THERASENSE INC
Form 424B4
October 12, 2001

FILED PURSUANT TO RULE 424(b)(4)
REGISTRATION NO. 333-64456

6,000,000 Shares

THERASENSE, INC.

[LOGO OF THERASENSE, INC.]

Common Stock

$19.00 per share

- TheraSense, Inc. is offering 6,000,000 shares.
- This is our initial public offering and no public market existed for our shares prior to this offering.
- Trading symbol: Nasdaq National Market - THER

This investment involves risk. You should carefully consider the "Risk Factors" beginning on page 5.

	Per Share	Total
Public offering price	$19.00	$114,000,000
Underwriting discounts and commissions	$ 1.33	$ 7,980,000
Proceeds to TheraSense, Inc.	$17.67	$106,020,000

The underwriters have a 30-day option to purchase up to 900,000 additional shares of common stock from us to cover over-allotments, if any.

Neither the Securities and Exchange Commission nor any state securities commission has approved of anyone's investment in these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

U.S. Bancorp Piper Jaffray

SG Cowen

Thomas Weisel Partners LLC

The date of this prospectus is October 11, 2001.

[Inside Front Cover]

DESCRIPTION OF GRAPHIC

Graphic depicting the important functions of FreeStyle.

Two-step graphic depicting FreeStyle's testing procedure. The first picture depicts a lanced forearm with FreeStyle pressed on top. The second picture depicts a blood sample applied to the FreeStyle test strip for testing.

Picture of a FreeStyle Blood Glucose Monitoring System.

Graphic depicting the sample sizes required by other meters along with the sample size required by FreeStyle, which is shown to be significantly smaller.

Picture depicting a fingertip being lanced by a traditional lancing device.

TEXT ACCOMPANYING THE GRAPHIC

"The FreeStyle Blood Glucose Monitoring System."

"Pain is one of the biggest barriers to frequent testing."

"FreeStyle lets people test on their forearm, thigh, calf, upper arm and hand where it's much less painful to test than their fingers."

"FreeStyle uses the world's smallest blood sample."

"FreeStyle is quick and easy to use."

"Most people said, 'FreeStyle is painless.' (During clinical studies, most people said testing on their forearms was painless.*)"

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You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized any other person to provide you with different information. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any state where the offer or sale is not permitted. The information in this prospectus is complete and accurate as of the date on the front cover, but the information may have changed since that date.

SUMMARY

Because this is only a summary, it does not contain all the information that may be important to you. You should read the entire prospectus, especially "Risk Factors" and the financial statements and notes to those statements appearing elsewhere in this prospectus, before deciding to invest in our common stock.

Our Business

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 began selling FreeStyle in the United States in June 2000. The FDA is currently reviewing our recent FreeStyle labeling changes, which are subject to clearance. In March 2001, we obtained the CE Mark, which permits us to commercially distribute FreeStyle throughout the European Union. As of July 31, 2001, we have shipped over 390,000 meters and over 79 million test strips. For the quarter ended June 30, 2001, our total revenues were $17.8 million. Meter and test strip shipments for the quarter ended June 30, 2001 increased 72% and 71%, respectively, compared to the preceding quarter. 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.

The Opportunity

The blood glucose self-monitoring market is the largest self-test market for

medical diagnostic products in the world, with a size of approximately $2.0 billion in the United States and $3.5 billion worldwide in 2000. It is estimated that the worldwide blood glucose self-monitoring market will amount to $9.0 billion by 2005.

Government studies in the United States and the United Kingdom have shown that complications from diabetes can be significantly reduced through regular testing--four or more times per day for Type 1 diabetes and two or more times per day for Type 2 diabetes--and improved therapy. Self-monitoring of blood glucose has become a standard of care, and glucose self-monitoring devices and disposable test strips are typically covered by health insurance, including Medicare and Medicaid. Despite the ability to significantly reduce complications of diabetes through regular testing and treatment and the availability of reimbursement, many people with diabetes under-test or fail to test at all. A study prepared for us indicated that pain is a leading factor that discourages people with diabetes from testing as recommended.

Our Solution

FreeStyle utilizes patented technologies that can accurately measure glucose concentrations from a tiny 0.3 microliter sample of blood, as opposed to competitive products that require from 1.0 to 10.0 microliters of blood. Our tiny sample size is easily obtained by lancing the forearm, thigh, calf, upper arm or hand and therefore avoids the pain associated with drawing a larger blood sample from the fingertip. These alternate sites are significantly less painful to lance than the traditional fingertip test site, which is more densely populated with highly sensitive nerve endings but yields the larger blood volumes required by competitive products. Nine out of ten people in our clinical studies found using FreeStyle less painful than their current finger-stick-based system. Because our product is less painful to use, we believe FreeStyle will enable us to both penetrate and expand the glucose self-monitoring market.

Our FreeStyle System kit includes a FreeStyle meter, an initial supply of proprietary FreeStyle test strips, a FreeStyle lancing device, FreeStyle lancets and FreeStyle control solution. We believe FreeStyle provides the following significant advantages over competing systems:

- reduction in pain;
- better performance; and
- improved quality of life.

Our direct sales force promotes FreeStyle in the United States to health care professionals who advise patients on the monitoring and management of their diabetes. We distribute and sell FreeStyle in the United States to nine of the ten largest national retailers, including Walgreens, Wal-Mart and CVS, through wholesalers, including McKesson, Cardinal Health and Bergen Brunswig, and directly to end users over the telephone and through our website. FreeStyle is currently being sold in Germany and Sweden by Disetronic Group, our European distributor that has exclusive distribution rights to FreeStyle in selected European countries. In April 2001, we entered into an agreement with Nipro Corporation for the exclusive distribution of FreeStyle in Japan, and an application for approval to market FreeStyle in Japan was recently submitted.

