THERASENSE INC
Form 10-Q
November 14, 2001

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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, 2001

OR

[_] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD
FROM _____ TO _____ .

Commission File Number:

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	94502
(Address of principal executive offices)	(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 ----- No X ---

As of November 1, 2001, Registrant had outstanding 39,490,229 shares of Common Stock, $0.001 par value.

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THERASENSE, INC.
QUARTERLY REPORT ON FORM 10-Q

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PART I: FINANCIAL INFORMATION
ITEM 1. CONDENSED FINANCIAL STATEMENTS

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

	Three Months Ended September 30,		
	2001	2000	
Revenues:			
Product sales	$ 19,608	$ 1,280	$
License income	250	--	
Research grant revenue	--	--	
Total revenues	19,858	1,280	
Cost of revenues	12,938	6,768	
Gross profit (loss)	6,920	(5,488)	
Operating expenses:			
Research and development	4,671	3,543	
Selling, general and administrative	15,250	5,574	
Total operating expenses	19,921	9,117	
Loss from operations	(13,001)	(14,604)	

Interest income	343	347	
Interest and other expense, net	(267)	(336)	
Net loss	(12,925)	(14,593)	
Deemed dividend related to beneficial conversion feature of preferred stock	--	--	
Net loss attributable to common stockholders	$ (12,925)	$ (14,593)	$
Net loss per common share, basic and diluted	$ (2.53)	$ (3.55)	$
Weighted-average shares used in computing net loss per common share, basic and diluted	5,115	4,105	

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

THERASENSE, INC.
CONDENSED BALANCE SHEETS
(in thousands)

	September 30, 2001
	(unaudited)
Assets	
Current assets:	
Cash and cash equivalents	$ 31,95
Accounts receivable, net	17,00
Inventories	5,39
Deferred cost of products sold	12,32
Prepaid expenses and other current assets	4,35
Total current assets	71,02
Property and equipment, net	5,30
Other assets	3,94
Total assets	$ 80,27
Liabilities, Convertible Preferred Stock and Stockholders' Deficit	
Current liabilities:	
Accounts payable	$ 14,00
Accrued liabilities	13,78
Deferred revenue	18,26
Current portion of capital lease obligations	1,10
Current portion of borrowings under lines of credit	2,29
Total current liabilities	49,45
Capital lease obligations, less current portion	1,22
Borrowings under lines of credit, less current portion	1,45
Convertible promissory note	-
Deferred revenue	3,51
Other liabilities	1,00

Total liabilities	56,64
Convertible preferred stock	119,24
Stockholders' deficit:	
Common stock	
Additional paid-in capital	28,35
Notes receivable from stockholders	(29
Deferred stock-based compensation, net	(21,10
Accumulated deficit	(102,58
Total stockholders' deficit	(95,61
Total liabilities, convertible preferred stock and stockholders' deficit	$ 80,27

(1) The balance sheet at December 31, 2000 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 financial statements.

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

	Nine Months Ended September 30,	
	2001	2000
Cash flows from operating activities:		
Net loss	$(39,858)	$(29,65
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,420	1,03
Amortization of deferred stock-based compensation	3,593	1,05
Other	424	11
Changes in operating assets and liabilities:		
Accounts receivable	(11,042)	(5,50
Inventories	(1,896)	(3,20
Deferred cost of products sold	(4,924)	(5,30
Prepaid expenses and other current assets	(3,174)	(1,16
Other assets	(2,207)	(31
Accounts payable	3,382	5,76
Accrued and other liabilities	10,359	4,40
Deferred revenue	13,089	5,41
Net cash used in operating activities	(30,834)	(27,37
Cash flows from investing activities:		
Purchase of property and equipment	(1,894)	(1,88
Proceeds from sale of property and equipment	6	1,60

Net cash used in investing activities	(1,888)	(27
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred stock, net	53,863	42,41
Proceeds from exercise of stock options	501	5
Proceeds from lines of credit	--	3,00
Proceeds from convertible promissory note	--	2,50
Principal payments on capital lease obligations	(552)	(8
Principal payments on lines of credit	(1,663)	(70
Other, net	--	2
Net cash provided by financing activities	52,149	47,20
Net increase in cash and cash equivalents	19,427	19,55
Cash and cash equivalents, beginning of period	12,532	2,32
Cash and cash equivalents, end of period	$ 31,959	$ 21,87

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

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

NOTE 1--Basis of Presentation:

The accompanying unaudited condensed financial statements have been prepared by TheraSense, Inc. ("TheraSense" or the "Company") 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 and nine month periods ended September 30, 2001 are not necessarily indicative of the results that may be expected for the year ending December 31, 2001, 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, 2000 included in the Company's Registration Statement on Form S-1, as amended (No. 333-64456), which was declared effective by the Securities and Exchange Commission on October 11, 2001.

