston Health Care Systems Inc., a division of UPS Global Logistics.

Manufacturers typically sell their glucose monitoring system kits at 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 currently distribute the FreeStyle System kit at a financial loss due in part to samples, discounts and rebates to establish an installed base of systems from which we expect to generate recurring revenues from our disposable FreeStyle 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.

Revenues are generated from sales of our FreeStyle System kit and from the recurring sales of disposable FreeStyle test strips and lancets. We recognize revenue on these products upon shipment. Generally, our 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. However, we have occasionally granted longer credit terms to match our competitors. 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 rights to return and payment terms, are similar to our competitors terms.

We have incurred significant operating losses and negative cash flows from operations since inception. We incurred net losses of $43.6 million in 2000, $52.9 million in 2001, $29.2 million in 2002 and $12.0 million for the six months ended June 30, 2003. As of June 30, 2003, we had an accumulated deficit of $156.8 million. We will need to continue to increase product revenues and reduce product costs to achieve profitability.

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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; and
- amortization of deferred stock-based compensation.

Research and development expenses include costs associated with the design, development and testing of our products. All research and development costs are expensed as incurred. 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.

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 June 30, 2003 we have recorded aggregate deferred stock-based compensation of $24.3 million, of which $8.1 million remains and will be amortized to expense on a straight-line basis through 2005. 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.

Critical Accounting Policies and Estimates

Our critical accounting policies and estimates are disclosed in the our Annual Report on Form 10-K for the year ended December 31, 2002 that was filed with the Securities and Exchange Commission on March 27, 2003. Our critical accounting policies and estimates have not materially changed since December 31, 2002.

Results of Operations

Non-GAAP financial information due to impact in 2002 of achieving ability to estimate product return rates. Prior to the quarter ending June 30, 2002 we did not have a sufficient historical basis from which we could estimate product return rates. Accordingly, we deferred recognition of revenue on products shipped to retailers and wholesalers until they were resold to end users and any rights of return had expired. We estimated end user purchases based on data provided to us by third-party data providers. Product shipments that were not recognized as revenue were recorded as deferred revenues on our condensed consolidated balance sheets. The associated cost of these deferred revenues were recorded as deferred cost of products sold on our balance sheet.

Commencing with the quarter ending June 30, 2002 we achieved the ability to estimate product return rates. This event caused a $20.4 million increase in total revenues for the second quarter of 2002 due to the recognition of previously deferred revenues. There was a corresponding $4.2 million increase to our gross profit for the second quarter of 2002 and our gross margin for the period was adversely impacted because the deferred revenues were

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comprised primarily of lower margin system kits rather than test strips. Similarly, our loss from operations was favorably impacted by the gross profit from the previously deferred revenue which mitigated the loss.

Due to the significance of the financial impact from achieving the ability to estimate product return rates in the second quarter of 2002, we have provided the non-GAAP financial information set forth in the tables below. We believe this non-GAAP financial information is useful supplemental information which facilitates meaningful comparisons of operational performance for the fiscal 2002 periods that include this event, with prior and subsequent periods that do not include this event. These non-GAAP measures are not in accordance with, or an alternative for, GAAP and may be different from non-GAAP measures used for other companies.

The following table sets forth, for the periods indicated, condensed consolidated statement of operations data in accordance with generally accepted accounting principals (GAAP) and on a non-GAAP basis adjusted to exclude the impact from achieving the ability to estimate product return rates and recognizing previously deferred revenues, costs and gross profit, in the second quarter of 2002. Set forth between the columns showing GAAP and non-GAAP results is a column indicating the reconciliation to the GAAP results.

	Three Months Ended June 30, 2002			Six Months Ended June 30, 2002		
	GAAP	Reconciliation	Non-GAAP	GAAP	Reconciliation	Non-GAAP
	(in thousands, except per share amounts) (unaudited)					
Total revenues	$ 59,227	$ 20,387	$ 38,840	$ 92,506	$ 20,387	$ 72,119
Cost of revenues	34,428	16,192	18,236	52,836	16,192	36,644
Gross profit	24,799	4,195	20,604	39,670	4,195	35,475
Operating expenses:						
Research and development	6,046		6,046	10,487		10,487
Selling, general and administrative	22,159		22,159	44,064		44,064
Total operating expenses	28,205		28,205	54,551		54,551
Income (loss) from operations	(3,406)	4,195	(7,601)	(14,881)	4,195	(19,076)
Interest income, net	310		310	800		800
Net income (loss)	$ (3,096)	$ 4,195	$ (7,291)	$ (14,081)	$ 4,195	$ (18,276)
Net loss per share, basic and diluted	$ (0.08)	$ 0.10	$ (0.18)	$ (0.36)	$ 0.10	$ (0.46)
Weighted-average shares used in computing net loss per share, basic and diluted.	39,838	39,838	39,838	39,634	39,634	39,364

The following table sets forth, for the periods indicated, the percentage of total revenues represented by certain items reflected in our condensed consolidated statement of operations in accordance with GAAP and on a non-GAAP basis adjusted to exclude the impact from achieving the ability to estimate product return rates and recognizing previously deferred revenues, costs and gross profit, in the second quarter of 2002.

