

CURON MEDICAL INC
Form 424B4
July 07, 2005
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Registration No. 333-125045

PROSPECTUS

28,220,969 Shares

CURON MEDICAL, INC.

Common Stock

This prospectus relates to the public offering, which is not being underwritten, of up to 28,220,969 shares of our common stock under this prospectus by the selling stockholders identified in this prospectus. The selling stockholders may sell these shares from time to time on or off the Nasdaq SmallCap Market in regular brokerage transactions, in transactions directly with market makers or in privately negotiated transactions. We issued these shares of our common stock to the selling stockholder in a private transaction.

For additional information on the methods of sale that may be used by the selling stockholders, see the section entitled "Plan of Distribution" on page 54. We will not receive any of the proceeds from the sale of these shares. We will bear the costs relating to the registration of these shares.

Our common stock is listed on the Nasdaq SmallCap Market under the symbol "CURN". On June 27, 2005, the last sale price of our common stock was \$0.64 per share. Our principal executive office is located at 46117 Landing Parkway, Fremont, California 94538. Our telephone number is (510) 661-1800.

THIS OFFERING INVOLVES MATERIAL RISKS. SEE RISK FACTORS BEGINNING ON PAGE 1.

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The Securities and Exchange Commission may take the view that, under certain circumstances, the selling stockholders and any broker-dealers or agents that participate with the selling stockholder in the distribution of the shares may be deemed to be underwriters within the meaning of the Securities Act of 1933, as amended. Commissions, discounts or concessions received by any such broker-dealer or agent may be deemed to be underwriting commissions under the Securities Act.

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

The date of this prospectus is July 7, 2005

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You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock. Except where the context requires otherwise, in this prospectus the Company, Curon, Curon Medical, we, us and our refer to Curon Medical, Inc., a Delaware corporation, and, where appropriate, its subsidiaries.

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RISK FACTORS

You should carefully consider the risks described below before making an investment decision. Our business, prospects, financial condition or operating results could be materially adversely affected by any of these risks, as well as other risks not currently known to us or that we currently deem immaterial. The trading price of our common stock could decline due to any of these risks and you may lose all or part of your investment. In assessing the risks described below, you should also refer to the other information contained in this prospectus, including our consolidated financial statements and the related notes, before deciding to purchase any shares of our common stock.

We may never achieve or maintain significant revenues or profitability.

We have incurred losses every year since we began operations. In particular, we incurred net losses of \$15.3 million in 2004, \$15.6 million in 2003, and \$15.4 million in 2002 and \$3.0 million for the three months ended March 31, 2005. As of March 31, 2005, we had an accumulated deficit of approximately \$97.6 million. Our revenues are, and will be, derived from the sale of radiofrequency generators and our disposable devices, such as the Stretta Catheter and Secca Handpiece. We have generated limited revenues, and it is possible that we will never generate significant revenues from product sales. Even if we do achieve significant revenues from our product sales, we expect to incur significant net losses over the next several years and these losses may increase. It is possible that we will never achieve profitable operations. The fact that we have very limited cash resources, cannot assure you that additional capital will be available to us when needed, if at all, or, if available, will be obtained on terms attractive to us and our failure to generate substantial revenues would harm our business.

Our internal controls may not be sufficient to ensure timely and reliable financial information.

In October 2004, we restated our financial results for the quarter ended March 31, 2004 to reflect adjustments to our previously reported financial information. The restatements arose, in part, out of an internal investigation by the Audit Committee. As a result of the investigation, management and the Audit Committee determined that certain sales employees had improperly offered rights of return and exchange in violation of our revenue recognition policy, and a manufacturer's representative had not actually made sales that it had reported to the Company. As a result of this investigation, we were also unable to timely file the Form 10-Q for the quarter ended June 30, 2004. In connection with the restatement of our financial results for the quarter ended March 31, 2004, our independent registered public accounting firm identified material weaknesses in our internal controls and procedures.

Our Audit Committee, with the assistance of independent legal and accounting advisors, evaluated the effectiveness of our disclosure controls and procedures. As a result of this evaluation, our Board of Directors has directed management to implement and management has implemented additional measures designed to ensure that information required to be disclosed in our periodic reports is recorded, processed, summarized and reported accurately. These measures include the adoption of a Disclosure Committee Charter, the adoption of a written revenue recognition policy, further controls on shipment of products for revenue transactions, and additional training of our sales and marketing staff to minimize the risk of revenue recognition errors. The effectiveness of our controls and procedures remain limited by a variety of factors including:

Faulty human judgment and simple errors, omissions or mistakes;

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Fraudulent action of an individual or collusion of two or more people;

Inappropriate management override of procedures; and

The possibility that our enhanced controls and procedures may still not be adequate to assure timely and accurate financial information.

If we fail to have effective internal control over financial reporting in place, we could be unable to provide timely and accurate financial information and be subject to delisting from Nasdaq, and civil or criminal sanctions.

We may be delisted from the Nasdaq SmallCap Market immediately if we fail to timely file our periodic reports. This may adversely affect trading in our stock and our ability to raise capital.

Due to our inability to timely file our Form 10-Q for the quarter ended June 30, 2004, we became subject to delisting from the Nasdaq SmallCap Market. Subsequent to an appeal proceeding, the Nasdaq Listing Qualifications Panel determined to continue our listing on the Nasdaq SmallCap Market, conditioned upon the timely filing of all periodic reports with the Securities and Exchange Commission and Nasdaq for all reporting periods beginning with September 30, 2004 and ending on September 30, 2005. Should we fail to make any filing in accordance with this condition, we will not be entitled to a new hearing with Nasdaq and our securities may be immediately delisted from the Nasdaq SmallCap Market.

There are no assurances that we will timely make our filings in accordance with the terms of Nasdaq's conditional continued listing determination. If we are delisted, trading in our common stock could be subject to the so-called "penny stock" rules that impose additional sales practice and market making requirements on broker-dealers who sell and/or make a market in those securities. Consequently, removal from the Nasdaq SmallCap Market, if it were to occur, could affect the ability or willingness of broker-dealers to sell and/or make a market on our common stock and the ability of purchasers of our common stock to sell their securities in the secondary market. These rules could further limit the market liquidity of our common stock and the ability of investors to sell our common stock in the secondary market. If we are delisted from the Nasdaq SmallCap Market, our stock price is likely to decline significantly.

If health care providers are not adequately reimbursed for the procedures, which use our products, or for the products themselves, we may never achieve significant revenues.

Our physician customers continue to encounter difficulties in readily obtaining adequate reimbursement for the Stretta procedure on a case-by-case basis, and this continues to impact our ability to market and sell the Stretta System.

While the American Medical Association has issued a Level I CPT code for the Stretta procedure effective January 1, 2005, there is no assurance that the established level of coverage will encourage physicians to perform the Stretta procedure or that local Medicare or private payers will choose to pay for this procedure. We have in the past received unfavorable Medicare coverage determinations. Physicians, hospitals and other health care providers are unlikely to purchase our products if they are not adequately reimbursed for the Stretta procedure or the products. Some payers may refuse adequate reimbursement even though significant peer-reviewed data has been published. If users of our products cannot obtain sufficient reimbursement from health care payers for the Stretta or Secca procedures or the Stretta or Secca Systems disposables, then it is unlikely that our products will ever achieve increased market acceptance.

Reimbursement from third-party health care payers is uncertain due to factors beyond our control and changes in third-party health care payers policies could adversely affect our sales growth.

Even if third-party payers provide adequate reimbursement for the Stretta procedure, adverse changes in third-party payers policies toward reimbursement could preclude market acceptance for our products and have a material adverse effect on our sales and revenue growth. We are unable to predict what changes will be made in the reimbursement methods used by third-party health care payers.

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For example, some health care payers are moving toward a managed care system in which providers contract to provide comprehensive health care for a fixed cost per person. We cannot assure you that in a prospective payment system, which is used in many managed care systems, the cost of our products will be incorporated into the overall payment for the procedure or that there will be adequate reimbursement for our products separate from reimbursement for the procedure.

Internationally, market acceptance of our products will be dependent upon the availability of adequate 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. Although we are seeking international reimbursement approvals, we cannot assure you that any such approvals will be obtained in a timely manner or at all. If foreign third-party payers do not adequately reimburse providers for the Stretta procedure and the products used with it, then our sales and revenue growth may be limited.

If physicians do not adopt our products, we will not achieve future sales growth.

To achieve increasing sales, our products must continue to gain recognition and adoption by physicians who treat gastrointestinal disorders. Our products represent a significant departure from conventional treatment methods. We believe that physicians will not increase rates of adoption of our systems unless they determine, based on published peer-reviewed journal articles, long-term clinical data and their professional experience, that our systems provide an effective and attractive alternative to conventional means of treatment. Some physicians may be slow to adopt new products and treatment practices, partly because of perceived liability risks and uncertainty of third-party reimbursement. Future adverse events or recalls could also impact future acceptance rates. Additionally, some of our customers and potential customers also find the 30-45 minutes necessary to perform a Stretta procedure to be a limiting issue, as their endoscopy unit schedule is typically dominated by short diagnostic procedures. If we cannot achieve increasing physician adoption rates of our products, we may never achieve significant revenues or profitability.

Failure in our physician education efforts could significantly reduce product sales.

It is important to the success of our sales efforts to educate physicians in the techniques of using our products. We rely on physicians to spend their time and money to attend pre-sale educational sessions. Positive results using the Stretta and Secca Systems are highly dependent upon proper physician technique. If physicians use either system improperly, they may have unsatisfactory patient outcomes or cause patient injury, which may give rise to negative publicity or lawsuits against us, any of which could have a material adverse effect on our sales and profitability.

We face competition from more established GERD treatments and from competitors with greater resources, which will make it difficult for us to achieve significant market penetration.

Companies that have well-established products, reputations and resources dominate the market for the treatment of GERD. Our primary competitors are large medical device manufacturers such as Ethicon Endo Surgery and United States Surgical, manufacturers of instrumentation for anti-reflux surgery, C.R. Bard, Wilson Cook and NDO Surgical, each of which manufactures an endoscopic sewing device for treating GERD, and Boston Scientific, which manufactures an injectable product for the treatment of GERD. Other competitive devices may be developed.

Most of these competitors are larger companies that enjoy several competitive advantages over us, which may include:

Existing anti-reflux surgical procedures and devices for the treatment of GERD;

Established reputations within the surgical and gastroenterological community;

Established distribution networks that permit these companies to introduce new products and have such products accepted by the physician community promptly;

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Established relationships with health care providers and payers that can be used to facilitate reimbursement for new treatments; and

Greater resources for product development and sales and marketing.

We do not feel that we compete with large pharmaceutical companies, such as AstraZeneca, Takeda Abbott Pharmaceutical, Wyeth Laboratories and Eisai, because candidate patients for Stretta are intolerant to drug therapy or have failed, or only partially responded to, drug therapy. However, these companies have an established relationship with the gastroenterology community and generate over \$12 billion in annual U.S. revenues from the proton pump inhibitor drug class. We could be adversely affected if one or more pharmaceutical companies elects to market aggressively against our product, or if a new, more effective, pharmaceutical product is developed.

We have limited sales and marketing experience, and failure to build and manage our sales force or to market and distribute our products effectively will hurt our revenues and profits.

We rely upon a small internal sales and marketing organization for most of our commercialization activities. There are significant risks involved in building and managing our sales force and marketing our products, including our:

Inability to hire a sufficient number of qualified sales people with the skills and understanding to sell the Stretta and Secca Systems effectively;

Failure to adequately train our sales force in the use and benefits of our products, making them less effective promoters; and

Failure to accurately price our products as attractive alternatives to conventional treatments.

Our failure to adequately address these risks will harm our ability to sell our products.

We also deploy an indirect sales channel of Manufacturers Representative firms to sell and market our products across the United States. The success of this indirect sales channel will depend upon a number of factors, many of which are beyond our control, including the willingness of such distributors to prioritize the sale of our products, and their effectiveness in such sales efforts.

Internationally, we rely on third-party distributors to sell our products, and we cannot assure you that these distributors will commit the necessary resources to effectively market and sell our products.

Internationally, we rely on a network of distributors to sell our products. We depend on these distributors in such markets and we will need to attract additional distributors to grow our business and expand the territories into which we sell our products. Distributors may not commit the necessary resources to market and sell our products to the level of our expectations. If current or future distributors do not perform adequately, we may not realize expected international revenue growth.

We depend on the suppliers who provide the materials and components used in our products, and if we lose our relationship with any individual suppliers, we will face regulatory requirements with regard to replacement suppliers that could delay the manufacture of our products.

Third-party suppliers provide materials and components used in our products, some of which are the single and/or sole source for the components they provide. If any of our suppliers become unwilling or unable to supply us with our requirements, replacement or alternative sources might not be readily obtainable due to regulatory requirements applicable to our manufacturing operations. Obtaining components from a new supplier may require a new or supplemental filing with applicable regulatory authorities and clearance or approval of the filing before we could resume product sales. This process may take a substantial period of time, and we cannot assure you that we would be able to obtain the necessary regulatory clearance or approval. This could create supply disruptions that would reduce our product sales and revenue.

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If we, or our suppliers, fail to comply with the FDA Quality System Regulation, manufacturing operations could be delayed and our business could be harmed.

Our manufacturing processes are required to comply with the Quality System Regulation, or QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging and shipping of our products. The FDA enforces the QSR through inspections. Our first QSR inspection was in March 2001, and we were also inspected in July 2003. There were no significant findings from either inspection. If we fail any future QSR inspections, our operations could be disrupted and our manufacturing delayed. Failure to take appropriate corrective action in response to a QSR inspection could force a shut-down of our manufacturing operations, a recall of our products, and potentially a revocation of the FDA 510(k) clearance of our products, which would have a material adverse effect on our product sales, revenues, expected revenues and profitability. Furthermore, we cannot assure you that our key component suppliers are, or will continue to be, in compliance with applicable regulatory requirements, will not encounter any manufacturing difficulties, or will be able to maintain compliance with regulatory requirements. Any such event could have a material adverse effect on our available inventory and product sales.

Our failure to obtain or maintain necessary FDA clearances or approvals could hurt our ability to commercially distribute and market our products in the United States.

Our products are medical devices and are therefore subject to extensive regulation in the United States and in foreign countries where we intend to do business. Unless an exemption applies, each new Class II or III 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, but may take longer. The premarket application, or PMA, approval process is much more costly, lengthy and uncertain. It generally takes from one to three years or even longer. Delays in obtaining regulatory clearance or approval will adversely affect our ability to generate revenues and profitability from new products. We cannot assure you that the FDA will ever grant 510(k) clearance or premarket approval for any new product we propose to market. If the FDA withdraws or refuses to grant approvals, we will be unable to market such products in the United States.

If we market our products for uses that the FDA has not approved, we could be subject to FDA enforcement action.

Our Stretta and Secca Systems are cleared by the FDA, the Stretta System for the treatment of GERD and the Secca System for the treatment of bowel incontinence in patients who have failed more conservative therapies such as diet modification and biofeedback. FDA regulations prohibit us from promoting or advertising either system, or any future cleared or approved devices, for uses not within the scope of our clearances or approvals. These determinations can be subjective, and the FDA may disagree with our promotional claims. If the FDA requires us to revise our promotional claims or takes enforcement action against us based upon our labeling and promotional materials, our sales could be delayed, our profitability could be harmed and we could be required to pay significant fines or penalties.

Modifications to our marketed devices may require new 510(k) clearances or PMA approvals or require us to cease marketing or recall the modified devices until such clearances are obtained.

Any modification to an FDA 510(k)-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, PMA 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 our products, but we believe that new 510(k) clearances are not required. We may modify future products after they have received clearance or approval, and, in appropriate circumstances, we may determine that new clearance or approval is unnecessary. Though we believe these changes fall within the acceptable

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scope of changes allowed for Class II devices, we cannot assure you that the FDA would agree with any of our decisions not to seek new clearance or approval. If the FDA requires us to seek 510(k) clearance or PMA approval for any modification to a previously cleared product, we also may be required to cease marketing or recall the modified device until we obtain such clearance or approval. Also, in such circumstances, we may be subject to significant regulatory fines or penalties.

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We face risks related to our international operations, including the need to obtain necessary foreign regulatory approvals.

To date we have international distribution agreements for Europe, Asia, and South Africa. We have obtained regulatory clearance to market the Stretta System in the European Union, Australia and Canada and to market the Secca System in the European Union, but we have not obtained any other international regulatory approvals for other markets or products. We cannot assure you that we will be able to obtain or maintain such approvals. Furthermore, although contracts already signed with European distributors specify payment in U.S. dollars, future international sales may be made in currencies other than the U.S. dollar. As a result, currency fluctuations may impact the demand for our products in countries where the U.S. dollar has increased compared to the local currency. Engaging in international business involves the following additional risks:

Export restrictions, tariff and trade regulations, and foreign tax laws;

Customs duties, export quotas or other trade restrictions;

Economic or political instability;

Shipping delays; and

Longer payment cycles.

In addition, contracts may be difficult to enforce and receivables difficult to collect through a foreign country's legal system, and the protection of intellectual property in foreign countries may be more difficult to enforce. Any of these factors could cause our international sales to decline, which would impact our expected sales and growth rates.

Product liability suits against us may result in expensive and time-consuming litigation, payment of substantial damages and an increase in our insurance rates.

The development, manufacture and sale of medical products involves a significant risk of product liability claims. The use of any of our products may expose us to liability claims, which could divert management's attention from our core business, could be expensive to defend, and could result in substantial damage awards against us. For example, we have been party to product liability lawsuits in which there were allegations that our products were defectively designed and that we were negligent in our manufacturing.

We maintain product liability insurance at coverage levels we believe to be commercially acceptable, and we re-evaluate annually whether we need to obtain additional product liability insurance. However there can be no assurance that product liability or other claims will not exceed such insurance coverage limits or that such insurance will continue to be available on the same or substantially similar terms, or at all. Any product liabilities claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing any coverage in the future.

We have limited protection for our intellectual property. If our intellectual property does not sufficiently protect our products, third parties will be able to compete against us more directly and more effectively.

We rely on patent, copyright, trade secret and trademark laws to protect our products, including our Stretta Catheter, our Secca Handpiece and our Curon Control Module, from being duplicated by competitors. However, these laws afford only limited protection. Our patent applications and the notices of allowance we have received may not issue as patents or, if issued, may not issue in a form that will be advantageous to us. Patents we have obtained and may obtain in the future may be challenged, invalidated or legally circumvented by third parties. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors, former employees or current employees, despite the existence of nondisclosure and confidentiality agreements and other contractual restrictions. Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. If our intellectual property rights do not adequately protect our commercial products, our competitors could develop new products or enhance existing products to compete more directly and effectively with us and harm our product sales and market position.

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Because, in the United States, patent applications are secret unless and until issued as patents, or corresponding applications are published in other countries, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to file patent applications for such inventions. Litigation or regulatory proceedings, which could result in substantial cost and uncertainty, may also be necessary to enforce patent or other intellectual property rights or to determine the scope and validity of other parties' proprietary rights. There can be no assurance that we will have the financial resources to defend our patents from infringement or claims of invalidity.

Because of our reliance on unique technology to develop and manufacture innovative products, we depend on our ability to operate without infringing or misappropriating the proprietary rights of others.

There is a substantial amount of litigation over patent and other intellectual property rights in the medical device industry. Because we rely on unique technology to develop and manufacture innovative products, we are especially sensitive to the risk of infringing intellectual property rights. While we attempt to ensure that our products do not infringe other parties' patents and proprietary rights, our competitors may assert that our products and the methods they employ may be covered by patents held by them or invented by them before they were invented by us. Although we may seek to obtain a license or other agreement under a third party's intellectual property rights to bring an end to certain claims or actions asserted against us, we may not be able to obtain such an agreement on reasonable terms or at all. If we were not successful in obtaining a license or redesigning our products, our product sales and profitability could suffer, and we could be subject to litigation and potentially substantial damage awards.

Also, one or more of our products may now be infringing inadvertently on existing patents. As the number of competitors in our markets grows, the possibility of a patent infringement claim against us increases. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Infringement and other intellectual property claims, with or without merit, can be expensive and time-consuming to litigate and divert management's attention from our core business. If we lose in this kind of litigation, a court could require us to pay substantial damages or grant royalties, and prohibit us from using technologies essential to our products. This kind of litigation is expensive to all parties and consumes large amounts of management's time and attention. In addition, because patent applications can take many years to issue, there may be applications now pending of which we are unaware and which may later result in issued patents that our products may infringe.

If we lose our rights to intellectual property that we have licensed we may be forced to develop new technology and we may not be able to develop that technology or may experience delays in manufacturing as a result.

Our license with Gyrus Group PLC, a public company incorporated and existing under the laws of England and Wales, allows us to manufacture and sell our products using their radiofrequency generator technology. In addition, the University of Kansas license allows us to apply radiofrequency energy to tissue. To the extent these license interests become jeopardized through termination or material breach of the license agreements, our operations may be harmed. We may have to develop new technology or license other technology. We cannot provide any assurance that we will be able to develop such technology or that other technology will be available for license. Even if such technology is available, we may experience delays in our manufacturing as we transition to a different technology.

If we are unable to attract and retain qualified personnel, we will be unable to expand our business.

We believe our future success will depend upon our ability to successfully manage our employees, which includes attracting and retaining engineers and other highly skilled personnel. Our employees are at-will employees and are not subject to employment contracts. The loss of

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services of one or more key employees could materially adversely affect our growth. In addition, our stock price is depressed and the results of our operations have been less successful than anticipated. This history of performance may make it difficult to attract and retain qualified personnel. Failure to attract and retain personnel, particularly management and technical personnel, would materially harm our ability to grow our business rapidly and effectively.

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Following the registration of the securities issued in our 2005 private placement, there will be substantial market dilution and the potential for increased market volatility in our stock.

As a result of the issuance of securities sold in our 2005 private placement, our total outstanding shares of common stock increased from approximately 24.9 million shares as of March 31, 2005 to approximately 43.3 million shares. This number may increase to nearly 53.1 million shares if warrants for an additional 9.8 million shares of our common stock issued in our 2005 private placement are exercised. The registration of the securities issued in the private placement will result in substantial market dilution and the potential for increased market volatility.

Our directors, executive officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

Our officers, directors and principal stockholders holding more than 5% of our common stock together control over 50% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to control the management and affairs of our company and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interest of our other stockholders.

Our stockholder rights plan, certificate of incorporation, bylaws and Delaware law contain provisions that could discourage a takeover.

In November 2001, we adopted a stockholder rights plan. The purpose of the plan is to assure fair value in the event of a future unsolicited business combination or similar transaction involving Curon. If an individual or entity accumulates 15% of our stock, or 20% in the case of certain existing stockholders, the rights become exercisable for additional shares of our common stock or, if followed by a merger or other business combination where Curon does not survive, additional shares of the acquirer's common stock. The intent of these rights is to force a potential acquirer to negotiate with the Board to increase the consideration paid for our stock. The existence of this plan, however, may deter a potential acquirer, which could negatively impact shareholder value.

In addition, our basic corporate documents and Delaware law contain provisions that might enable our management to resist a takeover. Any of the above provisions might discourage, delay or prevent a change in the control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward looking statements (as such term is defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934) and information relating to us that are based on the beliefs of our management as well as assumptions made by and information currently available to our management. In addition, when used in this report, the words likely, will, suggests, target, may, would, could, anticipate, believe, estimate, expect, intend, plan, predict, and similar expressions and their variants, as used by our management, may identify forward looking statements. Such statements reflect our judgment as of the date of this prospectus with respect to future events, the outcome of which are subject to certain known and unknown risks and uncertainties, including the factors discussed under the caption Risk Factors, and those discussed elsewhere in this prospectus, which may have a significant impact on our business, operating results or financial condition. Investors are cautioned that these forward looking statements are inherently uncertain. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results or outcomes may vary materially from those described herein. Although we believe that the expectations reflected in these forward looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. All forward looking statements included in this report are based on information available to us as of the date of this report. We undertake no obligation to update or revise any forward looking statements, whether as a result of new information, future events or otherwise, unless we are required to do so by law.

Table of Contents**USE OF PROCEEDS**

We will not receive any proceeds from the sale of shares by the selling stockholders. All net proceeds from the sale of the common stock covered by this prospectus will go to the selling stockholders. If and when all of the warrants are exercised, we will, however, receive up to approximately \$9,775,891. See **Principal and Selling Stockholders** and **Plan of Distribution** described below.

DIVIDEND POLICY

We have never declared or paid any cash dividend on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future.

MARKET PRICE INFORMATION

Our Common Stock trades under the symbol CURN. As of December 9, 2002, our Common Stock has been quoted on the NASDAQ SmallCap Market. Until that date, our Common Stock had been quoted on the NASDAQ National Market since our initial public offering on September 22, 2000. The following table shows the high and low sales prices for the Company's Common Stock for the periods indicated, as reported on the NASDAQ SmallCap Market.

	Common Stock Price	
	High	Low
Year Ended December 31, 2003		
First Quarter	\$ 1.35	\$ 0.60
Second Quarter	\$ 1.39	\$ 0.65
Third Quarter	\$ 2.05	\$ 0.70
Fourth Quarter	\$ 3.90	\$ 1.79
Year Ended December 31, 2004		
First Quarter	\$ 5.44	\$ 2.32
Second Quarter	\$ 2.95	\$ 1.43
Third Quarter	\$ 1.57	\$ 0.76
Fourth Quarter	\$ 1.84	\$ 0.90
Year Ended December 31, 2005		
First Quarter	\$ 2.02	\$ 0.95

As of June 27, 2005, the last reported sales price of our Common Stock on the NASDAQ SmallCap Market was \$0.64 per share, and the number of beneficial common stockholders was approximately 1,500. We currently intend to retain any earnings to fund the development and growth of our business.

