THERASENSE INC
Form 10-Q
November 13, 2002
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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 SEPTEMBER 30, 2002

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.

Yes x No o

As of November 1, 2002, Registrant had outstanding 40,651,819 shares of Common Stock, $0.001 par value.

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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 September 30,		Nine Months Ended September 30,	
	2002	2001	2002	2001
Total revenues	$ 39,029	$ 19,858	$ 131,535	$ 45,382
Cost of revenues	18,362	12,938	71,198	32,606
Gross profit	20,667	6,920	60,337	12,776
Operating expenses:				
Research and development	5,332	4,671	15,819	11,003
Selling, general and administrative	24,991	15,250	69,055	42,093
Total operating expenses	30,323	19,921	84,874	53,096
Loss from operations	(9,656)	(13,001)	(24,537)	(40,320)
Interest income, net	308	76	1,108	462
Net loss	(9,348)	(12,925)	(23,429)	(39,858)
Deemed dividend related to beneficial conversion feature of preferred stock				(26,783)
Net loss attributable to common stockholders	$ (9,348)	$ (12,925)	$ (23,429)	$ (66,641)
Net loss per common share, basic and diluted	$ (0.23)	$ (2.53)	$ (0.59)	$ (13.79)
Weighted-average shares used in computing net loss per common share, basic and diluted	39,999	5,115	39,918	4,832

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)

	September 30, 2002	December 31, 2001
	(unaudited)	(Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 38,205	$ 143,187
Available-for-sale investments	13,895	
Accounts receivable, net	36,697	18,495
Inventories	22,835	6,649
Deferred cost of products sold		16,359
Prepaid expenses and other current assets	9,680	8,239
Total current assets	121,312	192,929
Available-for-sale investments	33,271	4,278
Property and equipment, net	12,783	6,539
Other assets	3,047	2,830
Total assets	$ 170,413	$ 206,576
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 25,940	$ 20,223
Accrued liabilities	12,217	16,598
Deferred revenue	1,000	23,709
Current portion of long-term debt	5,690	3,990
Total current liabilities	44,847	64,520
Long-term debt	3,559	4,255
Other liabilities	3,011	4,262
Total liabilities	51,417	73,037
Stockholders equity:		
Common stock	41	39
Additional paid-in capital	271,156	270,376
Notes receivable from stockholders	(232)	(292)
Deferred stock-based compensation, net	(13,337)	(20,995)
Accumulated other comprehensive income	386	
Accumulated deficit	(139,018)	(115,589)
Total stockholders equity	118,996	133,539
Total liabilities and stockholders equity	$ 170,413	$ 206,576

(1)

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

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

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

	Nine Months Ended September 30,	
	2002	**2001**
Cash flows from operating activities:		
Net loss	$ (23,429)	$ (39,858)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,248	1,420
Amortization of deferred stock-based compensation	4,580	3,593
Other		424
Changes in operating assets and liabilities:		
Accounts receivable	(18,202)	(8,277)
Inventories	(16,186)	(1,896)
Deferred cost of products sold	16,359	(4,924)
Prepaid expenses and other current assets	(1,442)	(3,174)
Other assets	(217)	(2,207)
Accounts payable	5,717	3,382
Accrued and other liabilities	(4,882)	7,594
Deferred revenue	(23,459)	13,089
Net cash used in operating activities	(58,913)	(30,834)
Cash flows from investing activities:		
Proceeds from maturities of investments	3,000	
Purchases of investments	(45,422)	
Purchases of property and equipment	(8,492)	(1,894)
Proceeds from sales of property and equipment		6
Net cash used in investing activities	(50,914)	(1,888)
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred stock, net		53,863
Proceeds from exercise of stock options	3,861	501
Principal payments on lines of credit	(2,109)	(1,663)
Principal payments on long-term debt	(4,123)	(552)
Proceeds from long-term debt	7,236	
Repayment of notes receivable from stockholders	60	
Net cash provided by financing activities	4,925	52,149
Effect of foreign exchange rate changes on cash and cash equivalents	(80)	
Net change in cash and cash equivalents	(104,982)	19,427
Cash and cash equivalents, beginning of period	143,187	12,532
Cash and cash equivalents, end of period	$ 38,205	$ 31,959

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 Policies:

The accompanying unaudited condensed consolidated financial statements of TheraSense, Inc. and its subsidiaries (TheraSense or the Company) have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three month period and nine month period ended September 30, 2002 are not necessarily indicative of the results that may be expected for the year ending December 31, 2002, or for any future period. These financial statements and notes should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2001 included in the Company s Form 10-K for the year ended December 31, 2001.

NOTE 2 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, 2001. With the exception of the Company s revenue recognition policy and the two new significant accounting policies set forth below, the Company s significant accounting policies have not materially changed as of November 1, 2002.

Revenue Recognition

The Company recognizes revenue in accordance with Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements. Product revenues are generated from sales of the Company s FreeStyle System kit and from the recurring sales of disposable FreeStyle test strips and lancets. The Company s return policy allows end users in the United States of America and Canada to return FreeStyle System kits to the Company for a full cash refund within 30 days of purchase. There are no end-user return rights on sales of disposable FreeStyle test strips and lancets. In addition, the Company s FreeStyle System kit and FreeStyle test strips currently have an 18 month shelf life, and retailers and wholesalers in the United States of America and Canada can return these products to the Company up to six months beyond this expiration date. Prior to the second quarter of 2002, we lacked sufficient historical trends in sales and product returns, and we therefore deferred recognition of revenue on sales of FreeStyle test strips and lancets until resold by the retailers and wholesalers through to end-users, and we deferred recognition of revenue on FreeStyle System kits until 30 days after purchase by the end-user.