We are also developing a Continuous Glucose Monitoring System that utilizes a disposable miniaturized sensor that can be inserted under the skin by the user

and incorporates a wireless display unit that can be worn like a pager. This sensor system is intended to continuously measure and display a person's glucose levels in real time for up to three days. The ability of people with diabetes to adjust insulin dose, oral medication, diet and exercise according to the glucose readings obtained from the system should result in significantly improved health. We have recently commenced a pilot clinical study with people who have diabetes using our Continuous Glucose Monitoring System. We expect that this product will require premarket approval by the FDA. Therefore, even if the product is successfully developed, it will not be commercially available for a number of years.

Our Strategy

Our objective is to be a leading provider of innovative glucose monitoring products that reduce the pain of testing, are easy to use, accurate, cost effective and improve the lives of people with diabetes. To achieve this objective, we are pursuing the following business strategies:

- establish FreeStyle as a leading blood glucose self-monitoring device;
- maintain and enhance retail distribution of FreeStyle;
- focus on our core competencies in electrochemistry and sensor manufacturing technologies, while outsourcing other aspects of our business;
- provide high quality customer service;
- establish an international presence for FreeStyle; and
- leverage our proprietary technology platform.

Additional Information

We have a limited operating history and we have significant losses. As of June 30, 2001, our accumulated deficit was approximately $89.7 million. We will continue to have substantial future capital requirements. We expect to continue to incur significant net losses for the foreseeable future. In addition, we expect substantially all of our revenue will be derived from sales of FreeStyle, our only commercial product. FreeStyle faces intense competition in a market where four companies control approximately 90% of worldwide sales. We are subject to extensive regulation by the FDA and foreign regulatory bodies, and a recent FreeStyle labeling change is being reviewed by the FDA as a 510(k) submission. For a discussion of the foregoing factors and other factors that could adversely affect us, you should read "Risk Factors."

We were incorporated in California in 1996 and reincorporated in Delaware in 2000. Our principal executive offices are located at 1360 South Loop Road, Alameda, California 94502. Our telephone number at this location is (510) 749-5400. Our Internet address is www.therasense.com. The information contained on our website is not a part of this prospectus.

TheraSense(R), FreeStyle(TM), The Technology of Caring(TM), NanoSample(TM) and Wired Enzyme(TM) are trademarks and service marks of ours. Other service marks, trademarks and trade names referred to in this prospectus are the property of their respective owners.

The Offering

Common stock offered by us	6,000,000 shares
Common stock to be outstanding after this offering	38,089,847 shares
Use of proceeds	We intend to use the net proceeds from this offering for additional sales and marketing efforts, research and development, expansion of our facilities, as well as for working capital and other general corporate purposes.
Nasdaq National Market symbol	THER

The number of shares of common stock to be outstanding after this offering is based on 32,089,847 shares outstanding as of June 30, 2001, and excludes:

- 521,013 shares issuable upon exercise of outstanding warrants at a weighted average exercise price of $2.07 per share;
- 4,882,303 shares issuable upon exercise of outstanding options under our 1997 Stock Plan at a weighted average exercise price of $3.73 per share; and
- a total of 9,053,832 shares available for future issuance under our equity incentive plans.

Except as otherwise noted, all information in this prospectus:

- assumes the underwriters do not exercise their over-allotment option;
- reflects the filing of our amended and restated certificate of incorporation; and
- reflects the conversion of each share of preferred stock into one share of common stock immediately prior to the closing of this offering.

Summary Financial Data
(in thousands, except per share data)

The following table sets forth our summary financial data. This data has been derived from our financial statements for the years ended December 31, 1998, 1999 and 2000, the six month periods ended June 30, 2000 and 2001, and as of June 30, 2001 included elsewhere in this prospectus. You should read this information in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus.

	Years Ended December 31,			Six Months Ended June 30,	

	1998	1999	2000	2000	2001
				(unaudited)	
Statement of Operations Data:					
Total revenues	$ 60	$ 85	$ 5,503	$ 511	$ 25,524
Cost of revenues	--	--	11,948	296	19,668
Gross profit (loss)	60	85	(6,445)	215	5,856
Operating expenses:					
Research and development	3,056	7,672	12,019	5,841	6,332
Selling, general and administrative	1,810	5,557	25,460	9,787	26,843
Total operating expenses	4,866	13,229	37,479	15,628	33,175
Loss from operations	(4,806)	(13,144)	(43,924)	(15,413)	(27,319)
Interest income, net	142	86	332	354	386
Net loss	(4,664)	(13,058)	(43,592)	(15,059)	(26,933)
Deemed dividend related to beneficial conversion feature of preferred stock	--	--	(14,773)	(14,773)	(26,783)
Net loss attributable to common stockholders	$(4,664)	$(13,058)	$(58,365)	$(29,832)	$(53,716)
Net loss per common share, basic and diluted	$ (2.31)	$ (4.32)	$ (14.69)	$ (8.03)	$ (11.35)
Weighted-average shares used in computing net loss per common share, basic and diluted	2,015	3,024	3,973	3,713	4,732
Pro forma net loss per common share, basic and diluted (unaudited)			$ (2.06)		$ (0.92)
Weighted-average shares used in computing pro forma net loss per common share, basic and diluted (unaudited)			21,129		29,331

