

SOLTA MEDICAL INC
Form 424B3
May 14, 2010
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**Filed Pursuant to Rule 424(b)(3)
Registration No. 333-165618**

PROSPECTUS

2,435,897 Shares

Solta Medical, Inc.

Common Stock

This prospectus relates to the offer and sale of up to 2,435,897 shares of our common stock under this prospectus by the selling stockholders identified in the **Selling Stockholders** section of this prospectus or their transferees, pledgees, donees or successors in interest, which offer and sale is not being underwritten. We issued these shares of our common stock to the selling stockholders in connection with our acquisition of Aesthera Corporation on February 26, 2010.

The selling stockholders or their pledgees, donees, transferees or other successors in interest may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. We provide more information about how the selling stockholders may sell shares of common stock in the section titled **Plan of Distribution** on page 24. We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of these shares by the selling stockholders. We will pay the expenses incurred in registering the shares, including legal and accounting fees.

Our common stock is listed on The NASDAQ Global Market under the symbol **SLTM**. The last reported sale price for our common stock on May 13, 2010 was \$2.65 per share.

Investment in our common stock involves a high degree of risk.

See Risk Factors beginning on page 3 of this prospectus.

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 May 14, 2010.

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INFORMATION CONTAINED IN THIS PROSPECTUS

You should rely only on the information contained or incorporated by reference in this prospectus and any prospectus supplement. We have not, and the selling stockholders have not, authorized anyone to provide you with additional or different information. These securities are not being offered in any jurisdiction where the offer is not permitted. You should assume that the information in this prospectus or any prospectus supplement is accurate only as of the date on the front of the document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any prospectus supplement or of any sale of our common stock.

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PROSPECTUS SUMMARY

The following summary highlights information contained in this prospectus or incorporated into this prospectus by reference. While we have included what we believe to be the most important information about the company and this offering, the following summary may not contain all the information that may be important to you. You should read this entire prospectus carefully, including the risks of investing discussed under Risk Factors beginning on page 3, and the information to which we refer you and the information incorporated into this prospectus by reference, for a complete understanding of our business and this offering. References in this prospectus to our company, we, our, Solta, Solta Medical and us refer to Solta Medical, Inc. References to selling stockholders refer to the stockholders listed herein under the heading Selling Stockholders on page 23, who may sell shares from time to time as described in this prospectus.

About This Prospectus

This prospectus is part of a registration statement on Form S-3 filed by us with the Securities and Exchange Commission, or the Commission, to register 2,435,897 shares of our common stock, or the Shares. The Shares were issued in connection with our acquisition of Aesthera Corporation, which closed on February 26, 2010, as described in the Current Report on Form 8-K filed by us with the Commission on March 1, 2010. The Shares are being registered for resale or other disposition by the selling stockholders or their pledgees, donees, transferees or other successors in interest. We will not receive any proceeds from the sale or other disposition of the Shares registered hereunder, or interests therein.

About Solta Medical, Inc.

We design, develop, manufacture and market aesthetic energy devices to address aging skin. We were incorporated in 1996 and received FDA clearance for treatment of periorbital wrinkles and commercially launched our first Thermage system in 2002. In June 2004, we received FDA clearance for the treatment of facial wrinkles and rhytids. In December 2005, we received FDA clearance to market our system for the treatment of wrinkles and rhytids, without limitation to particular areas of the body. In October 2006, we received FDA clearance to market our system for the temporary improvement in the appearance of cellulite. In June 2007, we received clearance to market our system for treatment of wrinkles and rhytids for the upper and lower eyelids. In June 2009, we received FDA clearance to market our latest Thermage system and hand piece configuration for wrinkles, rhytides and for the temporary improvement in the appearance of cellulite. Our patented and FDA-cleared systems use radiofrequency, or RF, energy to heat and shrink collagen and tighten tissue while simultaneously cooling and protecting the surface of the skin.

Laser devices used for aesthetic procedures, such as skin resurfacing, are also generally regulated as Class II medical devices, requiring 510(k) clearance. The FDA has granted eleven 510(k) clearances for four Fraxel devices relating to multiple indications for use. We received FDA clearance to market our first generation Fraxel SR750 system for coagulation of soft tissue in November 2003 and subsequently for treatment of periorbital wrinkles (June 2004), pigmented lesions (June 2004), melasma (March 2005), skin resurfacing procedures (July 2005) and acne and surgical scars (March 2006). In March 2006, we received FDA clearance to market our Fraxel re:store system for soft tissue coagulation and for treatment of periorbital wrinkles, pigmented lesions, melasma and skin resurfacing. We subsequently received FDA clearance for the Fraxel re:store for treatment of acne and surgical scars in January 2007 and for actinic keratoses in May 2007. In April 2007, we received FDA clearance to market the Fraxel re:fine system for soft tissue coagulation and for treatment of periorbital wrinkles, pigmented lesions, melasma, skin resurfacing, acne scars and surgical scars. The Fraxel re:pair system was cleared for ablation, coagulation and resurfacing of soft tissue in April 2007 and for treatment of wrinkles, pigmentation, textural irregularities and vascular dyschromia in November 2007. We received FDA clearance for two additional Fraxel re:pair handpieces in July 2008, which deliver ablative and incisional treatments for surgical applications. As of September 30, 2009, we had an installed base of approximately 2,800 Thermage systems and 2,200 Fraxel systems and had sold over 695,000 treatment tips.