Now that we have a sufficient historical basis to estimate return rates, sales to retailers and wholesalers in the United States and Canada beginning with the second quarter of 2002 are recognized upon shipment. As a result, there are no deferred revenues from product sales for the third quarter of 2002 and previously deferred revenues were recognized in the second quarter of 2002.

Basis of Consolidation and Foreign Currency Translation

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

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

Other Comprehensive Income (Loss)

Comprehensive income (loss) generally represents all changes in stockholders equity except those resulting from investments or contributions by stockholders. The Company s unrealized gains on available-for-sale investments

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

and cumulative translation adjustment represent the components of comprehensive income (loss) that are excluded from the net loss.

Due to availability of net operating losses, there is no tax effect associated with any component of other comprehensive income (loss).

The following table lists the beginning balance, yearly activity, and ending balance of each component of accumulated other comprehensive income (loss):

	Unrealized gains (losses) on securities	Foreign currency translation adjustments	Accumulated other comprehensive gain (loss)
Balance December 31, 2001			
2002 change	466	(80)	386
Balance September 30, 2002	466	(80)	386

NOTE 3 Recent Accounting Pronouncements:

In April 2002, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 145 (SFAS 145), *Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections,* which is effective for fiscal years beginning after May 15, 2002. Under SFAS 145, gains and losses from the extinguishment of debt should be classified as extraordinary items only if they meet the criteria of Accounting Principles Board Opinion No. 30. SFAS 145 also addresses financial accounting and reporting for capital leases that are modified in such a way as to give rise to a new agreement classified as an operating lease. The Company believes that the adoption of SFAS 145 will not have a material impact on the consolidated financial position or results of the operations of the Company.

In June 2002, the FASB issued Statement of Financial Accounting Standards No. 146 (SFAS 146), *Accounting for Costs Associated with Exit or Disposal Activities,* which is effective for exit or disposal activities initiated after December 31, 2002. SFAS 146 nullifies Emerging Issues Task Force Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring).* Under SFAS 146, a liability is required to be recognized for a cost associated with an exit or disposal activity when the liability is incurred. SFAS 146 applies to costs associated with an exit activity that does not involve an entity newly acquired in a business combination or with a retirement or disposal activity covered by FASB Statements No. 143, Accounting for Asset Retirement Obligations, and No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets . The Company believes that the adoption of SFAS 146 will not have a material impact on the consolidated financial position or results of the operations of the Company.

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THERASENSE, INC.
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(unaudited)

NOTE 4 Net Loss Per Share:

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2001	2002	2001
	(unaudited)		(unaudited)	
Numerator:				
Net loss	$ (9,348)	$ (12,925)	$ (23,429)	$ (39,858)
Deemed dividend related to beneficial conversion feature of preferred stock				(26,783)
Net loss attributable to common stockholders	$ (9,348)	$ (12,925)	$ (23,429)	$ (66,641)
Denominator:				
Weighted-average common stock outstanding	40,037	5,415	39,988	5,274
Less: Weighted-average shares subject to Repurchase	(38)	(300)	(70)	(442)
Weighted-average shares used in computing basic and diluted net loss per common share	39,999	5,115	39,918	4,832

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

	September 30,	
	2002	2001
	(unaudited)	
Options to purchase common stock	6,815	5,714
Common stock subject to repurchase	28	272
Convertible preferred stock		26,722
Warrants		521

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THERASENSE, INC.
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(unaudited)

NOTE 5 Pro Forma Net Loss Per Common Share:

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

	Three Months Ended September 30, 2001	Nine Months Ended September 30, 2001
	(unaudited)	
Pro forma net loss per common share, basic and diluted:		
Net loss attributable to common stockholders	$ (12,925)	$ (66,641)
Deemed dividend related to beneficial conversion feature of preferred stock		26,783
Net loss	$ (12,925)	$ (39,858)
Weighted-average shares used in computing basic and diluted net loss per common share	5,115	4,832
Adjustments to reflect the effect of the assumed conversion of the preferred stock from the date of issuance	26,722	25,915
Weighted-average shares used in computing basic and diluted net loss per common share	31,837	30,747
Pro forma net loss per common share, basic and diluted	$ (0.41)	$ (1.30)

NOTE 6 Inventories:

At September 30, 2002 and December 31, 2001, inventories consisted of the following (in thousands):

	September 30, 2002	December 31, 2001
	(unaudited)	
Raw materials	$ 8,950	$ 2,090
Work-in-process	4,507	2,673
Finished goods	9,378	1,886
	$ 22,835	$ 6,649

NOTE 7 Long-Term Debt:

In May 2002, the Company entered into a revolving line of credit agreement with Wells Fargo Business Credit, Inc. The Company and Wells Fargo Business Credit, Inc. amended and restated the revolving line of credit agreement in September 2002. Under the terms of the amended and restated credit agreement, amounts the Company borrows from Wells Fargo Business Credit, Inc. are repaid to Wells Fargo Business Credit, Inc. directly by the Company s

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THERASENSE, INC.
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(unaudited)

accounts receivable debtors. Outstanding amounts owed to Wells Fargo Business Credit, Inc. under the amended and restated credit agreement are secured by all of the Company s assets excluding its intellectual property assets. The maximum amount the Company may borrow from Wells Fargo Business Credit, Inc. is based on its eligible accounts receivable and cannot exceed $15.0 million. All outstanding amounts bear interest at the prime rate announced by Wells Fargo Bank, N.A. plus 0.5%. The amended and restated credit agreement remains in full force and effect until terminated by either party under certain circumstances. As of September 30, 2002, $3.6 million in principal was outstanding under the amended and restated credit agreement.