NOTE 2--Net Loss Per Share:

Basic net loss per 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 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,	
	2001	2000
Numerator:		
Net loss	$(12,925)	$(14,593)
Deemed dividend related to beneficial conversion feature of preferred stock	--	--
Net loss attributable to common stockholders	$(12,925)	$(14,593)
Denominator:		
Weighted-average common stock outstanding	5,415	5,038
Less: Weighted-average shares subject to repurchase	(300)	(933)
Weighted-average shares used in computing basic and diluted net loss per common share	5,115	4,105

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

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

	September 30,	
	2001	2000
Options to purchase common stock	5,714	3,769
Common stock subject to repurchase	272	826
Convertible preferred stock	26,722	20,079
Warrants	521	521

NOTE 3--Recent Accounting Pronouncements:

In June 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 143, "Accounting for Asset Retirement Obligations," ("SFAS 143") which is effective for the Company beginning fiscal 2003. This Statement requires that the fair value of a liability for an asset retirement obligation be recognized in the period in which it is incurred if a reasonable estimate of fair value can be made, with the associated asset retirement costs capitalized as part of the carrying amount of the long-lived

asset. Management does not expect the adoption of SFAS 143 to have a material impact on the Company's financial position and results of operations.

In October 2001, the FASB issued Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," ("SFAS 144") which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal periods. SFAS 144 supersedes SFAS Statement No. 121 and portions of APB Opinion No. 30 ("Opinion 30"). However, SFAS 144 retains the requirement of Opinion 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of (by sale, by abandonment, or in a distribution to owners) or is classified as held for sale. SFAS 144 addresses financial accounting and reporting for the impairment of certain long-lived assets and for long-lived assets to be disposed of. Management does not expect the adoption of SFAS 144 to have a material impact on the Company's financial position and results of operations.

NOTE 4--Initial Public Offering:

On October 17, 2001, the Company closed its initial public offering in which it sold 6,900,000 shares of common stock at $19.00 per share for net proceeds of approximately $120.7 million, net of underwriting discounts, commissions and other offering costs. Immediately prior to the closing of the initial public offering, all the Company's convertible preferred stock automatically converted into 26,722,151 shares of common stock.

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

NOTE 5--Pro Forma Net Loss Per Share:

Pro forma basic and diluted net loss per share have been computed to give effect to convertible preferred stock that will convert to common stock upon the closing of the Company's initial public offering (using the as-if-converted method). 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 per share data):

	Three Months Ended September 30,	
	2001	2000
Pro forma net loss per common share, basic and diluted:		
Net loss attributable to common stockholders.....	$(12,925)	$(14,593)
Deemed dividend related to beneficial conversion feature of preferred stock.....	--	--
Net loss.....	$(12,925)	$(14,593)
Weighted-average shares used in computing basic and diluted net loss per common share.....	5,115	4,105

Adjustments to reflect the effect of the assumed conversion of the preferred stock from the date of issuance	26,722	20,079	
Weighted-average shares used in computing pro forma net loss per common share, basic and diluted	31,837	24,184	
Pro forma net loss per common share, basic and diluted	$ (0.41)	$ (0.60)	

NOTE 6--Deferred Stock-Based Compensation:

As of September 30, 2001, the Company has recorded a cumulative $26.6 million of deferred stock compensation related to stock options granted to consultants and employees. Stock compensation expense is being recognized on a straight-line basis over the vesting periods of the related options, generally four years. The Company recognized stock compensation expense of $1.6 million and $3.6 million for the three and nine month periods ended September 30, 2001, respectively, and $0.6 million and $1.1 million for the three and nine month periods ended September 30, 2000, respectively.

NOTE 7--Inventories:

At September 30, 2001 and December 31, 2000, inventories consisted of the following (in thousands):

	September 30, 2001	December 31, 2000
Raw materials	$2,051	$1,175
Work-in-process	1,549	783
Finished goods	1,790	1,536
	$5,390	$3,494

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

This Management's Discussion and Analysis of Financial Condition and Results of Operations and other parts of this Form 10-Q contain forward-looking statements that involve risks and uncertainties. These statements typically may be identified by the use of forward-looking words or phrases such as "believe," "expect," "intend," "anticipate," "should," "planned," "estimated," and "potential," among others. All forward-looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experience to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our businesses include but are not

limited to (1) our limited operating experience and history of losses; (2) limited manufacturing experience; (3) our dependence on FreeStyle for future revenues; (4) substantial competition; (5) risks related to noncompliance with FDA regulations; (6) risks related to failure to protect our intellectual property and litigation in which we may become involved; (7) our limited sales and marketing experience; (8) our dependence on single source suppliers and manufacturers for our FreeStyle products; and (9) other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission, including those set forth in this filing as "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, 2001, 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 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. We are also developing a Continuous Glucose Monitoring System that is intended to permit people with diabetes to accurately and discreetly measure their glucose levels on a continuous basis.

We incurred significant operating losses and negative cash flows from operations in each full fiscal year since inception. We incurred net losses of $4.7 million in 1998, $13.1 million in 1999, $43.6 million in 2000 and $39.9 million for the nine months ended September 30, 2001. As of September 30, 2001, we had an accumulated deficit of $102.6 million. We expect to incur significant additional losses as we expand our sales and marketing efforts and continue to develop new products.

Revenues are generated from sales of our FreeStyle System kit and from the recurring sales of disposable FreeStyle test strips and lancets. Our return policy allows end users in the United States 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 can return these products to us up to six months beyond this expiration date. As a result of these rights of return and the current unavailability of historical trends in sales and product returns, we defer recognition of revenue on sales of FreeStyle test strips until resold by the retailers and wholesalers to end users, and we defer recognition of revenue on FreeStyle System kits until 30 days after purchase by the end user. Because we lack a sufficient historical basis from which we could estimate return rates, we are required to rely on data estimates provided to us by third-party data providers in order to recognize revenue from sales to end users by retailers and wholesalers. These data estimates may cause imprecise revenue recognition, as these third-party data providers may not provide consistent, reliable data. We do not know how long we will be required to rely on these estimates. However, we believe that we will have a sufficient historical basis from which we can estimate return rates beginning with the quarter ending September 30, 2002. For the first quarter in which we use our own estimates for return rates, we anticipate that our deferred revenue from product sales will decrease and we will experience a corresponding increase in our recognized revenue from product sales. This one-time event could cause a

significant increase in our net revenues for the applicable period.