	As of June 30, 2001	
	Actual	As Adjusted
	(unaudited)	
Balance Sheet Data:		
Cash and cash equivalents	$ 45,152	$150,422
Working capital	34,806	140,076
Total assets	78,982	184,252
Deferred revenue	17,684	17,684
Long-term obligations, less current portion	3,685	3,685
Convertible preferred stock	119,246	--
Deferred stock-based compensation, net	(15,645)	(15,645)
Accumulated deficit	(89,657)	(89,657)

Total stockholders' equity (deficit).....	(84,319)	140,197

The as adjusted column of the balance sheet data reflects the conversion of all of our outstanding shares of convertible preferred stock into shares of common stock immediately prior to the closing of this offering and the sale of 6,000,000 shares of common stock offered by us at an initial public offering price of $19.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

RISK FACTORS

An investment in our common stock offered by this prospectus involves a substantial risk of loss. You should carefully consider these risk factors, together with all of the other information included in this prospectus, before you decide to purchase shares of our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our operations. The occurrence of any of the following risks could harm our business. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business

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 $26.9 million in the six months ended June 30, 2001. As of June 30, 2001, we had an accumulated deficit of approximately $89.7 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. 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 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. 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 we or our suppliers 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. 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, and we are continuing this expansion in 2001. 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 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 and we do not know how long we will be required to rely on these estimates. Further, these third parties may not provide consistent, reliable data.

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.

Risks Related to this Offering

Our common stock has not been publicly traded, and we expect that the price of our common stock will fluctuate substantially.

Prior to this offering, there has been no public market for shares of our common stock. An active public trading market may not develop following completion of this offering or, if developed, may not be sustained. The price of the shares of common stock sold in this offering was determined by negotiation between the underwriters and us. This price will not necessarily reflect the market price of the common stock following this offering. The market price for the common stock following this offering will 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.

There is a large number of shares that may be sold in the market following this offering which may cause the price of our common stock to decline.

After this offering, we will have 38,089,847 shares of common stock outstanding, or 38,989,847 shares if the underwriters' over-allotment is exercised in full. The 6,000,000 shares sold in this offering, or 6,900,000 shares if the underwriters' over-allotment is exercised in full, will be freely tradable without restriction or further registration under the federal securities laws unless purchased by our affiliates. The remaining 32,089,847 shares of common stock outstanding after this offering, based upon shares outstanding as of June 30, 2001, assuming no exercise of outstanding options prior to completion of this offering, will be available for sale in the public market as follows:

Number of Shares	Date of Availability for Sale
0	Immediately after the date of this prospectus
32,089,847	180 days after the effective date of the registration statement containing this prospectus (subject in some cases to volume and other limitations)

The above table assumes the effectiveness of the lock-up agreements under which holders of substantially all of our common stock have agreed not to sell or otherwise dispose of their shares of

common stock. Approximately 16.0 million of the shares that will be available for sale after the expiration of the lock-up period will be subject to volume restrictions because they are held by our affiliates. In addition, U.S. Bancorp Piper Jaffray Inc. may waive these lock-up restrictions prior to the expiration of the lock-up period without prior notice.

If our common stockholders sell substantial amounts of common stock in the public market, or the market perceives that these sales may occur, the market price of our common stock could fall. After this offering, the holders of approximately 27,243,164 shares of common stock issued upon conversion of our preferred stock and upon exercise of outstanding warrants will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Furthermore, if we were to include in a company-initiated registration statement shares held by those holders pursuant to the exercise of their registration rights, those sales could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

Purchasers in this offering will experience immediate and substantial dilution.

The initial public offering price of our shares is substantially higher than the net tangible book value per share of the outstanding common stock. Accordingly, investors purchasing shares of common stock in this offering will:

- pay a price per share that substantially exceeds the value of our assets after subtracting liabilities; and

- contribute 48.6% of the total amount invested to date to fund us, but will own only 15.8% of the shares of common stock outstanding. To the extent outstanding stock options or warrants are exercised, there will be further dilution to new investors.

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 your interests.

Our executive officers and directors and entities affiliated with them will, in the aggregate, beneficially own approximately 37.8% of our common stock following this 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 you.

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

INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled "Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," may contain forward-looking statements. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by the forward-looking statements. These risks and other factors include those listed under "Risk Factors"and elsewhere in this prospectus. We believe that the section entitled "Risk Factors" includes all material risks that could harm our business. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "intends," "potential," "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. Actual events or results may differ materially.

We believe that it is important to communicate our future expectations to our investors. However, there may be events in the future that we are not able to accurately predict or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. Investors are cautioned that all forward-looking statements involve risks and uncertainties, and actual results may differ materially from those discussed as a result of various factors, including those factors described in the "Risk Factors" section of this prospectus.

Potential investors should not place undue reliance on our forward-looking statements. Before you invest in our common stock, you should be aware that the occurrence of the events described in the "Risk Factors" section and elsewhere in this prospectus could harm our business, prospects, operating results and financial condition.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

USE OF PROCEEDS

We estimate that the net proceeds from the sale of the 6,000,000 shares of common stock that we are selling in this offering will be approximately $105.3 million based on an initial public offering price of $19.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters' over-allotment option is

exercised in full, we estimate that we will receive net proceeds of approximately $121.2 million.

We currently estimate that we will use the net proceeds of this offering, together with our cash on hand, to fund our operations, including:

- approximately $50.0 million to fund continued sales and marketing efforts for FreeStyle, including increases in advertising and product sampling;
- approximately $10.0 million for research and development of enhanced FreeStyle products and our Continuous Glucose Monitoring System;
- approximately $10.0 million to expand our facility in Alameda, California, including an expansion of our test strip manufacturing capacity; and
- the remainder for working capital and other general corporate purposes.