The Company has entered into an arrangement to finance the purchase of certain equipment the Company uses to manufacture the FreeStyle test strips with its supplier of test strip packaging vials. The purchase price of the equipment is approximately $1.6 million. The financed purchase price has an interest rate of 7.0% per year. The Company pays the equipment purchase price to the supplier through a portion of the purchase price for each packaging vial purchased from the supplier. To date, the Company has paid to the supplier approximately $137,000, consisting of approximately $40,000 in principal and approximately $97,000 in interest, pursuant to the financing arrangements. The Company will take title to the equipment once the equipment purchase price has been paid in full. The Company must pay the equipment purchase price to the supplier by not later than June 2008. The supplier has financed the equipment pursuant to a loan arrangement with CIB Bank. The supplier s loan obligations to CIB Bank are secured by the equipment. If the supplier defaults on its loan obligations to CIB Bank, the Company must assume and satisfy the supplier obligations to CIB Bank in order to take title to the equipment.

NOTE 8 Subsequent Events

In October 2002, the Company and UPS Supply Chain Management, formerly doing business as Livingston Healthcare Services, Inc., amended the Warehouse Distribution Contract dated March 15, 2000, as previously amended, between the parties. The amendment extended the term of the Warehouse Distribution Contract and reduced the price that the Company pays for certain of the logistics services performed by UPS Supply Chain Management on the Company s behalf.

In November 2002, the Company and Health Hero Network, Inc. (Health Hero) entered into a Patent License Agreement pursuant to which Health Hero granted the Company a license to certain patents. The license is co-exclusive with Health Hero in the field of diabetes. Health Hero will also perform some product development tasks and has agreed to issue to the Company warrants to purchase shares of Health Hero s Series D Preferred Stock. The warrants will be exercisable for ten years from the issuance date.

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

This Management s Discussion and Analysis of Financial Condition and Results of Operations and other parts of this Form 10-Q contain forward-looking statements that involve risks and uncertainties. These statements typically may be identified by the use of forward-looking words or phrases such as "believe," "expect," "intend," "anticipate," "should," "planned," "estimated," and "potential," among others. All forward-looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experience to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our businesses include but are not limited to: (1) our 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; (9) risks relating to international manufacturing operations; and (10) 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 nine month periods ended September 30, 2002, are not necessarily indicative of the results that may be expected for the full fiscal year or 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. Our first product, FreeStyle, received FDA clearance in January 2000, and we commenced commercial shipments in the United States in June 2000. We sell FreeStyle in the United States and Canada through national retailers and wholesalers, and directly to consumers over the telephone and through our website. In March 2001, we obtained the CE Mark for FreeStyle, and our European distributor commenced sales of FreeStyle in Germany and Sweden in May 2001 and commenced sales of FreeStyle in Finland, Austria, Norway, the Netherlands, Denmark, Switzerland, France, Italy and Belgium since that time. In January 2002, we obtained regulatory approval to market FreeStyle in Japan, and our Japanese distributor launched FreeStyle in Japan in February 2002. We 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 incurred significant operating losses and negative cash flows from operations since inception. We incurred net losses of $13.1 million in 1999, $43.6 million in 2000, $52.9 million in 2001 and $23.4 million for the nine months ended September 30, 2002. As of September 30, 2002, we had an accumulated deficit of $139.0 million. We will need to continue to increase product revenues and reduce product costs to achieve profitability.

Revenues are generated from sales of our FreeStyle System kit and from the recurring sales of disposable FreeStyle test strips and lancets. Our return policy allows end users in the United States and Canada to return FreeStyle System kits to us for a full cash refund within 30 days of purchase. There are no end-user return rights on sales of FreeStyle test strips and lancets. In addition, our FreeStyle System kit and FreeStyle test strips currently have an 18 month shelf life, and retailers and wholesalers in the United States and Canada can return these products to us up to six months beyond this expiration date. Sales to retailers and wholesalers in the United States and Canada are recognized upon shipment with a reserve for estimated product returns, which reserve is based on our historical experience of product returns by retailers and wholesalers in the United States and Canada.

Domestic sales to durable medical equipment suppliers do not have a return right so we recognize revenue from these sales upon shipment. Similarly, products distributed internationally, with the exception of shipments to Canada, have no right of return, and we recognize revenue on these products upon shipment. 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 granted longer credit terms to match our competitors. We perform ongoing credit evaluations of our customers financial condition and, generally, require no

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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.

Manufacturers typically sell their glucose monitoring devices 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 have been offering and expect to continue to offer similar discounts and rebates on, and free samples of, our FreeStyle System kits to establish an installed base of systems from which we expect to generate recurring revenues from our disposable FreeStyle test strips and lancets.

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

Cost of revenues consists primarily of:

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

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

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

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

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

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

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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 September 30, 2002 we have recorded aggregate deferred stock-based compensation of $25.4 million, of which $13.3 million will be amortized to expense on a straight line basis through 2006. This amount is being amortized over the respective vesting periods of these equity instruments, which is typically four years. Stock-based compensation expense has been allocated according to employees and their respective departments and by function for non-employees.