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	GAAP		NON-GAAP	GAAP		NON-GAAP
	Three Months Ended June 30		Three Months Ended June 30	Six Months Ended June 30		Six Months Ended June 30
	2003	2002	2002	2003	2002	2002
Revenues:						
Total revenues	100%	100%	100%	100%	100%	100%
Cost of revenues	44.2	58.1	47.0	45.3	57.1	50.8
Gross profit	55.8	41.9	53.0	54.7	42.9	49.2
Operating expenses:						
Research and development	11.2	10.2	15.6	11.8	11.3	14.5
Selling, general and administrative	51.9	37.4	57.0	56.4	47.7	61.1
Total operating expenses	63.1	47.6	72.6	68.2	59.0	75.6
Loss from operations	(7.3)	(5.7)	(19.6)	(13.5)	(16.1)	(26.4)
Interest income, net	0.5	0.5	0.8	0.4	0.9	1.1
Net loss	(6.8)%	(5.2)%	(18.8)%	(13.1)%	(15.2)%	(25.3)%

Three Months Ended June 30, 2003 and 2002

Revenues. Total GAAP revenues were $50.9 million for the three months ended June 30, 2003 as compared to GAAP revenues of $59.2 million for the comparable period of 2002. Non-GAAP revenues, as shown in the table above, were $38.8 million for the second quarter of 2002. The increase in the 2003 GAAP total revenues over the non-GAAP revenues for the comparable period of 2002 was 31%. The increase was due primarily to greater sales of FreeStyle System kits and Freestyle test strips. During the three months ended June 30, 2003, we recognized revenues of $0.6 million relating to the $15.0 million payment we received from the Disetronic Group in January 2003 in connection with the amendment of our international distributor agreement. The balance of the $15.0 million payment is reflected in the current and long-term deferred revenue line items of our consolidated balance sheet. Four of our customers, Walgreens, Cardinal, Disetronic, and McKesson, individually accounted for more than 10% and collectively 44% of our revenues for the three months ended June 30, 2003. Two of our customers, Cardinal and Nipro Corporation, individually accounted for more than 10% and collectively 24% of our total GAAP revenues for the three months ended June 30, 2002.

Cost of revenues. GAAP cost of revenues were $22.5 million for the three months ended June 30, 2003 as compared to GAAP cost of revenues of $34.4 million for the comparable period of 2002. Non-GAAP costs of revenues, as shown in the table above, were $18.2 million for the comparable period of 2002. The increase in the 2003 GAAP cost of revenues over the non-GAAP cost of revenues for the comparable period of 2002 was 23%. This increase is attributable to higher revenues versus the non-GAAP cost of revenues for the comparable period in 2002. Amortization of deferred stock-based compensation reported in cost of revenues for the three months ended June 30, 2003 was $0.1 million, as compared to $0.2 million for the three months ended June 30, 2002.

Gross profit. GAAP gross profit increased to $28.4 million for the three months ended June 30, 2003 from GAAP gross profit of $24.8 million for the comparable period of 2002. Non-GAAP gross profit, as shown in the table above, for the comparable period of 2002 was $20.6 million. The increase in the 2003 GAAP gross profit over the non-GAAP gross profit for the comparable period of 2002 was $7.8 million or 38%. The GAAP gross margin for the three months ended June 30, 2002 was 42% and the non-GAAP gross margin for the three months ended June 30, 2002 was 53%. The GAAP gross margin for this 2002 period was lower than the non-GAAP gross margin for the same period primarily because the GAAP gross margin included the recognition of previously deferred revenues from sales of lower margin system kits. Our GAAP

gross margin for the three months ended June 30, 2003 improved to 56%. Our improved GAAP gross margin and gross profit for the 2003 period resulted from test strip revenue composing a greater proportion of total revenue, a greater proportion of our product sales being made to retailers and wholesalers in the United States, fixed costs being spread over larger sales volumes and reduced test strip and system kit manufacturing costs. Our 2003 period GAAP gross margin was favorably impacted by the recognition of the $0.6 million of revenue during the period from the $15.0 million payment we received from the Disetronic Group.

Research and development expenses. Research and development expenses decreased to $5.7 million for the three months ended June 30, 2003 from $6.0 million for the three months ended June 30, 2002, representing a decrease of $0.3 million, or 5%. This decrease was primarily attributable to reduced product development spending in the quarter partially offset by increases in personnel related expenses. Product development expenses were greater

during the comparable period of 2002 due to in part to the development of our FreeStyle Tracker Diabetes Management System, our FreeStyle CoPilot Web-Based Data Management System and clinical trials for Navigator, our continuous glucose monitoring system. Amortization of deferred stock-based compensation was $0.3 million for both three month periods ended June 30, 2003 and 2002. We expect research and development spending to increase in absolute dollars over the next several years as we expand our research and development activities to support our current and future products, including Navigator, our continuous glucose monitoring system. As a percentage of revenues, we expect research and development spending to decrease over the next several years. We anticipate the research and development expenses will be in the range of 9% 11% of revenues for the next few quarters.