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	Years Ended December 31					For the Three Months Ended March 31,	
	2000	2001	2002	2003	2004	2004	2005
	(unaudited)						
Statement of operations data:							
Revenues	\$ 1,156	\$ 3,317	\$ 3,403	\$ 3,421	\$ 3,709	\$ 906	\$ 857
Cost of goods sold	1,812	4,604	4,080	4,322	4,358	1,022	982
Gross loss	(656)	(1,287)	(677)	(901)	(649)	(116)	(125)
Operating expenses:							
Research and development	4,161	2,825	2,668	1,823	1,736	497	293
Clinical and regulatory	2,095	2,135	1,784	1,497	1,096	353	200
Sales and marketing	3,461	6,973	7,065	6,825	8,083	2,069	1,785
General and administrative	4,181	4,443	4,023	3,505	5,073	985	939
Litigation charge (3)				1,250			
	13,898	16,376	15,540	14,900	15,988	3,904	3,217
Operating loss	(14,554)	(17,663)	(16,217)	(15,801)	(16,637)	(4,020)	(3,342)
Interest income	1,330	2,240	751	234	132	39	17
Interest expense (1)	(4,083)	(4)	(8)	(5)	(6)		
Decrease in warrant liability (2)					1,200	443	338
Other income (expense)	(68)	(2)	33	17	(9)	(14)	21
Net loss before extraordinary item	(17,375)	(15,429)	(15,441)	(15,555)	(15,320)	(3,552)	(2,966)
Extraordinary gain (1)	1,596						
Net loss	\$ (15,779)	\$ (15,429)	\$ (15,441)	\$ (15,555)	\$ (15,320)	\$ (3,552)	\$ (2,966)
Net loss per common share attributable to common shareholders, basic and diluted	\$ (2.27)	\$ (0.81)	\$ (0.79)	\$ (0.77)	\$ (0.64)	\$ (0.16)	\$ (0.12)
Shares used in computing net loss per common share attributable to common shareholders, basic and diluted	6,945	19,075	19,653	20,076	24,037	22,659	24,810
	December 31,					March 31,	
	2000	2001	2002	2003	2004	2004	2005
(unaudited)							
Balance sheet data:							
Cash, cash equivalents and marketable securities	\$ 39,206	\$ 35,128	\$ 22,967	\$ 10,134	\$ 5,892	\$ 17,905	\$ 2,908
Working capital	39,916	36,498	24,807	9,963	6,625	18,842	3,384

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Long-term investments	12,882	3,048	528				
Total assets	56,617	43,073	27,236	13,854	9,157	21,673	5,865
Long-term liabilities	53	52	18	115	593	1,386	254
Total stockholders equity	54,930	41,288	26,103	10,808	6,913	18,408	3,940

- (1) In September 2000, upon the extinguishment of the convertible debt unamortized debt discount of \$1,400,000 related to issued warrants was recorded immediately as interest expense. Additionally, beneficial conversion feature of \$2,996,000 was reversed.
- (2) In February 2004, warrants for common stock issued with financing were recorded as liability at fair value of \$1,669,000. The fair value of the warrants and corresponding liability were remeasured at the end of each reporting period using Black-Scholes model, resulting in other gain of \$1,200,000 during 2004 and \$338,000 for the period ended March 31, 2005.
- (3) This is a non-recurring litigation charge related to the settlement of litigation against the Company, in which the plaintiff alleges injury during a Secca procedure caused by the device being defective and/or in an unreasonably dangerous condition. The Plaintiff was a subject in a clinical trial.

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

The following discussion and analysis should be read in conjunction with our audited and condensed consolidated financial statements and the related notes that appear elsewhere in this prospectus. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results may differ materially from those discussed in these forward-looking statements due to a number of factors, including those set forth in the section entitled "Risk Factors" and elsewhere in this prospectus.

Overview

We were incorporated in the State of Delaware in May 1997 as Conway-Stuart Medical Inc. and changed our name to Curon Medical Inc., in March 2000. Business activities before January 1998 were negligible. Prior to December 31, 2000 we were in the development stage and until that time, we had devoted substantially all of our efforts to raising capital and developing, marketing and selling our products. We operate in one reportable segment, using one measurement of profitability to manage our business.

In 1998, our primary activity was developing the Curon Control Module and Stretta Catheter for the treatment of gastroesophageal reflux disease, or GERD. In October 1999, we received CE Mark approval of the Stretta System, indicating that the Stretta System meets MDD standards allowing us to market it within the European Union. We received 510(k) clearance from the FDA in April 2000 and commercially launched in the United States in May 2000.

In April 1999, we began developing our second set of products, the Secca System, for the treatment of fecal incontinence, otherwise known as bowel incontinence. In November 1999, we conducted a 10-patient human clinical pilot study outside the United States and, in July 2000, we began a U.S. multi-center clinical trial of the Secca System under an Investigational Device Exemption. In September 2001, we received CE Mark approval of the Secca System, indicating that the Secca System meets European medical device standards, allowing us to market it within the European Union. Our multi-center clinical trial was completed, and the results were used to support a 510(k) submission to the FDA in December 2001. We received 510(k) clearance from the FDA in March 2002 to market the system for the treatment of bowel incontinence in patients who have failed more conservative therapies such as diet modification and biofeedback. We made our first sales of the Secca System in June 2002.

We market the Stretta System, as a complement to anti-reflux surgery, primarily to high volume gastroenterologists and general surgeons who actively perform endoscopy. In the United States, we estimate that there are approximately 4,500 general surgeons and 7,000 gastroenterologists who actively perform endoscopy. We market the Secca System primarily to colon and rectal surgeons and to those general surgeons who perform colorectal surgery. We estimate that there are approximately 1,200 colon and rectal surgeons and approximately 3,000 general surgeons who perform colorectal surgery in the United States.

We are focusing our sales efforts in the United States through a direct sales force, supplemented by selected independent manufacturing representatives. In international markets, we rely primarily on third-party distributors. In November 2000, we incorporated a subsidiary company in Belgium to support European distributors' sales, marketing and clinical efforts. As of March 31, 2005, this subsidiary had two employees. To date, we have international distribution agreements in 26 countries, of which 11 are in the European Union. Our gross margins on sales through international third-party distributors will be lower than our gross margins on U.S. sales as a result of distributor discounts.

To date, we have generated limited revenues. Our revenues are, and will be, derived from the sale of radiofrequency generators and our disposable devices, such as the Stretta Catheter and Secca Handpiece. We expect that disposable sales will continue to form the basis of a recurring revenue stream. However, domestic disposable sales continue to grow more slowly than expected primarily due to difficulties encountered by our physician customers in easily obtaining reimbursement for the Stretta procedure on a case-by-case basis. Some of our customers also find the 45 minutes necessary to perform a Stretta procedure to be a limiting issue, as their endoscopy unit schedule is typically dominated by short diagnostic procedures. Although disposable sales from outside the United States are increasing, they are not yet sufficient to offset the current domestic situation. Our strategies of pursuing state and national reimbursement coverage, focusing on entrenching the therapy to promote repeat catheter sales and incorporating technical improvements to our systems to reduce treatment times are designed to address these issues and we expect that our revenue from disposables will increase on implementation.

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Through March 31, 2005, we recorded limited product sales while incurring cumulative net losses of \$97.6 million. In addition to increasing expenditures related to continuing selling activities of the Stretta and Secca Systems, we anticipate that our expenses will increase as we continue to develop new products, conduct clinical trials, commercialize our products and acquire additional technologies as opportunities arise. As a result, we expect our operating expenses and cumulative net losses to increase.

Critical Accounting Policies and Estimates

Management's Discussion and Analysis of Financial Condition and Results of Operations discusses our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

We believe the following critical accounting policies, among others, affect its more significant judgments and estimates in the preparation of its consolidated financial statements:

Revenue Recognition and Accounts Receivable We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 104, Revenue Recognition in Financial Statements (SAB 104), as amended. SAB 104 requires that four criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or service rendered; (3) the fee is fixed or determinable; and (4) collectibility is reasonably assured. Revenue from product sales is recognized on product shipment against a signed purchase order or sales quote provided no significant obligations remain and collection of the receivables is deemed probable for both sales of control modules and disposables. We also provide customers with training and assistance in obtaining reimbursement, and to the extent that these remaining obligations are not considered inconsequential or perfunctory to the sales arrangement, we will defer the recognition of the revenue related to these services until fulfillment of the obligation. Any change in our selling process or post-sale training and customer support could result in deferred revenue.

We assess collection based on historical experience and the credit-worthiness of the customer. Based on management's on-going analysis of accounts receivable balances, and after the initial recognition of the revenue, if an event occurs which adversely affects the ultimate collectibility of the related receivable, management will record an allowance for bad debts. To date, bad debts have not had a significant impact on our financial position, results of operations and cash flows.

Revenues for extended warranty contracts are deferred and recognized over the extended warranty period. To date, post-sale customer support and training have not been significant.

Inventories Inventories are stated at the lower of standard cost (which approximates average cost) or market. We record adjustments to the value of the inventory based on sales forecasts, physical condition, and potential obsolescence due to technological advancements in its products. These adjustments are estimates that could be materially different from actual results if future market conditions as they relate to our products differ from our expectations.

Impairment of Long-Lived Assets In accordance with the provisions of Statements of Financial Accounting Standards Board No. 144, Accounting for the Impairment or Disposal of Long-lived Assets (SFAS 144), we review long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may

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not be fully recoverable. Under SFAS No. 144, an impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying value. Impairment, if any, is measured as the amount by which the carrying amount of a long-lived asset exceeds its fair value. There have been no such losses through March 31, 2005.

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Accounting for Income Taxes Our income tax policy records the estimated future tax effects of temporary differences between the tax basis of assets and liabilities and amounts reported in the accompanying consolidated balance sheets, as well as operating loss and tax credit carryforwards. We have recorded a full valuation allowance to reduce the deferred tax asset, as based on available objective evidence, it is more likely than not that the deferred tax asset will not be realized. While we have considered potential future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for the full valuation allowance, in the event that we were to determine that we would be able to realize our deferred tax assets in the future, an adjustment to the deferred tax asset would increase income in the period such determination was made.

Stock-Based Compensation We have various stock option, stock purchase and incentive plans to reward employees and key executive officers of the Company. We continue to use the provisions of Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25), and apply the disclosure provisions of Statements of Financial Accounting Standards No. 123 (SFAS 123), as amended by SFAS No. 148, Accounting for Stock-Based Compensation, Transition and Disclosure . Under APB No. 25 stock compensation is measured as the difference, if any, on the date of grant between the fair value of our common stock and the exercise price. Under SFAS 123 stock compensation is based on the fair value of the stock award measured using option valuation models. Though we do disclose in the notes to the financial statements the pro-forma impact of applying the provision of SFAS 123 to our stock awards, if we were to change our accounting policy to fully adopt the fair value measurement provisions of SFAS 123, it could have a material impact on our financial position and results of operations.

Accounting for Common Stock Warrants We consider EITF 00-19 Accounting for derivative financial instruments indexed to, and potentially settled in a Company s own stock and SFAS No.150 Accounting for certain financial instruments with characteristics of both liabilities and equity to properly classify and value issued financial instruments. On February 6, 2004 and April 7, 2005, we issued warrants to several institutional investors in connection with the private placements of common stock. The common stock warrants have a five-year term. The February 6, 2004 warrant became exercisable on August 6, 2004 and the April 7, 2005 warrant will become exercisable on October 8, 2005. The warrants were valued using the Black-Scholes model. The fair value of the warrants is recorded as liability and the corresponding liability is re-measured at the end of each reporting period utilizing current inputs to the Black-Scholes model, with any change in fair value being recorded as a non-operating item in the statement of operations.

Legal Proceedings and Loss Contingencies We are involved in routine legal and administrative matters that arise from the normal conduct of business. Other matters contain allegations that are not routine and involve compensatory, punitive, and treble damages. The outcome of these proceedings which are not within our control, are often difficult to predict and often are resolved over long periods of time. We also maintain product liability insurance with third parties to mitigate any loss that is related to product liability claims. We record loss contingencies as liabilities in the financial statements when it is determined that we have incurred a loss that is probable and the amount of the loss is reasonably estimable, in accordance with SFAS 5 Accounting for Contingencies .

Restatement of Financial Statements We have restated our financial results for the quarter ended March 31, 2004 to reflect adjustments to our previously reported financial information. The restatements arose, in part, out of an internal investigation by the Audit Committee. As a result of the investigation, the Audit Committee determined that certain sales employees had improperly offered rights of return and exchange in violation of our revenue recognition policy, and a manufacturer s representative had not actually made sales that it had reported to the Company. As a result of this investigation, we were also unable to timely file our Form 10-Q and to timely announce our financial results for the quarter ended June 30, 2004.

Internal Accounting Review We announced on August 17, 2004 that the Audit Committee of our Board of Directors had initiated an Internal Accounting Review of our accounting and reporting practices, including the

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appropriateness and timing of the revenue recognition. The improper recognition of revenue did have an impact on Quarterly revenue for fiscal year 2003. Management and the Audit Committee performed an SAB 99 analysis on the impact of the improper revenue recognition, examining both quantitative and qualitative factors. From a quantitative standpoint, none of the quarters (or the 12 month impact) was deemed individually significant enough to warrant restatement without regard to qualitative factors. Upon assessment of the ten qualitative factors, management and the Audit Committee concluded that the impact of the improper revenue recognition did not warrant restating the 2003 audited financial statements nor any quarters in 2003. As a result of this evaluation, our Board of Directors directed management to implement and management has implemented additional measures designed to ensure that information required to be disclosed in our periodic reports is recorded, processed, summarized and reported accurately. These measures include the adoption of a Disclosure Committee Charter, the adoption of a written revenue recognition policy, further controls on shipment of products for revenue transactions, and additional training of our sales and marketing staff to minimize the risk of revenue recognition errors. Given the additional measures adopted by the company, we believe that our disclosure controls and procedures are now effectively designed to ensure that information we are required to disclose in reports that we file or submit to the SEC is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

Results of Operations

Three months ended March 31, 2005 and 2004

Revenues

Our revenues are comprised of sales of our Stretta and Secca generators and disposable devices. Revenues for the quarter ended March 31, 2005 were \$857,000, compared to \$906,000 for the same quarter in 2004. The decrease compared to 2004 was due primarily to a decline in sales of our Stretta System products of \$356,000, partially offset by an increase in Secca System products of \$311,000. Stretta System products accounted for \$483,000, or 57%, and Secca System products accounted for \$365,000, or 43%, of the quarter's revenues. In the first quarter of 2004, Stretta System products accounted for \$839,000, or 94%, and Secca System products were \$54,000, or 6%, of the quarter's revenues. The Stretta Control Module and Catheter accounted for \$103,000, or 21%, and \$341,000, or 71%, respectively, of the Stretta product line sales for the quarter ended March 31, 2005, compared to \$355,000, or 42%, and \$445,000, or 53%, respectively, for the same period in 2004. The Secca Control Module and Hand-pieces accounted for \$92,000, or 25%, and \$261,000, or 71%, respectively, of the Secca product line sales for the quarter ended March 31, 2005, compared to \$0, or 0%, and \$54,000, or 100%, respectively, for the same period in 2004. International sales accounted for \$135,000 in the quarter ended March 31, 2005, compared to \$9,000 in the same quarter of 2004.

Cost of goods sold

Our costs of goods sold represent the cost of producing generators and disposable devices. Cost of goods sold was \$982,000 in the quarter ended March 31, 2005, and \$1,022,000 for the same period in 2004. Our sales have not yet reached a level that would absorb our manufacturing capacity to the extent that we would experience positive gross profit.

Research and development expenses

Research and development expenses consist primarily of personnel costs, professional services, patent application and maintenance costs, materials, supplies and equipment. Research and development expenses were \$293,000 for the three months ended March 31, 2005, a decrease

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of \$204,000 or 41% over research and development expenses of \$497,000 for the three months ended March 31, 2004. The decrease in spending for the three months ended March 31, 2005 was due primarily to the reduced headcount in our research and development department as we implemented cost reduction measures in September 2004. We expect that research and development expenses will remain near current levels for the remainder of the current fiscal year.

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Clinical and regulatory expenses

Clinical and regulatory expenses consist primarily of expenses associated with the costs of clinical trials, clinical support personnel, the collection and analysis of the results of these trials, and the costs of submission of the results to regulatory agencies. Clinical and regulatory expenses were \$200,000 for the three months ended March 31, 2005, a decrease of \$153,000 or 43% over clinical and regulatory expenses of \$353,000 for the three months ended March 31, 2004. Cost reduction measures and reduced clinical trial activity have reduced expenses in the first quarter of 2005, as compared to the first quarter of 2004. We expect that clinical and regulatory expenses will remain near current levels for the remainder of the current fiscal year.

Sales and marketing expenses

Sales and marketing expenses consist of personnel related costs, advertising, public relations and attendance at selected medical conferences. Sales and marketing expenses for the three months ended March 31, 2005 were \$1,785,000, a decrease of \$284,000 or 14% over sales and marketing expenses of \$2,069,000 for the three months ended March 31, 2004. The decrease of \$148,000 from 2004 to 2005 was primarily attributable to trade shows and medical conferences. We also reduced our spending on consulting, travel and recruitment in the first quarter 2005 compared to 2004. We have recently put in place some new programs that we believe will accelerate sales growth through 2005 and beyond. We expect the sales and marketing expenses to increase due to the new program expenses for the remainder of the current fiscal year, and will fluctuate primarily as a result of both commission expenses that are related to sales levels and timing of various medical conferences that we attend.

General and administrative expenses

General and administrative expenses consist primarily of the cost of corporate operations and personnel, legal, accounting and other general operating expenses of our company. General and administrative expenses for the three months ended March 31, 2005 were \$939,000, a decrease of \$46,000 or 5% over general and administrative expenses of \$985,000 for the three months ended March 31, 2004. This decrease in general and administrative expenses for the three months ended March 31, 2005 was primarily due to decreased legal and professional fees. We anticipate that general and administrative expenses for the fiscal year 2005 will increase related to implementation of Section 404 of the Sarbanes-Oxley Act, which requires our management to assess the effectiveness of our internal controls over financial reporting.

Interest Income, net

During the quarter ended March 31, 2005, compared to the quarter ended March 31, 2004, net interest income decreased by \$22,000. The decrease was due to an average cash and investment decrease of approximately \$15.0 million, partially offset by an increase in investment yields to approximately 2.4% from 1.5%. Interest expense was not material for either period.

Decrease in warrant liability

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Our sale of 4,025,000 newly issued shares in February 2004, included warrants to purchase an additional 905,625 shares of common stock. These warrants provide for cash redemption by the holders upon the occurrence of certain events outside our control. As a result, the aggregate fair value of the warrants of \$1.7 million, determined using the Black-Scholes model, was recorded as a liability with subsequent changes to the fair value of the warrants being recorded as a non-operating item through the statement of operations. The fair value of the warrant decreased from \$1,668,000 on February 6, 2004 to \$1,225,000 at March 31, 2004 to \$469,000 at December 31, 2004 to \$131,000 at March 31, 2005, resulting in us recording a benefit of \$338,000 and \$443,000 at March 31, 2005 and 2004 respectively.

Years ended December 31, 2004, 2003, and 2002

Revenue

Total revenues for the year ended December 31, 2004 were \$3,709,000, an increase of \$288,000 or 8% over total revenues of \$3,421,000 for the year ended December 31, 2003. This increase was due primarily to increased sales

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of Secca product, which accounted for \$505,000 of the increase. Total revenues for the year ended December 31, 2003 were \$3,421,000, an increase of \$18,000 or essentially flat growth over total revenues of \$3,403,000 for the year ended December 31, 2002. Sales have been lower than anticipated, primarily due to the sales and marketing efforts involved in repositioning the Stretta System as an alternative to anti-reflux surgery, requiring us, mid-2002, to refocus our sales force to target surgeons as opposed to gastroenterologists. We now see our lower sales to gastroenterologists being replaced by higher sales to surgeons, a trend that we expect to continue. In all three years, our revenues have been impacted by our ongoing challenges in receiving favorable coverage decisions from both public and private carriers on a state-by-state basis for the Stretta procedures. Stretta System products accounted for 74% and Secca System products accounted for 24% of the revenues for the year ended December 31, 2004, as compared to 87% and 11%, respectively, for the same period in 2003 and 96% and 3% respectively in 2002. The Stretta Control Module and Catheter accounted for 38% and 58%, respectively, of the Stretta product line sales for the year ended December 31, 2004, compared to 43% and 54%, respectively, for the same period in 2003, and 52% and 46%, respectively, in 2002. The Secca Control Module and Handpieces accounted for 32% and 64%, respectively, of the Secca product line sales for the year ended December 31, 2004, compared to 52% and 41%, respectively, for the same period in 2003, and 54% and 40%, respectively, in 2002. International sales accounted for \$179,000 for the year ended December 31, 2004, compared to \$226,000 for the same period in 2003, and \$423,000 in 2002. International sales were higher in 2002 due to the sale of capital equipment to new distributors during that year. With the expansion and subsequent training of our sales organization complete, we expect to realize steady growth in new sales of both control modules and disposable components. In addition, we expect that increased patient awareness and subsequent demand for these two minimally invasive options will fuel further revenue growth in product usage with both existing and new customers.

Cost of goods sold

Our costs of goods sold represent the cost of producing generators and disposable devices. We also license a technology used in the generators that we sell. We are required to pay licensing fees based on the sales price of the units. We believe that there are alternative technologies that could be utilized should we choose to do so. Cost of goods sold was \$4,358,000, \$4,322,000 and \$4,080,000 in the twelve months ended December 31, 2004, 2003, and 2002, respectively. As sales volume increases, we expect gross profit to become positive and increase accordingly. Our sales have not yet reached a level that would absorb our manufacturing capacity to the extent that we would experience positive gross profit. For the twelve months ended December 31, 2002, \$235,000 of excess manufacturing capacity was used to support Secca Pilot manufacturing, prior to product commercialization in June 2002. This manufacturing capacity was therefore charged to research and development, as compared to the same period in 2004 and 2003, and no pilot manufacturing activities were done in 2004 or 2003.

Research and development expenses

Research and development expenses consist primarily of personnel costs, professional services, patent application and maintenance costs, materials, supplies and equipment. Research and development expenses were \$1,736,000, \$1,823,000, and \$2,668,000 in the twelve months ended December 31, 2004, 2003, and 2002, respectively. The decrease in expenses in 2004 compared to 2003 was due to the scaling back of disposables development activities. The decrease in expenses in 2003 compared to 2002 was due to cost reduction strategies as well as the completion of Secca pilot manufacturing activities in the second quarter of 2002, when commercialization occurred. Amortization of stock-based compensation accounted for \$1,000, \$27,000, and \$66,000 in the twelve months ended December 31, 2004, 2003, and 2002, respectively. During the quarter ended September 30, 2002, we reduced the number of research and development personnel from ten to seven. Costs associated with terminating these individuals were \$83,000. In September 2004, we reduced the level of research activities and reduced headcount by 5 employees. Costs associated with terminating these individuals were \$138,000. As a result of this action we expect spending for research and development expenses in 2005 to be lower than 2004.

Clinical and regulatory expenses

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Clinical and regulatory expenses consist primarily of expenses associated with the costs of clinical trials, clinical support personnel, the collection and analysis of the results of these trials, and the costs of submission of the results to the FDA. Clinical and regulatory expenses were \$1,096,000, \$1,497,000, and \$1,784,000 in the twelve months ended December 31, 2004, 2003, and 2002, respectively. Spending decreased in 2004 as compared to 2003 and 2002. Our clinical and regulatory costs fluctuate depending on the number of clinical trial patients treated in any period.

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Spending during 2004 and 2003 has been further reduced compared to 2002 due to decreased headcount. Clinical trial costs include payments to hospitals, and the related travel expense for Curon employees. Amortization of stock-based compensation accounted for \$29,000, \$142,000, and \$51,000 in the twelve months ended December 31, 2004, 2003, and 2002, respectively. The increase in stock-based compensation during 2003 was due to a consultant option. During the quarter ended September 30, 2002, we reduced the number of clinical personnel from four to three. Costs associated with terminating these individuals were \$13,000. We expect spending for clinical and regulatory expenses in 2005 to be comparable to 2004.

Sales and marketing expenses

Sales and marketing expenses consist of personnel related costs, advertising, public relations and attendance at selected medical conferences. Sales and marketing expenses were \$8,083,000, \$6,825,000, and \$7,065,000 in the twelve months ended December 31, 2004, 2003, and 2002, respectively. Spending increased in the twelve months ended December 2004 as compared to the same period in 2003 as we positioned our sales, marketing and reimbursement teams for projected increased sales volumes. Implementation of cost reduction strategies realized lower spending for the twelve months ended December 31, 2003 as compared to the same period in 2002. Amortization of stock-based compensation accounted for \$12,000, \$14,000, and \$47,000 in the twelve months ended December 31, 2004, 2003, and 2002, respectively. During the quarter ended September 30, 2002, we reduced the number of sales and marketing personnel from 28 to 26. Costs associated with terminating these individuals were \$147,000. We expect spending for sales and marketing in 2005 to be comparable to 2004.

General and administrative expenses

General and administrative expenses consist primarily of the cost of corporate operations and personnel, legal, accounting and other general operating expenses of our company. General and administrative expenses were \$5,073,000, \$3,505,000, and \$4,023,000 in the twelve months ended December 31, 2004, 2003, and 2002, respectively. The primary reason for the increase for the twelve months ended December 31, 2004 compared to 2003, was due to the cost associated with the investigation related to our revenue recognition policy in 2004, amounting to \$1.2 million. Apart from the Audit Committee investigation, higher spending is related to an increase in insurance rates, legal spending and investor relations. After eliminating the stock-based compensation and termination costs noted below, spending in 2003 is slightly higher in comparison to 2002, due to the relocation costs for our new CEO in the amount of \$225,000. Amortization of stock-based compensation accounted for \$9,000 and \$186,000 in the twelve months ended December 31, 2003 and 2002, respectively. During the quarter ended September 30, 2002, we reduced the number of general and administrative personnel from nine to seven. Costs associated with terminating these individuals were \$555,000, which included loan forgiveness in the amount of \$272,000, which occurred in July 2002. We expect spending for general and administrative in 2005 to be lower than to 2004.

Litigation charge

This is a non-recurring litigation charge related to a settlement of \$1,250,000 related to the settlement of litigation against the company, in which the Plaintiff alleges injury during a Secca procedure caused by the device being defective and/or in an unreasonably dangerous condition. The Plaintiff was a subject in a clinical trial. This is related to the lawsuit in the state of Pennsylvania, and also to the Chubb insurance suit.

Interest income and expense

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Interest income was \$132,000, \$234,000, and \$751,000 in the twelve months ended December 31, 2004, 2003, and 2002, respectively. Interest income has decreased in 2004 as compared to 2003 and 2002, due to a declining balance of marketable securities. Average cash and investment balances in 2004 were \$8.0 million, compared to the 2003 average of \$16.8 million and \$30.8 million in 2002. Earnings have also been affected by declining interest rates through 2002, 2003 and 2004.

Interest expense was \$6,000, \$5,000, and \$8,000 in the twelve months ended December 31, 2004, 2003, and 2002, respectively. In all three years, interest expense is related to notes payable related to insurance policies.

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Decrease in warrant liability

Our sale of 4,025,000 newly issued shares on February 6, 2004, included warrants to purchase an additional 905,625 shares of common stock. These warrants provide for cash redemption by the holders upon the occurrence of certain events outside our control. As a result, the aggregate fair value of the warrants of \$1,669,000, determined using the Black-Scholes model, was recorded as a liability at the time of sale with subsequent changes to the fair value of the warrants being recorded as a non-operating item through the statement of operations. As of December 31, 2004, the fair value of the warrants decreased from \$1,669,000 on February 6, 2004, to \$469,000 at December 31, 2004, resulting in us recording a benefit of \$1,200,000 in the twelve months ended December 31, 2004.