In September 2000, we entered into an exclusive distribution agreement with Disetronic Group relating to the distribution of FreeStyle in Germany, Switzerland, Denmark, Austria, Sweden, Finland, Norway and the Netherlands. In February 2002, this agreement was amended to, among other things, extend the term through December 31, 2006 and add France, Italy and Belgium to Disetronic s distribution territory. Disetronic commenced sales in Germany and Sweden in May 2001 and since that time has commenced sales in Norway, Finland, Austria, The Netherlands, Denmark, Switzerland, France, Italy and Belgium.

In April 2001, we entered into a five-year exclusive distribution agreement with Nipro Corporation relating to the distribution of FreeStyle in Japan. Nipro launched FreeStyle in Japan in February 2002. In connection with this agreement, we received a $5.0 million payment from Nipro, which is being recognized as revenue ratably over the term of the agreement. As of September 30, 2002, we have a balance of $3.5 million on the balance sheet as deferred revenue, of which $1.0 million is current.

Results of Operations

Three Months Ended September 30, 2002 and September 30, 2001

Revenues. Total revenues were $39.0 million for the three months ended September 30, 2002 as compared to $19.9 million for the comparable period in 2001. The increase in total revenues over the comparable period of 2001 was 96%. This increase is primarily due to increased sales of FreeStyle test strips and FreeStyle system kits. Two of our customers, McKesson and Disetronic, individually accounted for more than 10% and collectively accounted for approximately 24% of our total revenues from shipments in the three months ended September 30, 2002. Four of our customers, McKesson, Disetronic, Cardinal and Bergen Brunswig, individually accounted for more than 10% and collectively accounted for approximately 54% of our total revenues from product sales for the three months ended September 30, 2001. While revenues for the three months ended September 30, 2002 rose significantly over the comparable period in 2001, they were relatively flat when compared to the three months ended June 30, 2002 without the contribution to revenues in that period from the recognition of previously deferred revenues. We anticipate that the three-month period ending December 31, 2002 will show growth in revenues over the three-month period ended September 30, 2002.

Cost of revenues. Cost of revenues were $18.4 million for the three months ended September 30, 2002 as compared to $12.9 million for the comparable period of 2001. The increase in cost of revenues over the comparable period of 2001 was 42%. This increase is due to higher total revenues, which grew by 96% versus the recognized revenues of

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the comparable period in 2001. Amortization of deferred stock-based compensation expense reported in cost of revenues for the three months ended September 30, 2002 was $0.1 million as compared to $0.2 million for the comparable period of 2001.

Gross profit. Gross profit was $20.7 million for the three months ended September 30, 2002 as compared to $6.9 million for the comparable period of 2001. The increase in gross profit over the comparable period of 2001 was 199%. The gross margin for the three months ended September 30, 2002 was 53%, while the gross margin for the three months ended September 30, 2001 was 35%. The improved gross margin and gross profit resulted from test strip revenue composing a greater proportion of total revenue, reduced test strip and system kit manufacturing costs, and fixed costs being spread over larger sales volumes. While gross margin for the three months ended September 30, 2002 rose significantly over the comparable period in 2001, it did not rise in comparison to the three months ended June 30, 2002 without the contribution to revenues in that period from the recognition of previously deferred revenues. We anticipate that the three-month period ending December 31, 2002 will show an improvement in gross margin over the three-month period ended September 30, 2002.

Research and development expenses. Research and development expenses were $5.3 million for the three months ended September 30, 2002 as compared to $4.7 million for the comparable period of 2001. This represents an increase of 14%. The increase is primarily attributable to increased spending on product development efforts, including clinical trials. Amortization of deferred stock-based compensation was $0.3 million for the three months ended September 30, 2002 as compared to $0.3 million for the comparable period of 2001. We expect research and development spending to increase over the next several years as we expand clinical trials for our Continuous Glucose Monitoring System and expand our research and development activities to support our current and future products.

Selling, general and administrative expenses. Selling, general and administrative expenses were $25.0 million for the three months ended September 30, 2002 as compared to $15.3 million for the comparable period of 2001. This represents an increase of 64%. This increase is primarily attributable to increases of $2.5 million for television advertising, $1.9 million for personnel costs related to expanding our U.S. and international sales force, $1.7 million for our Canadian and United Kingdom subsidiaries, $1.4 million for sales data services, $0.8 million for our retail sales force and $0.5 million for travel costs, largely related to our sales force. Amortization of deferred stock-based compensation was $1.1 million for the three months ended September 30, 2002, as compared to $1.1 million in the comparable period of 2001. We expect our selling, general and administrative expenses to increase as we increase product sampling, expand our sales force, increase our marketing and promotional activities, and operate as a public company. Over subsequent quarters, we anticipate that selling, general and administrative expenses will comprise a smaller percentage of total revenues.

Interest income, net. Net interest income increased to $0.3 million for the three months ended September 30, 2002 from $0.1 million for the three months ended September 30, 2001. This increase was primarily attributable to higher cash, cash equivalents, and investment balances, resulting from the net proceeds of our initial public offering in October 2001. Interest expense remained comparable between the two periods.

Net loss attributable to common stockholders. Net loss attributable to common stockholders was $9.3 million or $0.23 loss per basic and diluted share for the three months ended September 30, 2002 as compared to a net loss of $12.9 million or $0.41 loss per basic and diluted share (pro forma for the assumed conversion of preferred stock) for the comparable period of 2001.