Our products distributed internationally have no right of return, and we recognize revenue on these products upon shipment. We recognize revenue on direct product sales over the telephone or through our website to end users upon shipment for FreeStyle test strips and lancets and 30 days after purchase on sales of FreeStyle System kits. Our current sales terms to retailers and wholesalers provide for customer payment within 60 days of shipment on initial orders and payment within 30 days for subsequent orders. We perform ongoing credit evaluations of our customers' financial condition and, generally, require no collateral from our customers. We believe our terms to retailers, wholesalers and end users, including their rights to return, are similar to our competitors' terms.

Manufacturers typically sell their glucose monitoring devices at substantial discounts to list prices, offer customer rebates or provide free product samples to expand their installed base of monitoring devices and thus increase the market for their disposable test strips and lancets. We have been offering and expect to continue to offer similar discounts and rebates on, and free samples of, our FreeStyle System kits to establish an installed base of systems from which we expect to generate recurring revenues from our disposable FreeStyle test strips and lancets. Due to the recent commencement of our sales, we do not have significant historical trends in rebates claimed by end users. As a result, we record an allowance for 100% of the allowable rebate as a reduction of revenues reported. As we accumulate trend data in rebates claimed, we are likely to change the percentage of the allowable rebate.

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 an 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;
- amortization of deferred stock-based compensation; and
- royalties payable under technology licenses.

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

Research and development expenses include costs associated with the design, development, testing and enhancement 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;
- amortization of deferred stock-based compensation; and
- overhead allocated to product development.

At the time we commenced commercial shipments in June 2000, we transitioned the recording of manufacturing-related costs from research and development expense to cost of revenues. All research and development costs are

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

Selling, general and administrative expenses primarily consist of:

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

Deferred stock-based compensation consists of amortization of deferred compensation in connection with stock option grants and sales of 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, 2001, we have recorded aggregate deferred stock-based compensation of $26.6 million, of which $21.1million will be amortized to expense on a straight line basis through 2005. This amount is being amortized over the respective vesting periods of these equity instruments, which is typically four years. Deferred 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 a five-year exclusive distribution agreement with Disetronic Group relating to the distribution of FreeStyle in Germany, Switzerland, Denmark, Austria, Sweden, Finland, Norway and the Netherlands. Disetronic commenced sales in Germany and Sweden in May 2001. In connection with this agreement, we received an advance payment on a purchase order from Disetronic of $1.5 million, which we recognized in the second quarter of 2001 as we shipped products.

In April 2001, we entered into a five-year exclusive distribution agreement with Nipro Corporation relating to the distribution of FreeStyle in Japan. 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 commencing in April 2001.

Results of Operations

Three Months Ended September 30, 2001 and September 30, 2000

Revenues. Total revenues were $19.9 million for the three months ended September 30, 2001 as compared to $1.3 million for the comparable period in 2000. The increase was due primarily to greater sales of FreeStyle System kits and FreeStyle test strips. In addition, we recognized revenues of $0.3 million for the three months ended September 30, 2001 related to the $5.0 million distribution agreement payment received from Nipro in April 2001. As of September 30, 2001, deferred revenue was $18.3 million, of which $17.3 million is attributable to product shipments awaiting sale through to end users and for the 30-day cash refund period on FreeStyle System kit sales to lapse. Deferred revenue on product shipments increased by $4.4 million during the current quarter principally due to expanding distribution to wholesalers in the United States. Four of our customers individually accounted for more than 10% and collectively accounted for approximately 54% of our total revenues from product sales and deferred revenue for the three months ended September 30, 2001.

Cost of revenues. Cost of revenues for the three months ended September 30, 2001 was $12.9 million. For this period, cost of revenues consists primarily of $12.7 million attributable to product sales, and there was no cost associated with the license fee income earned. Cost of revenues for the three months ended September 30, 2000 was $6.8 million. For this period, cost of revenues included primarily start-up production costs and a $3.5 million charge to reduce FreeStyle System kit inventories to estimated net realizable value. Amortization of stock-based compensation expense reported in cost of revenues for the three months ended September 30, 2001 was $0.2 million, as compared to an insignificant amount in the same prior year period.

Research and development expenses. Research and development expenses increased to $4.7 million for the three months ended September 30, 2001 from $3.5 million for the three months ended September 30, 2000, representing an increase of $1.2 million, or 32%. This increase was primarily attributable to hiring additional personnel and increased spending on product development efforts. Amortization of deferred stock-based compensation was $0.3 million for the three months ended September 30, 2001 as compared to $0.2 million in the same prior year period. We expect research and development spending to increase over the next several years as we increase clinical trials for our Continuous Glucose Monitoring System and expand our research and development activities to support our current and future products.