Selling, general and administrative expenses. Selling, general and administrative expenses increased to $26.5 million for the three months ended June 30, 2003 from $22.2 million for the three months ended June 30, 2002, representing an increase of $4.3 million, or 19%. This increase was primarily attributable to advertising, promotional and marketing expenses in the United States and expenses associated with our international sales subsidiaries in the three months ended June 30, 2003. We did not incur any expenses related to our sales subsidiary in the United Kingdom in the comparable period of 2002. Amortization of deferred stock-based compensation was $1.0 million for the three month period ended June 30, 2003 and $1.1 million for the three month period ended June 30, 2002. We expect our selling, general and administrative expenses to remain at approximately the same absolute dollar level for the next two quarters as the quarter ended June 30, 2003.

Interest income, net. Net interest income decreased to $0.2 million for the three months ended June 30, 2003 from $0.3 million for the three months ended June 30, 2002. This decrease was primarily attributable to lower cash, cash equivalents, and investment balances, as we used cash in our operations. Cash, cash equivalents, and investments at June 30, 2003 were $78.8 million compared to $103.1 million at June 30, 2002.

Six Months Ended June 30, 2003 and 2002

Revenues. Total GAAP revenues were $91.8 million for the six months ended June 30, 2003 as compared to GAAP revenues of $92.5 million for the comparable period in 2002. Non-GAAP total revenues, as shown in the table above, for the six-month period ended June 30, 2002 were $72.1 million. The increase in the GAAP total revenues for the six-month 2003 period over the non-GAAP total revenues for the comparable period of 2002 was 27%. This increase is primarily due to greater sales of FreeStyle test strips and Freestyle system kits. Three of our customers, Walgreens, Disetronic, and McKesson, individually accounted for more than 10% and collectively accounted for 33% of our total revenues from shipments in the six months ended June 30, 2003. One of our customers, Nipro Corporation, accounted for more than 10% of our total GAAP revenues from shipments in the six months ended June 30, 2002.

Cost of revenues. GAAP cost of revenues were $41.6 million for the six months ended June 30, 2003 as compared to GAAP cost of revenues of $52.8 million for the comparable period of 2002. Non-GAAP cost of revenues, as shown in the table above, for the six-month period ended June 30, 2002 was $36.6 million. The increase in GAAP cost of revenues for the 2003 period over the non-GAAP cost of revenues for the comparable period of 2002 was $5.0 million or 14%. This increase is due to higher 2003 period GAAP revenues versus the non-GAAP revenues for the comparable period of 2002. Amortization of deferred stock-based compensation expense reported in cost of revenues for the six months ended June 30, 2003 was $0.2 million as compared to $0.4 million for the comparable period of 2002.

Gross profit. GAAP gross profit was $50.2 million for the six months ended June 30, 2003 as compared to GAAP gross profit of $39.7 million for the comparable period of 2002. Non-GAAP gross profit, as shown in the table above, for the six-month period ended June 30, 2002 was $35.5 million. The increase in GAAP gross profit for the 2003 period over the non-GAAP gross profit for the comparable period of 2002 was 42%. The GAAP gross margin for the six months ended June 30, 2002 was 43% and the non-GAAP gross margin for the six months ended June 30, 2002 was 49%. The GAAP gross margin for this 2002 period was lower than the non-GAAP gross margin for the same period primarily because the GAAP gross margin included the recognition of previously deferred revenues from sales of lower margin system kits. The GAAP gross margin for the six months ended June 30, 2003 was 55%. The improved gross margin and gross profit for the 2003 period 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 were $10.8 million for the six months ended June 30, 2003 as compared to $10.5 million for the comparable period of 2002. This represents an increase of 3%. The increase is primarily attributable to increased spending on the hiring of additional personnel and personnel-related expenses partially offset by lower product development costs. Product development expenses were greater during the comparable period of 2002 due to in part to the development of our Freestyle Tracker Diabetes

Management System, our FreeStyle CoPilot Web-Based Data Management System and clinical trials for Navigator, our continuous glucose monitoring system. Amortization of deferred stock-based compensation was $0.6 million for both six month periods ended June 30, 2003 and 2002.

Selling, general and administrative expenses. Selling, general and administrative expenses were $51.7 million for the six months ended June 30, 2003 as compared to $44.1 million for the comparable period of 2002. This represents an increase of $7.6 million, or 17%. This increase was primarily attributable to advertising, promotional and marketing activity in the United States and expenses associated with our international sales subsidiaries in the six months ended June 30, 2003. We did not incur any expenses related to our sales subsidiary in the United Kingdom during the comparable period of 2002. Amortization of deferred stock-based compensation was $2.0 million for the six months ended June 30, 2003, as compared to $2.1 million in the same prior year period.