The amounts actually expended for these purposes may vary significantly and will depend on a number of factors, including the amount of our future revenues, expenses and the other factors described under "Risk Factors." In addition, we will retain broad discretion in the allocation of the net proceeds of this offering. Should we determine to employ cash resources for the acquisition of complementary businesses, products or technologies, the amounts available for the purposes cited above may be significantly reduced. Although we evaluate potential acquisitions in the ordinary course of business, we have no specific understandings, commitments or agreements with respect to any acquisition or investment at this time.

Until we use the net proceeds of this offering for the above purposes, we intend to invest the funds in short-term, investment grade, interest-bearing securities. We cannot predict whether the proceeds invested will yield a favorable return.

DIVIDEND POLICY

Since our incorporation, we have never declared or paid any dividends on our capital stock. We currently expect to retain our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying any dividends in the foreseeable future.

CAPITALIZATION

The following table sets forth our actual capitalization as of June 30, 2001. Our capitalization is also presented:

- on a pro forma basis to give effect to the conversion of all outstanding shares of convertible preferred stock into shares of common stock immediately prior to the completion of this offering; and
- on a pro forma as adjusted basis to reflect the sale in this offering of 6,000,000 shares of common stock at an initial public offering price of $19.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	As of June 30, 2001		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share data) (unaudited)		
Long-term obligations, less current portion....	$ 3,685	$ 3,685	$ 3,685
Convertible preferred stock, $0.001 par value; 28,309,647 shares authorized, 26,722,151 shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted.....	119,246	--	--
Stockholders' equity (deficit):			
Preferred stock, $0.001 par value; no shares authorized, issued or outstanding, actual and pro forma; 5,000,000 shares authorized, no shares issued or outstanding, pro forma as adjusted.....	--	--	--
Common stock, $0.001 par value; 50,000,000 shares authorized, 5,367,696 shares issued and outstanding, actual; 32,089,847 shares issued and outstanding, pro forma; 200,000,000 shares authorized and 38,089,847 shares issued and outstanding, pro forma as adjusted.....	5	32	38
Additional paid-in capital.....	21,272	140,491	245,755
Notes receivable from stockholders.....	(294)	(294)	(294)
Deferred stock-based compensation, net.....	(15,645)	(15,645)	(15,645)
Accumulated deficit.....	(89,657)	(89,657)	(89,657)
Total stockholders' equity (deficit).....	(84,319)	34,927	140,197
Total capitalization.....	$ 38,612	$ 38,612	$143,882

In addition to the shares of common stock to be outstanding after the offering, we may issue additional shares of common stock under the following plans and arrangements:

- 521,013 shares issuable upon exercise of outstanding warrants as of June 30, 2001 at a weighted average exercise price of $2.07 per share;
- 4,882,303 shares issuable upon exercise of outstanding options under our 1997 Stock Plan at a weighted average exercise price of $3.73 per share as of June 30, 2001; and
- a total of 9,053,832 shares available for future issuance under our equity incentive plans.

You should read the capitalization table together with the sections of this prospectus entitled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and with the financial statements and related notes beginning on page F-1.

DILUTION

Our pro forma net tangible book value at June 30, 2001 was approximately $34.9 million, or $1.09 per share, after giving effect to the conversion of all outstanding shares of our convertible preferred stock into shares of common stock upon completion of this offering. Pro forma net tangible book value per share is equal to our total tangible assets less our total liabilities, divided by the total number of shares of our common stock outstanding. After giving effect to the sale of the 6,000,000 shares of our common stock offered in this offering at an initial public offering price of $19.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value at June 30, 2001 would have been approximately $140.2 million, or $3.68 per share. This represents an immediate increase in net tangible book value of $2.59 per share to existing stockholders and an immediate dilution of $15.32 per share to new investors purchasing shares of our common stock in this offering.

The following table illustrates the per share dilution to the new investors:

Initial public offering price per share.....		$19.00
Pro forma net tangible book value per share at June 30, 2001....	$1.09	
Increase in pro forma net tangible book value per share attributable to this offering.....	2.59	
Pro forma net tangible book value per share as adjusted after this offering.....		3.68
Dilution per share to new investors in this offering.....		$15.32

If the underwriters exercise their over-allotment option in full, there will be an increase in pro forma net tangible book value to $4.00 per share to existing stockholders and an immediate dilution in pro forma net tangible book value of $15.00 to new investors.

The following table summarizes, on a pro forma basis as of June 30, 2001, the total number of stockholders and new investors with respect to the number of shares of common stock purchased from us, the total consideration paid and the average price per share paid by the existing stockholders and by the new investors in this offering before deducting the underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		
	Numbers	Percent	Amount	Percent	Average Price Per Share
Existing stockholders.....	32,089,847	84.25%	$120,396,078	51.36%	$ 3.75
New investors.....	6,000,000	15.75%	114,000,000	48.64%	$19.00
Total.....	38,089,847	100.00%	$234,396,078	100.00%	

If the underwriters exercise their over-allotment option in full, our existing

stockholders would own 82.3% and our new investors would own 17.7% of the total number of shares of our common stock outstanding after this offering.

Assuming the exercise in full of all options and warrants outstanding and exercisable as of June 30, 2001, the average price per share paid by our existing stockholders would be reduced by $0.02 per share to $3.73 per share.