Selling, general and administrative expenses. Selling, general and administrative expenses increased to $15.3 million for the three months ended September 30, 2001 from $5.6 million for the three months ended September 30, 2000, representing an increase of $9.7 million, or 174%. This increase was primarily attributable to increases of $3.1 million for marketing activities and other spending associated with expanding distribution for and developing consumer awareness of FreeStyle, $2.1 million spent on product sampling, $1.6 million for personnel costs largely related to expanding our U.S. direct sales force as well as marketing and business support functions, $1.2 million spent for customer service and support operations, and $0.8 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, 2001, as compared to $0.4 million in the same prior year period. We expect our selling, general and administrative expenses to increase as we increase product sampling,

expand our sales force, increase our marketing and promotional activities, and operate as a public company.

Interest income, net. Net interest income was $0.1 million for the three months ended September 30, 2001 and was insignificant in the same prior year period. Interest income results from our interest on cash and cash equivalents, while interest expense is associated with borrowings under lines of credit and capital lease obligations.

Nine Months Ended September 30, 2001 and September 30, 2000

Revenues. Total revenues were $45.4 million for the nine months ended September 30, 2001 as compared to $1.8 million for the comparable period in 2000. The increase was due primarily to greater sales of FreeStyle System kits and FreeStyle test strips. In addition, we recognized revenues of $0.5 million for the nine months ended September 30, 2001 related to the $5.0 million distribution agreement payment received from Nipro in April 2001. For the nine months ended September 30, 2000, we recognized revenue of $0.5 million from a specific non-refundable negotiation fee related to a potential distribution arrangement, which was never consummated. As of September 30, 2001, deferred revenue was $18.3 million, of which $17.3 million is attributable to product shipments awaiting sale through to end users and for the 30-day cash refund period on FreeStyle System kit sales to lapse. Deferred revenue on product shipments increased by $8.6 million during the current nine-month period principally due to expanding distribution to retailers and wholesalers in the United States. Three of our customers individually accounted for more than 10% and collectively accounted for approximately 37% of our total revenues from product sales and deferred revenue for the nine months ended September 30, 2001.

Cost of revenues. Cost of revenues for the nine months ended September 30, 2001 was $32.6 million. For this period, cost of revenues is attributable primarily to $32.3 million in product sales, and there was no cost associated with the license fee income earned. Cost of revenues for the nine months ended September 30, 2000 was $7.1 million. For this period, cost of revenues included primarily start-up production costs and a $3.5 million charge to reduce FreeStyle System kit inventories to estimated net realizable value. Amortization of stock-based compensation expense reported in cost of revenues for the nine months ended September 30, 2001 was $0.3 million, as compared to an insignificant amount in the same prior year period.

Research and development expenses. Research and development expenses increased to $11.0 million for the nine months ended September 30, 2001 from $9.4 million for the nine months ended September 30, 2000, representing an increase of $1.6 million, or 17%. This increase was primarily attributable to hiring additional personnel, higher spending associated clinical trials and increased spending on product development efforts. Prior to commencing commercial shipments of FreeStyle in June 2000, costs associated with start-up manufacturing activities were reported as research and development expenses. These expenses, which occurred in the first half of 2000, totaled $1.2 million, partially offsetting the increase in research and development expenses for the nine months ended September 30, 2001 over research and development expenses for the nine months ended September 30, 2000. Amortization of deferred stock-based compensation was $0.9 million for the nine months ended September 30, 2001 as compared to $0.3 million in the same prior year period.

Selling, general and administrative expenses. Selling, general and administrative expenses increased to $42.1 million for the nine months ended September 30, 2001 from $15.3 million for the nine months ended September 30,

2000, representing an increase of $26.8 million, or 174%. This increase was primarily attributable to increases of $8.0 million spent on product sampling, $5.7 million for marketing activities and other spending associated with expanding distribution for and developing consumer awareness of FreeStyle, $4.9 million for personnel costs largely related to expanding our U.S. direct sales force as well as marketing and business support functions, $3.3 million spent for customer service and support operations, and $1.3 million for travel costs, largely related to our sales force. Amortization of deferred stock-based compensation was $2.4 million for the nine months ended September 30, 2001, as compared to $0.7 million in the same prior year period.

Interest income, net. Net interest income remained relatively flat at $0.5 million for the nine months ended September 30, 2001 as compared to $0.4 million in the same prior year period. Interest income for the nine months ended September 30, 2001 increased due to higher average cash and cash equivalents balances, resulting from the net proceeds of a private equity offering initiated in January 2001. Interest expense for the nine months ended September 30, 2001 increased to a lesser extent, as a result of additional borrowings under available lines of credit, amortization of debt issuance costs associated with warrants issued in connection with lines of credit and capital lease obligations arising under a particular sale and leaseback transaction.

Dividends related to beneficial conversion feature of preferred stock. Dividends relating to 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 preferred stock in January, February and April 2001 for net proceeds of $56.4 million. Dividends relating to beneficial conversion of our preferred stock of $14.8 million were recorded in the nine months ended September 30, 2000. These dividends arose due to the issuance of 8,490,159 shares of Series C preferred stock in February 2000 for net proceeds of $42.4 million.

Liquidity and Capital Resources

In October 2001, we consummated our initial public offering of common stock in which we received net proceeds of $120.7 million. From our inception through September 30, 2001, we financed our operations primarily through private placements of convertible preferred stock resulting in net proceeds of $119.2 million. We have also financed our operations through equipment financing arrangements and other loans with $6.1million in principal outstanding at September 30, 2001. Our current principal debt arrangements include both a $5.0 million subordinated debt agreement at an effective interest rate of 22.3% per annum and a $2.5 million equipment line of credit at effective interest rates between 8.5% and 9.5% per annum with Comdisco Ventures, 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 each of these lenders. We may no longer borrow capital under these debt arrangements. As of September 30, 2001, we had cash and cash equivalents of $32.0 million.