Income taxes

As a result of our net losses, we did not incur any income tax obligations in each of the twelve-month periods ended December 31, 2004, 2003 and 2002.

Liquidity and Capital Resources

At March 31, 2005, we had \$3.4 million in working capital and our primary source of liquidity was \$2.9 million in cash and cash equivalents and marketable securities, compared to \$6.6 million and \$5.9 million, respectively, as of December 31, 2004. We have been financing our operations primarily through our cash and cash equivalents, revenues, marketable securities, and financing activities. On April 7 and April 19, 2005, we signed definitive agreements for the private placement of our common stock to institutional investors for a total of \$12.0 million, before transaction fees and expenses. The placement is structured to be completed in two closings, with the first closing having occurred on April 8, 2005, and the second closing being subject to stockholder approval. In this first closing, we raised approximately \$3.2 million by issuing a total of 4,962,614 shares of common stock at a price of \$0.65 per share. Investors received five-year warrants to purchase an aggregate of 2,481,298 shares of common stock at a price of \$1.00 per share. An additional amount of approximately \$8.8 million has been deposited to escrow and will be released to us in the event that we obtain stockholder approval for the subsequent sale of securities. We intend to seek stockholder approval at our Annual Meeting to be held on or about May 31, 2005. The terms of the second closing are identical to those of the first closing. In the event that stockholder approval is received, net proceeds to us from the second closing will be approximately \$8.4 million. We believe if we are successful in obtaining the stockholder approval, we will have enough cash to fund operations for at least the next twelve months. If we are unable to obtain the stockholder approval for the subsequent sale of securities, operations will need to be substantially reduced in order to conserve working capital and we will have to explore other options, such as a sale of the Company or a portion of our assets including selling or licensing some of our proprietary technologies.

Three months ended March 31, 2005 and 2004

Cash used in operating activities was \$2.9 million in the three month period ended March 31, 2005, and \$4.8 million in the same period in 2004. In the first quarter 2004, cash used in operating activities included \$1.25 million that we paid to settle a legal liability. The remaining decrease of cash used in operating activities relates primarily to decrease in net loss of \$3.6 million in the first quarter 2004 compared to \$3.0 million in the first quarter of 2005. We substantially decreased sales and marketing, clinical and regulatory spending, together with the staff headcount in research and development.

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Cash used in investing activities was \$5.5 million in the three months ended March 31, 2005, which consisted primarily of net proceeds from net maturities of marketable securities used to fund operations. As of March 31, 2005, we had no material commitments for capital expenditures. For the three months ended March 31, 2004, net cash provided by investing activities was \$10.3 million, which consisted primarily of net purchases of marketable securities, as we invested the cash received from our private placement financings in February 2004.

Cash used in financing activities was \$12,000 in the three months ended March 31, 2005, primarily related to the proceeds from the exercise of stock options offset by the payoff of a note payable to finance insurance policies. For the same period in 2004, cash provided by financing activities was \$12.8 million, related to the private placement of common stock and warrants to a group of institutional investors in the net amount of \$12.7 million, in addition to \$117,000 from the exercise of stock options.

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Years ended December 31, 2004, 2003, and 2002

Cash used in operating activities was \$16.7 million in the twelve months ended December 31, 2004, compared to \$12.5 million and \$14.4 million for the same period in 2003 and 2002 respectively. Cash used in operating activities for fiscal 2004 of \$16.7 million, primarily comprised net loss, net of non-cash related expenses. The increased in cash used in operating activities in 2004 was due to the \$1.25 million cash paid for the settlement of a lawsuit and the costs of the Audit Committee investigation totaling \$1.2 million. Working capital sources of cash were a decrease in accounts receivable and inventory.

Cash used in investing activities was \$941,000 in the twelve months ended December 31, 2004, which consists of net maturities of marketable securities of \$757,000 used to fund operations. Cash provided by investing activities was \$ 8.7 million and \$15.6 million for the same period in 2003 and 2002, respectively, which consisted of \$9.3 and \$15.8 million in net maturities of marketable securities to fund operations. Our investment balances have decreased over the past twelve months, and therefore the related volume of investment purchases and maturities is lower for the years ended December 31, 2004 and 2003, as compared to the same period in 2002.

Cash provided by financing activities was \$13.1 million in the twelve months ended December 31, 2004, related to the private placement of common stock to a group of institutional investors in the net amount of \$12.6 million, in addition to \$433,000 from exercise of stock options and the Employee Stock Purchase Plan, and net cash provided by financing of business insurance in the amount net amount of \$57,000. Cash provided by financing activities was \$72,000 for the twelve months ended December 31, 2003, primarily related to sales of common stock and proceeds from notes payable to finance insurance policies, offset by payments on those notes payable. Cash used by financing activities was \$76,000 for the twelve months ended December 31, 2002, primarily due to payments on the notes payable used to finance insurance policies. During 2002, sales of stock through employee stock plans were offset by purchases of treasury stock.

Contractual Obligations

The following table sets forth our contractual obligations as of March 31, 2005 and the years in which such obligations are expected to be settled.

	2005	2006	2007	Total
	_____	_____	_____	_____
Future minimum lease commitments	\$ 306	\$ 348	\$ 20	\$ 674
Inventory purchase commitments	623			623
	_____	_____	_____	_____
	\$ 929	\$ 348	\$ 20	\$ 1,297
	_____	_____	_____	_____

Recent Accounting Pronouncements

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs*. SFAS 151 amends the guidance in ARB No. 43, Chapter 4, *Inventory Pricing*, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs and spoilage. This statement requires that these items be expensed as incurred and not included in overhead. In addition, SFAS 151 requires that allocation of fixed production overhead to

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conversion costs should be based on normal capacity of the production facilities. This Statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of SFAS No. 151 is not expected to have a material impact on our financial position and results of operations.

In December 2004, the FASB issued Statement No. 123(R) (SFAS 123(R)), Share-Based Payment . This statement replaces Statement of Financial Accounting Standards No. 123 (SFAS 123), Accounting for Stock-Based Compensation , and supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees . SFAS 123(R) will require compensation costs related to share-based payment transactions to be recognized in the financial statements (with limited exceptions). The amount of compensation cost will be measured based on the grant-date fair value of the equity or liability instruments issued. Compensation cost will be recognized over the period that an employee provides service

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in exchange for the award. This statement is effective as of the beginning of the annual reporting period that begins after June 15, 2005. We are currently in the process of evaluating the impact from this standard on our results of operations and financial position.

Quantitative and Qualitative Disclosure About Market Risk

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may have market risk. That means that a change in prevailing interest rates may cause the fair value of the principal amount of an investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing rate rises, the fair value of the principal amount of our investment will probably decline. To minimize this risk in the future, we intend to maintain our portfolio of cash equivalents and short-term investments in a variety of securities, including commercial paper, money market funds, government and non-government debt securities. The average duration of all of our investments has generally been less than eighteen months. Due to the short-term nature of these investments, we believe we have no material exposure to interest rate risk arising from our investments.

Our exposure to market risk for changes in interest rates relates primarily to the increase or decrease in the amount of interest income we can earn on our available funds for investment. We do not plan to use derivative financial instruments in our investment portfolio. We plan to ensure the safety and preservation of our invested principal funds by limiting default risks, market risk and reinvestment risk. We plan to mitigate default risk by investing in high-credit quality securities.

All of our revenue is realized in U.S. dollars. Therefore, we do not believe that we currently have any significant direct foreign currency exchange rate risk.

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BUSINESS

Company Overview

Curon Medical, Inc. was incorporated in Delaware in May 1997 as Conway Stuart Medical, Inc. We develop, manufacture and market innovative proprietary products for the treatment of gastrointestinal disorders. Our products consist of radiofrequency generators and single-use disposable devices.

Our first product, the Stretta System, received United States Food and Drug Administration (FDA) clearance in April 2000 for the treatment of gastroesophageal reflux disease, or GERD, which affects approximately 15 million U.S. adults on a daily basis. In patients with GERD, acidic stomach contents reflux backward from the stomach into the esophagus, causing a wide range of symptoms and complications, including, most commonly, persistent heartburn and chest pain. Unlike medication, which addresses GERD symptoms, our Stretta System applies radiofrequency energy to treat the causes of GERD. The Stretta System consists of a disposable catheter with needle electrodes and our control module, which is a radiofrequency energy generator. Using the Stretta System, the physician delivers temperature-controlled radiofrequency energy to the muscle of the lower esophageal sphincter and upper portion of the stomach. The delivery of this energy creates heat, causing tissue contraction and creating thermal lesions that resorb over time, resulting in improved sphincter function. Clinical studies show a significant reduction in GERD symptom scores, esophageal acid exposure, and use of anti-secretory medications.

We commercially launched the Stretta System in May 2000. We have sold over 300 control modules and approximate that over 7,000 patients have been treated with the Stretta Procedure.

Our second product, the Secca System, is a radiofrequency energy-based system for the treatment of bowel incontinence (formerly and clinically referred to as Fecal incontinence). Bowel incontinence is caused by damage to the anal sphincter from childbirth, surgery, neurological disease, injury or age, and affects up to 16 million adults in the United States. Using the Secca System, physicians deliver radiofrequency energy to the anal sphincter muscle in the anal canal. Clinical studies have shown a reduction in bowel incontinence symptoms and improvement in general quality of life. In March 2002, we received 510(k) clearance from the FDA to market the Secca System for the treatment of fecal incontinence in patients who have failed more conservative therapies such as diet modification and biofeedback. We undertook a limited test launch of Secca in June 2002, and fully launched the product commercially in May 2003.

We have a direct sales force to market and sell our products in the United States. We market the Stretta System, as an alternative to anti-reflux surgery, primarily to high volume general surgeons and gastroenterologists. In the United States, we estimate that there are approximately 4,500 general surgeons and 7,000 gastroenterologists who actively perform endoscopy. We market the Secca System primarily to colon and rectal surgeons and to those general surgeons who perform colorectal surgery. We estimate that there are approximately 1,200 colon and rectal surgeons and up to 3,000 general surgeons that routinely perform colorectal surgery in the United States.

Our Stretta System has also received European, Australian and Canadian regulatory approval, and our Secca System has also received regulatory approval in Europe. We incorporated a subsidiary company in Belgium in November 2000 to manage distribution of our products in Europe, the Middle East and Africa. In March 2003, we entered into distribution agreements for the Stretta System in Switzerland, Austria, and the Netherlands, and have international distribution agreements with a distributor for the Far East, giving us representation in the countries of the Peoples Republic of China, Taiwan, Hong Kong, South Korea, Singapore, Malaysia, Indonesia, Vietnam, Thailand and India. To date, we have international distribution agreements for our products in 11 European and Middle Eastern countries and in South Africa. The Secca System is also sold through distributors in Europe. The first European Secca Procedures were performed in Germany, Denmark and Italy in March 2002,

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as part of our clinical trials. The first international commercial Secca procedure was performed in March 2003. We are organized into a single reportable segment consisting of the development, manufacture, and marketing of proprietary products for the treatment of gastrointestinal disorders. We use one measurement of profitability and do not disaggregate our business for internal reporting.

The American Medical Association recently issued a Category I CPT code for the Stretta procedure that became effective January 1, 2005, which will make it easier for physicians to code for the procedure from this date.

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Business Strategy

Our strategy is to establish our Stretta and Secca Systems as standard treatment options for patients with GERD and bowel incontinence, respectively. We believe that our products offer substantial improvements over the current treatment options in the care of patients with these disorders.

The typical Stretta patient has not achieved adequate symptom control on, or is intolerant of, escalated medical therapy, or does not wish to continue indefinite anti-secretory medication use. Until recently, the only option for these patients has been a surgical anti-reflux procedure. We believe that the Stretta System offers several significant benefits over anti-reflux surgery, including that it is most commonly an outpatient procedure rather than inpatient surgery, that it is typically performed under conscious sedation rather than general anesthesia, and that it has a lower incidence of side effects and complications. Patients also return to normal activities faster after the Stretta procedure than after anti-reflux surgery. Due to these features, the Stretta procedure is significantly less expensive than anti-reflux surgery, and thus insurance companies may benefit through cost savings.

The Secca procedure offers a treatment option for patients with bowel incontinence who have failed more conservative therapies such as diet modification and biofeedback. Currently, bowel incontinence patients have few treatment options. These options include fiber therapy, anti-diarrheal medications, biofeedback therapy, and major surgery, which may involve reconstruction of the sphincter muscle or implantation of a continence device. These therapies have only modest effectiveness, and we believe that there is a need for a minimally invasive treatment option that may be offered to patients as an alternative to major surgery. We believe that the Secca procedure has several significant benefits over surgery, including that it is most commonly an outpatient procedure rather than inpatient surgery, that it is typically performed under conscious sedation rather than general anesthesia, and that it has a lower incidence of side effects and complications. Recovery after incontinence surgery may take several months, whereas patients who have the Secca procedure may usually return to their normal daily activities the following day.

We have established both a direct and indirect sales and distribution network in the United States to target the approximately 4,000 hospital endoscopy suites and approximately 4,000 ambulatory treatment centers. We currently have fourteen direct sales territories, a sales vice president, a marketing vice president, two regional direct sales managers, and two clinical applications specialists. In addition, we have an indirect sales channel comprised of 6 Manufacturer Representative firms, with 15 salespeople to sell and market our products, on a part time basis, across the United States. In Europe and other selected areas, we have distributors covering 26 countries. We may hire additional salespeople or enter new distributor relationships to increase market penetration of our products.

We have acquired and may continue to acquire complementary technologies. We have a license agreement with Gyrus Group PLC (formerly Somnus Medical Technologies, Inc) for the use of technology related to Gyrus' radiofrequency generator. We also have entered into license agreements with the University of Kansas Medical Institute and with Messrs. Shadduck and Baker relating to applying radiofrequency energy to tissue. We may enter into license agreements with other persons or companies covering technology relating to gastrointestinal tract diseases.

GERD: The problem and conventional treatment options

GERD is the frequent backward flow, or reflux, of stomach contents into the esophagus, the muscular tube that connects the mouth to the stomach. In the lower part of the esophagus, there is an area of thickened muscle known as the lower esophageal sphincter which, when functioning properly, acts as a one-way valve, allowing food to pass down from the esophagus into the stomach, but preventing reflux. In GERD patients, the lower esophageal sphincter does not function properly and allows chronic reflux to occur. Stomach acid, enzymes and bile irritate

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the esophagus and cause a wide range of symptoms and complications, most commonly persistent severe heartburn and chest pain. In some GERD sufferers, the pain is acute enough to require an emergency room visit. People with GERD often have difficulty sleeping due to increased reflux and heartburn when they lie down. Also, damage to the esophagus caused by reflux may result in more serious complications, such as erosion or ulceration of the esophagus, build-up of scar tissue that can narrow and obstruct the esophagus, and Barrett's epithelium, a condition that is associated with an elevated risk of esophageal cancer.

Prescription medication is the primary treatment option for patients with GERD. The most widely prescribed medications from the proton pump inhibitor drug class is Prilosec or Nexium. Although these medications temporarily

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ease heartburn symptoms by reducing stomach acid, they do not prevent reflux or treat the underlying causes of GERD. Side effects may include diarrhea, headaches, dizziness and nausea. Taken regularly, these medications are expensive, costing an estimated average of \$2,300 per year, based solely on retail prices for medication requirements of the patients in our clinical trial. Many GERD patients do not want to be dependent on medications and have difficulty complying with prescribed lifestyle modifications that require ongoing fundamental changes in eating, drinking and sleeping behavior.

The most common corrective treatment for GERD is an anti-reflux surgical procedure generally known as a laparoscopic Nissen fundoplication where the fundus of the stomach is wrapped around the lower esophageal sphincter and sutured in position to provide a mechanical barrier to reflux. This inpatient surgical procedure costs between \$11,000 and \$15,000, involves a hospital stay of several days and a prolonged recovery period, and has a significant morbidity risk. We believe that approximately 250,000 patients are referred for this procedure annually, of which up to 100,000 actually undergo the anti-reflux surgery. The remainder of those referred who do not undergo the procedure are either contra-indicated or choose not to proceed after learning the details of the surgery.

The Stretta System: Treatment of GERD

Our proprietary Stretta System provides physicians with the tools to perform a minimally invasive, outpatient, and cost-effective procedure for the treatment of GERD. Unlike medication, the Stretta procedure treats GERD, rather than simply managing the symptoms by neutralizing or inhibiting acid secretion in the stomach. Unlike anti-reflux surgery, the Stretta procedure is most commonly an outpatient procedure with minimal side effects. The Stretta Procedure, which typically costs between \$3,000 and \$5,000, takes less than an hour, and utilizes techniques commonly used by general surgeons and gastroenterologists who perform endoscopy. Most treated patients have been able to return to normal activities within one day of treatment and reduce or eliminate medication use shortly thereafter. We believe that the Stretta Procedure's effectiveness and relatively low cost, combined with the absence of significant discomfort and side effects, makes it a clinically and economically attractive GERD treatment for those patients with unsatisfactory symptom control on drugs, who are considering an anti-reflux surgical procedure.

The Stretta System consists of the Stretta Catheter, which is a disposable flexible catheter with needle electrodes, and the Curon Control Module, which is a radiofrequency energy generator. Using these devices, the physician delivers temperature-controlled radiofrequency energy to create thermal lesions in the muscle of the lower esophageal sphincter and upper stomach. These lesions reabsorb over several weeks and cause tissue contraction, which increases the ability of the lower esophageal sphincter to act as a barrier to reflux.

The Secca System: Treatment of Bowel Incontinence

The Secca System is designed to treat bowel incontinence, a condition that affects up to 16 million U.S. adults. Bowel incontinence is caused by damage to the anal sphincter from childbirth, surgery, neurological disease, injury or age. It is a life-altering condition that, unlike GERD, lacks effective corrective treatment alternatives. The most common treatment options control, but do not correct, the condition, and include the use of protective undergarments, diet modification and over-the-counter dietary supplements. Current corrective treatment options include major surgery, limited to those patients with a specific anatomic sphincter defect, and are rarely utilized.

The Secca System provides a minimally invasive, outpatient, and cost-effective procedure for the treatment of bowel incontinence. The Secca procedure utilizes the same radiofrequency technology and treatment concepts as the Stretta System. Using our Curon Control Module and our handheld disposable device called the Secca Handpiece, physicians deliver radiofrequency energy into the muscle of the anal sphincter to improve its barrier function. We completed a U.S. clinical trial of the Secca System in April 2001, and submitted the results to the FDA in

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December 2001. In March 2002, we received 510(k) clearance from the FDA to market the Secca System for the treatment of bowel incontinence in patients who have failed more conservative therapies such as diet modification and biofeedback.

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Product Description

We have developed a suite of products incorporating proprietary design features for use in the Stretta and Secca procedures. These products consist of a disposable catheter and a disposable handpiece for delivery of controlled radiofrequency energy to tissue, and a radiofrequency generator, known as the Curon Control Module. Both our current products and products under development utilize proprietary software to interface with our Curon Control Module.

Single-use disposable devices

Both the Stretta Catheter and the Secca Handpiece are disposable products incorporating innovative designs that enable a physician to easily access the treatment site and accurately deliver radiofrequency energy into the tissue. Features include:

A balloon in the Stretta Catheter, which is inflated once the Stretta Catheter reaches the lower esophageal sphincter to maintain catheter positioning;

Four electrode needles, which are deployed into the tissue at the treatment site for delivery of radiofrequency energy;

Thermocouples located at each needle tip and base, which provide continuous temperature readings to the Curon Control Module, enabling precise temperature control;

Irrigation ports located at the base of each electrode, which deliver water to the surface tissue during treatment; and

An illuminated clear window in the Secca Handpiece that enables the physician to view the treatment area.

Curon Control Module

The Stretta System and the Secca System both incorporate our radiofrequency energy generator, the Curon Control Module. The Curon Control Module has four channels, each of which independently control the four needle electrodes on the Stretta Catheter and Secca Handpiece. The generator uses continuous data feedback to achieve precise tissue temperatures at the treatment site. The generator tracks surface tissue temperatures from each electrode, and if temperatures at either the treatment site or surface tissue exceed pre-set levels, the generator automatically stops delivering energy to that electrode. An integrated pump delivers water to surface tissue during the procedure. The Stretta System and the Secca System each utilize proprietary software installed onto the Curon Control Module. The software provides a distinct graphical user interface and the functions and parameters that are required for the particular procedure.

Radiofrequency energy

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Our products are based on radiofrequency energy delivery, which has a long history of use in medical applications. Radiofrequency energy has been cleared by the FDA for many therapies involving tissue heating, tissue remodeling and nerve pathway interruption, including:

Shrinking prostatic tissue to treat enlarged prostates;

Interrupting nerve pathways in the heart to treat irregular heartbeats;

Shrinking tissue in the shoulder joint to prevent repeated shoulder dislocation; and

Shrinking tissue in the base of the tongue to alleviate obstructive sleep apnea.

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Clinical and Regulatory Status

Stretta clinical studies

In April 2000, we received 510(k) clearance from the FDA to market the Stretta System for the treatment of GERD. To evaluate the Stretta System, we conducted an open label multi-center U.S. clinical trial with leading investigators at 14 institutions, in which 131 patients were treated. We measured how well the procedure eliminated the need for heartburn medication, improved symptoms, improved quality of life, and reduced the amount of acid detected in the esophagus. Results from the initial 47 patients treated were submitted to the FDA. Six-month data was available for 44 of the 47 treated patients. The follow-up data indicated that the Stretta procedure led to significant improvement in both objective and subjective measurements. Six and twelve-month data for 118 of the 131 patients was published in *Gastrointestinal Endoscopy* in 2002.

Patients in our trials experienced no persistent side effects or other significant complications during the treatment and follow-up period. Most patients resumed normal levels of activity on the day after treatment. A few patients reported difficulty swallowing, increased flatulence or mild abdominal discomfort for a period of days. These symptoms were significantly milder and shorter in duration than those typically experienced after anti-reflux surgery.

We have conducted an eight-center, clinical trial of the Stretta System in the United States, treating 64 patients. Results of this trial were published in *Gastroenterology* in September 2003. This trial demonstrated significant improvements in GERD symptom scores and satisfaction that were not present in the sham (control) group. Further, there were significant improvements in acid exposure in the Stretta treated group at 12 months versus baseline.

To date, twenty-seven peer-reviewed clinical articles and meeting presentations have been published, augmenting the knowledgebase associated with the Stretta procedure, symptom response, and long-term results, and supporting the use of the Stretta system for patients with GERD. We expect that this data will influence physician adoption rates, facilitate reimbursement approvals, and enhance marketing activity.

Secca clinical studies

In November 1999, we conducted a pilot study at a leading medical institution in Mexico City. Ten patients with bowel incontinence were treated with the Secca System. Six months and two years following the procedure, most patients showed significant improvements in bowel incontinence symptoms, incontinence-related quality of life and general quality of life, each as measured by validated questionnaires, without persistent complications or side effects. The six-month data demonstrating improved incontinence scores was published in *Diseases of the Colon & Rectum* in July 2002. The two-year data demonstrating durability of the effect of Secca procedure on improving bowel incontinence symptoms was presented at the 2002 Meeting of the American Society of Colon and Rectal Surgeons, and was published in *Diseases of the Colon & Rectum* in March 2003.

Based on these encouraging preliminary results, we further evaluated the Secca System in a multi-center U.S. clinical study involving six sites and 50 patients. The data from this study was compiled and submitted to the FDA, and in March 2002 we received 510(k) clearance to market the Secca System for the treatment of bowel incontinence in patients who have failed more conservative therapies such as diet modification and biofeedback. The results of this clinical trial were published in *Diseases of the Colon and Rectum* in December 2003. The study demonstrated

that the Secca procedure resulted in significant improvements in bowel incontinences scores, bowel incontinence related quality of life, and general quality of life. In June 2002, we started a limited commercial release of the Secca System and in June 2003, we launched the Secca System on a full commercial basis.

Research and Development

Our research and development activities are conducted internally by a research and development staff and are focused on continuing improvements to design changes of existing product alternatives and product accessories. In addition to working on new products, our research and development organization is improving products and developing fixtures that are designed to reduce the time to manufacture, improve quality and reduce cost of products. Our research and development expenditures were \$1.7 million in 2004, \$1.8 million in 2003 and \$2.7 million in 2002. Pilot manufacturing costs included in research and development were \$235,000 in 2002 for the Secca System. No pilot manufacturing was performed in either 2003 or 2004.

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Manufacturing

We manufacture, assemble and test our products in-house. The manufacturing process consists primarily of assembling internally manufactured and externally purchased components and sub-assemblies in an environmentally controlled area. After assembly, each Stretta Catheter and Secca Handpiece is inspected and then sent to a sub-contractor for sterilization. Final assembly and test of Curon Control Module is performed in-house.

We purchase various materials and components from qualified suppliers that are subject to stringent quality specifications and inspections. We conduct quality audits of our key suppliers, several of which are experienced in the supply of components to manufacturers of medical devices. Most purchased components and services are available from more than one supplier. For the few components for which relatively few alternate supply sources exist, we have identified back-up suppliers. The qualification of these back-up suppliers may require regulatory approval, which may or may not be available on a timely basis or at all.

Currently, only one supply source exists for the peristaltic pump. Our supplier in accordance with our specifications manufactures this pump. We have contracted with this supplier for ongoing supply, but we would need additional time to locate and qualify a new pump supplier should our current supplier fail to fulfill our needs. If a new pump is incorporated into the Control Module, then the Control Module may require regulatory clearance under the FDA's 510(k) process, which could take several months or more. Also, a computer chip in the Control Module is no longer manufactured. We have purchased an inventory of these chips sufficient to meet our projected manufacturing needs for at least the next 6 months and have developed a revision to our current generator that has incorporated an updated version of this chip.

Our manufacturing facility is subject to periodic inspection by regulatory authorities. Our quality assurance systems are subject to FDA regulations. These regulations require that we conduct our product design, testing, manufacturing, and control activities in conformance with these regulations and that we maintain our documentation of these activities in a prescribed manner. Our manufacturing facility is licensed by the California Department of Health Services, Food and Drug Branch. In addition, our facility has received ISO 9001/EN46001/ISO13485 certification and the European Union Certificate pursuant to the European Union Medical Device Directive 93/42/EEC, allowing us to CE mark our products after assembling appropriate documentation. ISO 9001/EN46001/ISO13485 certification standards for quality operations have been developed to ensure that companies know the standards of quality on a worldwide basis. Failure to maintain the CE mark will preclude us from selling our products in Europe. We cannot assure you that we will be successful in maintaining certification requirements in Europe or elsewhere.