Interest income, net. Net interest income decreased to $0.3 million for the six months ended June 30, 2003 from $0.8 million for the six months ended June 30, 2002. This decrease was primarily attributable to lower cash, cash equivalents, and investment balances as we used cash in our operations, compared to the comparable period s higher cash, cash equivalents, and investment balances resulting from the net proceeds of our initial public offering in October 2001.

Liquidity and Capital Resources

On October 17, 2001, we consummated our initial public offering of common stock in which we received net proceeds of $120.9 million. Previously, we had 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 capital leases with $2.5 million in principal outstanding at June 30, 2003.

As of June 30, 2003, our principal debt arrangements included a $2.0 million senior loan and security agreement with a lending company at an effective interest rate of 13.1% per annum (inclusive of amortization of the fair value of warrants issued) and a $3.0 million equipment line of credit at an interest rate of 7.28% with a lending company.

In April 2003, we entered into an agreement with one of our lenders pursuant to which we paid $844,451 to the lending company as a compromised and final payment of all amounts outstanding under this arrangement, and we took title to all of the equipment that had been leased pursuant to this arrangement.

In March 2002, we entered into an arrangement to finance the purchase of certain equipment we use to manufacture our Freestyle test strips with our supplier of test strip packaging vials. The purchase price of the equipment was approximately $1.6 million. From March 2002 to June 2003, we paid down the equipment purchase price to the supplier through a portion of the purchase price for each packaging vial purchased from the supplier. In April 2003, we paid the remaining purchase price of approximately $1.5 million for the equipment to the supplier and took title to the equipment.

In May 2002, we entered into a revolving line of credit agreement with a lending company, which was amended and restated in December 2002. Under the terms of the credit agreement, amounts we borrow from the lending company are repaid to the lending company directly by our accounts receivable debtors. Outstanding amounts owed to the lending company under the credit agreement are collateralized by all of our assets excluding our intellectual property assets. The maximum amount we may borrow from the lending company is based on our eligible accounts receivable and cannot exceed $15.0 million. All outstanding amounts bear interest at the prime rate plus 0.5%. The amended and restated credit agreement includes certain covenants requiring minimum liquidity and minimum net income over time. As of June 30, 2003, we were not in compliance with certain of these covenants. In August 2003, we entered into an amendment to the amended and restated credit and security agreement with the lending company that brought us into compliance with these covenants. As of June 30, 2003, there were no borrowings outstanding under the credit agreement.

In January 2003, we received a $15.0 million payment from Disetronic, our European distributor, pursuant to the amendment of our international distributor agreement. We are recognizing this payment as revenue over the term of the international distributor agreement, which expires in December 2006, if not terminated earlier. In the six months ended June 30, 2003, we recognized revenue of $1.2 million from this payment.

As of June 30, 2003, we had cash, cash equivalents and investments of $78.8 million.

Cash provided by or used in operating activities. Net cash provided by operating activities was approximately $10.0 million for the six months ended June 30, 2003. This was largely due to the $15.0 million payment from

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Disetronic, our European distributor in January 2003 pursuant to the amendment of our international distributor agreement in January 2003. In addition, decreases in inventories of $6.6 million and in prepaid expenses and other current assets of $2.8 million were offset by increases in accounts receivable of $0.9 million, and a reduction of accounts payable of $6.6 million. Inventories decreased as we sold the inventory manufactured in the quarter ended December 31, 2002. Accounts receivable increased due primarily to higher revenues. The decrease in accounts payable is due primarily to lower purchase prices we pay for our system kits. We do not expect to have positive cash flow from operating activities for the quarter ending September 30, 2003, as we will make royalty payments to our third-party licensors pursuant to our technology license agreements. For the six months ended June 30, 2002, cash used in operations was $40.9 million. The difference between our net loss and our net cash used in operating activities reflected increases in accounts receivable of $14.7 million and increases in inventories of $8.5 million as well as decreases in accounts payable and accrued liabilities of $5.8 million. The increase in accounts receivable principally related to the growth in revenues for the six months ended June 30, 2002. The increase in inventories during the six months ended June 30, 2002 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. Accrued liabilities decreased as we paid royalties and bonuses that were accrued at the end of 2001.

Cash used in investing activities. Net cash used in investing activities was approximately $24.2 million and $51.5 million for the six month periods ended June 30, 2003 and 2002, respectively. For the period ended June 30, 2003, investing activities consisted of capital expenditures of $4.8 million, mainly for the new building, and purchases of investments, net of $19.4 million. For the six-month period ended June 30, 2002, some of the proceeds used in investing activities consisted of capital expenditures of $4.8 million for manufacturing equipment used in the production of our disposable test strips, as we increased production capacity to meet planned growth and by purchases of investments, net of $46.6 million, as some of the proceeds from the initial public offering in October 2001 were invested in corporate bonds, municipal securities, and governmental securities.