Cash used in operations. Net cash used in operating activities was approximately $30.8 million and $27.4 million for the nine months ended September 30, 2001 and 2000, respectively. For these periods, net cash used in operating activities resulted primarily from net losses. For the nine months ended September 30, 2001, the difference between our net loss and our net cash used in operating activities is primarily attributable to our receipt of Nipro's $5.0 million distribution agreement payment and the non-cash expense for stock-based compensation in the amount of $3.6 million.

Cash used in investing activities. Net cash used in investing activities was approximately $1.9 million and $0.3 million for the nine months ended September 30, 2001 and 2000, respectively. These investing activities consisted of capital

expenditures. For the nine months ended September 30, 2000, net cash used in investing activities included $1.6 million in proceeds from the sale of capital assets under a sale and leaseback transaction.

Cash provided by financing activities. Net cash provided by financing activities was approximately $52.1 million and $47.2 million for the nine months ended September 30, 2001 and 2000, respectively. The net cash provided by financing activities was primarily attributable to the proceeds from private placements of equity securities and proceeds from long-term borrowings.

We expect to have negative cash flow from operations for approximately the next 12 months. We also expect increased sales and marketing expenses related to the promotion of FreeStyle, increased research and development

expenses, as well as expenses for additional personnel and product enhancement efforts and expenses related to our operations as a public company. Our future capital requirements will depend on a number of factors, including market acceptance of FreeStyle, the resources we devote to developing and supporting our products, continued progress of our research and development of potential products, the need to acquire licenses to technology and the availability of other financing. Our capital expenditures for the nine months ended September 30, 2001 were $1.9 million, and we believe that our capital requirements for the next 12 months will increase as a result of expanding our facilities and our test strip manufacturing capacity. We believe that our current cash balances, together with the net proceeds of our initial public offering in October 2001 and revenue to be derived from sales of FreeStyle, will be sufficient to fund our operations for at least the next two years. 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 in this offering will be further diluted. In the event we incur additional indebtedness to fund our operations, we may have to grant the lender a security interest in our assets.

Inflation

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

Recently Issued Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 143, "Accounting for Asset Retirement Obligations," ("SFAS 143") which is effective for us beginning fiscal 2003. SFAS 143 requires that the fair value of a liability for an asset retirement obligation be recognized in the period in which it is incurred if a reasonable estimate of fair value can be made, with the associated asset retirement costs capitalized as part of the carrying amount of the long-lived asset. We do not expect the adoption of SFAS 143 to have a material impact on our financial position and results of operations.

In October 2001, the FASB issued Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," ("SFAS 144") which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal periods. SFAS 144 supersedes SFAS Statement

No. 121 and portions of APB Opinion No. 30 ("Opinion 30"). However, SFAS 144 retains the requirement of Opinion 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of (by sale, by abandonment, or in a distribution to owners) or is classified as held for sale. SFAS 144 addresses financial accounting and reporting for the impairment of certain long-lived assets and for long-lived assets to be disposed of. We do not expect the adoption of SFAS 144 to have a material impact on our financial position and results of operations.

Factors Affecting Operations and Future Results

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

We have a limited history of operations and have focused primarily on research and development, product engineering, clinical trials and seeking FDA regulatory clearance to market our products. We received FDA clearance for FreeStyle, our first commercial product, in January 2000, and we commenced commercial shipments in June 2000. We have generated only limited revenues from the sale of our products to date and have incurred losses every year since 1997. We incurred losses of $13.1 million in 1999, $43.6 million in 2000 and $39.9 million in the nine months ended September 30, 2001. As of September 30, 2001, we had an accumulated deficit of approximately $102.6 million. It is possible that we will never generate sufficient revenues from product sales to achieve profitability. Even if we do achieve significant revenues from our product sales, we expect that increased operating expenses will result in significant operating losses over the next several quarters as we, among other things:

- expand our domestic and international selling and marketing activities as we attempt to gain market share for FreeStyle;
- increase our research and development efforts to improve our existing products and develop new products such as our Continuous Glucose Monitoring System;
- perform clinical research and trials in an effort to obtain governmental clearance and approval for the commercial sale of our Continuous Glucose Monitoring System; and
- expand our facilities in Alameda, California, including an expansion of our test strip manufacturing capacity.

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

We 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. If demand for FreeStyle

increases, we will need to purchase additional specialized equipment with substantial lead times and obtain additional raw materials in order to increase the output volume of our test strips. If we are unable to obtain the necessary equipment or raw materials to effectively manufacture and meet customer demand for our FreeStyle test strips, we may not improve our sales growth sufficiently to achieve profitability.

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

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

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

- the significant influence of established glucose monitoring products;

- the ability of some of our competitors to price products below a price at which we can competitively manufacture and sell our products;
- cost constraints; and
- the introduction or acceptance of competing products or technologies.

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

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

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

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

publicly-traded company, and enjoys several competitive advantages, including:

- significantly greater name recognition;
- established relations with health care professionals, customers and third-party payors;
- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or incentives to gain a competitive advantage;
- established distribution networks and relationships with retailers; and
- greater resources for product development, sales and marketing and patent litigation.