The preceding discussion and tables assume no exercise of stock options or warrants outstanding as of June 30, 2001. As of June 30, 2001, there were:

- 521,013 shares issuable upon exercise of outstanding warrants at a weighted average exercise price of $2.07 per share;
- 4,882,303 shares issuable upon exercise of outstanding options under our 1997 Stock Plan at a weighted average exercise price of $3.73 per share; and
- a total of 9,053,832 shares available for future issuance under our equity incentive plans.

After this offering and assuming the exercise in full of all options and warrants outstanding and exercisable as of June 30, 2001, our pro forma net tangible book value per share as of June 30, 2001 would be $3.67 per share, representing an immediate increase in net tangible book value of $2.58 per share to existing stockholders and an immediate dilution in net tangible book value of $15.33 per share to new investors.

SELECTED FINANCIAL DATA

The selected financial data set forth below are derived from our financial statements. The statement of operations data for the years ended December 31, 1996 and 1997, and the balance sheet data as of December 31, 1996, 1997 and 1998 are derived from our audited financial statements not included in this prospectus. The statement of operations data for the years ended December 31, 1998, 1999 and 2000, and the balance sheet data as of December 31, 1999 and 2000 are derived from our audited financial statements included in this prospectus. The statement of operations data for the six months ended June 30, 2000 and 2001 and the balance sheet data as of June 30, 2001 are derived from our unaudited financial statements included in this prospectus. Our unaudited financial statements have been prepared by us on a basis consistent with our audited financial statements and, in management's opinion, include all adjustments necessary, consisting only of normal recurring adjustments, for a fair presentation of this information. The results of operations for the six months ended June 30, 2001 are not necessarily indicative of the results to be expected for the entire year, for any other interim period or for any future year. The selected financial data set forth below should be read in conjunction with our financial statements, the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

Period from April 3, 1996 (inception) to December 31, 1996	Years Ended December 31,				Six Months Ende June 30,	
	1997	1998	1999	2000	2000	200

		(in thousands, except per share data)				(unaudited)	
Statement of Operations Data:							
Research grant revenue..	$618	$ --	$ 60	$ 60	$ 3	$ 3	$
Product sales.....	--	--	--	25	5,000	8	25,
License income.....	--	--	--	--	500	500	
Total revenues.....	618	--	60	85	5,503	511	25,
Cost of revenues.....	--	--	--	--	11,948	296	19,
Gross profit (loss).....	618	--	60	85	(6,445)	215	5,
Operating expenses:							
Research and development.....	228	977	3,056	7,672	12,019	5,841	6,
Selling, general and administrative.....	199	703	1,810	5,557	25,460	9,787	26,
Total operating expenses.....	427	1,680	4,866	13,229	37,479	15,628	33,
Income (loss) from operations.....	191	(1,680)	(4,806)	(13,144)	(43,924)	(15,413)	(27,
Interest income (expense), net.....	(9)	163	142	86	332	354	
Net income (loss).....	182	(1,517)	(4,664)	(13,058)	(43,592)	(15,059)	(26,
Deemed dividend related to beneficial conversion feature of preferred stock.....	--	--	--	--	(14,773)	(14,773)	(26,
Net income (loss) attributable to common stockholders.....	$182	$(1,517)	$(4,664)	$(13,058)	$(58,365)	$(29,832)	$(53,
Net income (loss) per common share, basic and diluted.....		$ (1.66)	$ (2.31)	$ (4.32)	$ (14.69)	$ (8.03)	$ (11
Weighted-average shares used in computing net loss per common share, basic and diluted.....		914	2,015	3,024	3,973	3,713	4,
Pro forma net loss per common share, basic and diluted (unaudited)....					$ (2.06)		$ (0
Weighted-average shares used in computing pro forma net loss per common share, basic and diluted (unaudited)....					21,129		29,

	As of December 31,					As of June 30,
	1996	1997	1998	1999	2000	2001
			(in thousands)			(unaudited)
Balance Sheet Data:						
Cash and cash equivalents	$ 122	$ 4,088	$11,438	$ 2,322	$ 12,532	$ 45,152
Working capital	121	3,595	10,956	792	4,240	34,806
Total assets	178	4,680	12,379	8,026	37,565	78,982
Deferred revenue	--	72	11	511	8,687	17,684
Long-term obligations, less current portion	--	--	520	3,321	7,994	3,685
Convertible preferred stock	--	5,526	17,361	20,472	62,883	119,246
Deferred stock-based compensation, net	--	--	--	(1,244)	(11,263)	(15,645)
Retained earnings (accumulated deficit)	107	(1,410)	(6,074)	(19,132)	(62,724)	(89,657)
Total stockholders' equity (deficit)	129	(1,387)	(6,047)	(18,159)	(59,848)	(84,319)

See our financial statements and related notes for a description of the calculation of the historical and pro forma net loss per common share and the weighted-average number of shares used in computing the historical and pro forma per common share data.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our financial statements and related notes appearing elsewhere in this prospectus. This discussion may contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of selected factors, including those set forth under "Risk Factors" and elsewhere in this prospectus. We believe that the section entitled "Risk Factors" includes all material risks that could harm our business.

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 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 $26.9 million for the six months ended June 30, 2001. As of June 30, 2001, we had an accumulated deficit of $89.7 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 and we do not know how long we will be required to rely on these estimates. Further, these third parties may not provide consistent, reliable data.