Cash provided by or used in financing activities. Net cash used in financing activities for the six months ended June 30, 2003 of $3.9 million was primarily attributable to net principal payments on long-term debt and lines of credit of $5.8 million offset by $1.8 million from proceeds from the exercise of stock options, and from the repayment of notes receivable from stockholders of $0.1 million. Net cash provided by financing activities for the six months ended June 30, 2002 of $1.6 million was from the $3.3 million proceeds from the exercise of stock options offset by $1.7 million net principal payments on long-term debt.

We expect to have negative cash flows from operations for the third quarter of 2003. 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 six months ended June 30, 2003 were $4.8 million, and we believe that our capital expenditure for the next six months will be in line with the first six months of 2003. 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 until we become profitable. To the extent our capital resources are insufficient to meet our future capital requirements, we would 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 interest in our assets.

Inflation

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

Recently Issued Accounting Pronouncements

In November 2002, the Emerging Issues Task Force (EITF) reached a consensus on Issue No. 00-21, Revenue Arrangements with Multiple Deliverables. EITF Issue No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after

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June 15, 2003. We believe that the adoption of EITF No. 00-21 will not have a material impact on our financial statements.

In January 2003, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 46 (FIN 46), Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. We do not expect the adoption of FIN 46 to have a material impact on our consolidated financial statements.

In May 2003, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity (SFAS 150). SFAS No. 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS No. 150 requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. SFAS No. 150 is to be implemented by reporting the cumulative effect of a change in an accounting principle for financial instruments created before the issuance date of SFAS No. 150 and still existing at the beginning of the interim period of adoption. Restatement is not permitted. We do not expect the adoption of SFAS No. 150 to have a material impact upon our financial position, cash flows or results of operations.

RISK FACTORS AFFECTING OPERATIONS AND FUTURE RESULTS

We have a history of net losses and variable quarterly results and may never achieve or maintain profitability.

We have incurred losses every year since 1997. We incurred losses of $43.6 million in 2000, $52.9 million in 2001, $29.2 million in 2002 and $12.0 million for the six months ended June 30, 2003. As of June 30, 2003, we had an accumulated deficit of approximately $156.8 million. We will need to continue to increase product revenues and reduce product costs to achieve profitability. 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. As a relatively new entrant to the blood glucose monitoring market that has been experiencing rapid growth, revenues can vary from quarter to quarter due to various factors, including:

- changes in customer stocking and inventory levels;
- the timing of promotions and price changes by us or our competitors; and
- new product introductions or enhancements by us or our competitors.

We maintain a limited inventory of finished goods and typically ship products within a short period after orders are received. Historically, customer buying patterns and our revenue growth have caused a substantial portion of our revenues to occur in the last month of the quarter. Delays in the receipt of orders or the manufacture of product near the end of the quarter could cause quarterly revenues to fall short of anticipated levels. Because our operating expenses are based on anticipated revenue levels and a high percentage of our expenses are relatively fixed, less than anticipated revenues for a quarter could have a significant adverse impact on our operating results.

We expect to derive substantially all of our future revenue from sales of FreeStyle and this product could fail to generate increased revenues.

Currently, the primary products we market are the Freestyle test strips, Freestyle System kit and Freestyle lancets, all of which we commercially introduced in June 2000. Our Freestyle products are expected to account for substantially all of our revenues for 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. Relative to the overall size of the blood glucose monitoring market, a limited number of people have used Freestyle, and people with diabetes or the medical community may not substantially endorse Freestyle as a preferred blood glucose self-monitoring device. In addition, Freestyle may not achieve significant market acceptance on a timely basis, if at all, due to:

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- the significant influence of established glucose monitoring products with healthcare professionals, customers and third-party payors;
- 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.

Furthermore, FreeStyle may not encourage significantly 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 increased 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 increased recurring revenue from the sale of our test strips, we may not achieve profitability.

We have less sales and marketing experience relative to other companies in the blood glucose self-monitoring market and any failure to expand sales of FreeStyle will negatively impact future revenues.

We have less experience in marketing and selling our products relative to other companies in the blood glucose self-monitoring market. We received regulatory clearance for our initial product in January 2000 and commenced commercial shipments in June 2000. Our products require a complex marketing and sales effort targeted at health care professionals, diabetes educators, people with diabetes, pharmacists, national retailers and managed care plans. We have significantly expanded our sales and marketing teams in 2001, 2002 and 2003. We face significant challenges and risks in training, managing and retaining these teams, including managing geographically dispersed efforts. In addition, we currently have only one distributor in most of Europe and one distributor in Japan. We are dependent upon the sales and marketing efforts of our third-party distributors in these large international markets. 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. Recently, the Disetronic Group, the parent company of our European distributor, announced that its insulin pump business was acquired by Roche Diagnostics, one of our competitors. While Disetronic Injections Systems AG, our European distributor, will continue to distribute our products, we may not have the level of access and we have access to Disetronic s (now Roche Diagnostics) insulin pump user base that we enjoyed before the acquisition, and this could translate into decreased sales of our products. In addition, the recent amendment to the international distributor agreement with Disetronic lowered Disetronic Injections Systems AG s annual minimum purchase obligations. Our financial condition would be harmed if our marketing and sales efforts are unsuccessful.