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

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. We expect that our Continuous

Glucose Monitoring System under development will require premarket approval. Therefore, even if the product is successfully developed, it may not be commercially available for a number of years. We may not be able to obtain additional clearances or approvals in a timely fashion, or at all. Delays in obtaining clearance or approval could adversely affect our revenues and profitability.

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. 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 the FDA does not clear our recent FreeStyle labeling changes, we may be required to include significantly more restrictive labeling, cease marketing FreeStyle under this labeling or recall FreeStyle.

In June 2001, we submitted additional information to the FDA in support of a labeling change we previously implemented. This labeling change sought to clarify the safe and effective use of FreeStyle in light of physiological differences between the finger and alternate blood glucose testing sites. The FDA has decided to review our submission as a 510(k). Because FreeStyle is currently being marketed with the revised more cautionary labeling, unless and until we obtain clearance of that 510(k), we are technically out of compliance with FDA regulations. In response, the FDA could require us to cease marketing FreeStyle with the more cautionary labeling, publish a public health notification disclosing warnings regarding the use of blood glucose monitoring systems that can be utilized with blood samples obtained from sites other than the fingertip or recall FreeStyle until we obtain 510(k) clearance. Also, in these circumstances, we may be subject to significant regulatory fines or penalties.

We will work closely with the FDA to address their questions and resolve any issues around our labeling. On October 19, 2001, we had an individual meeting with the FDA where we specifically discussed our pending FreeStyle 510(k). In addition, on October 29, 2001 we attended a scheduled meeting of the FDA's Clinical Chemistry and Clinical Toxicology Panel to provide advice and recommendations on the types of data and/or labeling needed in 510(k) submissions for blood glucose monitoring systems that can be utilized with blood samples obtained from sites other than the fingertip. However, the FDA may not accept our cautionary language as sufficient, and the FDA could require us to include significant restrictions on use in the labeling. In discussions with the FDA, we have been informed that, since the labeling changes are due to human physiology, all manufacturers of off-fingertip glucose self-monitoring products are being treated the same, and when such a manufacturer has submitted a labeling change similar to ours, the FDA has required a 510(k). If the FDA orders us to cease marketing FreeStyle with its current labeling, to recall such product, to pay fines or penalties, or to include significant restrictions on use in the FreeStyle labeling, our sales growth would be adversely impacted, and we may not reach profitability.

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 and lancets, 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. We recently went through a Quality System Regulation inspection at our facilities in Alameda, California and have submitted a corrective action plan to the FDA addressing the observations noted in the

audit. 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 or if our corrective action plan is not sufficient, our operations could be disrupted and our manufacturing delayed. If we fail to take adequate corrective action in response to any FDA observations, we could face various enforcement actions, which could include a shut-down of our manufacturing operations and a recall of our products, which would cause

our product sales and profitability to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements.

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

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

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. We have recently received a letter from the exclusive licensee of a recently issued patent alleging that FreeStyle infringes the patent and requesting that we contact the licensee regarding sublicense opportunities. We are evaluating the patent and have responded to the letter indicating that we would be willing to discuss potential sublicensing terms.

If we were unable to obtain 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, including those already allowed, 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. 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, as well as new products such as our Continuous Glucose Monitoring System. Marketing of these products will require FDA and other regulatory clearances and approvals. Development of these products will require additional research and development expenditures. We may not be successful in developing, marketing or manufacturing these new products. In addition, several of our competitors are in various

stages of development of products similar to our Continuous Glucose Monitoring System, and the FDA has approved two of these products. If any of our competitors succeeds in developing a commercially viable product and obtains government approval or successfully commercializes its FDA-approved product, this could negatively affect our future revenues.

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, retail pharmacists and national retailers. We significantly expanded our sales and marketing teams in 2000. We are continuing this expansion in 2001 and we expect this expansion to continue in 2002. We will face significant challenges and risks in training, managing and retaining these teams, including managing geographically dispersed efforts and adequately training our people in the use and benefits of our products. We may not be able to hire sufficient additional personnel to create increasing demand for our products. In addition, we have distribution arrangements for the sale of our products internationally and are dependent upon the sales and marketing efforts of our third-party distributors. These distributors may not commit the necessary resources to effectively market and sell our products. Further, they may not be successful in selling our products. Our financial condition would be harmed if our marketing and sales efforts are unsuccessful.

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. 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, 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.

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.

We may have difficulty managing our growth.

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

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

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

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

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

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

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

Our ability to provide superior customer service to our customers, health care professionals and educators is critical. To effectively compete, we must build

strong brand awareness among our customers, much of which is based upon personal referrals. In order to gain these referrals, we must provide customer service representatives who are able and available to provide our customers with answers to questions regarding our products. This will require us to

continue to build and maintain customer service operations, for which we currently rely on a single third-party provider. We will require increased staff at our third-party provider to further support a 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.

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

In September 2000, we entered into an agreement for the exclusive marketing and sale of FreeStyle in several European countries, subject to regulatory approval. In May 2001, our third-party distributor commercially introduced FreeStyle in Germany and Sweden. In April 2001, we entered into an agreement for the exclusive marketing and sale of FreeStyle in Japan, subject to regulatory approval. We will be dependent on these distributors in those markets, and we will need to attract additional distributors in other markets. If our current or future third-party distributors do not succeed, we may never realize significant international revenues.

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. Nipro Corporation, our exclusive distributor in Japan, submitted an application for approval to market FreeStyle in Japan with the Ministry of Health, Labor and Welfare. Failure to receive the approval in Japan or 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.