Due to the necessity of continuous compliance with the above regulatory regimes and other support activities we have a high fixed manufacturing cost. To generate positive gross profit, we will need to increase our sales to \$1.5 million per quarter, or thereby, to absorb fully these necessary fixed costs.

Patents and Proprietary Technology

We have an aggressive program to obtain or license intellectual property in the United States, Europe and Asia for our medical advances. We are building a portfolio of apparatus and method patents covering aspects of our current and future technology.

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We have 36 issued or allowed U.S. patents and 27 pending U.S. patent applications. We intend to continue to file for patents for our technologies to strengthen our position. We require our employees, consultants and advisors to execute confidentiality agreements in connection with their employment, consulting or advisory relationships with us. We also require employees, consultants and advisors who work on our products to agree to disclose and assign to us all inventions conceived during the work day, using our property or which relate to our business. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain and use information that we regard as proprietary.

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Certain aspects of our products incorporate technology subject to patents that we have licensed from others. We have licensed in 22 issued and allowed U.S. patents and 3 pending U.S. patent applications. We have a license with Gyrus Group PLC (formerly, Somnus Medical Technologies, Inc.) for their generator technology. The non-exclusive license gives us the right to manufacture, have manufactured, use, offer to sell, sell and import Gyrus radiofrequency generator technology for use in the treatment of GERD and other medical disorders of the digestive tract. The license expires on October 6, 2017. During the term of the license, we are obligated to pay a royalty to Gyrus for our sale of generators that incorporate the licensed technology. We have also licensed patented technology from the University of Kansas Medical Research Institute relating to applying radiofrequency energy to tissue. This is an exclusive, worldwide and royalty-bearing license allowing us to incorporate the patented technology in our products to treat medical disorders throughout the gastrointestinal tract. The license expires on September 17, 2013 and may be terminated earlier for breach. We have also licensed other patents that we believe may apply to our current business or that we may incorporate into future products. We intend to continue to license technologies to strengthen our competitive position.

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. As the number of entrants into our market increases, the possibility of an infringement claim against us grows. While we attempt to ensure that our products do not infringe other parties' patents and proprietary rights, our competitors may assert that our products and the methods they employ may be covered by U.S. patents held by them. In addition, our competitors may assert that future products we may market infringe their patents.

Competition

Companies that have well-established products, reputations and resources dominate the market for the treatment of GERD. Our primary competitors are large medical device manufacturers such as Ethicon Endo Surgery and United States Surgical, manufacturers of instrumentation for anti-reflux surgery, C.R. Bard, Wilson Cook and NDO Surgical, each of which manufactures an endoscopic sewing device for treating GERD and Boston Scientific, which manufactures an injectable product for the treatment of GERD. In addition, Medtronic is currently in clinical trials with an implantable product for treating GERD that may, in the future, provide competition for the Stretta procedure. Other competitive devices may be developed.

Most of these competitors are larger companies that enjoy several competitive advantages over us, which may include:

Existing anti-reflux surgical procedures and devices for the treatment of GERD;

Established reputations within the surgical and gastroenterological community;

Established distribution networks that permit these companies to introduce new products and have such products accepted by the physician community promptly;

Established relationships with health care providers and payers that can be used to facilitate reimbursement for new treatments; and

Greater resources for product development and sales and marketing.

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We do not feel that we compete with large pharmaceutical companies, such as AstraZeneca, Takeda Abbott Pharmaceutical, Wyeth Laboratories and Eisai, because candidate patients for Stretta are intolerant to drug therapy or have failed, or only partially responded to, drug therapy. However, these companies have an established relationship with the gastroenterology community. We could be adversely affected if one or more pharmaceutical companies elects to market aggressively against our product, or if a new, more effective, pharmaceutical product is developed. Further, less expensive generic drugs have been introduced to treat GERD as AstraZeneca's patent for Prilosec, the leading prescription medication for the treatment of GERD, expired in 2001. Prilosec, formerly a prescription medication, is now available over the counter.

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In the bowel incontinence market, we consider our primary competitors to be American Medical Systems, who received FDA clearance in December 2001 to market its implanted Artificial Bowel Sphincter for the treatment of severe bowel incontinence, and Medtronic, which is developing an implantable sacral nerve stimulation device for treatment of incontinence. There are also a small number of companies pursuing injectable therapies for bowel incontinence including Boston Scientific and Uroplasty.

Government Regulation

Our products are medical devices subject to extensive regulation by the FDA and other regulatory bodies. FDA regulations govern, among other things, the following activities that we will perform:

Product development;

Product testing;

Product labeling;

Product storage;

Premarket clearance or approval;

Advertising and promotion; and

Product sales and distribution.

FDA's premarket clearance and approval requirements

Each medical device that we wish to commercially distribute in the United States will likely require either prior 510(k) clearance or prior PMA approval from the U.S. Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act. Devices deemed to pose relatively minimal risk are placed in either Class I or II, which requires the manufacturer to submit a premarket notification requesting permission for commercial distribution; this is known as 510(k) clearance. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously 510(k) cleared device or a preamendment Class III device for which PMA applications have not been called, are placed in Class III, requiring PMA approval.

510(k) Clearance Pathway: To obtain 510(k) clearance for one of our products, we must submit a premarket notification demonstrating that the proposed device is substantially equivalent in intended use and in safety and effectiveness to a previously 510(k) cleared device or a device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for submission of PMA applications. The FDA's

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510(k) clearance pathway usually takes from four to 12 months, but it can last longer.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA approval. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained.

PMA Approval Pathway: If the FDA denies 510(k) clearance for one of our products, the product must follow the PMA approval pathway, which requires proof of the safety and effectiveness of the device to the FDA's satisfaction. A PMA application must provide extensive preclinical and clinical trial data and also information about the device and its components regarding, among other things, device design, manufacturing and labeling. After approval of a PMA, a new PMA or PMA supplement is required in the event of a modification to the device, its labeling or its manufacturing process. The PMA approval pathway is much more costly, lengthy and uncertain than 510(k) clearance. It generally takes from one to three years or even longer.

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Clinical Trials: A clinical trial is almost always required to support a PMA application and is sometimes required for a 510(k) premarket notification. Such trials generally require submission of an application for an Investigational Device Exemption, or IDE. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The FDA must approve the IDE in advance for a specified number of patients unless the product is deemed a non-significant risk device eligible for more abbreviated IDE requirements. Clinical trials may begin once the IDE application is approved by the FDA and the appropriate institutional review boards at the clinical trial sites. In June 2000, we received IDE approval allowing us to commence a multicenter clinical trial of the Secca System. We began the trial in July 2000. In April 2001, we completed this trial and the results were submitted to the FDA in December 2001.

In April 2000, we received 510(k) premarket clearance from the FDA for the Stretta System for the treatment of GERD, and in March 2002 we received 510(k) premarket clearance from the FDA for the Secca System for the treatment of bowel incontinence in patients who have failed more conservative therapies such as diet modification and biofeedback. We cannot assure you that the FDA will not deem one or more of our future products to be a class III device subject to the more burdensome PMA approval process.

Pervasive and continuing FDA regulation

After a device is placed on the market, numerous regulatory requirements apply. These include: the quality system regulation, or QSR, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process; labeling regulations; the FDA's general prohibition against promoting products for unapproved or off-label uses; and the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur. Class II devices also can have special controls such as performance standards, postmarket surveillance, patient registries, and FDA guidelines that do not apply to Class I devices. Unanticipated changes in existing regulatory requirements or adoption of new requirements could hurt our business, financial condition and results of operations.

We are subject to inspection and marketing surveillance by the FDA to determine our compliance with regulatory requirements. If the FDA finds that we have failed to comply, the Agency can institute a wide variety of enforcement actions against us, ranging from a public Warning Letter to more severe sanctions such as:

Fines, injunctions, and civil penalties;

Recall or seizure of our products;

Operating restrictions, partial suspension or total shutdown of production;

Refusing our requests for 510(k) clearance or PMA approval of new products;

Withdrawing 510(k) clearance or PMA approvals already granted; and

Criminal prosecution.

The FDA also has the authority to require repair, replacement or refund of the cost of any medical device manufactured or distributed by us. Our failure to comply with applicable requirements could lead to an enforcement action that may have an adverse effect on our financial condition and results of operations.

We have been an FDA registered medical device facility since January 1999 and we obtained our manufacturing license from the California Department of Health Services, or CDHS, in September 1999. We are subject to inspection by both the FDA and CDHS for compliance with the quality systems regulations and other applicable regulations.

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Other U.S. regulation

We also must comply with numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and hazardous substance disposal. We may be required to incur significant costs to comply with such laws and regulations in the future and such laws and regulations may hurt our business, financial condition and results of operations. We are subject to quarterly audits performed by Underwriters Laboratories to ensure that our Control Module products continue to comply with the applicable requirements. Failure to comply could result in production delays, and potential product recall.

Foreign regulation

Our products are also regulated as medical devices outside the United States by government agencies and are subject to registration requirements in many of the foreign countries in which we plan to sell our products. Our Stretta and Secca Systems carry a CE Mark, which is required for European product sales. The Stretta System carries a Therapeutic Goods Administration license, which is required for product sales in Australia, and a license issued by Health Canada, which allows commercialization in Canada. Our facility is subject to inspection by RWTUV for compliance with the quality system and other applicable regulations. Our facility has been audited and certified to be ISO9001/EN46001/ISO13485 compliant, which allows us to sell our products in Europe. We plan to seek approval to sell the Stretta and Secca Systems in additional foreign countries. The time and cost required to obtain clearance required by foreign countries may be longer or shorter than that required for FDA clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements.

Third Party Reimbursement

In the United States, health care providers generally rely on third-party payers, principally private health insurance plans, Medicare and Medicaid, to reimburse all or part of the cost of procedures in which medical devices are used. Medicare reimburses hospital outpatient clinics on a prospectively determined fixed amount for the costs associated with an outpatient procedure. Individual outpatient procedures are assigned Ambulatory Payment Classification (APC) codes. Effective October 1, 2001, the Center for Medicare and Medicaid Services, CMS (formerly HCFA), designated a code for the Stretta System, which pays the hospital component of the procedure cost, including the cost of the disposable device. In 2003, CMS reassigned the Stretta procedure to a new APC, which maintained essentially the same payment rate of \$1,850. In 2004, CMS announced a revision downwards of the APC value from \$1,850 to \$1,264.79. CMS published its April 2005 Hospital Outpatient Prospective Payment System update on March 18, 2005, in which they indicated that the previously published APC reimbursement rate for the Stretta procedure was incorrect. In its Addendum A published subsequently, the new national payment rate for the Stretta procedure is set at \$1,335.65 retroactive to January 1, 2005. This translates to a range of actual reimbursement amounts, depending on the geographic adjustments, of between \$977.43 and \$2,583.55.

Effective January 1, 2004 the American Medical Association issued a Category III CPT code for the Stretta procedure. Effective January 1, 2005, the Stretta procedure was awarded a Level I CPT code by the AMA with an associated national average payment of \$305.45. CPT codes are used to specify the physician component of the procedure cost.

Effective July 1, 2004, CMS designated an APC code for the Secca System, which pays the hospital component of the procedure \$1,750 including the cost of the disposable device. For each of the procedures, private insurers will set their own reimbursement levels that are typically higher than the Medicare level.

The current cost reduction orientation of the third-party payer community makes it exceedingly difficult for new medical devices and surgical procedures to obtain reimbursement. Often, it is necessary to convince these payers that the new devices or procedures will establish an overall cost savings compared to currently reimbursed devices and procedures. We believe that the Stretta System may offer an opportunity for payers to reduce the cost of treating GERD patients by possibly eliminating or reducing the costs of medication or anti-reflux surgery.

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While we believe that the Stretta System possesses economic advantages that will be attractive to payers, we cannot assure you that they will make reimbursement decisions based upon these advantages.

Reimbursement by third-party payers is often positively influenced by the existence of peer-reviewed publications of long-term safety and efficacy data. We have collected data on six-month results after treatment with the Stretta System, and this information was published in a peer-reviewed journal in 2001. We have collected and published data on twelve-month results, and this information was published in a peer-reviewed journal in 2002. Follow-up data in the form of a Stretta Registry, supporting the durability of the procedure for up to 33 months, was published in a peer-reviewed journal in December 2002. Subsequently, data has been presented at physician society medical meetings demonstrating positive durability of the Stretta procedure to four years. While we cannot assure you that our products will be reimbursed without publications of longer-term data, we are actively encouraging ongoing research studies to evaluate and publish the long-term safety and efficacy of the Stretta System. In addition, many third-party payers require that randomized studies be conducted to determine the effect of the procedure versus placebo or another standard of care. We have completed a double-blinded, randomized, sham-controlled, multi-center study to generate this data, and these results were published in September 2003.

To facilitate reimbursement for the Stretta and Secca Systems, we continue to maintain a dedicated reimbursement department. The department assists physicians with case-by-case pre-determination for coverage and appeals of denied claims, and actively pursues local coverage decisions. For the Stretta procedure, Curon Medical has established numerous Medicare coverage policies, as well as individual case-by-case Medicare coverage in various states. In addition, an increasing number of private payors have issued policies or are covering procedures on an individual basis.

We believe that achieving appropriate reimbursement for the Stretta procedure removes the major impediments to growth in sales. We believe that we are making progress toward wider reimbursement of the procedure. However, while we are actively pursuing reimbursement through case-by-case approvals and by pursuing coverage decisions by local carriers, we cannot guarantee the speed or the scale to which payers will approve reimbursement of the Stretta Procedure. While the Secca procedure has been on the market a shorter amount of time, we anticipate similar challenges in achieving reimbursement for this product.

Reimbursement systems in international markets vary significantly by country and, within some countries, by region. Reimbursement approvals must be obtained on a country-by-country basis or a region-by-region basis. In addition, reimbursement systems in international markets may include both private and government sponsored insurance. We have so far obtained limited international reimbursement approvals. We cannot assure you that we will obtain any further approvals in a timely manner, if at all. If we fail to receive international reimbursement approvals at all, or in acceptable amounts, market acceptance of our products would be adversely affected.

Employees

As of March 31, 2005, we employed 68 people worldwide, of which 2 are in Europe and 66 are in the U.S. which includes 28 employees in operations, two employees in research and development, 24 employees in sales and marketing, 10 employees in general and administrative, two employees in reimbursement and two employees in clinical and regulatory affairs. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel. None of our employees are represented by a labor union, and we believe our employee relations are good.

Properties

We are headquartered in Fremont, California, where we lease one building with approximately 35,000 square feet of office, research and development, and manufacturing space under leases expiring October 31, 2006. We believe that the facility is suitable and adequate for our current and future needs for the foreseeable future. We are currently utilizing approximately 65% of the facility's total space.

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Legal Proceedings

We are not a party to any material pending litigation.

Available Information

Our Web Site is <http://www.curonmedical.com>. We make available free of charge, on or through our Web Site, our annual, quarterly and current reports, as well as any amendments to these reports, as soon as reasonably practicable after electronically filing these reports with the Securities and Exchange Commission (SEC).

Information contained on our Web Site is not a part of this report. We have adopted a code of ethics applicable to our principal executive, financial and accounting officers. We make available free of charge, on or through our Web Site s investor relations page, our code of ethics.

The SEC maintains an Internet site at <http://www.sec.gov> that contains reports, proxy and information statements of the Company. All reports that the Company files with the SEC may be read and copied at the SEC s Public Reference Room at 450 Fifth Street, N.W., Washington, DC 20549. Information about the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330.

Table of Contents**MANAGEMENT****Executive Officers and Directors**

The following table provides information regarding our directors and executive officers as of June 27, 2005:

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
Larry C. Heaton II	48	President and Chief Executive Officer, Director
Alistair F. McLaren	64	Chief Financial Officer and Vice President of Finance and Administration
Patrick J. Rimroth	50	Chief Operating Officer and Senior Vice President, Operations/Research and Development
Carlos Babini	54	Executive Vice President of Sales & Marketing, President of International and Chief Sales & Marketing Officer
Gary Tegan	38	Vice President, Marketing
Mark Gordon	48	Vice President of Quality, Clinical and Regulatory
Michael Berman	47	Director
David I. Fann	41	Director
Robert F. Kuhling, Jr.	56	Director
Larry J. Strauss	53	Director

Larry C. Heaton II. Mr. Heaton has served as a director and as President and Chief Executive Officer since January 2003. From October 2000 until December 2002, Mr. Heaton was President, Chief Executive Officer and a Director of Response Genetics, a private biotechnology services company. From April 1982 until June, 2000, Mr. Heaton served in a variety of positions at United States Surgical Corporation, a publicly traded medical device manufacturer, including as President and Chief Operating Officer from October 1998 until June 2000. Mr. Heaton studied Political Science at Eastern Illinois University and Business Administration at the University of Illinois.

Alistair F. McLaren. Mr. McLaren has served as our Chief Financial Officer and Vice President of Finance and Administration since January 1998. Mr. McLaren is a member of the Institute of Chartered Accountants of Scotland.

Patrick J. Rimroth. Mr. Rimroth has served as our Chief Operating Officer since October 2004. In addition, Mr. Rimroth has served as our Senior Vice President of Operations/Research and Development since September 2001. From November 1995 to September 2001, Mr. Rimroth was Vice President of Operations for Symphonix Devices, Inc., a developer of long-term implantable hearing devices. Mr. Rimroth holds B.S. degrees in both Electrical Engineering and Biology from Purdue University.

Carlos Babini. Mr. Babini has served as our Executive Vice President of Sales & Marketing, President of International and Chief Sales & Marketing Officer since April 2005. From October 2003, Mr. Babini was our Vice President of Sales. Previously, Mr. Babini held the position of Chief Operating Officer of Infomedix Communication, a leading developer of products for the medical education market, from 1999 to 2000. Mr. Babini holds a degree in Pharmacy from Wayne State University.

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Gary Tegan. Mr. Tegan has served as our Vice President of Marketing since May 2004. Prior to joining Curon, Mr. Tegan held the position of Director of Marketing at Coalescent Surgical, Inc. a Sunnyvale, California, company specializing in the cardiac surgical market, from 2001 to May of 2004. Previously, Mr. Tegan was Senior Director of Marketing for Starion Instruments, a manufacturer of radiofrequency based surgical devices from 2000 to 2001. Prior to that position, Mr. Tegan served as Senior Director of Marketing at United States Surgical Corporation, a division of Tyco Healthcare, where he served in various sales and marketing roles from 1993 to 2000. Mr. Tegan holds a degree in Economics from the University of California, San Diego.

Mark Gordon. Mr. Gordon has served as our Vice President of Regulatory Affairs, Quality Assurance & Clinical Affairs since July 2004. Prior to his employment at Curon, he served in various roles including consultant; VP Regulatory Affairs and Quality Assurance at Tescient, Inc., from August 2002 to August 2003; VP Regulatory Affairs and Quality Assurance at Kyphon, Inc., from November 2000 to September 2001; VP Regulatory Affairs at Medtronic

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Inc. (AVE), April to November 2000; and VP Regulatory, Quality and Clinical Affairs at LuMend, Inc., from May 1998 to April 2000. Mr. Gordon is RAC certified, and holds a BS and MS in Bioengineering from the University of California, San Diego.

Michael Berman. Mr. Berman has served as a director since July 2000 and as Chairman since the end of February 2001. From February 2000 until August 2001, Mr. Berman was Senior Vice President of Boston Scientific/Scimed. From June 1995 until February 2000, Mr. Berman was President and from January to June 1995 he was Vice President of Sales and Marketing of Boston Scientific/Scimed. He serves as a director of several private companies. Mr. Berman holds both an M.B.A. and a B.S. in Industrial and Labor Relations from Cornell University.

David I. Fann. Mr. Fann has served as a director since September 1999. Since July 2004, Mr. Fann has been a general partner of Inflection Capital. From March 1997 until June 2004, he has been President and Chief Executive Officer of Excelsior Private Equity Fund II, Inc., a business development company, and, since September 1994, he has also served as President and Chief Executive Officer of UST Private Equity Investors Fund, Inc., a business development company, and as a managing director of U.S. Trust Company of New York. Mr. Fann holds a B.A.S. in Industrial Engineering and Economics from Stanford University.

Robert F. Kuhling, Jr. Mr. Kuhling has served as a director since December 1999. Since February 1987, Mr. Kuhling has been a general partner or managing director of several venture capital partnerships managed by ONSET Ventures. He also serves as a director of several private companies. Mr. Kuhling holds an M.B.A. from Harvard Business School and an A.B. in Economics from Hamilton College.

Larry J. Strauss. Mr. Strauss has served as a director since April 2005. He is currently Chief Financial Officer of Hansen Medical, Inc., a medical device company developing a robotic catheter control system. From September 2003 to August 2004, Mr. Strauss was Vice President, Finance and Chief Financial Officer of Vivus, Inc., a specialty pharmaceutical company. From May 2002 to September 2003, Mr. Strauss was a Vice President, Finance of Baxter Healthcare Corporation. From June 1999 to May 2002, Mr. Strauss was Vice President, Finance and Chief Financial Officer of Fusion Medical Technologies, Inc., a developer of surgical products, which was acquired by Baxter Healthcare Corporation. Mr. Strauss earned an M.S. degree in Industrial Engineering and Operations Research from the University of California, Berkeley and a B.S. degree in Mathematics, cum laude, from Claremont McKenna College.

Board of Directors

Pursuant to our Amended and Restated Certificate of Incorporation, our Board of Directors currently consists of six persons, divided into three classes serving staggered terms of three years. Currently, there are two directors in Class I, two directors in Class II and one director in Class III, with one open Class III seat. Two Class II directors are to be elected at the 2005 Annual Meeting of Stockholders. All Class I and Class III directors will be elected at the 2007 and 2006 Annual Meeting of Stockholders, respectively. The two Class II directors elected at the 2005 Annual Meeting of Stockholders will hold office until the 2008 Annual Meeting of Stockholders or until their earlier resignation or removal.

There are no family relationships among any of our directors or executive officers.

Committees of the Board of Directors

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The Board of Directors has three standing committees: the Audit Committee, the Compensation Committee and the Nominating and Corporate Governance Committee. Each of these committees operate under written charters adopted by the Board of Directors. These charters are available on our website at <http://investor.curonmedical.com>.

Audit Committee and Audit Committee Financial Expert

Curon has a separately-designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. The Audit Committee currently consists of three directors: Messrs. Fann, Kuhling, and Strauss, all of whom are independent as independence for Audit Committee members is defined in the Nasdaq listing standards. Mr. Strauss serves as Chairman of the committee.

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The Audit Committee includes at least one independent member who is determined by the Board of Directors to meet the qualifications of an audit committee financial expert in accordance with SEC rules, including that the person meets the relevant definition of an independent director. Mr. Strauss is the independent director who has been determined by the Board of Directors to be an audit committee financial expert. Stockholders should understand that this designation is a disclosure requirement of the SEC related to Mr. Strauss' experience and understanding with respect to certain accounting and auditing matters. The designation does not impose upon Mr. Strauss any duties, obligations or liability that are greater than are generally imposed on him as the Chairman of the Audit Committee and a member of the Board, and his designation as an Audit Committee financial expert pursuant to this SEC requirement does not affect the duties, obligations or liability of any other member of the Audit Committee or the Board.

Compensation Committee. The Compensation Committee reviews and makes recommendations to the Board of Directors concerning salaries and incentive compensation for our executive officers and certain employees. This Committee, which currently consists of directors David Fann, Michael Berman and Robert Kuhling, held six meetings during 2004.

Nominating Committee. The Nominating and Corporate Governance Committee (the Nominating Committee) assists the Board in identifying qualified individuals to become directors, determines the composition of the Board and its committees, monitors the process to assess Board effectiveness and helps develop and implement our corporate governance guidelines. The Nominating Committee held one meeting during 2004. The Nominating Committee currently consists of directors Michael Berman, David Fann, Robert Kuhling. While Mr. Berman is not independent under the Nasdaq rules, the Board at that time determined that Mr. Berman's membership on the Nominating Committee is permitted by Nasdaq's Nominating Committee composition exceptional and limited circumstances provision and is in the best interests of the corporation and its stockholders. The Board of Directors currently does not believe that the reliance on the exceptional and limited circumstances provision would materially adversely affect the ability of the Nominating Committee to act independently and to satisfy other listing standards requirements.

Compensation Committee Interlocks and Insider Participation

No interlocking relationships exist between any member of Curon's Board of Directors or Compensation Committee and any member of the Board of Directors or Compensation Committee of any other company, nor has any such interlocking relationship existed in the past. No member of the Compensation Committee is an officer or an employee of Curon.

Director Compensation

Directors who are employees of Curon Medical, Inc. do not receive any additional compensation for their services as directors. The non-employee directors receive \$2,500 for each Board meeting attended in person and \$1,500 by teleconference. Until June 16, 2004, non-employee directors received \$1,500 for each Board meeting attended in person or by teleconference, excluding committee meetings and special telephonic meetings. Effective June 17, 2004, non-employee directors received a payment of \$500 for each in-person or teleconference committee meeting attended. All directors are reimbursed for reasonable expenses in connection with attendance at Board and committee meetings.

The Compensation Committee has authorized an annual amount of \$10,000 to be paid to the director holding the position of Chairman of the Audit Committee. The Chairman of the Audit Committee is also entitled to per diem compensation of \$350.00 per hour for additional extraordinary activities conducted with prior authorization of Audit Committee. Mr. Strauss is currently the Chairman of the Audit Committee entitled to the foregoing benefits.

In addition, our 2000 Stock Plan provides outside directors with two automatic option grants, including (a) an initial share option grant to purchase shares of our Common Stock on the later of the effective date of the 2000 Stock Plan or the date the outside director first became a director and (b) an annual share option grant to purchase shares of our Common Stock, provided the outside director has been a director for at least 6 months on the date of the grant. Each share option grant under the 2000 Stock Plan has an exercise price per share equal to 100% of the fair market value per share of our Common Stock on the date of the grant, and a ten-year term. Each initial share option grant becomes vested and exercisable in four successive and equal, annual installments measured from the date of the option grant. Each annual share option grant becomes vested and exercisable in full on the first anniversary of the option grant date.

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With effect from June 16, 2004, the 2000 Stock Option Plan was amended to include each non-employee director elected to the Board of Directors for the first time following the Annual Meeting will receive upon election an initial grant of options to purchase 15,000 shares of common stock at fair market value on the date of grant as well as an annual grant of options to purchase 15,000 shares for each year during the director's term. All of the foregoing options have a ten-year term. The initial option grants as well as the annual grants are fully vested and immediately exercisable on the day of grant. All grants issued to outside Board members will be exercisable for up to a year from the date of such Board member's termination of service.