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

The market for blood glucose monitoring 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. In addition, Becton, Dickinson and Company recently launched a new blood glucose monitoring system. Each of these companies is either publicly traded or a division of a publicly-traded company, and they enjoy 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; 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. These resources also allow them to

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aggressively promote and discount their products, particularly system kits. 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. Medtronic, Inc., a large medical device company, has recently filed a lawsuit against Deltec, Inc., alleging that Deltec s Cozmo insulin pump infringes certain Medtronic patents. The CozMore Insulin Technology System is a product we are developing with Deltec that permits the electronic transmission of a blood glucose reading taken using our FreeStyle blood glucose monitoring technology to the Cozmo pump. If Deltec were found to infringe the Medtronic patents, it would have to obtain a license or redesign its Cozmo insulin pump to avoid infringing Medtronic s patents, which could delay the launch of the CozMore system or possibly reduce its features. We are not a named party in this lawsuit.

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 we are discussing a possible sublicense or cross-license with the licensee. In August 2002, we received a letter from the owner of an issued United States patent that states our Freestyle Tracker System may infringe the patent. We are discussing a possible license or cross-license with that patent owner.

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 and 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 Inverness Medical Innovations, Inc. 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 often do not control the prosecution of the patents to which we hold licenses or the strategy for determining when such patents should be enforced. As a result, we

are largely dependent upon our licensors to determine the appropriate strategy for prosecuting and enforcing those patents.

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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. In addition, over $91 billion is spent annually on the treatment of diabetes and its complications 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. We are also developing new products such as Freestyle Flash, our new *in vitro* blood glucose monitoring system, the CozMore Insulin Technology System, a product we are developing with Deltec, Inc. that permits the electronic transmission of a blood glucose reading taken using our Freestyle blood glucose monitoring technology to Deltec's Cozmo pump, and Navigator, our continuous glucose monitoring system. Marketing of these products will require FDA and other regulatory clearances and approvals. We experienced some delays in the clinical trials conducted to support the approval of Navigator due to problems with the electronics portion of the system. Development of Navigator and other 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 Navigator, and the FDA has approved two of these products for adjunctive use with *in vitro* blood glucose monitoring systems. If any of our competitors succeeds in developing a continuous glucose monitor that is approved for marketing as a replacement for *in vitro* blood glucose monitoring, this would negatively affect our future revenues.

Similarly, several of our competitors and some new market entrants are developing products that have small sample size requirements and the ability to test on the fingertip and other body sites. Becton, Dickinson and Company, for instance, recently launched a blood glucose monitoring system that claims the same sample size requirement as Freestyle This competitor also recently received 510(k) clearance from the FDA for a system similar to the CozMore system. This system incorporates an insulin pump from Medtronic, Inc., the leading provider of such pumps. The successful development and introduction of such products by competitors or new entrants would reduce the product benefits of our Freestyle products versus the competition and could adversely impact 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. Therefore, even if a product is successfully developed, it may not be commercially available for a number of years. Navigator, our continuous glucose monitoring system under development, will require premarket approval. We experienced some delays in the clinical trials conducted to support the approval of Navigator due to problems with the electronics portion of the system. We may not be able to obtain additional clearances or approvals for Navigator or other products in a timely fashion, or at all. Delays in obtaining clearance or approval could adversely affect our revenues and profitability.

Modification to our marketed devices may require new 510(k) clearances or premarket approvals. 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 and potentially 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 lines for our FreeStyle meters at Flextronics International Ltd. in China have 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 harm our reputation and 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 or field corrective actions 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 or field corrective actions for our products in the event of material deficiencies or defects in design or manufacture. A government mandated or firm-initiated recall or field corrective action by us could occur as a result of component failures, manufacturing errors or design defects. We commenced a firm-initiated field corrective action due to software bugs associated with the diabetes management features of our FreeStyle Tracker diabetes management system shortly after its launch. Any recall of or material field corrective action for product may divert managerial and financial resources and harm our reputation with customers.

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 previously 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 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.

If we are 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. Increasing demand since the launch of FreeStyle has necessitated an increase in our test strip manufacturing capacity. In response, we have expanded our manufacturing capacity at our facilities in Alameda, California. We anticipate the need to continue expanding manufacturing capacity and have ordered certain specialized equipment. Delays in receiving certain specialized equipment extended the date when we were able to

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begin operations on our second test strip line. If we are unable to expand manufacturing capacity in a timely manner we could be unable to meet customer demand for FreeStyle test strips, which would adversely affect our financial results and restrict our sales growth.