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 June 30, 2001, we have recorded aggregate deferred stock-based compensation of $19.6 million, of which $15.6 million 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

Six Months Ended June 30, 2000 and June 30, 2001

Revenues. There were nominal product revenues for the six months ended June 30, 2000. However, we recognized revenue of $0.5 million from a specific non-refundable negotiation fee related to a potential distribution arrangement, which was never consummated. We recognized revenues of $25.5 million for the six months ended June 30, 2001, principally consisting of sales of FreeStyle System kits and FreeStyle test strips. Two of our customers, McKesson and Walgreens, and our European distributor, Disetronic, individually accounted for more than 10% and collectively accounted for approximately 40% of our revenues for the six months ended June 30, 2001. As of June 30, 2001, deferred revenue, awaiting sale through to end users and for the 30-day cash refund period on FreeStyle System kit sales to lapse, was approximately $12.9 million. In addition, we recognized revenues of $0.3 million for the six months ended June 30, 2001 related to the $5.0 million distribution agreement payment received from Nipro.

Cost of revenues. Cost of revenues for the six months ended June 30, 2000 was $0.3 million, and principally related to start-up production costs, as there was no cost associated with the nonrefundable negotiation fee income earned. Cost of revenues for the six months ended June 30, 2001 was $19.7 million, attributable to product sales, as there was no cost associated with the license fee income earned. Amortization of stock-based compensation expense reported in cost of revenues for the six months ended June 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 from $5.8 million for the six months ended June 30, 2000 to $6.3 million for

the six months ended June 30, 2001, representing an increase of $0.5 million, or 8%. This increase was primarily attributable to $0.5 million from hiring additional personnel, $0.5 million spent on clinical trials and $0.4 million from 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 six months ended June 30, 2001 over research and development expenses for the six months ended June 30, 2000. Amortization of deferred stock-based compensation was $0.5 million for the six months ended June 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 from $9.8 million for the six months ended June 30, 2000 to $26.8 million for the six months ended June 30, 2001, representing an increase of $17.0 million, or 174%. This increase was primarily attributable to increases of $6.0 million spent on product sampling, $4.0 million for marketing activities and other spending associated with expanding distribution and developing consumer awareness of FreeStyle, $3.3 million for personnel costs largely related to expanding our U.S. direct sales force as well as marketing and business support functions, $1.0 million spent for customer service and support operations, and $0.5 million for travel costs, largely related to our sales force. Amortization of deferred stock-based compensation was $1.3 million for the six months ended June 30, 2001, as compared to $0.3 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 remained relatively flat at $0.4 million for the six months ended June 30, 2000 and 2001. 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. Interest income for the six months ended June 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 six months ended June 30, 2000 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.

Dividend 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 six months ended June 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.

Years Ended December 31, 1998, 1999 and 2000

Revenues. Revenues in 1998 and 1999 principally related to research grants and the sale of clinical evaluation units. Revenues recognized in 2000 totaled $5.5 million, principally consisting of product sales of FreeStyle System kits and FreeStyle test strips which commenced in June 2000. Revenue in 2000 also included $0.5 million from a specific non-refundable negotiation fee related to a potential distribution arrangement, which was never consummated. Four of our customers, CVS, Walgreens, Wal-Mart and McKesson, individually accounted for more than 10% and collectively accounted for approximately 53% of our revenues

for the year ended December 31, 2000. As of December 31, 2000,

deferred revenue, awaiting sale through to end users and for the 30-day cash refund period on FreeStyle System kit sales to lapse, was approximately $8.7 million.

Cost of revenues. There was no cost of revenues recorded in fiscal years 1998 and 1999. Cost of revenues in 2000 was $11.9 million and was comprised of internal manufacturing costs, purchase costs for FreeStyle System kits and FreeStyle lancets from our contract manufacturing partners, costs of product warranties, royalties payable under technology licenses, 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 2000 was insignificant. Prior to commencing commercial shipments of FreeStyle in June 2000, costs associated with start-up manufacturing-related activities, including stock-based compensation expense, were reported as research and development expenses. There was no cost associated with the license fee income earned.

Research and development expenses. Research and development expenses increased from $3.1 million in 1998 to $7.7 million in 1999 and to $12.0 million in 2000. The increase from 1998 to 1999 was principally due to $2.2 million from hiring of additional personnel and increased spending of $1.6 million associated with the development of FreeStyle. The increase from 1999 to 2000 was primarily attributable to increases of $1.6 million for materials and supplies used in product development efforts, $1.1 million from hiring of additional personnel, a $0.5 million payment for the purchase of technology and license rights from E. Heller & Co., which owns more than five percent of our stock, $0.4 million for overhead costs associated with our new facility and $0.2 million for payments to outside service providers. The technology and license rights purchased from E. Heller & Co. concern the measurement of biochemicals other than glucose. This technology is at an early stage of development, and it is currently uncertain whether it will have commercial application. Amortization of deferred stock-based compensation was $0.6 million for the year ended December 31, 2000. Stock-based compensation expense for the corresponding period in 1999 was insignificant.

Selling, general and administrative expenses. Selling, general and administrative expenses increased from $1.8 million in 1998 to $5.6 million in 1999 and to $25.5 million in 2000. The increase from 1998 to 1999 was primarily attributable to increases of $1.5 million in personnel costs, $0.8 million in marketing expenses, $0.7 million in costs associated with moving into our new facility in August 1999, $0.3 million in legal and professional services and $0.2 million in travel costs. The increase from 1999 to 2000 was primarily attributable to increases of $6.2 million for personnel costs, largely related to recruiting and hiring our U.S. direct sales force, as well as expanding marketing and business support functions, $4.6 million for advertising, marketing activities and other spending associated with the launch of FreeStyle, $2.8 million spent on the cost of product sampling, $1.5 million spent on establishing customer service and support operations, $1.1 million for overhead costs, $1.0 million for travel costs, largely related to our new sales force, $0.9 million spent on professional fees relating to a proposed public offering withdrawn in December 2000 and $0.5 million for legal fees for both patent and general corporate matters. Amortization of deferred stock-based compensation was $1.2 million for the year ended December 31, 2000. Stock-based compensation expense for the corresponding period in 1999 was insignificant.