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 may 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.

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 $20.0 million. A product liability claim in excess of our insurance coverage would have to be paid out of cash reserves and would harm our reputation in the industry.

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

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

We may have warranty claims that exceed our reserves.

FreeStyle meters carry a five-year warranty against defects in materials and workmanship. We will be responsible for all claims, actions, damages, liens, liabilities, costs and expenses for defects attributable to the FreeStyle meter. We have established reserves for the liability associated with product warranties. However, any unforeseen warranty exposure could adversely affect our operating results.

All 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, test strip manufacturing and management activities at a single location in Alameda, California near known earthquake fault zones. In addition, our facilities were built on fill material dredged from the San Francisco Bay in the 1960s. Our sole supplier of FreeStyle meters also currently manufactures these devices at a single facility in San Jose, California near known earthquake fault zones. We have taken precautions to safeguard our facilities, including insurance, health and safety protocols, and off-site storage of computer data. However, a natural disaster, such as an earthquake, fire or flood, could cause substantial delays in our operations, damage or destroy our manufacturing equipment or inventory, and cause us to incur additional expenses. A disaster

could seriously harm our business and adversely affect our reputation with customers. The insurance we maintain against fires, floods, and earthquakes may not be adequate to cover our losses in any particular case.

Power outages in California may adversely affect us.

We conduct all of our scientific, test strip manufacturing and management activities in California and rely on a continuous power supply to conduct operations. Our sole-source supplier of FreeStyle meters is currently manufacturing our meters in a single facility that is also in California. California's current energy crisis could substantially disrupt our operations and increase our expenses. California has recently implemented, and may in the future continue to implement, rolling blackouts throughout the state. If blackouts interrupt our power supply, we may be temporarily unable to continue

operations at our facilities, which includes the manufacture and production of our FreeStyle test strips. Interruptions in our ability to continue operations at our facilities could delay our shipments of FreeStyle test strips, delay the development of our products, and disrupt communications with our customers, suppliers and third-party manufacturing operations. Future interruptions could result in lost revenue and damage our reputation, either of which could harm our business and results of operations. Furthermore, shortages in wholesale electricity supplies have caused power prices to increase. If wholesale prices continue to increase, our operating expenses will likely increase, which will have a negative effect on our operating results.

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

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

We consummated the initial public offering of our common stock in October 2001. Accordingly, there has only been a public market for shares of our common stock since October 2001. An active public trading market may not develop or, if developed, may not be sustained. Further, we expect that the market price of our common stock may fluctuate substantially. The market price for the common stock may be affected by a number of factors, including:

- volume and timing of orders for our products;
- our ability to develop, obtain regulatory clearance for, and market, new and enhanced products on a timely basis;
- the announcement of new products or product enhancements by us or our competitors;
- announcements of technological or medical innovations in the monitoring or treatment of diabetes;
- product liability claims or other litigation;
- quarterly variations in our or our competitors' results of operations;
- changes in governmental regulations or in the status of our regulatory approvals or applications;

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

- changes in earnings estimates or recommendations by securities analysts; and

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

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

Sales of substantial number of shares of our common stock in the public market or the market perception that these sales may occur, could significantly and negatively affect the market price for our common stock. As of September 30, 2001, we had 39,052,222 shares of common stock outstanding after giving effect to the issuance of 6,900,000 shares of common stock in our October 2001 initial public offering and the automatic conversion of all of our outstanding shares of preferred stock into an equal number of shares of common stock immediately prior to the closing of our October 2001 initial public offering. The 6,900,000 shares of our common stock sold in our October 2001 initial public offering are freely tradable. The remaining 32,152,222 of these shares are subject to a lock-up agreement under which the holders of these shares have agreed not to sell or otherwise dispose of their shares of common stock until 180 days after the effective date of our October 2001 initial public offering. All of these shares will be available for sale after the expiration of the lock-up period on April 10, 2002, and approximately 16.0 million of these shares will be subject to volume restrictions because they are held by our affiliates. In addition, U.S. Bancorp Piper Jaffray Inc., the lead underwriter of our initial public offering, may waive these lock-up restrictions prior to the expiration of the lock-up period without prior notice.

In addition, the holders of approximately 27,243,164 shares of common stock and warrants exercisable for shares of common stock will have rights (after giving effect to the automatic conversion of all of our outstanding shares of preferred stock into an equal number of shares of common stock immediately prior to the closing of our October 2001 initial public offering), subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Furthermore, if we were to include in a company-initiated registration statement shares held by those holders pursuant to the exercise of their registration rights, those sales could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

Our principal stockholders, executive officers and directors 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 37.0% of our common stock as of September 30, 2001 after giving effect to the issuance of 6,900,000 shares of common stock in our October 2001 initial public offering and the automatic conversion of all of our outstanding shares of preferred stock into an equal number of shares of common stock immediately prior to the closing of our October 2001 initial public offering. This significant concentration of share ownership

may adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. These stockholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. In addition, they could dictate the management of our business and affairs. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control, or impeding a merger or consolidation, takeover or other business combination that could be favorable to our investors.

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

Our amended and restated 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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. As of September 30, 2001, our cash and cash equivalents consisted primarily of money market funds maintained at one major U.S. financial institution. The recorded carrying amounts of cash and cash equivalents approximate fair value due to their short-term maturities. We do not believe that an increase in market rates would have any significant negative impact on the realized value of our investments, but an increase in market rates could negatively impact the interest expense associated with a portion of our long-term debt. Substantially all of our long-term debt obligations have a fixed rate of interest.