Significant product returns could harm our operating results.

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 in accordance with our returned goods policy within six months after this expiration date. We have established reserves for the liability associated with product returns. However, unforeseen returns from retailers, wholesalers or end users could adversely affect our operating results.

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.

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, the operation of our customer service function, and certain distribution and logistics functions. 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 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 may 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 not be successful in securing managed care contracts.

Many people with diabetes obtain reimbursement for their purchase of glucose self-monitoring devices and test strips through managed care organizations. Accordingly, entering into reimbursement arrangements with managed care organizations is important to our business, and we are actively seeking these arrangements. If we are not successful in securing reimbursement for our products from managed care organizations that cover a significant number of insured lives, we may have difficulty growing our business and retaining our customers. Some managed care organizations leverage their buying power and limit the number of products that they reimburse at preferred rates, and in order to obtain reimbursement arrangements we often agree to a net sales price lower than the net sales price we charge in other sales channels.

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We may have difficulty managing our growth.

We have experienced significant growth in the scope of our operations and the number of our employees. We expect this growth to continue though at reduced rates. 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.

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

Our ability to provide quality 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 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.

Our meters are manufactured in China, and we are subject to risks of international manufacturing operations and risks associated with SARS.

Our FreeStyle meters are manufactured according to our specifications by a single third-party manufacturer at its facility in China. The geographical distance between our principal facility in Alameda, California and the manufacturing facility in China creates a number of logistical and communications challenges. These challenges include managing operations across multiple time zones, directing the manufacture and delivery of products across distances, coordinating procurement and delivery of components and raw materials and coordinating the activities and decisions of the core manufacturing team, which is based in China and California.

Governmental authorities in China exercise significant influence over many aspects of the economy, and their actions could have a significant effect on the manufacture of our Freestyle meters. Risks of changes in economic and political conditions in China, include:

- labor unrest and difficulties in staffing;
- increases in duties and taxation levied on our Freestyle meters;
- limitations on imports of Freestyle meter components or exports of assembled Freestyle meters, or other travel restrictions;
- expropriation of private enterprises;
- a potential reversal of current favorable policies encouraging foreign trade; and
- fluctuations in the value of local currency.

In addition, the recent outbreak of severe acute respiratory syndrome (SARS) may adversely impact our business and particularly Flextronics Freestyle meter manufacturing operations. The SARS outbreak has been most notable in Asia, in particular China. Flextronics manufacture of our Freestyle meters in China could suffer if its employees contract SARS or otherwise are unable to fulfill their responsibilities. In addition, our business could also be harmed if travel to or from China and the United States is restricted or inadvisable.

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Any delay or disruption in the manufacture of our Freestyle meters, including delays or disruptions relating to these logistical and communication challenges, changes in the economic or political conditions in China or the recent outbreak of SARS, could delay or disrupt shipments of Freestyle meters to our customers. Shipment delays or disruptions 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, engaging an additional manufacturer or commencing Freestyle meter manufacturing obligations on an alternative line in a timely manner could impose increased costs that would negatively impact our gross margins.

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.

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 various countries outside the United States. 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 $22.0 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.

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. 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;
- expenses we incur in developing and selling our products;
- the commercial success of our research and development efforts; and

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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.

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. 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.

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 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 and our company in particular 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.

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The sales of a substantial number of shares of our common stock 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 August 1, 2003, we had 41,317,153 shares of common stock outstanding. 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.

Our executive officers and directors and entities affiliated with them 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 and directors and entities affiliated with them beneficially own, in the aggregate, approximately 22% of our common stock as of August 1, 2003. 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 concentrated ownership. These stockholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the 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 Stockholder Rights Plan, charter documents and Delaware law may inhibit a takeover that stockholders consider favorable and could also limit the market price of investors stock.

In February 2003, our Board of Directors adopted a Stockholder Rights Plan. The Stockholder Rights Plan provides for a dividend distribution of one Preferred Shares Purchase Right on each outstanding share of our common stock. Each Right entitles stockholders to buy 1/1000th of a share of the company s Series A participating preferred stock at an exercise price of $100.00. The Rights will become exercisable after a person or group announces the acquisition of 15% or more of our common stock, or announces commencement of a tender offer, the consummation of which would result in ownership by the person or group of 15% or more of our common stock. We will be entitled to redeem the Rights at $0.001 per Right at any time on or before the tenth day following acquisition by a person or group of 15% or more of our common stock. The Stockholder Rights Plan could have the effect of delaying, deferring or preventing a change in control of TheraSense, including without limitation, discouraging a proxy contest or making more difficult the acquisition of a substantial block of our common stock

Our certificate of incorporation and bylaws contain provisions that could also delay or prevent a change in control of our company. Among these provisions are the following:

- 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. Section 203 of Delaware General Corporate Law, our Stockholder Rights Plan 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

Because we translate foreign currencies into United States dollars for reporting purposes, exchange rates can have an impact on our financial results, although this impact is generally immaterial. We believe that our exposure to currency exchange risk is low because our Canadian and United Kingdom subsidiaries satisfy their financial obligations almost exclusively in their local currencies. As of June 30, 2003, we did not engage in foreign currency hedging activities.