Nine Months Ended September 30, 2002 and September 30, 2001

Revenues. Total revenues were $131.5 million for the nine months ended September 30, 2002 as compared to $45.4 million for the comparable period in 2001. This increase includes a $20.4 million contribution from achieving the ability to estimate product return rates for sales to retailers and wholesalers in the United States and Canada beginning with the quarter ended June 30, 2002. Prior to the quarter ended June 30, 2002 we deferred revenue recognition until product had been purchased by an end-user and all rights of return had lapsed. The increase in total revenues over the comparable period of 2001 was 145% before the $20.4 million contribution. This increase is primarily due to greater sales of FreeStyle test strips and FreeStyle system kits. Due to the recognition of previously deferred revenues from product sales during the quarter ended June 30, 2002, there were no deferred revenues from product sales as of September 30, 2002. Two of our customers, McKesson, and Disetronic, individually accounted for more than 10% and collectively accounted for approximately 20% of our total revenues from shipments in the nine months ended September 30, 2002. Three of our customers, McKesson, Walgreens and Disetronic, individually accounted for approximately 10% and collectively accounted for approximately 38% of our total revenues from

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shipments in the nine months ended September 30, 2001.

Cost of revenues. Cost of revenues were $71.2 million for the nine months ended September 30, 2002 as compared to $32.6 million for the comparable period of 2001. This increase includes a $16.2 million charge associated with the recognition of previously deferred revenues. The increase in cost of revenues over the comparable period of 2001 was 69% excluding the $16.2 million charge. This increase is due to higher total revenues, which grew by 145% compared with total revenues for the comparable period in 2001, before the $20.4 million contribution. Amortization of deferred stock-based compensation expense reported in cost of revenues for the nine months ended September 30, 2002 was $0.5 million as compared to $0.3 million in the comparable period of 2001.

Gross profit. Gross profit was $60.3 million for the nine months ended September 30, 2002 as compared to $12.8 million for the comparable period of 2001. This increase includes a $4.2 million contribution associated with recognition of previously deferred revenues. The increase in gross profit over the comparable period of 2001 was 339% excluding the $4.2 million contribution associated with recognition of previously deferred revenues. The gross margin for the nine months ended September 30, 2002 was 46% and, excluding the effects of the recognition of previously deferred revenue, it would have been 50%. Our reported gross margin decreased as a result of the recognition of previously deferred revenue as it had a high proportion of revenues from system kits which have a lower gross margin than test strip revenues. The gross margin for the nine months ended September 30, 2001 was 28%. The improved gross margin and gross profit over the comparable period of 2001 resulted from fixed costs being spread over larger sales volumes, test strip revenue composing a greater proportion of total revenue, and reduced test strip and system kit manufacturing costs.

Research and development expenses. Research and development expenses were $15.8 million for the nine months ended September 30, 2002 as compared to $11.0 million for the comparable period of 2001. This represents an increase of 44%. The increase is primarily attributable to increased spending on product development efforts and the hiring of additional research and development personnel. Amortization of deferred stock-based compensation was $0.9 million for the nine months ended September 30, 2002 as compared to $0.9 million in the comparable period of 2001.

Selling, general and administrative expenses. Selling, general and administrative expenses were $69.1 million for the nine months ended September 30, 2002 as compared to $42.1 million for the comparable period of 2001. This represents an increase of 64%. This increase is primarily attributable to increases of $6.4 million for personnel costs related to expanding our U.S. and international sales force, $5.8 million spent on product sampling, $2.6 million for our retail sales force, $2.5 million for television advertising, $2.5 million for our Canadian and United Kingdom subsidiaries, $2.3 million for sales data services and computer services, and $2.0 million for travel costs. Amortization of deferred stock-based compensation was $3.2 million for the nine months ended September 30, 2002, as compared to $2.4 million in the comparable period of 2001.

Interest income, net. Net interest income increased to $1.1 million for the nine months ended September 30, 2002 from $0.4 million for the nine months ended September 30, 2001. This increase was primarily attributable to higher cash, cash equivalents, and investment balances, resulting from the net proceeds of our initial public offering in October 2001. Interest expense remained comparable between the two periods.

Dividends related to beneficial conversion feature of preferred stock. Dividends relating to the beneficial conversion of our preferred stock of $26.8 million were recorded in the nine months ended September 30, 2001. These dividends arose due to the issuance of 6,643,371 shares of Series D convertible preferred stock in January, February and April 2001 for net proceeds of $56.4 million.

Net loss attributable to common stockholders. Net loss attributable to common stockholders was $23.4 million or $0.59 loss per basic and diluted share for the nine months ended September 30, 2002 as compared to a net loss of $66.6 million or $1.30 loss per basic and diluted share (pro forma for the assumed conversion of preferred stock) for the comparable period of 2001. This net loss includes a $4.2 million gross profit associated with the recognition of previously deferred revenues. Excluding the $4.2 million gross profit, our net loss would have been $19.2 million or $0.48 loss per basic and diluted share for the nine months ended September 30, 2002.

Liquidity and Capital Resources

In October 2001, we consummated our initial public offering of common stock in which we received net proceeds of $120.9 million. Previously, we financed our operations primarily through private placements of convertible

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preferred stock resulting in net proceeds of $119.2 million.

We have also financed our operations through equipment financing arrangements and other bank loans with Comdisco Ventures, GE Healthcare Financial Services and Phoenix Capital. Our current principal debt with these lenders include a $2.5 million equipment line of credit with an effective interest rate between 8.5% and 9.5% per annum with Comdisco Ventures, a $3.0 million equipment line of credit at an effective rate 7.3% with GE Healthcare Financial Services, and a $2.0 million senior loan and security agreement at an effective interest rate of 13.1% per annum with Phoenix Capital. These effective annual interest rates include the amortization of the fair value of warrants issued to Comdisco Ventures and Phoenix Capital. As of September 30, 2002, $4.9 million in principal was outstanding under these arrangements. We may no longer borrow capital from these lenders under the terms of these debt arrangements.