Employment Agreements

In January 2003, we entered into an at-will employment agreement with Larry C. Heaton II whereby we agreed to provide Mr. Heaton with a lump sum severance payment equal to six months of his then current monthly salary upon termination of his employment other than for cause. The agreement also provides that if, within 12 months following an acquisition, merger or sale of a majority of our assets, Mr. Heaton is terminated other than for cause or subject to constructive termination, Mr. Heaton will receive a lump sum severance payment equal to 12 months of his then current monthly salary and his outstanding stock options will fully and immediately vest. The agreement also provides for an annual salary of \$295,000, annual performance bonuses of up to 40% of the annual salary, a housing allowance in the amount of \$57,000 per year for up to the first four years of employment, reimbursement of relocation expenses of up to \$125,000, an additional payment of \$100,000 upon purchase of a home and an option to purchase 750,000 shares of Common Stock which vests as to 25% of the shares after the first year of employment and in equal monthly installments thereafter over the following 36 months.

We have entered into employment arrangements with Carlos Babini, Alistair McLaren, and Patrick J. Rimroth which provide that they will receive continued salary, medical benefits and stock option vesting for six months following involuntary termination of employment without cause, and eighteen months acceleration of stock option vesting if involuntarily terminated following a change of control transaction.

Each of our other named executive officers signed an offer letter before commencing their employment with us. The offer letters set forth each officer's:

position and title,

salary and other compensation,

health benefits,

option grant and vesting schedule, and

obligation to abide by confidentiality provisions.

Additionally, each offer letter states that employment with us is at-will and may be terminated by either party at any time with or without notice or cause.

Code of Ethics

We have a code of ethics that applies to all of our employees, including our principal executive officer, principal financial officer and principal accounting officer. A copy of this code is available on our website at <http://investor.curonmedical.com>. We intend to disclose any changes in or waivers from our code of ethics by posting such information on our website or by filing a Form 8-K.

Table of Contents**Executive Compensation**

The following table sets forth all compensation awarded to, earned by, or paid to our Chief Executive Officer and the other four most highly paid executive officers, each of whose total cash compensation exceeded \$100,000 during the years ended December 31, 2004, December 31, 2003 and December 31, 2002.

Summary Compensation Table

Name and Principal Position	Year	Annual Compensation		Other Annual Compensation (1)	Long-Term Compensation Awards Securities	All Other Compensation (\$ (3)
		Salary (\$)	Bonus (\$)		Underlying Options (#)	
Larry Heaton (3)	2004	\$ 295,000		\$ 57,000		\$ 180
Chief Executive Officer & President	2003	295,000		282,000	750,000	
Alistair F. McLaren	2004	197,192		6,000		792
Chief Financial Officer and Vice President of Finance Administration	2003	192,613		6,000	50,000	
	2002	190,000	16,450	6,000	50,000	
Patrick J. Rimroth (4)	2004	230,907			25,000	204
Chief Operating Officer And Senior Vice President	2003	218,763			25,000	
	2002	215,796			125,000	
John W. Gaiser (5)	2004	280,064		2,700		165
Vice President of Engineering and Research and Development	2003	196,784		3,600	20,000	
	2002	194,994	15,910	3,600	40,000	
Carlos Babini (6)	2004	184,427	90,000	6,000	150,000	276
Executive Vice President of Sales & Marketing; President of International and Chief Sales & Marketing Officer	2003	25,000	40,000	1,800	90,000	
David W.J. Smith (7)	2004	243,079	37,500			80
	2003	150,000			300,000	
Gary Tegan (8)	2004	116,590	23,488		150,000	68
Vice President, Marketing						

- (1) The amounts in this column represent car allowances unless otherwise noted.
- (2) Life insurance premiums paid by the Company on behalf of the Named Executive Officers.
- (3) Mr. Heaton was paid \$225,000 in taxable and non-taxable relocation reimbursement related his move to California and, for each of the past two years, \$57,000 in housing allowance.
- (4) Mr. Rimroth's 2004 salary includes vacation pay in the amount of \$4,212.
- (5) Mr. Gaiser's employment terminated effective September 13, 2004. Mr. Gaiser's salary includes severance pay in the amount of \$51,084 and vacation pay in the amount of \$26,491.
- (6) Includes commission earned in the amount of \$40,000 and bonus earned in the amount of \$50,000 in 2004 and \$40,000 in commission in 2003.
- (7)

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Mr. Smith resigned effective September 1, 2004. Mr. Smith's salary includes severance pay in the amount of \$104,750 and vacation pay in the amount of \$1,072.

(8) Includes commission earned in the amount of \$3,988.

Stock Option Grants in Last Fiscal Year

The following table sets forth information with respect to stock options granted pursuant to our 2000 Stock Plan during the fiscal year ended December 31, 2004 to each of the executive officers named in the Summary Compensation Table above.

The amounts shown as potential realizable value represent hypothetical gain that could be achieved for the respective options if exercised at the end of the option term. These amounts represent assumed rates of appreciation in

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the value of our common stock from the fair market value at the date of grant. The 5% and 10% assumed annual rates of compounded stock price appreciation are mandated by rules of the Commission and do not represent our estimate of projection of the future price of our common stock. Actual gains, if any, on stock option exercises depend on the future performance of the trading price of our common stock. The amounts reflected in the table may not necessarily be achieved.

Name	Individual Grants				Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Options Term	
	Number of Securities Underlying Options	Percent of Total Options Granted to Employees in Fiscal	Exercise Price Per Share	Expiration Date		
					Granted (1)	2004(2)
Larry C. Heaton II						
Alistair F. McLaren						
Patrick J. Rimroth	25,000	2.3%	\$ 1.25	9/8/14	\$ 19,653	\$ 49,804
John W. Gaiser						
Carlos Babini	50,000	4.6%	\$ 2.71	3/12/14	\$ 85,215	\$ 215,952
David W. J. Smith	100,000	9.2%	\$ 1.25	9/8/14	\$ 78,612	\$ 199,218
Gary Tegan	50,000	4.6%	\$ 1.75	5/5/14	\$ 55,028	\$ 135,452
	50,000	4.6%	\$ 1.25	9/08/14	\$ 39,306	\$ 99,609
	50,000	4.6%	\$ 0.90	10/15/14	\$ 28,300	\$ 71,718

- (1) Option grants were made under our 2000 Stock Plan. Each grant allows the officer to acquire shares of our Common Stock at a fixed price per share (the market price on the grant date) over a specified period of time. These options have a 10 year term and twenty-five percent (25%) of the shares subject to the option vest on the first anniversary of the grant date with the remaining shares vesting in thirty-six successive equal monthly installments over the optionee's continued service.
- (2) Based on options granted to purchase an aggregate of 1,165,320 shares of common stock to employees, consultants and members of the Board of Directors in 2004. We never granted any stock appreciation rights.

Option Exercises in Last Fiscal Year and Fiscal Year-End Option Values

The following table provides information regarding the exercise of stock options during the year ended December 31, 2004, by the named executive officers, and the value of securities underlying options held by our named executive officers at December 31, 2004.

Name	Shares		Number of Securities Underlying Unexercised Options at		Value of Unexercised	
	Acquired on	Value	Fiscal Year-End		In-the-Money Options at Fiscal Year-End (\$) (1)	
			Exercise	Realized (\$)	Exercisable	Unexercisable
Larry C. Heaton II	0	0	359,375	390,625	\$ 384,531	\$ 417,969

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Alistair F. McLaren	0	0	105,604	54,584	\$ 74,393	\$ 40,803
Patrick J. Rimroth	0	0	207,811	117,189	\$ 79,296	\$ 64,454
John W. Gaiser	0	0	68,749	0	\$ 29,766	\$ 0
Carlos Babini	0	0	26,250	213,750	\$ 0	\$ 50,000
David W.J. Smith	143,750	18,527	0	0	\$ 0	\$ 0
Gary Tegan	0	0	0	150,000	\$ 0	\$ 67,500

- (1) The value of unexercised in-the-money options equals the difference between the option exercise price and the closing price of our Common Stock on December 31, 2004 multiplied by the number of shares underlying the options. The closing price of our Common Stock on December 31, 2004, as reported on the NASDAQ Small Cap Market was \$1.75 per share.

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Employee Benefit Plans

1997 Stock Option Plan

On May 1, 1997, our sole director at the time adopted our 1997 Stock Option Plan, referred to as the 1997 Plan, and the stockholders approved our 1997 Plan in March 1998. Our board of directors has decided not to grant any additional awards under the 1997 Plan as of the effective date of this offering. However, the 1997 Plan will continue to govern the terms and conditions of the outstanding awards granted under the 1997 Plan.

A total of 2,679,000 shares of our common stock are authorized for issuance under the 1997 Plan. The first options were issued in 1998. No further options will be granted under the 1997 Plan.

Our board of directors or a committee of our board administers the 1997 Plan. The administrator of the 1997 Plan has the authority to determine the terms and conditions of the options and stock purchase rights granted under the 1997 Plan.

Our 1997 Plan provides for the grant of options and stock purchase rights. Stock purchase rights and nonstatutory stock options may be granted to our employees, directors and consultants, and incentive stock options within the meaning of Section 422 of the Internal Revenue Code may be granted to our employees.

The exercise price of options granted under our 1997 Plan may not be less than 85% of fair market value of our common stock on the date of grant, or 100% of fair market value in the case of an incentive stock option and the term of an option may not exceed 10 years. An outstanding option may terminate before the end of its 10 year term if an optionee ceases to be a service provider.

Stock purchase rights provide an eligible service provider the right to purchase shares of our common stock. The shares under a stock purchase right may or may not be fully vested on the date of grant. If the shares are initially unvested, the shares will vest over the individual's period of continued service with us. We will have the right to repurchase any unvested shares upon the individual's termination of service with us.

Our 1997 Plan provides that in the event of our merger with or into another corporation or a sale of substantially all of our assets, the successor corporation will assume or substitute each option. If the outstanding options are not assumed or substituted, the options will terminate. However, the administrator of the 1997 Plan has the discretionary authority to provide that each option that is not assumed or substituted in a merger or asset sale will accelerate and become fully exercisable before termination.

2000 Stock Plan

Our board of directors adopted the 2000 Stock Plan, referred to as the 2000 Plan, in June 2000 and the stockholders approved our 2000 Plan in August 2000, subject to the closing of the offering. Our 2000 Plan is the successor equity incentive plan to our 1997 Plan.

Purpose. The 2000 Plan is designed to allow us to retain and attract employees, directors and consultants who are essential to our future growth and success by providing such individuals with an opportunity to acquire shares of our common stock. Our 2000 Plan provides for the grant of nonstatutory stock options to our employees, directors and consultants, and for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code, to our employees and employees of our corporations.

Shares Available. A total of 2,000,000 shares of our common stock are authorized for issuance under the 2000 Plan. On the first day of each fiscal year during the term of the 2000 Plan, beginning with our fiscal year 2001, the number of shares available for issuance under our 2000 Plan will increase by an amount of shares equal to the lesser of 5% of the outstanding shares of our common stock on the last day of our immediately preceding fiscal year, 2,000,000 shares, or such lesser number of shares as our board may determine.

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Administration. Our board of directors or a committee of our board administers the 2000 Plan. In the case of options intended to qualify as performance-based compensation within the meaning of Section 162(m) of the Internal Revenue Code, the committee will consist of two or more outside directors within the meaning of Section 162(m) of the Internal Revenue Code. The administrator has the power to determine the terms of the options granted, including the exercise price, the number of shares subject to each option, the exercisability of the options, and the form of consideration payable upon exercise.

Options. The administrator determines the exercise price of options granted under the 2000 Plan, but with respect to nonstatutory stock options intended to qualify as performance-based compensation within the meaning of Section 162(m) of the Internal Revenue Code and all incentive stock options, the exercise price must at least be equal to the fair market value of our common stock on the date of grant. The term of an incentive stock option may not exceed 10 years, except that with respect to any participant who owns 10% of the voting power of all classes of our outstanding capital stock, the term must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. The administrator determines the term of all other options. Nonstatutory stock options exercise price shall not be less than 100% and 85% of the estimated fair value of the shares on the date of grant.

No optionee may be granted an option to purchase more than 1,000,000 shares in any fiscal year. In connection with his or her initial service, an optionee may be granted options to purchase up to an additional 2,000,000 shares.

After termination of one of our employees, directors or consultants, he or she may exercise his or her option for the period of time stated in the option agreement. Generally, if termination is due to death or disability, the option will remain exercisable for 12 months. In all other cases, the option will generally remain exercisable for three months. However, an option may never be exercised later than the expiration of its term.

Automatic Grants. With effect from June 16, 2004, the 2000 Stock Option Plan was amended such that each non-employee director elected to the Board of Directors for the first time following the Annual Meeting will receive upon election an initial grant of options to purchase 15,000 shares of common stock at fair market value on the date of grant as well as an annual grant of options to purchase 15,000 shares for each year during the director's term. All of the foregoing options have a ten-year term. The initial option grants as well as the annual grants are fully vested and immediately exercisable on the day of grant. All grants issued to outside Board members will be exercisable for up to a year from the date of such Board member's termination of service with the Company.

Transferability of Options. Our 2000 Plan generally does not allow for the transfer of options and only the optionee may exercise an option during his or her lifetime. The administrator may, however, allow options to be transferable.

Adjustments upon Merger or Asset Sale. Our 2000 Plan provides that in the event of our merger with or into another corporation or a sale of substantially all of our assets, the successor corporation will assume or substitute each option. If the outstanding options are not assumed or substituted, the administrator will provide notice to the optionee that he or she has the right to exercise the option as to all of the shares subject to the option, including shares which would not otherwise be exercisable, for a period of 15 days from the date of the notice. The option will terminate upon the expiration of the 15-day period.

Amendment and Termination. Our 2000 Plan will automatically terminate in 2010, unless we terminate it sooner. In addition, our board of directors has the authority to amend, suspend or terminate the 2000 Plan provided it does not adversely affect any option previously granted under our 2000 Plan.

2000 Employee Stock Purchase Plan

Our board of directors adopted the 2000 Employee Stock Purchase Plan, referred to as the Purchase Plan, in June 2000 and the stockholders approved our Purchase Plan in August 2000, subject to the closing of the offering. Our Purchase Plan provides eligible employees the opportunity to purchase shares of our common stock at a discount through payroll deductions.

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Shares Available. A total of 400,000 shares of our common stock are authorized for issuance under the Purchase Plan. In addition, the number of shares authorized for issuance under the Purchase Plan will increase annually on the first day of each fiscal year, beginning with our fiscal year 2001, equal to the lesser of 1.5% of the outstanding shares of our common stock on the last day of the immediately preceding fiscal year, 500,000 shares, or such lesser number of shares as may be determined by our board of directors.

Administration. Our board of directors or a committee of our board administers the Purchase Plan. Our board of directors or its committee has full and exclusive authority to interpret the terms of the Purchase Plan and determine eligibility.

Eligibility. All of our employees are eligible to participate if they are customarily employed by us for at least 20 hours per week and more than five months in any calendar year. However, an employee may not be granted an option to purchase stock under the Purchase Plan if such employee:

immediately after grant owns stock possessing 5% or more of the total combined voting power or value of all classes of our capital stock; or

whose rights to purchase stock under all of our employee stock purchase plans accrues at a rate that exceeds \$25,000 worth of stock for each calendar year.

Offering Periods and Contributions. Our Purchase Plan is intended to qualify under Section 423 of the Internal Revenue Code and contains consecutive, overlapping 24-month offering periods. Each offering period includes four six-month purchase periods. The offering periods generally start on the first trading day on or after May 1st and November 1st of each year, except for the first such offering period which will begin on the first trading day on or after the effective date of this offering and will end on the last trading day on or after May 1, 2002.

Our Purchase Plan permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation which includes a participant's base straight time gross earnings and commissions. A participant may purchase a maximum of 5,000 shares during a six-month purchase period.

Purchase of Shares. Amounts deducted from a participant's eligible compensation and accumulated during a six-month purchase period are used to purchase shares of our common stock at the end of the six-month purchase period. The price is 85% of the lower of the fair market value of our common stock at the beginning of an offering period or at the end of a purchase period. If the fair market value at the end of a purchase period is less than the fair market value at the beginning of the offering period, participants will be withdrawn from the current offering period after their purchase of shares on the purchase date and will be automatically re-enrolled in a new offering period. Participants may end their participation at any time during an offering period, and will be paid their payroll deductions to date. Participation ends automatically upon termination of employment with us.

Transferability of Rights. A participant may not transfer rights granted under the Purchase Plan other than by will, the laws of descent and distribution or as otherwise provided under the Purchase Plan.

Adjustments upon Merger or Asset Sale. In the event of our merger with or into another corporation or a sale of all or substantially all of our assets, a successor corporation may assume or substitute each outstanding option. If the successor corporation refuses to assume or substitute for

the outstanding options, the offering period then in progress will be shortened, and a new exercise date will be set.

Amendment and Termination. Our Purchase Plan will terminate in 2010. However, our board of directors has the authority to amend or terminate our Purchase Plan, except that, subject to certain exceptions described in the Purchase Plan, no such action may adversely affect any outstanding rights to purchase stock under our Purchase Plan.

Table of Contents**Equity Compensation Plan Information**

The following table provides certain information with respect to our equity compensation plans in effect as of December 31, 2004.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted Average Exercise of Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by stockholders (1)	5,018,230	\$ 2.71	4,268,123
Equity compensation plans not approved by security holders (2)			
Total	5,018,230	\$ 2.71	4,072,024

(1) Consists of the 2000 Stock Plan, the 1997 Stock Plan, and the 2000 Employee Stock Purchase Plan

(2) We do not have any equity compensation plan not approved by security holders

Limitation on Liability and Indemnification Matters

Our bylaws provide that we will indemnify our directors and executive officers, and may indemnify our other officers, employees and other agents, to the fullest extent permitted by the General Corporation Law of the State of Delaware. Under our bylaws, we also are empowered to enter into indemnification agreements with our directors and officers and to purchase insurance on behalf of any person whom we are required or permitted to indemnify.

We have entered into indemnification agreements with our directors and executive officers. Under these agreements, we would be required to indemnify them against all expenses, judgments, fines, settlements and other amounts actually and reasonably incurred, in connection with any actual, or any threatened, proceeding if any of them may be made a party because he or she is or was one of our directors or officers. We are obligated to pay these amounts only if the officer or director acted in good faith and in a manner that he or she reasonably believed to be in or not opposed to our best interests. With respect to any criminal proceeding, we are obligated to pay these amounts only if the officer or director had no reasonable cause to believe that his or her conduct was unlawful. The indemnification agreements also set forth procedures that will apply in the event of a claim for indemnification thereunder.

In addition, our amended and restated certificate of incorporation provides that the liability of our directors for monetary damages shall be eliminated to the fullest extent permissible under the General Corporation Law of the State of Delaware. This provision in our amended and restated certificate of incorporation does not eliminate a director's duty of care, and, in appropriate circumstances, equitable remedies such as an injunction or other forms of non-monetary relief would remain available. Each director will continue to be subject to liability for any breach of the director's duty of loyalty to us, for acts or omissions not in good faith or involving intentional misconduct or knowing violations of law, for acts or omissions that the director believes to be contrary to our best interests or our stockholders, for any transaction from which the director derived an improper personal benefit, for improper transactions between the director and us, and for improper distributions to stockholders and

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loans to directors and officers. This provision also does not affect a director's responsibilities under any other laws, such as the federal environmental laws.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933, as amended, and is, therefore, unenforceable.

We also maintain insurance on behalf of our directors and officers against any loss arising from any claim asserted against them and expense incurred by them in any capacity, subject to certain exclusions.

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CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

In the last fiscal year, there has not been nor is there currently proposed any transaction or series of similar transactions to which we were or are to be a party in which the amount involved exceeds \$60,000 and in which any of our directors, executive officers, holders of more than 5% of our common stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest.

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PRINCIPAL AND SELLING STOCKHOLDERS

The 28,220,969 shares of common stock covered by this prospectus were acquired by the selling stockholders from us in a private placement consummated in two closings on April 8, 2005 and June 3, 2005. We issued a total of 4,962,614 shares of common stock and warrants exercisable for five years to purchase up to an additional 2,481,298 shares of common stock with an exercise price of \$1.00 per share at the first closing. We issued a total of 13,482,464 shares of common stock and warrants exercisable for five years to purchase up to an additional 6,741,241 shares of common stock with an exercise price of \$1.00 per share at the second closing. In connection with the private placement, we also agreed to issue warrants exercisable for five years to purchase up to 553,352 shares of common stock with an exercise price of \$1.00 per share to a placement agent. The following table sets forth certain information with respect to the beneficial ownership of our common stock at June 27, 2005 for:

each person who we know beneficially owns more than five percent of our common stock;

each of our directors;

each of our named executive officers;

all of our directors and executive officers as a group; and

all of the selling stockholders.

We have determined beneficial ownership in accordance with the rules of the SEC. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons and entities named in the table below have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership is based on 29,806,154 shares of our common stock outstanding at April 30, 2005. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to options, warrants or other convertible securities held by that person or entity that are currently exercisable or exercisable within 60 days of April 30, 2005. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person together with applicable options or warrants for such stockholder. Beneficial ownership representing less than one percent is denoted with an *.

Except for the purchase of securities in connection with our 2004 private placement, none of the selling stockholders had a material relationship with us or any of our subsidiaries within the past three years.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Curon Medical, Inc., 46117 Landing Parkway, Fremont, CA 94538.

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Name of Beneficial Owner	Shares Beneficially Owned Prior to Offering		Shares Being Offered	Shares Beneficially Owned After Offering	
	Common Stock			Common Stock	
	Shares (1)	% (1)	Shares (1)	% (1)	
Selling Stockholders:					
Atlas Equity I, Ltd (2)	158,300	*	4,038,462	158,300(3)	*
181 W. Madison					
Suite 3600					
Chicago, IL 60602					

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<u>Name of Beneficial Owner</u>	<u>Shares Beneficially Owned Prior to Offering</u>		<u>Shares Being Offered</u>	<u>Shares Beneficially Owned After Offering</u>	
	<u>Common Stock</u>			<u>Common Stock</u>	
	<u>Shares (1)</u>	<u>% (1)</u>		<u>Shares (1)</u>	<u>% (1)</u>
Cimarron Overseas Equity Master Fund L.P. (4) 2626 Cole Avenue Suite 200 Dallas, TX 75204			634,614	0(3)	
Crown Growth Partners II (5) The Lincoln Building 60 East 42nd Street Suite 3405 New York, NY 10165	4,300	*	26,550	4,300(3)	*
Crown Growth Partners, L.P. (6) The Lincoln Building 60 East 42nd Street Suite 3405 New York, NY 10165	81,200	*	366,450	81,200(3)	*
Harvest Capital, LP (7) 600 Madison Avenue; 11th Floor New York, NY 10022	44,196	*	138,105	44,196(3)	*
Harvest Offshore Investors, Ltd. (8) 600 Madison Avenue; 11th Floor New York, NY 10022	113,160	*	354,570	113,160(3)	*
New Americans, LLC (9) 600 Madison Avenue; 11th Floor New York, NY 10022	15,093	*	40,215	15,093(3)	*
CL Harvest, LLC (10) 600 Madison Avenue; 11th Floor	5,076	*	15,330	5,076(3)	*

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New York, NY 10022					
Harvest AA Capital, LP (11)	9,676	*	29,280	9,676(3)	*
600 Madison Avenue; 11th Floor					
New York, NY 10022					
Lewis Opportunity Fund LP (12)			112,500	0(3)	
45 Rockefeller Plaza					
New York, NY 10011					
Meadowbrook Opportunity Fund, LLC (13)	179,162	*	450,000	179,162(3)	
520 Lake Cook Road					
Suite 690					
Deerfield, IL 60015					
Micro Cap Partners, L.P. (14)	844,454	3.4	2,538,459	844,454(3)	1.6
470 University Avenue					
Palo Alto, CA 94301					
Palo Alto Healthcare Fund, L.P. (15)	415,215	1.7	923,076	1,367,000(3)	*
470 University Avenue					
Palo Alto, CA 94301					
Stroller Tod White and Linda White,			461,538	0(3)	
Trustees of the Tod & Linda White					
Revocable Trust, dated 5/21/98. (16)					
c/o Jim Fitzpatrick					
Princeton Capital Management, Inc.					
47 Hulfish Street					
Suite 500					
Princeton, NJ 08542					

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<u>Name of Beneficial Owner</u>	<u>Shares Beneficially Owned Prior to Offering</u>		<u>Shares Being Offered</u>	<u>Shares Beneficially Owned After Offering</u>	
	<u>Common Stock</u>			<u>Common Stock</u>	
	<u>Shares (1)</u>	<u>% (1)</u>	<u>Shares (1)</u>	<u>% (1)</u>	
Branco Weiss (17) c/o Jim Fitzpatrick Princeton Capital Management, Inc. 47 Hulfish Street Suite 500 Princeton, NJ 08542			1,153,845	0(3)	
William H. Reaves - PCM (18) c/o Jim Fitzpatrick Princeton Capital Management, Inc. 47 Hulfish Street Suite 500 Princeton, NJ 08542			576,921	0(3)	
Young Enterprise Securities, LLC (19) c/o Jim Fitzpatrick Princeton Capital Management, Inc. 47 Hulfish Street Suite 500 Princeton, NJ 08542			461,538	0(3)	
Hugh and Constance Fitzpatrick (20) c/o Jim Fitzpatrick Princeton Capital Management, Inc. 47 Hulfish Street Suite 500 Princeton, NJ 08542	30,000	*	138,459	30,000(3)	*

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Nancye Allen Fitzpatrick (21)	30,000	*	92,307	30,000(3)	*
c/o Jim Fitzpatrick					
Princeton Capital Management, Inc.					
47 Hulfish Street					
Suite 500					
Princeton, NJ 08542					
ProMed Partners, L.P. (22)			718,305	0(3)	
237 Park Avenue					
9th Floor					
New York, NY 10017					
ProMed Partners II, L.P. (23)			186,060	0(3)	
237 Park Avenue					
9th Floor					
New York, NY 10017					
ProMed Offshore Fund, L.P. (24)			116,790	0(3)	
237 Park Avenue					
9th Floor					
New York, NY 10017					
ProMed Offshore Fund II, L.P. (25)	109,427	*	2,440,395	109,427(3)	*
237 Park Avenue					
9th Floor					
New York, NY 10017					
SF Capital Partners Ltd. (26)	252,899	*	6,923,079	252,899(3)	*
3600 South Lake Drive					
St. Francis, WI 53235					
Walker Smith Capital, L.P. (27)			101,307	0(3)	
300 Crescent Court, Suite 1111					
Dallas, TX 75201					

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Name of Beneficial Owner	Shares Beneficially Owned Prior to Offering		Shares Being Offered	Shares Beneficially Owned After Offering	
	Common Stock			Common Stock	
	Shares (1)	% (1)	Shares (1)	% (1)	
Walker Smith Capital (QP), L.P. (28) 300 Crescent Court, Suite 1111 Dallas, TX 75201			533,076	0(3)	
Walker Smith International Fund, Ltd. (29) 300 Crescent Court, Suite 1111 Dallas, TX 75201			750,231	0(3)	
SRB Greenway Capital, L.P. (30) 300 Crescent Court, Suite 1111 Dallas, TX 75201			211,386	0(3)	
SRB Greenway Capital (QP), L.P. (31) 300 Crescent Court, Suite 1111 Dallas, TX 75201			134,769	0(3)	
SRB Greenway Offshore Operating Fund, L.P. (32) 300 Crescent Court, Suite 1111 Dallas, TX 75201			1,500,000	0(3)	
Iroquois Master Fund Ltd. (33) 641 Lexington Avenue, 26 th Floor New York, NY 10022	10,322	*	1,500,000	10,322(3)	*
The Robins Group LLC (34) 3220 SW First Ave Suite 201 Portland, OR 97239			553,352	0(3)	
Directors and Executive Officers:					
Larry C. Heaton II (35)	460,400	1.8	0	493,997	*
Michael Berman (36)	296,026	1.2	0	311,026	*
David I. Fann (37)	63,400	*	0	91,900	*
Robert F. Kuhling, Jr. (38)	3,505,489	13.4	0	3,520,489	6.6

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Larry Strauss (39)	15,000	*	0	15,000	*
Alistair McLaren (40)	282,986	1.1	0	287,152	*
Patrick J. Rimroth (41)	242,832	1.0	0	254,811	*
Carlos Babini (42)	53,124	*	0	58,958	*
Gary Tegan (43)	13,541	*	0	15,625	*
Mark Gordon (44)			0	13,541	
All executive officers and directors as a group (10 persons) (45)	4,932,798	18.6%	0	5,062,499	9.2%

* Less than one percent.