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. As of June 30, 2003, our cash, cash equivalents and available-for-sale securities consisted primarily of money market funds maintained at three major U.S. financial institutions. The recorded carrying amounts of cash and cash equivalents approximate fair value due to their short-term maturities. 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.

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures. Our chief executive officer and our chief financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934 Rules 13a-14(c) and 15-d-14(c)) as of the end of the period covered by this report, have concluded that as of the end of the period covered by this report, our disclosure controls and procedures were adequate and designed to ensure that material information relating to us and our consolidated subsidiaries would be made known to them by others within those entities.

(b) Changes in internal controls over financial reporting. There were no changes in our internal controls over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rule 13a-15 or 15d-15 that occurred during the quarter ended June 30, 2003 or to our knowledge, in other factors that have materially affected or are reasonably likely to materially affect our internal controls over financial reporting.

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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.

To date, we have spent a portion of the net proceeds as follows (i) approximately $8.0 million for the purchase of capital equipment, (ii) approximately $3.6 million to expand our facility in Alameda, California, (iii) approximately $24.6 million to sponsor free product samples and accelerate the hiring of additional sales representatives, (iv) approximately $5.2 million for research and development of enhanced FreeStyle products and our Continuous Glucose Monitoring System and (v) approximately $38.4 million 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, 2003 through June 30, 2003, we did not issue any unregistered securities.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None

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

At our Annual Meeting of Stockholders held on May 9, 2003, the following proposals were adopted by the margins indicated below. There were 40,872,514 shares of Common Stock entitled to vote at the Annual Meeting of Stockholders and a total of 35,716,911 shares were represented at the Annual Meeting of Stockholders.

1. To elect Ross A. Jaffe, M.D., Jonathan T. Lord, M.D. and W. Mark Lortz as our Class II directors, each to serve until the 2006 Annual Meeting or until their respective successors have been elected or appointed.

	Number of Shares		
Name of Director	**Yes**	**No**	**Abstain**
Ross A. Jaffe, M.D.	34,982,904		734,007
Jonathan T. Lord, M.D.	35,321,254		395,657
W. Mark Lortz	35,249,953		466,958

2. To ratify the appointment of PricewaterhouseCoopers LLP as our independent accountants for the fiscal year ending December 31, 2003.

	Number of Shares
Yes	35,485,924
No	222,060
Abstain	8,927
Broker Non-Vote	

ITEM 5. OTHER INFORMATION

None

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

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Exhibit 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 (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
***10.8(a)	Second Amendment to Standard Industrial/Commercial Single-Tenant Lease between TheraSense, Inc. and PlyProperties, a Partnership dated May 7, 2002
*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
****10.13(a)	October 23, 2002 amendment to Warehouse Distribution Contract between TheraSense, Inc. and UPS Supply Chain Management f/d/b/a 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
*#10.15(b)	Amendment No. 2 to International Distributor Agreement between TheraSense, Inc. and Disetronic Handels AG, dated January 1, 2003
*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	Amended and Restated Investors Rights Agreement by and among holders of TheraSense Preferred Stock and TheraSense, Inc., dated January 23, 2001, as amended
*10.19	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
*10.20	Form of Change of Control Agreement between TheraSense, Inc. and each Vice President of TheraSense, Inc.
*****10.21	Rights Agreement dated as of March 7, 2003 between TheraSense, Inc. and Computershare Investor Services, as Rights Agent, which includes the Form of Certificate of Designation of Series A Participating Cumulative Preferred Stock as Exhibit A, the Summary of Terms of the Rights Agreement as Exhibit B and the Form of Right Certificate s Exhibit C.
31.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002.

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Exhibit Number	Description of Document
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350

* 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 the same exhibit filed with our Form 10-K for the year ended December 31, 2001.

*** Incorporated by reference to the same exhibit filed with our Form 10-Q for the period ended June 30, 2002.

**** Incorporated by reference to the same exhibit filed with our Form 10-Q for the period ended September 30, 2002.

***** Incorporated by reference to the same exhibit filed with our Registration Statement on Form 8-A, which was declared effective on March 11, 2003.

*# Incorporated by reference to the same exhibit filed with our Form 10-K for the year ended December 31, 2002.

Confidential treatment granted for portions of these exhibits.

Confidential treatment requested for portions of this exhibit.

(b) Reports on Forms 8-K.

On April 23, 2003, we furnished a report on Form 8-K under Item 12 disclosing that we announced our financial results for the quarter ended March 31, 2003 and attaching the corresponding press release.

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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.
(Registrant)

Date: August 11, 2003

/s/ CHARLES T. LIAMOS

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