In May 2002, we entered into a revolving line of credit agreement with Wells Fargo Business Credit, Inc. The revolving line of credit agreement was amended and restated in September 2002. Under the terms of the amended and restated credit agreement, amounts we borrow from Wells Fargo Business Credit, Inc. are repaid to Wells Fargo Business Credit, Inc. directly by our accounts receivable debtors. Outstanding amounts owed to Wells Fargo Business Credit, Inc. under the amended and restated credit agreement are secured by all of our assets excluding our intellectual property assets. The maximum amount we may borrow from Wells Fargo Business Credit, Inc. is based on our eligible accounts receivable and cannot exceed $15.0 million. The amended and restated credit agreement includes certain covenants requiring minimum liquidity and minimum net income over time. We are not currently in compliance with certain of these covenants. We are currently negotiating an amendment to the amended and restated credit and security agreement that would bring us into compliance with these covenants. As of September 30, 2002, $3.6 million in principal was outstanding under the credit agreement.

We have 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 is approximately $1.6 million. We pay the equipment purchase price to the supplier through a portion of the purchase price for each packaging vial purchased from the supplier. To date, we have paid to the supplier approximately $137,000, consisting of approximately $40,000 in principal and approximately $97,000 in interest, pursuant to the financing arrangement. We will take title to the equipment once the equipment purchase price has been paid in full. We must pay the equipment purchase price to the supplier by not later than June 2008. The supplier has financed the equipment pursuant to a loan arrangement with CIB Bank. The supplier s loan obligations to CIB Bank are collateralized by the equipment. If the supplier defaults on its loan obligations to CIB Bank, we must assume and satisfy the the supplier obligations to CIB Bank in order to take title to the equipment. At September 30, 2002 the amount owing to the supplier is $1,567,500, consisting of $1,530,200 of principal and $37,300 of interest.

As of September 30, 2002, we had cash and cash equivalents of $38.2 million, short-term available-for-sale investments of $13.9 million and long-term available-for-sale investments of $33.3 million.

Cash used in operations. Net cash used in operating activities was approximately $58.9 million and $30.8 million for the nine months ended September 30, 2002 and 2001, respectively. For the nine months ended September 30, 2002, the difference between our net loss and our net cash used in operating activities reflected increases in accounts receivable and inventories and decreases in deferred cost of products sold and deferred revenue. The increase in accounts receivable is principally related to the growth in revenues as compared to the prior year period and the lengthening of customer payment terms to match our competitors customer payment terms. The increase in inventories was primarily attributable to increasing system kit inventories to ensure a smooth transition of our meter manufacturing to the People s Republic of China, a planned increase in test strip inventories, and an inventory of personal digital assistants to support sales of our FreeStyle Tracker system. The decrease in deferred cost of products sold and deferred revenue is attributable to achieving the ability to estimate product return rates for sales to retailers and wholesalers in the United States and Canada beginning with the quarter ended June 30, 2002. Previously deferred revenue on product sales and associated costs of products sold were recognized in the quarter ended June 30, 2002. In the nine months ended September 30, 2001, increases in accounts receivable and inventories were partially offset by increases in deferred revenue and accrued liabilities.

Cash used in investing activities. Net cash used in investing activities was approximately $50.9 million and $1.9 million for the nine months ended September 30, 2002 and 2001, respectively. During the current nine-month period, some of the proceeds from the initial public offering in October 2001 were invested in corporate bonds, municipal securities, and governmental securities. All investments are classified as available-for-sale securities. Capital expenditures for the current nine-month period include manufacturing equipment used in the production of

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our disposable test strips, as we increased production capacity to meet planned growth. In the nine months ended September 30, 2001, investing activities consisted of capital expenditures.

Cash provided by financing activities. Net cash provided by financing activities for the nine months ended September 30, 2002 was approximately $4.9 million, with $3.9 million proceeds from exercise of stock options, $5.7 million from proceeds from line of credit, $1.6 million from loan proceeds offset by $4.1 million attributable to principal payments on long-term debt, and $2.1 million principal payments on line of credit. Net cash provided by financing activities was $52.1 million for the nine months ended September 30, 2001, primarily attributable to the net proceeds from private placements of equity securities, partially offset by principal payments on long-term debt.

We have experienced negative cash flows from operations since inception. We do not expect positive cash flows from operations, on a quarterly basis, until we have been able to sustain profitability on a quarterly basis for two or more sequential quarters. 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 or fund litigation, and the availability of other financing. Our capital expenditures for the nine months ended September 30, 2002 were $8.5 million, and we believe that our capital requirements for the next 12 months will increase as a result of expanding our facilities. We believe that our current cash, cash equivalents and investment balances, together with the revenue to be derived from sales of FreeStyle, will be sufficient to fund our operations for at least the next 18 months. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to raise additional capital or incur additional indebtedness to fund our operations. Additional equity or debt financing, if required, may not be available on acceptable terms, or at all. If we are unable to obtain additional capital, we may be required to reduce our selling and marketing activities for FreeStyle, delay, reduce the scope of or eliminate our research and development programs, or relinquish rights to technologies or products that we might otherwise seek to develop or commercialize. In the event that we do raise additional equity financing, investors will be further diluted. In the event we incur additional indebtedness to fund our operations, we may have to grant the lender a security interest in our assets.