- (1) This table is based upon information supplied by officers, directors and principal stockholders, and in Schedules 13D and 13G filed with the Securities and Exchange Commission. Unless otherwise indicated in the footnotes to this table and subject to community property laws, where applicable, we believe that each stockholder named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. The number and percentage of shares beneficially owned prior to offering are based on an aggregate of 29,806,154 shares of our common stock outstanding as of April 30, 2005, less 4,962,614 shares that were acquired by the selling stockholders from us in a private placement consummated on April 8, 2005 and are determined under rules promulgated by the Securities and Exchange Commission. The number and percentage of shares beneficially owned after offering are based on an aggregate of 53,125,356 shares of our common stock outstanding. This information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares as to which the individual has sole or shared voting power or investment power and also any shares which the individual has the right to acquire within 60 days of April 30, 2005 through the exercise of any stock option or other right.
- (2) Includes 2,692,308 shares and 1,346,154 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. Jacob Gottlieb and Dmitry Balyasny have voting and dispositive control over the shares held by Atlas Equity I, LTD.

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- (3) Assumes that selling stockholder sells all shares registered under this registration statement. However, to our knowledge, there are no agreements, arrangements or understandings with respect to the sale of any of our common stock, and selling stockholder may decide not to sell its shares that are registered under this registration statement. This registration statement also shall cover any additional shares of common stock that become issuable in connection with the shares registered for sale hereby by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration that results in an increase in the number of our outstanding shares of common stock.
- (4) Includes 423,076 shares and 211,538 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. These shares are beneficially owned by Cimarron Biomedical Equity Master Fund, L.P., formerly known as Cimarron Overseas Equity Master Fund, L.P. Cimarron Biomedical Equity Master Fund, L.P. is wholly owned by Cimarron Biomedical Equity Fund, L.P., formerly known as Cimarron Overseas Equity Fund (QP), L.P. Cimarron Biomedical Investors, L.P. is the general partner of Cimarron Biomedical Equity Fund, L.P. Cimarron Global Management, LLC is the general partner of Cimarron Biomedical Investors, L.P. J.H. Cullum Clark is the sole principal of Cimarron Global Management, LLC, and in such capacity has full voting and investment control over the shares beneficially owned by Cimarron Biomedical Equity Master Fund, L.P. Mr. Clark expressly disclaims beneficial ownership of the shares beneficially owned by Cimarron Biomedical Equity Master Fund, L.P.
- (5) Includes 17,700 shares and 8,850 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. David Bellet possesses voting and dispositive power over all of the shares owned by Crown Growth Partners LP and Crown Growth Partners II.
- (6) Includes 244,300 shares and 122,150 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. David Bellet possesses voting and dispositive power over all of the shares owned by Crown Growth Partners LP and Crown Growth Partners II.
- (7) Includes 92,070 shares and 46,035 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. Harvest Management LLC votes shares on behalf of Harvest Capital, L.P., Harvest Offshore Investors, Ltd, New Americans, L.L.C., Harvest AA Capital, L.P. and CL Harvest, LLC in its capacity as Investment manager. The Principals of Harvest Management, LLC are Marjorie Gochberg Kellner, Nathaniel Boher and J. Morgan Rutman act on behalf of Harvest Management. Harvest Management LLC is not a broker dealer, nor is it affiliated with one.
- (8) Includes 236,380 shares and 118,190 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. Harvest Management LLC votes shares on behalf of Harvest Capital, L.P., Harvest Offshore Investors, Ltd, New Americans, L.L.C., Harvest AA Capital, L.P. and CL Harvest, LLC in its capacity as Investment manager. The Principals of Harvest Management, LLC are Marjorie Gochberg Kellner, Nathaniel Boher and J. Morgan Rutman act on behalf of Harvest Management. Harvest Management LLC is not a broker dealer, nor is it affiliated with one.
- (9) Includes 26,810 shares and 13,405 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. Harvest Management LLC votes shares on behalf of Harvest Capital, L.P., Harvest Offshore Investors, Ltd, New Americans, L.L.C., Harvest AA Capital, L.P. and CL Harvest, LLC in its capacity as Investment manager. The Principals of Harvest Management, LLC are Marjorie Gochberg Kellner, Nathaniel Boher and J. Morgan Rutman act on behalf of Harvest Management. Harvest Management LLC is not a broker dealer, nor is it affiliated with one.
- (10) Includes 10,220 shares and 5,110 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. Harvest Management LLC votes shares on behalf of Harvest Capital, L.P., Harvest Offshore Investors, Ltd, New Americans, L.L.C., Harvest AA Capital, L.P. and CL Harvest, LLC in its capacity as Investment manager. The Principals of Harvest Management, LLC are Marjorie Gochberg Kellner, Nathaniel Boher and J. Morgan Rutman act on behalf of Harvest Management. Harvest Management LLC is not a broker dealer, nor is it affiliated with one.
- (11) Includes 19,520 shares and 9,760 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. Harvest Management LLC votes shares on behalf of Harvest Capital, L.P., Harvest Offshore Investors, Ltd, New Americans, L.L.C., Harvest AA Capital, L.P. and CL Harvest, LLC in its capacity as Investment manager. The Principals of Harvest Management, LLC are Marjorie Gochberg Kellner, Nathaniel Boher and J. Morgan Rutman act on behalf of Harvest Management. Harvest Management LLC is not a broker dealer, nor is it affiliated with one.
- (12) Includes 75,000 shares and 37,500 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. Harvest Management LLC votes shares on behalf of Harvest Capital, L.P., Harvest Offshore Investors, Ltd, New Americans, L.L.C., Harvest AA Capital, L.P. and CL Harvest, LLC in its capacity as Investment manager. The Principals of Harvest Management, LLC are Marjorie Gochberg Kellner, Nathaniel Boher and J. Morgan Rutman act on behalf of Harvest Management. Harvest Management LLC is not a broker dealer, nor is it affiliated with one.
- (13) Includes 300,000 shares and 150,000 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. Michael Ragins has sole voting and dispositive power with respect to the shares held of record by offered by Meadowbrook Opportunity Fund LLC. Michael Ragins is the Managing Member of MYR Partners LLC, the Manager of Meadowbrook Capital Management LLC, and the Investment Manager of Meadowbrook Opportunity Fund LLC. Meadowbrook Opportunity Fund LLC is not a broker dealer, nor is it affiliated with one.
- (14) Includes 1,692,306 shares and 846,153 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. These shares are held directly by Micro Cap Partners, L.P. (Micro Cap) for the benefit of its investors. Palo Alto Investors LLC (PAI LLC) beneficially owns such shares because it is the general partner and investment adviser of Micro Cap and, as such, Micro Cap has delegated

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voting and dispositive power with respect to such shares to PAI LLC. William L. Edwards, the president and controlling shareholder of Palo Alto Investors, the manager of PAI LLC, indirectly beneficially owns such shares.

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- (15) Includes 615,384 shares and 307,692 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. These shares are held directly by Palo Alto Healthcare Fund, L.P. (Healthcare) for the benefit of its investors. Palo Alto Investors LLC (PAI LLC) beneficially owns such shares because it is the general partner and investment adviser of Healthcare and, as such, Healthcare has delegated voting and dispositive power with respect to such shares to PAI LLC. William L. Edwards, the president and controlling shareholder of Palo Alto Investors, the manager of PAI LLC, indirectly beneficially owns such shares.
- (16) Includes 307,692 shares and 153,846 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. Jim Fitzpatrick of Princeton Capital Management, Inc. is the investment advisor to Stroller Tod White and Linda White, Trustees of the Tod & Linda White Revocable Trust, dated 5/21/98, and as such has investment power and voting control over these securities. Mr. Fitzpatrick and Princeton Capital Management, Inc. disclaim beneficial ownership of these securities.
- (17) Includes 769,230 shares and 384,615 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. Jim Fitzpatrick of Princeton Capital Management, Inc. is the investment advisor to Branco Weiss, and as such has investment power and voting control over these securities. Mr. Fitzpatrick and Princeton Capital Management, Inc. disclaim beneficial ownership of these securities.
- (18) Includes 384,614 shares and 192,307 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. Jim Fitzpatrick of Princeton Capital Management, Inc. is the investment advisor to William H. Reaves - PCM, and as such has investment power and voting control over these securities. Mr. Fitzpatrick and Princeton Capital Management, Inc. disclaim beneficial ownership of these securities.
- (19) Includes 307,692 shares and 153,846 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. Jim Fitzpatrick of Princeton Capital Management, Inc. is the investment advisor to Young Enterprise Securities, LLC, and as such has investment power and voting control over these securities. Mr. Fitzpatrick and Princeton Capital Management, Inc. disclaim beneficial ownership of these securities.
- (20) Includes 92,306 shares and 46,153 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. Jim Fitzpatrick of Princeton Capital Management, Inc. is the investment advisor to Hugh and Constance Fitzpatrick, and as such has investment power and voting control over these securities. Mr. Fitzpatrick and Princeton Capital Management, Inc. disclaim beneficial ownership of these securities.
- (21) Includes 61,538 shares and 30,769 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. Jim Fitzpatrick of Princeton Capital Management, Inc. is the investment advisor to Nancye Allen Fitzpatrick, and as such has investment power and voting control over these securities. Mr. Fitzpatrick and Princeton Capital Management, Inc. disclaim beneficial ownership of these securities.
- (22) Includes 478,870 shares and 239,435 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. Barry Kurokawa and David B. Musket have voting and dispositive power over all shares held in the ProMed funds.
- (23) Includes 124,040 shares and 62,020 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. Barry Kurokawa and David B. Musket have voting and dispositive power over all shares held in the ProMed funds.
- (24) Includes 77,860 shares and 38,930 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. Barry Kurokawa and David B. Musket have voting and dispositive power over all shares held in the ProMed funds.
- (25) Includes 1,626,930 shares and 813,465 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. Barry Kurokawa and David B. Musket have voting and dispositive power over all shares held in the ProMed funds.
- (26) Includes 210,234 shares, 42,665 shares issuable upon the exercise of warrants issued prior to our 2005 private placement, and an additional 4,615,386 shares and 2,307,693 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. Michael A. Roth and Brian J. Stark possess voting and dispositive power over all of the shares owned by SF Capital Partners Ltd.
- (27) Includes 67,538 shares and 33,769 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. WS Capital Management, L.P. is the general partner of Walker Smith Capital, L.P. and Walker Smith Capital (Q.P.), L.P. and the agent and attorney-in-fact for Walker Smith International Fund, Ltd. WS Capital, L.L.C. is the general partner of WS Capital Management, L.P. Reid S. Walker and G. Stacy Smith are the principals of WS Capital, LLC and, in such capacity, have voting and investment control over the shares of common stock beneficially owned by Walker Smith Capital, L.P., Walker Smith Capital (Q.P.), L.P. and Walker Smith International Fund, Ltd. Messrs. Walker and Smith expressly disclaim beneficial ownership of the shares of common stock beneficially owned by Walker Smith Capital, L.P., Walker Smith Capital (Q.P.), L.P. and Walker Smith International Fund, Ltd.
- (28) Includes 355,384 shares and 177,692 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. WS Capital Management, L.P. is the general partner of Walker Smith Capital, L.P. and Walker Smith Capital (Q.P.), L.P. and the agent and attorney-in-fact for Walker Smith International Fund, Ltd. WS Capital, L.L.C. is the general partner of WS Capital Management, L.P. Reid S. Walker and G. Stacy Smith are the principals of WS Capital, LLC and, in such capacity, have voting and investment control over the shares of common stock beneficially owned by Walker Smith Capital, L.P., Walker Smith Capital (Q.P.), L.P. and Walker Smith International Fund, Ltd. Messrs. Walker and Smith expressly disclaim beneficial ownership of the shares of common stock beneficially owned by Walker Smith Capital, L.P., Walker Smith Capital (Q.P.), L.P. and Walker Smith International Fund, Ltd.
- (29) Includes 500,154 shares and 250,077 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. WS Capital Management, L.P. is the general partner of Walker Smith Capital, L.P. and Walker Smith Capital (Q.P.), L.P. and the agent and attorney-in-fact for Walker Smith International Fund, Ltd. WS Capital, L.L.C. is the general partner of WS Capital Management, L.P. Reid S. Walker and G. Stacy Smith are the principals of WS Capital, LLC and, in

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such capacity, have voting and investment control over the shares of common stock beneficially owned by Walker Smith Capital, L.P., Walker Smith Capital (Q.P.), L.P. and Walker Smith International Fund, Ltd. Messrs. Walker and Smith expressly disclaim beneficial ownership of the shares of common stock beneficially owned by Walker Smith Capital, L.P., Walker Smith Capital (Q.P.), L.P. and Walker Smith International Fund, Ltd.

- (30) Includes 140,924 shares and 70,462 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. SRB Management, L.P. is the general partner of SRB Greenway Capital, L.P., SRB Greenway Capital (Q.P.), L.P. and SRB Greenway Offshore Operating Fund L.P. BC Advisors, LLC is the general partner of SRB Management, L.P. Steven R. Becker is the sole principal of BC Advisors, LLC and, in such capacity, has voting and investment control over the shares of common stock beneficially owned by SRB Greenway Capital, L.P., SRB Greenway Capital (Q.P.), L.P. and SRB Greenway Offshore Operating Fund L.P. Mr. Becker expressly disclaims beneficial ownership of the shares of common stock beneficially owned by SRB Greenway Capital, L.P., SRB Greenway Capital (Q.P.), L.P. and SRB Greenway Offshore Operating Fund L.P.
- (31) Includes 89,846 shares and 44,923 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. SRB Management, L.P. is the general partner of SRB Greenway Capital, L.P., SRB Greenway Capital (Q.P.), L.P. and SRB Greenway Offshore Operating Fund L.P. BC Advisors, LLC is the general partner of SRB Management, L.P. Steven R. Becker is the sole principal of BC Advisors, LLC and, in such capacity, has voting and investment control over the shares of common stock beneficially owned by SRB Greenway Capital, L.P., SRB Greenway Capital (Q.P.), L.P. and SRB Greenway Offshore Operating Fund L.P. Mr. Becker expressly disclaims beneficial ownership of the shares of common stock beneficially owned by SRB Greenway Capital, L.P., SRB Greenway Capital (Q.P.), L.P. and SRB Greenway Offshore Operating Fund L.P.
- (32) Includes 1,000,000 shares and 500,000 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement. SRB Management, L.P. is the general partner of SRB Greenway Capital, L.P., SRB Greenway Capital (Q.P.), L.P. and SRB Greenway Offshore Operating Fund L.P. BC Advisors, LLC is the general partner of SRB Management, L.P. Steven R. Becker is the sole principal of BC Advisors, LLC and, in such capacity, has voting and investment control over the shares of common stock beneficially owned by SRB Greenway Capital, L.P., SRB Greenway Capital (Q.P.), L.P. and SRB Greenway Offshore Operating Fund L.P. Mr. Becker expressly disclaims beneficial ownership of the shares of common stock beneficially owned by SRB Greenway Capital, L.P., SRB Greenway Capital (Q.P.), L.P. and SRB Greenway Offshore Operating Fund L.P.
- (33) Includes 10,322 shares, issuable upon the exercise of warrants issued prior to our 2005 private placement, and an additional 1,000,000 shares and 500,000 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement.
- (34) Includes 553,352 shares issuable upon the exercise of warrants issued in connection with our 2005 private placement.
- (35) Includes 484,374 shares of Common Stock issuable upon the exercise of stock options exercisable within 60 days of June 27, 2005.
- (36) Includes 185,0000 shares of Common Stock issuable upon the exercise of stock options exercisable within 60 days of June 27, 2005.
- (37) Includes 72,100 shares of Common Stock issuable upon the exercise of stock options exercisable within 60 days of June 27, 2005.
- (38) Includes 3,006,639 shares, 129,100 options and 384,750 warrants held by ONSET. Mr. Kuhling is a general partner of ONSET and disclaims beneficial ownership of the shares held by ONSET except to the extent of his proportionate partnership interest therein.
- (39) Includes 15,000 shares of Common Stock issuable upon the exercise of stock options exercisable within 60 days of June 27, 2005.
- (40) Includes 124,770 shares of Common Stock issuable upon the exercise of stock options exercisable within 60 days of June 27, 2005.
- (41) Includes 254,164 shares of Common Stock issuable upon the exercise of stock options exercisable within 60 days of June 27, 2005.
- (42) Includes 58,958 shares of Common Stock issuable upon the exercise of stock options exercisable within 60 days of June 27, 2005.
- (43) Includes 15,625 shares of Common Stock issuable upon the exercise of stock options exercisable within 60 days of June 27, 2005.
- (44) Includes 13,541 shares of Common Stock issuable upon the exercise of stock options exercisable within 60 days of June 27, 2005.

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DESCRIPTION OF CAPITAL STOCK

General

As of the date of this prospectus, our authorized capital stock consists of 105,000,000 shares. Those shares consist of (1) 100,000,000 shares designated as common stock, with a par value of \$0.001 and (2) 5,000,000 shares designated as preferred stock, with a par value of \$0.001. The only equity securities currently outstanding are shares of common stock. As of June 27, 2005, there were 43,349,465 shares of common stock issued and outstanding.

The following information describes our common stock and preferred stock, as well as options to purchase our common stock, and provisions of our certificate of incorporation and our bylaws. This description is only a summary. You should also refer to the certificate and bylaws which have been filed with the Securities and Exchange Commission as exhibits to our registration statement, of which this prospectus forms a part.

Common stock

The holders of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the shares voting are able to elect all of the directors. Subject to preferences that may be granted to any then outstanding preferred stock, holders of common stock are entitled to receive ratably only those dividends as may be declared by the board of directors out of funds legally available therefor, as well as any distributions to the stockholders. See Dividend policy. In the event of our liquidation, dissolution or winding up, holders of common stock are entitled to share ratably in all of our assets remaining after we pay our liabilities and distribute the liquidation preference of any then outstanding preferred stock. Holders of common stock have no preemptive or other subscription or conversion rights. There are no redemption or sinking fund provisions applicable to the common stock.

Our common stock is listed on the Nasdaq SmallCap Market under the symbol CURN. The transfer agent and registrar for the common stock is Mellon Investor Services.

Preferred stock

The following description of preferred stock and the description of the terms of a particular series of preferred stock that will be set forth in the related prospectus supplement are not complete. These descriptions are qualified in their entirety by reference to the certificate of determination relating to that series. The rights, preferences, privileges and restrictions of the preferred stock of each series will be fixed by the certificate relating to that series. The prospectus supplement also will contain a description of certain United States federal income tax consequences relating to the purchase and ownership of the series of preferred stock that is described in the prospectus supplement.

The Board of Directors has the authority, without further action by the shareholders, to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions granted to or imposed upon the preferred stock. Any or all of these rights

may be greater than the rights of the common stock.

The Board of Directors, without shareholder approval, can issue preferred stock with voting, conversion or other rights that could negatively affect the voting power and other rights of the holders of common stock. Preferred stock could thus be issued quickly with terms calculated to delay or prevent a change in control of us or make it more difficult to remove our management. Additionally, the issuance of preferred stock may have the effect of decreasing the market price of the common stock.

The prospectus supplement for a series of preferred stock will specify:

the maximum number of shares;

the designation of the shares;

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the annual dividend rate, if any, whether the dividend rate is fixed or variable, the date dividends will accrue, the dividend payment dates, and whether dividends will be cumulative;

the price and the terms and conditions for redemption, if any, including redemption at our option at the option of the holders, including the time period for redemption, and any accumulated dividends or premiums;

the liquidation preference, if any, and any accumulated dividends upon the liquidation, dissolution or winding up of our affairs;

any sinking fund or similar provision, and, if so, the terms and provisions relating to the purpose and operation of the fund;

the terms and conditions, if any, for conversion or exchange of shares of any other class or classes of our capital stock or any series of any other class or classes, or of any other series of the same class, or any other securities or assets, including the price or the rate of conversion or exchange and the method, if any, of adjustment;

the voting rights; and

any or all other preferences and relative, participating, optional or other special rights, privileges or qualifications, limitations or restrictions.

Preferred stock will be fully paid and nonassessable upon issuance.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Our bylaws provide for our board of directors to be divided into three classes, with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Our stockholders have no cumulative voting rights, our stockholders representing a majority of the shares of common stock outstanding will be able to elect all of the directors. Our bylaws also provide that all stockholder action must be effected at a duly called meeting of stockholders and not by a consent in writing, and that only our board of directors, chairman of the board, chief executive officer, president and one or more stockholders holding shares in the aggregate in at least 10% of the voting shares of our stock may call a special meeting of stockholders.

The combination of the classification of our board of directors and the lack of cumulative voting makes it difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of Curon Medical by replacing our board of directors. Since the board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for the board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of Curon Medical.

These provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of Curon Medical. These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and in the policies furnished them and to discourage certain types of transactions that may involve an actual or threatened change of control of Curon Medical. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. The provisions also are intended to discourage certain

tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they also may inhibit fluctuations in the market price of our shares that could result from actual or rumored takeover attempts. Such provisions may also have the effect of preventing changes in our management.

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PLAN OF DISTRIBUTION

The selling stockholders may, from time to time, sell any or all of their shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling stockholders may use any one or more of the following methods when selling shares:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

short sales;

broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;

a combination of any such methods of sale; and

any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved. Any profits on the resale of shares of common stock by a broker-dealer acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. Discounts, concessions, commissions and similar selling expenses, if any, attributable to the sale of shares will be borne by a selling stockholder. The selling stockholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares if liabilities are imposed on that person under the Securities Act.

The selling stockholders may from time to time pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common

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stock from time to time under this prospectus after we have filed an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus and may sell the shares of common stock from time to time under this prospectus after we have filed an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

The selling stockholders and any broker-dealers or agents that are involved in selling the shares of common stock may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In

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such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares of common stock purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act.

We are required to pay all fees and expenses incident to the registration of the shares of common stock other than fees and expenses of any counsel or advisors to the selling stockholders or brokerage fees and commissions incurred by them. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

The selling stockholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their shares of common stock, nor is there an underwriter or coordinating broker acting in connection with a proposed sale of shares of common stock by any selling stockholder. If we are notified by any selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of shares of common stock, if required, we will file a supplement to this prospectus. If the selling stockholders use this prospectus for any sale of the shares of common stock, they will be subject to the prospectus delivery requirements of the Securities Act.

The anti-manipulation rules of Regulation M under the Securities Exchange Act of 1934 may apply to sales of our common stock and activities of the selling stockholders.

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LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Wilson Sonsini Goodrich & Rosati, Professional Corporation, Palo Alto, California.

EXPERTS

The financial statements as of December 31, 2004 and 2003 and for each of the three years in the period ended December 31, 2004 included in this prospectus have been so included in reliance on the report (which contains an explanatory paragraph related to the Company's ability to continue as a going concern as described in Note 1 to the financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the common stock offered hereby, reference is made to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. A copy of the registration statement and the exhibits and schedules filed therewith may be inspected without charge at the public reference room maintained by the SEC, located at 450 Fifth Street, N.W., Room 1200, Washington, D.C. 20549, and copies of all or any part of the registration statement may be obtained from such offices upon the payment of the fees prescribed by the SEC. Please call the SEC at 1-800-SEC-0330 for further information about the public reference room. The SEC also maintains an Internet web site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the site is www.sec.gov.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Curon Medical, Inc:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations of stockholders' equity and comprehensive income (loss) and of cash flows present fairly, in all material respects, the financial position of Curon Medical, Inc. and its subsidiaries at December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 16(b) on page II-3 presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and the financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and the financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ PricewaterhouseCoopers LLP

San Jose, California

March 28, 2005,

except for Note 11, as to

which the date is July 5, 2005

Table of Contents**CURON MEDICAL, INC.****Consolidated Balance Sheets****(in thousands, except share amounts)**

	December 31,	
	2004	2003
Assets		
Current assets:		
Cash and cash equivalents	\$ 374	\$ 4,865
Marketable securities	5,518	5,269
Accounts receivable, net of allowance for doubtful accounts of \$54 and \$15, respectively	620	834
Inventories, net	777	1,063
Prepaid expenses and other current assets	987	863
Total current assets	8,276	12,894
Property and equipment, net	551	836
Other assets	330	124
Total assets	\$ 9,157	\$ 13,854
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	\$ 473	\$ 517
Accrued liabilities	1,121	1,164
Litigation reserve		1,250
Notes payable	57	
Total current liabilities	1,651	2,931
Warrant Liability	469	
Other	124	115
Total liabilities	2,244	3,046
Contingencies and commitments (Note 5)		
Stockholders equity:		
Preferred stock, \$.001 par value: 5,000,000 shares authorized Issued and outstanding: none		
Common stock, \$.001 par value: 50,000,000 shares authorized Issued and outstanding: 24,756,000 and 20,209,000, respectively	25	20
Additional paid-in capital	101,739	90,314
Deferred stock compensation		(4)
Accumulated deficit	(94,607)	(79,287)
Treasury stock, at cost 326,000 shares at December 31, 2004 and 2003	(234)	(234)
Accumulated other comprehensive loss	(10)	(1)
Total stockholders equity	6,913	10,808

Total liabilities and stockholders' equity	<u>\$ 9,157</u>	<u>\$ 13,854</u>
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See accompanying notes to consolidated financial statements.