Interest income, net. Net interest income remained relatively flat at $0.1 million in 1998 and 1999, and $0.3 million in 2000. Interest income in 2000

increased due to higher average cash and cash equivalents balances, resulting from the net proceeds of a private equity offering completed in February 2000. Interest expense for the same period increased to a lesser extent, reflecting 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.

Provision for income taxes. We incurred net operating losses for the years ended December 31, 1998, 1999 and 2000 and, accordingly, we did not pay any federal or state income taxes. As of December 31, 2000, we had accumulated approximately $44.8 million and $31.2 million in federal and state net operating loss carryforwards, respectively, to reduce future taxable income. If not utilized, the federal carryforward will expire in various amounts beginning in 2012, and the state carryforward will expire in 2005. Our net operating loss carryforwards are subject to annual limitation under Internal Revenue Code Section 382 due to substantial changes in ownership. Changes have already occurred on April 21, 1997 and February 23, 1999 as a result of our preferred stock financings. An additional change may occur as a result of this offering. The annual limitations do not result in the expiration of net operating losses prior to utilization. We have not recorded a benefit from our net operating loss carryforwards because we believe that it is uncertain that we will have sufficient income from future operations to realize the carryforwards prior to their expiration. Accordingly, we have established a valuation allowance against the deferred tax asset arising from the carryforwards.

We also had federal and state research and development tax credit carryforwards as of December 31, 2000 of approximately $0.7 million and $0.6 million, respectively. If not utilized, the federal research credit will expire in various amounts beginning in 2012. The state research credit can be carried forward indefinitely.

Dividend related to beneficial conversion feature of preferred stock. Dividends relating to beneficial conversion of our preferred stock of $14.8 million were recorded in the year ended December 31, 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.

Quarterly Results of Operations

The following table sets forth selected quarterly statement of operations data for each of the five quarters indicated below. This information is derived from our unaudited financial statements, which have been prepared by us on a basis consistent with our audited financial statements and, in management's opinion, include all adjustments necessary, consisting only of normal recurring adjustments, for a fair presentation of this information. These quarterly results of operations are not necessarily indicative of results of operations in any future period.

	Quarter Ended				
June 30, 2000	September 30, 2000	December 31, 2000	March 31, 2001	June 30, 2001
	(in thousands) (unaudited)			

Revenues.....	$ 11	$ 1,280	$ 3,712	$ 7,677	$ 17,847
Cost of revenues.....	306	6,763	4,879	6,225	13,443
Gross profit (loss).....	(295)	(5,483)	(1,167)	1,452	4,404
Operating expenses:					
Research and development.....	2,633	3,561	2,615	2,798	3,534
Selling, general and administrative.....	5,444	5,522	10,163	11,033	15,810
Total operating expenses.....	8,077	9,083	12,778	13,831	19,344
Loss from operations....	(8,372)	(14,566)	(13,945)	(12,379)	(14,940)
Interest income (expense), net.....	218	11	(32)	199	187
Net loss.....	$(8,154)	$(14,555)	$(13,977)	$(12,180)	$(14,753)

Revenues. The increase in revenues beginning with the quarter ended September 30, 2000 reflects increased market acceptance of FreeStyle since commercial shipments commenced in June 2000.

Gross profit (loss). Gross profit (loss) is influenced by both sales volume and the product mix between FreeStyle System kits and FreeStyle test strips, as we currently distribute the FreeStyle System kit at a financial loss due in part to samples, discounts and rebates. The gross loss for the quarter ended September 30, 2000 was negatively impacted by a $3.5 million charge to reduce FreeStyle System kit inventories to estimated net realizable value. The gross profit for the two most recent quarters resulted from higher sales volume and an increased percentage of FreeStyle test strip revenues versus FreeStyle System kit revenues.

Operating expenses. 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. Research and development expenses for the third quarter of 2000 included an expense accrual in the amount $1.2 million related to incorporating engineering modifications into FreeStyle. Selling, general and administrative expenses increased in absolute dollars throughout 2000 and the first half of 2001, reflecting increased personnel costs, including recruiting and hiring our U.S. direct sales force, advertising, marketing and other spending associated with the launch of FreeStyle. In addition, costs were incurred beginning in the fourth quarter of 2000 related to increases in product sampling to stimulate consumer adoption of FreeStyle.

Liquidity and Capital Resources

From our inception through June 30, 2001, we have financed our operations primarily through private placements of convertible preferred stock resulting in net proceeds of $119.2 million. We have also financed our operations through equipment financing arrangements and other loans with $6.9 million in principal outstanding at June 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 June 30, 2001, we had cash and cash equivalents of $45.2 million.

Cash used in operations. Net cash used in operating activities was approximately $4.5 million, $11.8 million, $36.8 million and $19.4 million for the years ended December 31, 1998, 1999, 2000 and for the six months ended June 30, 2001, respectively. For these periods, net cash used in operating activities resulted primarily from net losses. For the year ended December 31, 2000 and the six months ended June 30, 2001, increases in accounts receivable and inventories, which reflected commencement of commercial product shipments in June 2000, were partially offset by increases in deferred revenue and accrued liabilities.