Inflation

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

Recent Accounting Pronouncements

In April 2002, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 145 (SFAS 145), *Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections,* which is effective for fiscal years beginning after May 15, 2002. Under SFAS 145, gains and losses from the extinguishment of debt should be classified as extraordinary items only if they meet the criteria of Accounting Principles Board Opinion No. 30. SFAS 145 also addresses financial accounting and reporting for capital leases that are modified in such a way as to give rise to a new agreement classified as an operating lease. We believe that the adoption of SFAS 145 will not have a material impact on our consolidated financial position or our results of operations.

In June 2002, the FASB issued Statement of Financial Accounting Standards No. 146 (SFAS 146), *Accounting for Costs Associated with Exit or Disposal Activities,* which is effective for exit or disposal activities initiated after December 31, 2002. SFAS 146 nullifies Emerging Issues Task Force Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring).* Under SFAS 146, a liability is required to be recognized for a cost associated with an exit or disposal activity when the liability is incurred. SFAS 146 applies to costs associated with an exit activity that does not involve an entity newly acquired in a business combination or with a retirement or disposal activity covered by FASB Statements No. 143, Accounting for Asset Retirement Obligations, and No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets . We believe that the adoption of SFAS 146 will not have a material impact on our consolidated financial position or our results of operations.

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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 $13.1 million in 1999, $43.6 million in 2000, $52.9 million in 2001 and $23.4 million in the nine months ended September 30, 2002. As of September 30, 2002, we had an accumulated deficit of approximately $139.0 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 our expenses are relatively fixed, less than anticipated revenues for a quarter could have a significant adverse impact on the Company s operating results.

We expect to derive substantially all of our future revenue from sales of FreeStyle and this product could fail to generate significant 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. To date, relative to market size, 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:

the significant influence of established glucose monitoring products;

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

the introduction or acceptance of competing products or technologies; and

cost constraints.

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 significant revenues or achieve profitability because we do not have alternative products.

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

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

We currently have limited experience in marketing and selling our products. We received regulatory clearance for our initial product in January 2000 and commenced commercial shipments in June 2000. We currently sell our products in the United States directly, using a sales organization that we assembled following regulatory clearance. Our products require a complex marketing and sales effort targeted at health care professionals, diabetes educators, people with diabetes, pharmacists and national retailers. We significantly expanded our sales and marketing teams in 2001, and we continued this expansion in 2002. We face significant challenges and risks in hiring, training, managing and retaining these teams, including managing geographically dispersed efforts and adequately training our people in the use and benefits of our products. 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. Our financial condition would be harmed if our marketing and sales efforts were 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 medical devices is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. We compete directly with Roche Diagnostics Corporation, LifeScan, Inc., a division of Johnson & Johnson, MediSense, a division of Abbott Laboratories, and Bayer AG, which currently account for approximately 90% of the worldwide sales of blood glucose self-monitoring systems. Each of these companies is either publicly traded or a division of a publicly-traded company, and 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 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.

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.

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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 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 currently evaluating the patent owner s claims.

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

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

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

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

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

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

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

We are currently developing additional enhancements for FreeStyle, and we are developing new products such as our Continuous Glucose Monitoring System. Marketing of these products will require FDA and other regulatory clearances and approvals. We have experienced some delays in the clinical trials being conducted to support the approval of our Continuous Glucose Monitoring System due to problems with the electronics portion of the system. Development of the Continuous Glucose Monitoring System 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 our Continuous Glucose Monitoring System, and the FDA has approved two of these products. If any of our competitors succeeds in

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developing a commercially viable product for continuous glucose monitoring and obtains government approval or successfully commercializes its FDA-approved product, this could negatively affect our future revenues. 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. The successful development and introduction of such products 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. Our Continuous Glucose Monitoring System under development will require premarket approval. We have experienced some delays in the clinical trials being conducted to support the approval of our Continuous Glucose Monitoring System due to problems with the electronics portion of the system. We may not be able to obtain additional clearances or approvals for the Continuous Glucose Monitoring System 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 or require us to cease marketing or recall the modified devices until these clearances are obtained.

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

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

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

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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 action 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 recently commenced a self-initiated field corrective action due to software bugs associated with the diabetes management features of our FreeStyle Tracker diabetes management system. Any recall of or material field corrective action for product diverts managerial and financial resources and harms our reputation with customers.

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

To be successful, we must manufacture our FreeStyle test strips in substantial quantities at acceptable costs. If we do not succeed in manufacturing sufficient quantities of our test strips to meet customer demand, we could lose customers and fail to acquire new customers, if they choose a competitor s product because our product is not available. We currently manufacture our Freestyle test strips using a process with which we have limited experience. Increasing demand since the launch of Freestyle has necessitated an increase in our test strip manufacturing capacity. In response, we 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 begin operations on the second 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.

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

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

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

Most of 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:

- fluctuations in the value of local currency;
- labor unrest and difficulties in staffing;

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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; and

a potential reversal of current favorable policies encouraging foreign trade.

Any delay or disruption in the manufacture of our FreeStyle meters, including delays or disruptions relating to these logistical and communication challenges or changes in the economic or political conditions in China, 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 could negatively impact our gross margins.

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

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

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

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

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

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

We may have difficulty managing our growth.

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

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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.

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 within six months after this expiration date. If we experience significant returns from retailers, wholesalers or end users, this could seriously harm our business and results of operations.

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

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

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 million. A product

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liability claim in excess of our insurance coverage would have to be paid out of cash reserves and would harm our reputation in the industry.

We are subject to additional risks associated with international operations.

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

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

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

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

We may have warranty claims that exceed our reserves.