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. Our managing underwriters for the offering were U.S. Bancorp Piper Jaffray Inc., SG Cowen Securities Corporation and Thomas Weisel Partners LLC. Of the $131,100,000 in gross proceeds raised in connection with the offering, (i) $9,177,000 was paid to the managing underwriters in connection with underwriting discounts and commissions, and (ii) approximately $1,174,000 is payable by us in connection with expenses, including legal, printing and filing fees, in connection with the offering. There were no direct or indirect payments to our directors or officers or to any other person or entity. 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 July 1, 2001 through September 30, 2001, TheraSense issued unregistered securities to a limited number of persons as described below:

1. TheraSense granted stock options to purchase an aggregate of 1,046,300 shares of common stock at an exercise price of $9.00 per share to employees and consultants pursuant to its 1997 Stock Plan.

2. TheraSense issued an aggregate of 60,889 shares of common stock upon exercise of options under its 1997 Stock Plan.

No underwriters were engaged in connection with the foregoing issuances of securities. Issuances of these securities were deemed to be exempt from registration under the Securities Act of 1933, as amended, in reliance upon Regulation D promulgated under Section 4(2) thereof, as transactions by an issuer not involving a public offering or in reliance on Rule 701 promulgated under Section 3(b) thereof, as transactions pursuant to compensatory benefit plans and contracts relating to compensation as provided under such rule. The recipients of securities in each transaction represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the securities issued in such transactions. All recipients had adequate access, through their relationship with TheraSense, to information about the company.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None

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

Effective August 17, 2001, the holders of a majority of our then outstanding shares approved an increase in the number of shares of common stock reserved for future issuance under our 1997 Stock Plan by 500,000 pursuant to an action by written consent. We made a corresponding decrease in the number of shares approved for issuance under our 2001 Stock Plan by 500,000.

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
***3.2	Bylaws of TheraSense, Inc. as currently in effect
*4.1	Specimen Common Stock Certificate
*10.1	1997 Stock Plan 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
+*10.6	Technology Purchase Agreement between TheraSense and E. Heller & Co. dated as
+*10.7	Cooperative Development Agreement between TheraSense, Inc. and Facet Technolo North America LLC), dated as of December 1, 1998
+*10.7(a)	First Amendment to Cooperative Development Agreement between TheraSense, Inc. Gainor Medical North America LLC), effective June 1, 2001
+*10.7(b)	Master Purchase Agreement between TheraSense, Inc. and Facet Technologies LLC
*10.8	Standard Industrial/Commercial Single-Tenant Lease between TheraSense, Inc. a dated as of February 26, 1999, and addendum thereto
+*10.9	Master Purchase Agreement between TheraSense and Flextronics International US 1999
+*10.10	Assignment of Patent Rights and Technology by and among Board of Regents of t agency of the State of Texas, Dr. Adam Heller, E. Heller & Company and TheraS
+*10.11	First Amendment, dated March 19, 1998, to the Agreement entitled Assignment o and among Board of Regents of the University of Texas System, an agency of th E. Heller & Company and TheraSense Inc. dated August 1, 1991
+*10.12	License Agreement between TheraSense, Inc. and Asulab SA., dated February 23,
+*10.13	Warehouse Distribution Contract between TheraSense, Inc. and Livingston Healt 15, 2000
+*10.14	International Distributor Agreement between TheraSense, Inc. and Nipro Corpor
+*10.15	International Distributor Agreement between TheraSense, Inc. and Disetronic H
*10.16	Management Services Agreement between TheraSense, Inc. and ICT Group, Inc., d
*10.17	License Agreement between TheraSense, Inc. and Unilever PLC dated February 10
*10.18	Promissory Note dated March 5, 1999 for the principal aggregate amount of $72 TheraSense
*10.19	Promissory Note dated July 30, 1998 for the principal aggregate amount of $17 TheraSense
*10.20	Promissory Note dated March 5, 1999 for the principal aggregate amount of $15 to TheraSense
*10.21	Promissory Note dated September 1, 1999 for the principal aggregate amount of Liamos to TheraSense
*10.22	Promissory Note dated December 1, 1997 for the principal aggregate amount of TheraSense, Inc.
*10.23	Amended and Restated Investors Rights Agreement by and among holders of Thera TheraSense, Inc., dated January 23, 2001, as amended
*10.24	First Amendment to the Agreement Entitled Sponsored Research Agreement No. UT

Exhibit Number	Description of Document
	entered into as of October 10, 2000, by and between TheraSense, Inc. and the of Texas System on behalf of the University of Texas at Austin
*10.25	Form of Change of Control Agreement between TheraSense, Inc. and each Vice Pr

* Incorporated by reference to the same exhibit filed with our Registration Statement on Form S-1 (Registration No. 333-64456), which was declared effective on October 11, 2001.

** Incorporated by reference to Exhibit 3.1(b) filed with our Registration Statement on Form S-1 (Registration No. 333-64456), which was declared effective on October 11, 2001.

*** Incorporated by reference to Exhibit 3.2(b) filed with our Registration Statement on Form S-1 (Registration No. 333-64456), which was declared effective on October 11, 2001.

\+ Confidential treatment granted for portions of these exhibits.

(b) Reports on Forms 8-K.

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

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 14, 2001

/s/ Charles T. Liamos

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