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Table of Contents**CURON MEDICAL, INC.****Consolidated Statements of Operations****(in thousands, except per share amounts)**

	For the Years Ended December 31,		
	2004	2003	2002
Revenues	\$ 3,709	\$ 3,421	3,403
Cost of goods sold	4,358	4,322	4,080
Gross loss	(649)	(901)	(677)
Operating expenses:			
Research and development	1,736	1,823	2,668
Clinical and regulatory	1,096	1,497	1,784
Sales and marketing	8,083	6,825	7,065
General and administrative	5,073	3,505	4,023
Litigation charge		1,250	
Total operating expenses	15,988	14,900	15,540
Operating loss	(16,637)	(15,801)	(16,217)
Interest income	132	234	751
Interest expense	(6)	(5)	(8)
Decrease in warrant liability	1,200		
Other income (expense), net	(9)	17	33
Net loss	\$ (15,320)	\$ (15,555)	\$ (15,441)
Net loss per share, basic and diluted (Note 8)	\$ (0.64)	\$ (0.77)	\$ (0.79)
Shares used in computing net loss per share, basic and diluted (Note 8)	24,037	20,076	19,653

See accompanying notes to consolidated financial statements.

Table of Contents**CURON MEDICAL, INC.****Consolidated Statements of Stockholders Equity And Comprehensive Income (Loss)****For the Years Ended December 31, 2004, 2003, and 2002****(in thousands)**

	Common		Additional	Deferred	Accumulated	Treasury	Accumulated	Total	
	Stock		Paid-in	Stock			Other		Stockholders
	Shares	Amount	Capital	Compensation			Income		Equity
							(Loss)		
Balance at January 1, 2002	19,641	\$ 19	\$ 90,368	\$ (956)	\$ (48,291)	\$	\$ 148	\$ 41,288	
Net loss					(15,441)			(15,441)	
Change in unrealized loss on investment							(102)	(102)	
Total comprehensive loss								(15,543)	
Issuance of common stock upon exercise of stock options	212		49					49	
Issuance of common stock through Employee Stock Purchase Plan	140	1	185					186	
Deferred stock compensation			(474)	474					
Amortization of deferred stock compensation				357				357	
Repurchase of common stock						(234)		(234)	
Balance at December 31, 2002	19,993	20	90,128	(125)	(63,732)	(234)	46	26,103	
Net loss					(15,555)			(15,555)	
Change in unrealized gain on investment							(47)	(47)	
Total comprehensive loss								(15,602)	
Issuance of common stock upon exercise of stock options	64		30					30	
Issuance of common stock through Employee Stock Purchase Plan	152		84					84	
Deferred stock compensation			(70)	70					
Amortization of deferred stock compensation			142	51				193	
Balance at December 31, 2003	20,209	20	90,314	(4)	(79,287)	(234)	(1)	10,808	
Net loss					(15,320)			(15,320)	
Change in unrealized loss on investment							(9)	(9)	

Total comprehensive loss									(15,329)
Issuance of common stock upon exercise of stock options	346	1	314						315
Issuance of common stock through Employee Stock Purchase Plan	176		118						118
Common stock issued pursuant to private equity financing, net of issuance costs of \$896,000	4,025	4	10,955						10,959
Amortization of deferred stock compensation			38		4				42
Balance at December 31, 2004	24,756	\$ 25	\$ 101,739	\$	\$ (94,607)	\$ (234)	\$ (10)	\$	6,913

See accompanying notes to the consolidated financial statements.

Table of Contents**CURON MEDICAL, INC.****Consolidated Statements of Cash Flows****(in thousands)**

	For the Years Ended December 31,		
	2004	2003	2002
Cash Flows From Operating Activities			
Net loss	\$ (15,320)	\$ (15,555)	\$ (15,441)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	329	517	702
Loss on forgiveness of related party notes receivable			410
Amortization of acquired technology			133
Loss on disposal of fixed assets	38	17	21
Decrease of warrant liability	(1,200)		
Amortization of stock-based compensation	42	193	357
Amortization of premium (accretion of discount) on securities, net	499	283	(185)
Changes in current assets and liabilities:			
Accounts receivable, net	214	(146)	(22)
Inventories, net	286	232	115
Prepaid expenses and other current assets	(124)	109	(89)
Other assets	(104)	(104)	71
Accounts payable	(44)	326	(258)
Accrued liabilities	(43)	282	(195)
(Decrease)/Increase in liability settlement reserve	(1,250)	1,250	
Other long-term liabilities	9	97	(34)
	<u> </u>	<u> </u>	<u> </u>
Net cash used in operating activities	(16,668)	(12,499)	(14,415)
	<u> </u>	<u> </u>	<u> </u>
Cash Flows From Investing Activities			
Purchase of property and equipment	(184)	(614)	(343)
Sale of property and equipment		10	70
Purchase of marketable securities	(11,961)	(5,374)	(20,376)
Proceeds from maturities of marketable securities	11,204	14,700	36,201
	<u> </u>	<u> </u>	<u> </u>
Net cash (used in) provided by investing activities	(941)	8,722	15,552
	<u> </u>	<u> </u>	<u> </u>
Cash Flows From Financing Activities			
Proceeds from issuance of notes payable	454	309	140
Principal payments on notes payable	(397)	(351)	(305)
Proceeds from related party notes receivable			143
Payments of related party notes receivable			(55)
Proceeds from issuance of common stock and warrants, net of issuance costs	12,628		
Exercise of stock options and ESPP	433	114	235
Purchase of treasury stock			(234)
	<u> </u>	<u> </u>	<u> </u>
Net cash provided by (used in) financing activities	13,118	72	(76)
	<u> </u>	<u> </u>	<u> </u>

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Net (decrease) increase in cash and cash equivalents	(4,491)	(3,705)	1,061
Cash and cash equivalents at beginning of period	4,865	8,570	7,509
	<u> </u>	<u> </u>	<u> </u>
Cash and cash equivalents at end of period	\$ 374	\$ 4,865	\$ 8,570
	<u> </u>	<u> </u>	<u> </u>
Supplemental Disclosure Of Cash Flow Information			
Cash paid for interest	\$ 6	\$ 5	\$ 8

See accompanying notes to the consolidated financial statements.

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CURON MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Tabular amounts in thousands, except share and per share amounts)

NOTE 1 FORMATION AND BUSINESS OF THE COMPANY:

Curon Medical, Inc. (the Company) was incorporated in the State of Delaware on May 1, 1997. The Company develops, manufactures and markets proprietary products for the treatment of gastrointestinal disorders.

Going Concern

In the course of its operations, the Company has sustained operating losses and negative cash flows from operations and expects such losses to continue in the foreseeable future. As of December 31, 2004 the Company had cash and cash equivalents on hand of \$5.9 million, working capital of \$6.6 million, and an accumulated deficit of approximately \$94.6 million. The Company intends to finance its operations primarily through its cash and cash equivalents, marketable securities, future financing and future revenues. Although the Company recognizes the need to raise funds in the near future, there can be no assurance that it will be successful in consummating any such transaction, or, if it did consummate such a transaction, that the terms and conditions of such financing will be favorable to the Company. The Company believes that its cash balances as of December 31, 2004 will not be sufficient to fund planned expenditures in the third quarter of 2005. This raises substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in preparation of the consolidated financial statements.

Use of Estimates

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The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Certain Risks and Uncertainties

The Company's products and services are currently concentrated in a single segment of the gastrointestinal treatment field, which is characterized by increasing technological advances and changes in customer requirements. The success of the Company depends on management's ability to anticipate or to respond quickly and adequately to technological developments in its industry, changes in customer requirements or industry standards. Failure to obtain or maintain necessary FDA clearances or approvals could hurt the Company's ability to commercially distribute and market its products in the United States. Any significant delays in the development or introduction of products or services could have a material adverse effect on the Company's business and operating results. The Company has two products that it is currently marketing: radio-frequency generators and single use disposable devices. A single supplier currently provides some components and materials necessary for manufacturing of products. Any technical or quality problems in the manufacturing of these components, changes to the product specifications, changes in rights to currently licensed intellectual property, or lack of essential equipment by suppliers, could have a significant impact on the Company's financial condition and results of operations.

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Table of Contents**CURON MEDICAL, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(Tabular amounts in thousands, except share and per share amounts)****Cash and Cash Equivalents**

The Company considers all highly liquid investments purchased with remaining maturities of three months or less at the date of purchase to be cash equivalents. The Company's cash and cash equivalents include deposit funds, money market funds and commercial paper.

Marketable Securities

Investments consist primarily of marketable corporate bonds and commercial paper with a remaining maturity at the date of purchase of greater than three months. Investments with maturities beyond 2004 are classified as long-term investments and those maturing during 2004 are shown as current marketable securities. These investments are classified as available-for-sale securities and are stated at market value, with any temporary differences between an investment's amortized cost and its market value recorded as a separate component of stockholders' equity until such gains or losses are realized. Gains or losses on the sales of securities are determined on a specific identification basis. The following is a summary of investments at December 31, 2004 and 2003, respectively:

	Gross		
	Cost	Unrealized Holding Losses	Fair Value
	<u>Cost</u>	<u>Holding Losses</u>	<u>Value</u>
Maturities under one year			
Corporate obligations	\$ 5,528	\$ (10)	\$ 5,518
Total at December 31, 2004	<u>\$ 5,528</u>	<u>\$ (10)</u>	<u>\$ 5,518</u>
Maturities under one year			
Corporate obligations	\$ 5,270	\$ (1)	\$ 5,269
Total at December 31, 2003	<u>\$ 5,270</u>	<u>\$ (1)</u>	<u>\$ 5,269</u>

Inventories

Inventories are stated at the lower of standard cost (which approximates average cost) or market.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Leasehold improvements are amortized using the straight-line method over the estimated useful life of the improvement, or the lease term, if shorter. Useful lives by principal classifications are as follows:

Office furniture and equipment	5 years
Computers and software	3 years
Leasehold improvements	3 years

Upon retirement or sale, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in operations. Maintenance and repairs are charged to operations as incurred.

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CURON MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Tabular amounts in thousands, except share and per share amounts)

Impairment of Long-Lived Assets

Long-lived assets to be held and used are reviewed for impairment when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable, or its estimated useful life has changed significantly. When an asset's expected future undiscounted cash flows are less than its carrying value, an impairment loss is recognized and the asset is written down to its estimated fair value. Long-lived assets and certain identifiable intangible assets to be disposed of are reported at the lower of the carrying amount or fair value less cost to dispose. There have been no impairment charges recorded to date.

Revenue Recognition

The Company recognizes revenue in accordance with SEC SAB 104, as amended. Revenue from product sales is recognized on product shipment against a signed purchase order or sales quote provided no significant obligations remain and collection of the receivables is deemed probable for both sales of control modules and catheters. Revenues for extended warranty contracts are recognized over the extended warranty period. To date, post-sale customer support and training have not been significant.

The Company may sell products under a purchase commitment, with delivery of the control module at inception of the contract and catheters generally delivered over a period of six months. Revenue for the control module is deferred and recognized ratably over shipment of catheters under contract. Revenue on the catheters is recognized upon shipment at an amount representing their fair value based on verifiable objective evidence of such.

Shipping and handling costs charged to customers are recognized as revenue and the associated costs incurred by the Company are expensed under cost of goods sold.

Product Warranty

The Company generally warrants its products against defects for a period of one year and records a liability for such product warranty obligations at the time of sale based upon historical experience. The Company also sells separately priced extended warranties to provide additional warranty coverage and recognizes the related revenue on a straight-line basis over the extended warranty period, which are generally one to four years. Costs associated with services performed under the extended warranty obligation are expensed as incurred.

Changes in product warranty obligations, including separately priced extended warranty obligations, for the years ended December 31, 2004 and 2003 is as follows:

	<u>2004</u>	<u>2003</u>
Balance as of the beginning of the year	\$ 58	\$ 44
Add: Accruals for warranties issued	26	35
Cost incurred under separately priced extended warranty obligations	12	3
Less: Settlements made	(1)	(15)
Revenue recognized under separately priced extended warranty obligations	(12)	(9)
	<u> </u>	<u> </u>
Balance of the end of the year	\$ 83	\$ 58
	<u> </u>	<u> </u>

Research and Development

Research and development costs are expensed as incurred. Legal expenses related to patent development costs are expensed as incurred.

Table of Contents**CURON MEDICAL, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(Tabular amounts in thousands, except share and per share amounts)****Advertising Costs**

Advertising costs are expensed as incurred and were \$380,000 in 2004 and \$327,000 in 2003, and \$348,000 in 2002.

Income Taxes

The Company accounts for income taxes under the liability method whereby deferred tax asset or liability account balances are calculated at the balance sheet date using current tax laws and rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

Accounting for Stock-Based Compensation

The Company accounts for stock-based employee compensation arrangements in accordance with provisions of Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB No. 25) and complies with the disclosure provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS No. 123), as amended by SFAS No. 148, Accounting for Stock-Based Compensation, Transition and Disclosure. Under APB No. 25, unearned stock compensation is based on the difference, if any, on the date of grant, between the fair value of the Company's common stock and the exercise price. Had the Company determined its stock-based compensation based on the fair value at the grant dates for the awards under a method prescribed by SFAS No. 123, the Company's net loss would have been increased to the FAS 123 adjusted amounts indicated below, as amended by SFAS No. 148:

	Years Ended December 31,		
	2004	2003	2002
Net loss, as reported	\$ (15,320)	\$ (15,555)	\$ (15,441)
Add: Stock-based employee compensation expense in reported net income	4	51	357
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(724)	(878)	(1,072)
Net loss FAS 123 adjusted	\$ (16,040)	\$ (16,382)	\$ (16,156)

Net loss per share as reported Basic and diluted	\$ (0.64)	\$ (0.77)	\$ (0.79)
Net loss per share FAS 123 adjusted Basic and diluted	\$ (0.67)	\$ (0.82)	\$ (0.82)

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. The equity instruments are valued using the Black-Scholes model. All unvested shares are marked to market until such options vest.

Net Loss per Share

Basic net loss per share is calculated based on the weighted-average number of common shares outstanding during the period excluding those shares that are subject to repurchase. Diluted net loss per share would give effect to the dilutive effect of common stock equivalents consisting of stock options, warrants, and common stock subject to repurchase (calculated using the treasury stock method). Potentially dilutive securities have been excluded from the diluted net loss per share computations as they have an antidilutive effect due to the Company's net loss.

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CURON MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Tabular amounts in thousands, except share and per share amounts)

Fair Value of Financial Instruments

The carrying value of the Company's financial instruments, including cash and cash equivalents, trade accounts receivable, and accounts payable approximate fair value. Based on borrowing rates currently available to the Company for loans with similar terms, the carrying value of obligations approximates fair value.

Segments

The Company operates in one reportable segment, using one measurement of profitability to manage its business. All long-lived assets are maintained in the United States.

Recent accounting pronouncements

At its March 2004 meeting, the EITF reached a consensus on recognition and measurement guidance previously discussed under EITF 03-01. The consensus clarifies the meaning of other-than-temporary impairment and its application to investments classified as either available-for-sale or held-to-maturity under SFAS No. 115 and investments accounted for under the cost method or the equity method. The recognition and measurement guidance for which the consensus was reached in the March 2004 meeting is to be applied to other-than-temporary impairment evaluations in reporting periods beginning after June 15, 2004. The Company does not believe that this consensus on the recognition and measurement guidance will have an impact on its results of operations.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs*. SFAS 151 amends the guidance in ARB No. 43, Chapter 4, *Inventory Pricing*, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs and spoilage. This statement requires that these items be expensed as incurred and not included in overhead. In addition, SFAS 151 requires that allocation of fixed production overhead to conversion costs should be based on normal capacity of the production facilities. This Statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company's adoption of SFAS No. 151 is not expected to have a material impact on the Company's financial position and results of operations.

In December 2004, the FASB issued Statement No. 123(R), *Share-Based Payment*. This statement replaces SFAS No. 123, *Accounting for Stock-Based Compensation*, and supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*. SFAS 123(R) will require

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compensation costs related to share-based payment transactions to be recognized in the financial statements (with limited exceptions). The amount of compensation cost will be measured based on the grant-date fair value of the equity or liability instruments issued. Compensation cost will be recognized over the period that an employee provides service in exchange for the award. This statement is effective as of the annual reporting period that begins after June 15, 2005. The Company is currently evaluating the impact from this standard on its results of operations and financial position.

NOTE 3 BALANCE SHEET COMPONENTS:

	December 31,	
	2004	2003
Inventories:		
Raw materials	\$ 563	\$ 712
Work-in-process	13	89
Finished goods	201	262
	<u>\$ 777</u>	<u>\$ 1,063</u>

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CURON MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Tabular amounts in thousands, except share and per share amounts)

	December 31,	
	2004	2003
Property & Equipment:		
Computer and office equipment	\$ 593	\$ 518
Equipment	1,298	1,654
Furniture and fixtures	126	176
Leasehold improvements	319	301
Software	254	248
	<u>2,590</u>	<u>2,897</u>
Less: Accumulated depreciation and amortization	(2,039)	(2,061)
	<u>\$ 551</u>	<u>\$ 836</u>

Depreciation and amortization expense of property and equipment totaled \$329,000, \$517,000 and \$702,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

	December 31,	
	2004	2003
Accrued Liabilities:		
Compensation and benefits	\$ 496	\$ 728
Clinical trials	175	130
Professional fees	199	203
Other accrued expenses	251	103
	<u>\$ 1,121</u>	<u>\$ 1,164</u>

NOTE 4 NOTES PAYABLE:

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The Company had short-term notes payable at December 31, 2004 in the amount of \$57,000. The note bears interest at 3.99% with the final payment due in January 2005 and is related to the financing of corporate insurance policies in the amount of \$454,000. During 2003, a note payable in the amount of \$309,000, bearing interest at 3.99% was used to finance the corporate liability insurance policy renewal. This note was paid in full in December 2003.

NOTE 5 COMMITMENTS AND CONTINGENCIES:

Leases

The Company leases office space under a noncancelable operating leases expiring through August 2007. Rent expense for the years December 31, 2004, 2003, and 2002 was \$348,000, \$576,000 and \$528,000 respectively.

At December 31, 2004, future minimum facility lease payments are as follows:

2005	\$ 398
2006	345
2007	18
	<hr/>
Total future minimum lease payments	\$ 761
	<hr/>

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CURON MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Tabular amounts in thousands, except share and per share amounts)

Purchase commitments

The Company had noncancelable commitments to purchase raw material and finished goods inventory totaling \$243,000 in aggregate at December 31, 2004. These purchase commitments represent outstanding purchase orders submitted to the Company's third party suppliers for goods to be delivered to the Company in 2005.

Contingencies

The Company is involved in routine legal and administrative proceedings that arise from the normal conduct of business. Management believes that the ultimate disposition of these matters will not have a material adverse effect on the financial results or condition of the Company.

In June 2001, a civil action was filed against the Company in the United States District Court, Western District of Kentucky, Louisville Division, alleging that the plaintiff sustained injury when undergoing a procedure utilizing the Stretta System, caused by defects in design and manufacture. This matter was amicably resolved in February 2005 without material financial impact on the Company.

In June 2002, a civil action was filed against a number of defendants, including the Company, in the Court of Common Pleas, Philadelphia County, in the State of Pennsylvania, alleging that the Plaintiff sustained injury during a Secca procedure caused by the device being defective and/or in an unreasonably dangerous condition. The Company has settled the case, resulting in a payment to Plaintiff in March 2004 of \$1.25 million. This amount had been reserved at December 31, 2003.

In April 2003, a civil action was filed against the Company in United States District Court for the Northern District of California by Federal Insurance Corporation, the Company's insurance carrier, for rescission, reformation, and restitution in connection with the Company's liability insurance policy. This policy covers, among other things, product liability claims made against the Company by people treated with the Company's product. In October 2004, the Plaintiff's summary judgment motion was granted. Consequently, there will be no coverage in the Pennsylvania suit described above and the payment of the \$1.25 million will be the limit of the Company's liability in that case. The Company has decided not to appeal the result of the summary judgment and is engaged with settlement discussions with Federal Insurance Corporation. The Company believes that the resolution of this matter will not have a material effect, if any, on its business, financial position, and results of operations and cash flows.

Development and Technology License Agreements

The Company licenses certain radiofrequency technology through an agreement that gives the Company an irrevocable license to manufacture, have manufactured, use, offer to sell, sell and import radiofrequency generators based on the licensed technology in the licensed field. The agreement expires on October 6, 2017. Royalties are accrued at the time of sale, based on the revenues recognized when the related licensed technology is part of the sold item and were \$60,000 in 2004, \$66,000 in 2003 and \$75,000 in 2002.

In February and April 2000, the Company entered into two separate licensing agreements for the use of proprietary radiofrequency technologies used in certain of the Company's products. The Company issued 86,000 shares of its common stock, valued at \$831,000 on the date of the agreements, in exchange for the right to use the technologies. In addition, \$73,000 was paid in conjunction with the licensed technology. As part of the February agreement, the Company is also required to pay a royalty on all revenues collected when the related licensed technology is part of the sold item.

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CURON MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Tabular amounts in thousands, except share and per share amounts)

NOTE 6 STOCKHOLDERS EQUITY:

The Company's Certificate of Incorporation, as amended, authorizes the Company to issue 50,000,000 shares of \$.001 par value common stock. Certain of the shares issued are subject to a right of repurchase by the Company, which lapses over a three or four-year period from the issuance dates. At December 31, 2004, there were no shares subject to repurchase. At December 31, 2003 and 2002 there were 1,000 and 34,000 shares subject to repurchase, respectively.

Issuance of Common Stock

On February 6, 2004, the Company completed a private placement of 4,025,000 shares of common stock for aggregate gross proceeds of approximately \$13.5 million to a group of institutional investors. The shares were purchased at a price of at a price of \$3.36 per share. Net proceeds after offering costs and expenses were approximately \$12.6 million. Investors received warrants with a term of five years to purchase an aggregate of 905,625 common shares at an exercise price of \$4.71 per share.

Common Stock Warrants

In May 2000, the company issued warrants to purchase 568,917 shares of common stock in connection with convertible notes payable. These warrants are exercisable immediately and expire in 2005. The value of the warrants, \$2.1 million, was determined using the Black-Scholes option-pricing model and was amortized to interest expense in 2000. These warrants are outstanding at December 31, 2004.

On February 6, 2004, the Company issued warrants to purchase an aggregate of 905,625 shares of common stock an exercise price of \$4.71 per share to several institutional investors in connection with the private placement of common stock. The common stock warrants have a five-year term and became exercisable on August 6, 2004. In addition, on or after August 6, 2007, should the company's stock price close at or above 175% of the exercise price on any 15 out of 30 consecutive trading days, and other certain conditions are met as defined in the warrant agreement, the company has the right, on one occasion, to require the holders of the common stock warrants to exercise such common stock warrants. The warrant agreement contains a provision (Section 9(c)) providing that if the Company enters into a fundamental transaction, as defined further in the agreement (i.e. merger/consolidation, sale of substantially all of its assets, tender offer, reclassification common stock) that is consummated after the second anniversary of the date of the warrant and the cash consideration to be received by the holder is not greater than or equal to 30% over the exercise price, then at the request of the holder, the Company shall cash settle the warrants, purchasing such warrants for cash equal to the Black-Scholes value (assuming a 55% volatility) of the remaining unexercised portion of the warrant. As a result, the aggregate fair value of the warrants of \$1,669,000 was recorded as a liability. The warrants were valued on February 6, 2004, using the

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Black-Scholes model with the following assumptions: 5 year expected life, risk free interest rate of 3.23%, dividend yield of zero, volatility of 73%.

The fair value of the warrants and the corresponding liability is re-measured at the end of each reporting period utilizing current inputs to the Black-Scholes model, with any change in fair value being recorded as a non-operating item in the statement of operations. The aggregate fair value of the warrant decreased from \$1669,000 upon issuance on February 6, 2004, to \$469,000 at December 31, 2004. The warrants were valued on December 31, 2004, using the Black-Scholes model with the following assumptions: 4.1 year expected life, risk free interest rate of 3.6%, dividend rate of zero and volatility of 67%.

Stockholder Rights Plan

In October 2001, the Company adopted a Preferred Stock Rights Agreement. Under this agreement, the Company will issue a dividend of one Preferred Share Purchase Right (a Right) for each share of common stock held by stockholders of record as of the close of business on November 20, 2001. Each Right entitles the registered

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CURON MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Tabular amounts in thousands, except share and per share amounts)

stockholder to purchase from the Company one one-thousandth of a share of the Company's Series A Participating Preferred Stock (Preferred Stock) at an exercise price of \$30.00. The agreement is designed to assure stockholders fair value in the event of a future unsolicited business combination or similar transaction.

The Rights do not have any voting rights, and will expire upon the earlier of redemption or November 20, 2011. If the Rights are exercised, each stockholder receives one one-thousandth of a share of Preferred Stock, which entitles the holder to one additional vote and dividends and liquidation rights equal to that paid on common stock.

NOTE 7 STOCK OPTION PLANS AND OTHER EMPLOYEE BENEFITS:

Stock Option Plans

During 1997, the Company adopted the 1997 Stock Plan (the 1997 Plan). The 1997 Plan provides for the granting of stock options to employees and consultants of the Company. Options granted under the 1997 Plan may be either incentive stock options or non statutory stock options. Incentive stock options (ISO) may be granted only to Company employees (including officers and directors who are also employees). Non statutory stock options (NSO) may be granted to Company employees, officers, directors, and consultants. The Company reserved 2,679,000 of common stock for issuance under the 1997 Plan. The first options were issued in 1998. No further options will be granted under the 1997 Plan. The remaining shares reserved for issuance under this plan are being used for grant under the 2000 Stock Plan.

During 2000, the 2000 Stock Plan (the 2000 Plan) was adopted by the Board of Directors and became effective on September 21, 2000. The terms of this plan are generally the same as under the 1997 Plan. At December 31, 2004, there were 5,950,091 shares authorized for issuance under this plan.

Under both plans, options are granted for a period of up to ten years and at prices no less than 85% of the estimated fair value of the shares on the date of grant, provided, however, that (i) the exercise price of an ISO and NSO shall not be less than 100% and 85% of the estimated fair value of the shares on the date of grant, respectively, and (ii) the exercise price of an ISO and NSO granted to a 10% shareholder shall not be less than 110% of the fair market value of the shares on the date of grant. Options generally vest 25% one year from the vest start date and ratably over the next 36 months and expire 10 years from the date of grant.