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

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

We currently conduct all our scientific and test strip manufacturing and most of our management activities at a single location in Alameda, California near known earthquake fault zones. In addition, our facilities were built on fill material dredged from the San Francisco Bay in the 1960s. 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

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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 have been highly volatile and are likely to continue to be highly volatile in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our stock:

- volume and timing of orders for our products;
- monthly variations in market data relative to our competitors;
- our ability to develop, obtain regulatory clearance for, and market, new and enhanced products on a timely basis;
- the announcement of new products or product enhancements by us or our competitors;
- announcements of technological or medical innovations in the monitoring or treatment of diabetes;
- product liability claims or other litigation;
- quarterly variations in our or our competitors results of operations;
- changes in governmental regulations or in the status of our regulatory approvals or applications;
- changes in the availability of third-party reimbursement in the United States or other countries;
- changes in earnings estimates or recommendations by securities analysts; and
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

The sales of a substantial number of shares of our common stock 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 November 1, 2002, we had 40,651,819 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. All of these shares are available for sale.

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 22.4% of our common stock as of November 1, 2002. This significant concentration of share ownership may adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with 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.

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

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

- authorize the issuance of preferred stock which can be created and issued by the board of directors without prior stockholder approval, commonly referred to as blank check preferred stock, with rights senior to those of common stock;
- prohibit stockholder actions by written consent; and
- provide for a classified board of directors.

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

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

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

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Although we transact substantially all of our business in U.S. dollars, future fluctuations in the value of the U.S. dollar may affect the price competitiveness of our products. We derive a portion of our revenues in foreign currencies, predominantly in Canada and the United Kingdom. We also have a subsidiary in Canada and the United Kingdom. Due to the relative volume of transactions from Canada and the United Kingdom, we do not believe that we have significant exposure to foreign currency exchange rate risks. We currently do not use derivative financial instruments to mitigate this exposure and will continue to review our foreign currency positions.

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

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 a date (the Evaluation Date) within 90 days before the filing date of this quarterly report, have concluded that as of the Evaluation Date, our disclosure controls and procedures were adequate and designed to ensure that material information relating to us and our consolidated subsidiaries would be known to them by others within those entities.

(b) Changes in internal controls. Since the Evaluation Date, we have hired a Director of Internal Audit, otherwise there were no significant changes in our internal controls or to our knowledge, in other factors that could significantly affect our internal controls subsequent to the Evaluation Date.

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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 $1,022,000 for the purchase of machinery we use to manufacture our test strips, (ii) approximately $1,701,000 to expand our facility in Alameda, California, (iii) approximately $14,462,000 to sponsor free product samples and accelerate the hiring of additional sales representatives in an effort to expand our installed base of FreeStyle system kits intended to increase our market for disposable test strips and lancets, (iv) approximately $3,474,000 for research and development of enhanced FreeStyle products and our Continuous Glucose Monitoring System and (v) additional amounts for general working capital purposes. We are currently investing the remaining net proceeds from the offering for future use as additional working capital. Such remaining net proceeds have been invested in highly liquid instruments, such as commercial paper and U.S. Government obligations, with an average maturity of twelve months or less.

From January 1, 2002 through September 30, 2002, TheraSense did not issue any unregistered securities.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None

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

None

ITEM 5. OTHER INFORMATION

None

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

Exhibit 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

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Exhibit Number	Description of Document
	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
*10.16	Management Services Agreement between TheraSense, Inc. and ICT Group, Inc., dated January 31, 2000
*10.17	License Agreement between TheraSense, Inc. and Unilever PLC dated February 10, 2000
*10.18	Promissory Note dated March 5, 1999 for the principal aggregate amount of $72,495 issued by W. Mark Lortz to TheraSense
*10.19	Promissory Note dated March 5, 1999 for the principal aggregate amount of $15,187.50 issued by Charles T. Liamos to TheraSense
*10.20	Promissory Note dated September 1, 1999 for the principal aggregate amount of $61,250 issued by Charles T. Liamos to TheraSense
*10.21	Promissory Note dated December 1, 1997 for the principal aggregate amount of $62,650 issued by W. Mark Lortz to TheraSense, Inc.
**10.21(a)	Amendment to Promissory Note dated December 1, 1997 for the principal aggregate amount of $62,650 issued by W. Mark Lortz to TheraSense, Inc.
*10.22	Amended and Restated Investors Rights Agreement by and among holders of TheraSense Preferred Stock and TheraSense, Inc., dated January 23, 2001, as amended
*10.23	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
*10.24	Form of Change of Control Agreement between TheraSense, Inc. and each Vice President of TheraSense, Inc.
99.1	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.

Confidential treatment granted for portions of these exhibits.

Confidential treatment requested for portions of this exhibit.

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(b) Reports on Forms 8-K.

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

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SIGNATURE

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

THERASENSE, INC.
(Registrant)

Date: November 13, 2002

/s/ CHARLES T. LIAMOS

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

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CERTIFICATIONS

I, W. Mark Lortz, certify that:

1. I have reviewed this quarterly report on Form 10-Q of TheraSense, Inc., a Delaware corporation;

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

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

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

   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

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

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

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent functions):

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

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

6. The registrant s other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 13, 2002

/s/ W. MARK LORTZ

W. Mark Lortz
Chief Executive Officer

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I, Charles T. Liamos, certify that:

1. I have reviewed this quarterly report on Form 10-Q of TheraSense, Inc., a Delaware corporation;

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

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

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

   d) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

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

   f) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent functions):

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

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

6. The registrant s other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 13, 2002

/s/ CHARLES T. LIAMOS

Charles T. Liamos
Chief Financial Officer