Cash used in or provided by investing activities. Net cash used in investing activities was approximately $0.6 million, $3.3 million and $0.9 million for the years ended December 31, 1998 and 1999 and for the six months ended June 30, 2001, respectively. These investing activities consisted of capital expenditures. The increase in 1999 resulted from purchases of machinery and equipment for manufacturing our FreeStyle test strips in addition to expenses associated with our move into a new facility in August 1999. For the year ended December 31, 2000, net cash provided by investing activities, totaling $0.6 million, included $2.7 million in proceeds from the sale of capital assets under sale and leaseback transactions.

Cash provided by financing activities. Net cash provided by financing activities was approximately $12.5 million, $6.0 million, $46.4 million and $52.9 million for the years ended December 31, 1998, 1999, 2000 and the six months ended June 30, 2001, 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 at least the next 12 months. We also expect increased sales and marketing expenses related to the promotion of FreeStyle, increased research and development expenses, as well as expenses for additional personnel and product enhancement efforts. Our future capital requirements will depend on a number of factors, including market acceptance of FreeStyle, the resources we devote to developing and supporting our products, continued progress of our research and development of potential products, the need to acquire licenses to technology and the availability of other financing. Our capital expenditures for the year ended December 31, 2000 were $2.1 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 this offering and revenue to be derived from sales of FreeStyle, will be sufficient to fund our operations for at least the next 18 months. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to raise additional capital or incur additional indebtedness to fund our operations. Additional equity or debt financing, if required, may not be available on acceptable terms, or at all. If we are unable to obtain additional capital, we may be required to reduce our selling and marketing activities for FreeStyle, delay, reduce the scope of or eliminate our research and development programs, or relinquish rights to technologies or products that we might otherwise seek to develop or commercialize. In the event that we do raise additional equity financing,

investors 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.

Quantitative and Qualitative Discussion of 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 June 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.

Inflation

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

Recently Issued Accounting Pronouncements

Effective January 1, 2001, we adopted SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." SFAS No. 133 establishes accounting and reporting standards for derivative instruments and hedging activities. It requires that an entity recognize all derivatives as either assets or liabilities in the statement of financial position and measure those instruments at fair value. To date, we

have not engaged in derivative and hedging activities, and therefore the adoption had no impact on our financial statements.

In July 2001, the Financial Accounting Standards Board issued SFAS No. 141 "Business Combinations" which establishes financial accounting and reporting for business combinations and supersedes APB Opinion No. 16, Business Combinations, and FASB Statement No. 38, Accounting for Preacquisition Contingencies of Purchased Enterprises. SFAS No. 141 requires that all business combinations be accounted for using one method, the purchase method. The provisions of this statement apply to all business combinations initiated after June 30, 2001. We will adopt SFAS No. 141 during the first quarter of fiscal 2002, and this adoption is expected to have no impact on our financial reporting and related disclosures.

In July 2001, the Financial Accounting Standards Board issued SFAS No. 142 "Goodwill and Other Intangible Assets," which establishes financial accounting and reporting for acquired goodwill and other intangible assets and supersedes APB Opinion No. 17, Intangible Assets. SFAS No. 142 addresses how intangible assets that are acquired individually or with a group of other assets (but not those acquired in a business combination) should be accounted for in financial statements upon their acquisition, and after they have been initially recognized in the financial statements. The provisions of this statement are

effective for fiscal years beginning after December 15, 2001. We will adopt SFAS No. 142 during the first quarter of fiscal 2002, and this adoption is expected to have no material impact on our financial reporting and related disclosures.

BUSINESS

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 began selling FreeStyle in the United States in June 2000. FreeStyle utilizes patented technologies that can accurately measure glucose concentrations from a tiny 0.3 microliter sample of blood, as opposed to competitive products that require from 1.0 to 10.0 microliters of blood. Our tiny sample size is easily obtained by lancing the forearm, thigh, calf, upper arm or hand and therefore avoids the pain associated with drawing a larger blood sample from the fingertip. These alternate sites are significantly less painful to lance than the traditional fingertip test site, which is more densely populated with highly sensitive nerve endings but yields the larger blood volumes required by competitive products. Nine out of ten people in our clinical studies found using FreeStyle less painful than their current finger-stick-based system.

We believe that FreeStyle is well positioned to capture a meaningful share of the blood glucose self-monitoring market. The blood glucose self-monitoring market is the largest self-test market for medical diagnostic products in the world, with a size of approximately $2.0 billion in the United States and $3.5 billion worldwide in 2000. It is estimated that the worldwide blood glucose self-monitoring market will amount to $9.0 billion by 2005. We believe that FreeStyle and other products based on our proprietary technologies can expand this market by substantially reducing the pain associated with testing and thereby bring non-testers into the market and encourage under-testers to test more regularly. 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.

Our direct sales force promotes FreeStyle in the United States to health care professionals who advise patients on the monitoring and management of their diabetes. We distribute and sell FreeStyle in the United States to nine of the ten largest national retailers, including Walgreens, Wal-Mart and CVS, through wholesalers, including McKesson, Cardinal Health and Bergen Brunswig, and directly to end users over the telephone and through our website. In September 2000, we entered into an agreement with Disetronic Group for the exclusive distribution of FreeStyle in selected European countries. In March 2001, we obtained the CE Mark, which permits us to commercially distribute FreeStyle throughout the European Union. Disetronic commenced sales in Germany and Sweden in May 2001. In April 2001, we entered into an agreement with Nipro Corporation for the exclusive distribution of FreeStyle in Japan, and an application for approval to market FreeStyle in Japan was recently submitted. Disetronic and Nipro are the leading suppliers of insulin pumps in Europe and Japan, r