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With effect from June 16 2004, the 2000 Stock Option Plan was amended to include each non-employee director elected to the Board of Directors for the first time following the Annual Meeting will receive upon election an initial grant of options to purchase 15,000 shares of common stock at fair market value on the date of grant as well as an annual grant of options to purchase 15,000 shares for each year during the director's term. All of the foregoing options have a ten-year term. The initial option grants as well as the annual grants are fully vested and immediately exercisable on the day of grant. All grants issued to outside Board members will be exercisable for up to a year from the date of such Board member's termination of service with the Company.

Deferred Stock Compensation

Prior to its IPO in September 2000, the Company issued stock options under the 1997 Plan at exercise prices, deemed by the Board of Directors at the date of grant to be equal to the fair value of the common stock. In anticipation of the Company's initial public offering, the Company subsequently determined that, for financial statement purposes, the estimated value of its common stock was in excess of the exercise prices. Accordingly, the Company has recorded deferred stock compensation for stock options issued to both employees and non-employees.

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CURON MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Tabular amounts in thousands, except share and per share amounts)

For stock options granted to employees (1,155,320 in 2004, 1,661,000 in 2003 and 1,098,000 in 2002), the difference, if any, between the exercise price of the stock options and the fair value of the Company's stock at the date of grant is recorded as deferred compensation on the date of grant.

For stock options granted to non-employees, generally for future services (10,000 in 2004, 10,000 in 2003, and none in 2002), the fair value of the options, was determined using the Black-Scholes valuation model. The Company records stock as the non-employee fulfills the terms of the option grants, with changes in fair value of the unvested options from period to period recorded as an adjustment to compensation expense.

Stock compensation expense is classified as follows:

	Years Ended December 31,		
	2004	2003	2002
Cost of goods sold	\$ 1	\$ 1	\$ 7
Research and development	29	142	66
Clinical and regulatory	12	14	51
Sales and marketing		9	47
General and administrative			186
	\$ 42	\$ 193	\$ 357

Activity under stock option plans is as follows:

2004		2003		2002	
Shares	Weighted	Shares	Weighted	Shares	Weighted
under	average	under	average	under	average
options	exercise	options	exercise	options	exercise

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		price		price		price
Beginning balance	3,629,000	\$ 1.92	2,416,000	\$ 2.52	2,083,000	\$ 3.11
Granted	1,165,000	\$ 1.65	1,671,000	\$ 1.07	1,098,000	\$ 1.01
Exercised	(346,000)	\$ 0.89	(64,000)	\$ 0.47	(212,000)	\$ 0.23
Cancelled	(922,000)	\$ 1.87	(394,000)	\$ 2.26	(553,000)	\$ 2.61
Ending balance	3,526,000	\$ 1.94	3,629,000	\$ 1.92	2,416,000	\$ 2.52
Exercisable at year-end	1,852,000	\$ 2.48	1,301,000	\$ 2.96	853,000	\$ 3.40

The options outstanding and currently exercisable by exercise price at December 31, 2004 are as follows:

Options Outstanding and Exercisable				Exercisable		
Range of Exercise Prices		Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.18	\$0.19	146,000	3.87	\$ 0.19	146,000	\$ 0.19
0.61	0.78	1,352,000	7.84	0.69	775,000	0.69
0.90	1.25	491,000	9.52	1.13	36,000	1.13
1.41	2.71	746,000	8.99	2.01	206,000	2.38
3.03	3.87	420,000	7.30	3.27	318,000	3.26
4.39	7.00	264,000	6.03	4.49	264,000	4.49
11.84	12.50	107,000	5.50	11.84	107,000	11.84
		3,526,000	7.88	\$ 1.94	1,852,000	\$ 2.48

Table of Contents**CURON MEDICAL, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

(Tabular amounts in thousands, except share and per share amounts)

Fair Value Disclosures

The fair value of options granted is estimated on the date of grant using the Black-Scholes option pricing model, using the following assumptions:

	Stock Option Plans			ESPP		
	2004	2003	2002	2004	2003	2002
Assumptions:						
Risk-free interest rate	3.18%	2.55%	3.35%	1.80%	1.47%	2.07%
Expected life	4.1 years	4 years	4 years	1.25 years	0.7 years	0.6 years
Expected volatility	106.6%	100%	100%	104.3%	100%	100%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Weighted average fair values:						
Exercise price less than market price	\$	\$	\$	\$ 0.78	\$ 0.29	\$ 1.12
Exercise price equal to market price	\$ 1.19	\$ 0.75	\$ 0.71	\$	\$	\$
Exercise price greater than market price	\$	\$	\$	\$	\$	\$

401(k) Savings Plan

In October 1999, the Company began a 401(k) savings plan (the 401(k) Plan). The 401(k) Plan is a defined contribution plan intended to qualify under Section 401(a) and 401(k) of the Internal Revenue Code. All full-time employees of the Company are eligible to participate in the 401(k) Plan pursuant to the terms of the Plan. Contributions by the Company are discretionary and the Company has made no contributions for the years ended December 31, 2004, 2003, or 2002.

Employee Stock Purchase Plan

Effective September 21, 2000, the Company adopted the 2000 Employee Stock Purchase Plan (ESPP). A total of 400,000 shares of common stock were initially reserved for issuance under this plan. In addition, subject to the Board of Directors' discretion, on January 1, 2001 and on each anniversary thereafter, the aggregate number of shares reserved for issuances under the ESPP will be increased automatically by the lesser of: 500,000 shares, 1.5% of the outstanding shares of the Company's Common Stock, or a lesser amount determined by the Board of Directors.

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During 2004, 2003 and 2002, the shares reserved for issuance under the ESPP were increased by 303,000, 300,000 and 295,000 shares, respectively.

Under the ESPP, eligible employees may have up to 15% of their earnings withheld, subject to certain limitations, to be used to purchase shares of the Company's common stock. Unless the Board of Directors shall determine otherwise, each offering period provides for consecutive 24-month periods commencing on each May 1 and November 1. Each offering period is comprised of four 6-month purchase periods. The price at which common stock may be purchased under the ESPP is equal to 85% of the lower of the fair market value of common stock on the commencement date of each offering period or the fair market value on the last day of the purchase period. During 2004, the shares purchased under the ESPP were 103,000 and 72,000 on May 1 and November 1, respectively.

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CURON MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Tabular amounts in thousands, except share and per share amounts)

NOTE 8 NET LOSS PER SHARE:

Basic and diluted net loss per share is calculated as follows:

	Year Ended December 31,		
	2004	2003	2002
Numerator:			
Net loss	\$ (15,320)	\$ (15,555)	\$ (15,441)
Demoninator:			
Weighted average shares outstanding	24,037,000	20,085,000	19,785,000
Weighted average unvested common shares subject to repurchase		(9,000)	(132,000)
Weighted average shares used in basic and diluted net loss per share	24,037,000	20,076,000	19,653,000
Net loss per share	\$ (0.64)	\$ (0.77)	\$ (0.79)

The Company has issued shares to employees and non-employees that are subject to repurchase should an employee terminate employment with the Company. The shares vest monthly and the vesting periods range from 36 months to 48 months. Shares subject to repurchase are excluded from the average shares used in the calculation of basic and diluted net loss per share.

Equity instruments that could dilute basic earnings per share in the future that were not included in the computation of diluted earnings per share as their effect is antidilutive are as follows:

	At December 31,		
	2004	2003	2002
Unvested common shares (shares subject to repurchase)		1,000	34,000

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Shares issuable upon exercise of stock options	3,526,000	3,629,000	2,416,000
Shares issuable through ESPP	17,553	39,392	40,493
Shares issuable upon exercise of warrants	1,475,000	569,000	569,000
	<u> </u>	<u> </u>	<u> </u>
Total	5,018,553	4,238,392	3,059,493
	<u> </u>	<u> </u>	<u> </u>

NOTE 9 GEOGRAPHIC SEGMENT INFORMATION

The Company has determined that it has a single reportable segment consisting of the development, manufacture, and marketing of proprietary products for the treatment of gastrointestinal disorders. Management uses one measurement of profitability and does not disaggregate its business for internal reporting. Operations outside the United States primarily consist of a sales office in Belgium that is responsible for promoting sales activities to foreign customers who are invoiced by the Company's headquarters in the United States, and a subsidiary in Australia that was used to coordinate Australian clinical trials in the past, and currently is inactive. The foreign subsidiaries do not carry any significant long-lived assets, and income and assets of the Company's foreign subsidiaries were not significant.

Table of Contents**CURON MEDICAL, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****(Tabular amounts in thousands, except share and per share amounts)**

Revenue from external customers by geographic area for each of the three years in the period ended December 31, 2004, were as follows:

	<u>2004</u>	<u>2003</u>	<u>2002</u>
United States	\$ 3,530	\$ 3,195	\$ 2,980
% of total	95.2%	93.4%	87.6%
Europe	\$ 179	\$ 226	\$ 423
% of total	4.8%	6.6%	12.4%

NOTE 10 INCOME TAXES:

The components of net deferred tax assets and liabilities as of December 31, 2004 and 2003 are as follows:

	<u>December 31,</u>	
	<u>2004</u>	<u>2003</u>
Deferred tax assets		
Depreciation and amortization	\$ 388	\$ 501
Reserves	275	674
Credits	1,150	1,022
Capitalized research & development costs	305	
Capitalized start-up costs	16	316
Net operating loss carryforwards	31,227	24,196
	<u>33,361</u>	<u>26,709</u>
Valuation allowance	(33,361)	(26,709)
Net deferred tax assets	<u>\$</u>	<u>\$</u>

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Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance is increased by \$6,652,000 and \$5,548,000 for the period ended December 31, 2004 and 2003 respectively.

As of December 31, 2004, the Company has a net operating loss carry forward for federal purposes of approximately \$81.8 million, which expire beginning in the year 2018. The Company also has California net operating loss carry forward of approximately \$58.5 million which expire beginning in the year 2008.

The Company has research and development credit carry forwards of approximately \$715,000 and \$574,000 for federal and state income tax purposes, respectively. If not utilized, the federal carry forward will expire in various amounts beginning in 2018. The California credit can be carried forward indefinitely.

The Tax Reform Act of 1986 limits the use of net operating loss and tax credit carryforwards in certain situations where changes occur in the stock ownership of a company. In the event the Company has had a change in ownership, utilization of the carryforwards could be restricted.

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CURON MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Tabular amounts in thousands, except share and per share amounts)

NOTE 11 SUBSEQUENT EVENT:

Subsequent to the year end, the Company completed a private placement of 18,445,078 shares of common stock and warrants to purchase 9,222,539 shares of common stock for aggregate gross proceeds of approximately \$12.0 million to a group of institutional investors. The shares were purchased at a price of \$0.65 per share. On April 8, 2005, the Company issued a total of 4,962,614 shares of common stock and warrants exercisable for five years to purchase up to an additional 2,481,298 shares of common stock with an exercise price of \$1.00 per share at the first closing. On June 3, 2005, the Company issued a total of 13,482,464 shares of common stock and warrants exercisable for five years to purchase up to an additional 6,741,241 shares of common stock with an exercise price of \$1.00 per share at the second closing. Net proceeds after offering costs and expenses were approximately \$10.9 million. The Company paid to the parties that acted as its agents in connection with this private placement fees of \$859,000 in cash and issued warrants to purchase 553,352 shares of its common stock as additional consideration. The terms of this warrant is identical to those issued to the investors. In a similar manner to the warrants issued in February 2004, the Company will account for the warrants as a liability based on fair market value at the date of sale. The Company will re-measure the value of the liability each quarter based on the fair market value at the end of the quarter.

NOTE 12 QUARTERLY FINANCIAL DATA (UNAUDITED):

The following table presents certain unaudited consolidated quarterly financial information for each of the eight quarters ended December 31, 2004. In our opinion, this quarterly information has been prepared on the same basis as the consolidated financial statements and includes all adjustments (consisting only of normal recurring adjustments, except for the litigation charge in the fourth quarter of 2003) necessary to present fairly the information for the periods presented. The results of operations for any quarter are not necessarily indicative of results for the full year or for any future period.

	Year	Quarter Ended			
		March 31,	June 30,	September 30,	December 31,
Net Sales	2004	\$ 906	\$ 931	\$ 862	\$ 1,010
	2003	709	868	783	1,061
Gross Loss	2004	(116)	(179)	(174)	(180)
	2003	(274)	(178)	(389)	(60)
Net Loss	2004	(3,552)	(3,211)	(4,348)	(4,209)
	2003	(3,265)	(3,575)	(3,866)	(4,849)
Earnings per share, basic and diluted	2004	(0.16)	(0.13)	(0.18)	(0.17)
	2003	(0.16)	(0.18)	(0.19)	(0.24)

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Shares used in computing net loss per share, basic and diluted	2004	22,659	24,385	24,470	24,622
	2003	19,977	20,055	20,100	20,171

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Condensed Consolidated Balance Sheets

(Unaudited, in thousands)

	March 31, 2005	December 31, 2004
	<u> </u>	<u> </u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,908	\$ 374
Marketable securities		5,518
Accounts receivable, net	601	620
Inventories, net	863	777
Prepaid expenses and other current assets	683	987
	<u> </u>	<u> </u>
Total current assets	5,055	8,276
Property and equipment, net	511	551
Other assets	299	330
	<u> </u>	<u> </u>
Total assets	\$ 5,865	\$ 9,157
	<u> </u>	<u> </u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 428	\$ 473
Accrued liabilities	1,243	1,121
Notes payable		57
	<u> </u>	<u> </u>
Total current liabilities	1,671	1,651
Warrant obligation	131	469
Other	123	124
	<u> </u>	<u> </u>
Total liabilities	1,925	2,244
	<u> </u>	<u> </u>
Contingencies and commitments (Note 5)		
Stockholders' equity:		
Common stock	25	25
Additional paid-in capital	101,722	101,739
Accumulated deficit	(97,573)	(94,607)
Treasury stock	(234)	(234)
Accumulated other comprehensive loss		(10)
	<u> </u>	<u> </u>
Total stockholders' equity	3,940	6,913
	<u> </u>	<u> </u>
Total liabilities and stockholders' equity	\$ 5,865	\$ 9,157
	<u> </u>	<u> </u>

See accompanying notes to condensed consolidated financial statements.

Table of Contents**CURON MEDICAL, INC.**

Condensed Consolidated Statements of Operations

(Unaudited)

(in thousands, except per share amounts)

	For the Three Months Ended March 31,	
	2005	2004
Revenues	\$ 857	\$ 906
Cost of goods sold	982	1,022
Gross loss	(125)	(116)
Operating expenses:		
Research and development	293	497
Clinical and regulatory	200	353
Sales and marketing	1,785	2,069
General and administrative	939	985
Total operating expenses	3,217	3,904
Operating loss	(3,342)	(4,020)
Interest income	17	39
Decrease in warrant obligation	338	443
Other income (expense), net	21	(14)
Net loss	\$ (2,966)	\$ (3,552)
Net loss per share, basic and diluted	\$ (0.12)	\$ (0.16)
Shares used in computing net loss per share, basic and diluted	24,810	22,659

See accompanying notes to condensed consolidated financial statements.

Table of Contents**CURON MEDICAL, INC.**

Condensed Consolidated Statements of Cash Flows

(Unaudited, in thousands)

	For the Three Months Ended, March 31,	
	2005	2004
Cash Flows From Operating Activities		
Net loss	\$ (2,966)	\$ (3,552)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	75	118
Stock-based compensation	(11)	31
Loss on disposal of fixed assets		3
Decrease of warrant obligation	(338)	(443)
Amortization of premium on securities	28	100
Changes in assets and liabilities:		
Accounts receivable, net	19	160
Inventories, net	(86)	(274)
Prepaid expenses and other current assets	304	58
Other assets	31	
Accounts payable	(45)	(11)
Accrued liabilities	71	209
Decrease in liability settlement reserve		(1,250)
Other long-term assets and liabilities	(1)	49
	<u>(2,919)</u>	<u>(4,802)</u>
Net cash used in operating activities	(2,919)	(4,802)
Cash Flows From Investing Activities		
Purchase of property and equipment	(35)	(116)
Purchase of marketable securities		(11,960)
Proceeds from maturities of marketable securities	5,500	1,750
	<u>5,465</u>	<u>(10,326)</u>
Net cash provided by (used in) investing activities	5,465	(10,326)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock and warrants, net of issuance costs		12,690
Exercise of stock options and ESPP	45	117
Principal payments on notes payable	(57)	
	<u>(12)</u>	<u>12,807</u>
Net cash (used in) provided by financing activities	(12)	12,807
Net increase (decrease) in cash and cash equivalents	2,534	(2,321)
Cash and cash equivalents at beginning of period	374	4,865
	<u>\$ 2,908</u>	<u>\$ 2,544</u>
Cash and cash equivalents at end of period	\$ 2,908	\$ 2,544

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See accompanying notes to the condensed consolidated financial statements.

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CURON MEDICAL, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited, tabular amounts in thousands, except per share amounts)

NOTE 1. The Company and Summary of Significant Accounting Policies

The Company

Curon Medical, Inc. (the Company) was incorporated in the State of Delaware in May 1997 as Conway-Stuart Medical Inc. and changed its name to Curon Medical, Inc., in March 2000. The Company develops, manufactures and markets proprietary products for the treatment of gastrointestinal disorders.

The Company has been financing its operations primarily through its cash and cash equivalents, revenues, marketable securities, and financing activities. On April 7 and April 19, 2005, the Company signed definitive agreements for the private placement of common stock and warrants to institutional investors for a total of \$12.0 million, before transaction fees and expenses. The placement is structured to be completed in two closings, with the first closing having occurred on April 8, 2005, and the second closing being subject to stockholder approval. In this first closing, the Company raised approximately \$3.2 million by issuing a total of 4,962,614 shares of common stock at a price of \$0.65 per share. Investors received five-year warrants to purchase an aggregate of 2,481,298 shares of common stock at a price of \$1.00 per share. An additional amount of approximately \$8.8 million has been deposited to escrow and will be released to the Company in the event that the Company obtains stockholder approval for the subsequent sale of securities. The Company intends to seek stockholder approval at its Annual Meeting to be held on or about May 31, 2005. The terms of the second closing are identical to those of the first closing. In the event that stockholder approval is received, net proceeds to the Company from the second closing will be approximately \$8.4 million. Management believes if the Company is successful in obtaining stockholder approval, with the proceeds from the second closing it will have enough cash to fund operations for at least the next twelve months. If the Company is unable to obtain stockholder approval for the subsequent sale of securities, operations will need to be substantially reduced in order to conserve working capital and the Company will have to explore other options, such as a sale of the Company or a portion of its assets including selling or licensing some of its proprietary technologies.

Basis of Presentation

The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries after elimination of all intercompany balances and transactions. The Company operates in one reportable segment.

The accompanying unaudited condensed consolidated financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States of America for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X promulgated by the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, contain all adjustments (all of which are normal and recurring in nature) necessary to state fairly the financial position, results of operations and cash flows of the Company for the periods indicated. Interim results of operations are not necessarily indicative of the results to be expected for the full year or any other interim periods.

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These condensed consolidated financial statements should be read in conjunction with the audited financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2004, as filed with the SEC.

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CURON MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Tabular amounts in thousands, except share and per share amounts)

Net Loss Per Share

Basic and diluted net loss per share is calculated as follows:

	For the Three Months Ended March 31,	
	2005	2004
Net loss (numerator):		
Net loss	\$ (2,966)	\$ (3,552)
Shares (denominator):		
Weighted average common shares outstanding	24,810	22,659
Net loss per share-basic and diluted	\$ (0.12)	\$ (0.16)

Equity instruments that could dilute basic earnings per share in the future, that were not included in the computation of diluted earnings per share as their effect is antidilutive, are as follows:

	March 31,	
	2005	2004
Shares issuable through ESPP	44	89
Shares issuable upon exercise of stock options	3,380	3,621
Shares issuable upon exercise of warrants	1,475	1,475
Total	4,899	5,185

Stock-Based Compensation

The Company accounts for stock-based employee compensation arrangements in accordance with provisions of Accounting Principles Board Opinion, APB, No. 25, Accounting for Stock Issued to Employees and complies with the disclosure provisions of Statement of Financial Accounting Standards, SFAS, No. 123, Accounting for Stock-Based Compensation, as amended by SFAS No. 148, Accounting for Stock-Based Compensation, Transition and Disclosure. Under APB No. 25, unearned stock compensation is based on the difference, if any, on the date of grant, between the fair value of the Company's common stock and the exercise price. Had the Company determined its stock-based compensation based on the fair value at the grant dates for the awards under a method prescribed by SFAS No. 123, the Company's net loss would have been increased to the FAS 123 adjusted amounts indicated below, as amended by SFAS No. 148:

	For the Three Months Ended March 31,	
	2005	2004
Net loss, as reported	\$ (2,966)	\$ (3,552)
Add: Stock-based employee compensation expense in reported net income		4
Deduct : Total stock-based employee compensation expense determined under fair value based for all awards	(186)	(146)
Net loss - FAS 123 adjusted	<u>\$ (3,152)</u>	<u>\$ (3,694)</u>
Net loss per share - as reported Basic and diluted	<u>\$ (0.12)</u>	<u>\$ (0.16)</u>
Net loss per share - FAS 123 adjusted Basic and diluted	<u>\$ (0.13)</u>	<u>\$ (0.16)</u>

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. The equity instruments are valued using the Black-Scholes model. All unvested shares are marked to market until such options vest.

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CURON MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Tabular amounts in thousands, except share and per share amounts)

Product Warranty

The Company generally warrants its capital equipment products against defects for a period of one year and records a liability for such product warranty obligations at the time of sale based upon historical experience. The Company also sells separately priced extended warranties to provide additional warranty coverage and recognizes the related revenue on a straight-line basis over the extended warranty period, which is generally one to four years. Costs associated with services performed under the extended warranty obligation are expensed as incurred.

Changes in product warranty obligations, including separately priced extended warranty obligations, for the three months ended March 31, 2005 and 2004 are as follows:

	For the Three Months Ended March 31,	
	2005	2004
Balance as of the beginning of the period	\$ 83	\$ 58
Add: Accruals for warranties issued	6	5
Less: Revenue recognized under separately priced extended warranty obligations	(2)	(3)
Balance as of the end of the period	<u>\$ 87</u>	<u>\$ 60</u>

NOTE 2. Issuance of Common Stock and Warrants

In February 2004, the Company raised approximately \$13.5 million in gross proceeds from the private placement of common stock and warrants to several institutional investors. Net proceeds to the Company after estimated offering costs and expenses were approximately \$12.6 million. The transaction involved the sale of 4,025,000 newly issued shares of the Company's common stock at a price of \$3.36 per share and warrants to purchase an aggregate of 905,625 shares of common stock at an exercise price of \$4.71 per share. The common stock warrants have a five-year term and became exercisable in August 2004. In addition, commencing in August 2007, should the Company's stock price close at or above 175% of the exercise price on any 15 out of 30 consecutive trading days, and other certain conditions are met as defined in the warrant agreement, the Company has the right, on one occasion, to require the holders of the common stock warrants to exercise such common stock warrants. These warrants provide for cash redemption by the warrant holders upon the occurrence of certain events outside the control of the Company. As a result, the aggregate fair value of the warrants of \$1.7 million was recorded as a liability with the remaining net proceeds of

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\$10.9 million recorded as equity in the accompanying condensed consolidated balance sheet. The warrants were valued in February 2004, using the Black-Scholes model with the following assumptions: 5 year expected life, risk free interest rate of 3.23 %, dividend yield of zero, volatility of 73%.

The fair value of the warrants and the corresponding liability is re-measured at the end of each reporting period utilizing current inputs to the Black-Scholes model, with any change in fair value being recorded as a non-operating item in the statement of operations. The aggregate fair value of the warrant decreased from \$469,000 at December 31, 2004, to \$131,000 at March 31, 2005. The warrants were valued on March 31, 2005, using the Black-Scholes model with the following assumptions: 3.8 year expected life, risk free interest rate of 4.22%, dividend rate of zero and volatility of 65%.

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CURON MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Tabular amounts in thousands, except share and per share amounts)

NOTE 3. Inventories

	March 31, 2005	December 31, 2004
Inventories:		
Raw materials	\$ 549	\$ 563
Work-in-process	137	13
Finished goods	177	201
	<u>\$ 863</u>	<u>\$ 777</u>

NOTE 4. Non-Employee Stock Compensation

Stock-based compensation (benefit) expense included in the Condensed Consolidated Statements of Operations is as follows:

	For the Three Months Ended March 31,	
	2005	2004
Research and development	\$	\$ 1
Clinical and regulatory	(9)	26
Sales and marketing	(2)	4
	<u>\$ (11)</u>	<u>\$ 31</u>

NOTE 5. Contingencies

The Company is involved in routine legal and administrative proceedings that arise from the normal conduct of business. Management believes that the ultimate disposition of these matters will not have a material adverse effect on the financial results or condition of the Company.

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In June 2001, a civil action was filed against the Company in the United States District Court, Western District of Kentucky, Louisville Division, alleging that the plaintiff sustained injury when undergoing a procedure utilizing the Stretta System, caused by defects in design and manufacture. This matter was amicably resolved in February 2005 without material financial impact on the Company.

In April 2003, a civil action was filed against the Company in United States District Court for the Northern District of California by Federal Insurance Corporation, the Company's insurance carrier, for rescission, reformation, and restitution in connection with the Company's liability insurance policy. This policy covers, among other things, product liability claims made against the Company by people treated with the Company's product. In October 2004, the plaintiff's summary judgment motion was granted. The Company has decided not to appeal the result of the summary judgment and is engaged with settlement discussions with Federal Insurance Corporation. The Company believes that the resolution of this matter will not have a material effect, if any, on its business, financial position, and results of operations and cash flows.

NOTE 6. Subsequent Event

Subsequent to the quarter end, the Company completed a private placement of 18,445,078 shares of common stock and warrants to purchase 9,222,539 shares of common stock for aggregate gross proceeds of approximately \$12.0 million to a group of institutional investors. The shares were purchased at a price of \$0.65 per share. On April 8, 2005, the Company issued a total of 4,962,614 shares of common stock and warrants exercisable for five years to purchase up to an additional 2,481,298 shares of common stock with an exercise price of \$1.00 per share at the first closing. On June 3, 2005, the Company issued a total of 13,482,464 shares of common stock and warrants exercisable for five years to purchase up to an additional 6,741,241 shares of common stock with an exercise price of \$1.00 per share at the second closing. Net proceeds after offering costs and expenses were approximately \$10.9 million. The Company paid to the parties that acted as its agents in connection with this private placement fees of \$859,000 in cash and issued warrants to purchase 553,352 shares of its common stock as additional consideration. The terms of this warrant is identical to those issued to the investors. In a similar manner to the warrants issued in February 2004, the Company will account for the warrants as a liability based on fair market value at the date of sale. The Company will re-measure the value of the liability each quarter based on the fair market value at the end of the quarter.