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We were incorporated in California in 1996. In September 2001, we reincorporated in Delaware. In December 2008, we acquired Reliant Technologies, Inc. The acquisition combined two companies with strong brand names with one of the largest direct U.S. sales forces in the industry. Following the acquisition, we changed our name from Thermage, Inc. to Solta Medical, Inc. In February 2010, we acquired Aesthera Corporation, a developer, manufacturer and marketer of light-based aesthetic treatment systems the Isolaz and Isolaz Pro platforms based on proprietary Photopneumatic technology.

Our principal executive offices are located at 25881 Industrial Boulevard, Hayward, CA 94545 and our telephone number at that address is (510) 782-2286.

Thermage , ThermaCool , NXT , Reliant , Fraxel , Aesthera , Isolaz , Isolaz Pro and Photoneumatic are registered trademarks in the and several other countries. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risk factors described below, and all other information contained in or incorporated by reference in this prospectus, before deciding to invest in our common stock. If any of the following risks actually occur, they may materially harm our business, financial condition, operating results or cash flows. As a result, the market price of our common stock could decline, and you could lose all or part of your investment. Additional risks and uncertainties that are not yet identified or that we think are immaterial may also materially harm our business, operating results or financial condition and could result in a complete loss of your investment.

Risks Related to Our Business

We are in a difficult economic period, and the uncertainty in the economy has reduced and may continue to reduce patient demand for our products; if there is not sufficient patient demand for Thermage, Fraxel or our recently acquired Isolaz and Isolaz Pro procedures, practitioner demand for our Thermage, Fraxel or our recently acquired Isolaz and Isolaz Pro systems could drop, resulting in unfavorable operating results.

Recent distress in the financial markets has had an adverse impact on our business. The aesthetic treatment system industry in which we operate is particularly vulnerable to economic trends. The decision to undergo a Thermage, Fraxel Isolaz or Isolaz Pro procedure is driven by consumer demand. Most procedures performed using our Thermage, Fraxel and our recently acquired Isolaz and Isolaz Pro systems are elective procedures, the cost of which must be borne by the patient, and are not reimbursable through government or private health insurance. In times of economic uncertainty or recession, individuals often reduce the amount of money that they spend on discretionary items, including aesthetic procedures. The general economic difficulties being experienced by our customers and the lack of availability of consumer credit for some of our customers are adversely affecting the market in which we operate.

If the current situation continues or deteriorates further, our business would be negatively impacted and our financial performance would be materially harmed in the event that any of the above factors discourage patients from seeking Thermage, Fraxel or our recently acquired Isolaz and Isolaz Pro procedures.

We are totally dependent upon the success of our Thermage, Fraxel and our recently acquired Isolaz and Isolaz Pro systems, which have a limited commercial history. If our products fail to achieve sufficient market acceptance, our business will suffer.

We expect that sales of our Thermage, Fraxel and our recently acquired Isolaz and Isolaz Pro systems, including our treatment tips, will account for substantially all of our revenue for the foreseeable future. We expect to continue to expand our line of systems and treatment tips. This may not occur when expected, or at all, which would negatively affect our anticipated revenue. Our Thermage, Fraxel and our recently acquired Isolaz and Isolaz Pro systems may not significantly penetrate current or new markets. If demand for our Thermage, Fraxel and our recently acquired Isolaz and Isolaz Pro systems does not increase as we anticipate, or declines, our business, financial condition and results of operations will be harmed.

Our financial results may fluctuate unpredictably, making it difficult to forecast future performance.

Our limited operating history makes it difficult for us to predict future performance. Historically, the demand for our Thermage and Fraxel systems has varied from quarter to quarter. A number of factors, over which we have limited or no control, may contribute to fluctuations in our financial results, such as:

delays in receipt of anticipated purchase orders;

seasonal variations in patient demand for aesthetic procedures;

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the impact of general economic conditions on the demand for aesthetic procedures;

performance of our independent distributors;

the lack of credit available to physicians to finance capital equipment purchases;

positive or negative media coverage of our products or products of our competitors or our industry;

our ability to obtain further regulatory clearances or approvals;

delays in, or failure of, product and component deliveries by our subcontractors and suppliers;

changes in the length of the sales process;

the costs of litigation claims or adverse outcomes from legal proceedings;

customer response to the introduction of new product offerings;

fluctuations in foreign currency; and

excess or obsolete inventory charges.

Our success depends on growing physician adoption of our Thermage, Fraxel and our recently acquired Isolaz and Isolaz Pro systems and continued use of our treatment tips.

Our target physician customers typically already own one or more aesthetic device products. Our ability to grow our business and convince physicians to purchase our systems and products depends on the success of our clinical and sales and marketing efforts. Our business model involves both a capital equipment purchase of our Thermage, Fraxel and our recently acquired Isolaz and Isolaz Pro systems and continued purchases by our customers of our treatment tips. This may be a novel business model for many potential customers who may be used to competing products that are either exclusively capital equipment, such as many laser-based systems, or that are exclusively single-use products, such as Botox or dermal fillers. In addition, the lack of credit available to physicians to finance the purchase of Thermage, Fraxel and our recently acquired Isolaz and Isolaz Pro systems may also impact the adoption of these systems. We must be able to demonstrate that the cost of our Thermage, Fraxel and our recently acquired Isolaz and Isolaz Pro systems and the revenue that the physician can derive from performing procedures using our product are compelling when compared to the cost and revenue associated with alternative products. When marketing to plastic surgeons, we must also, in some cases, overcome a bias against non-invasive or minimally invasive aesthetic procedures. If we are unable to increase physician adoption of our Thermage, Fraxel and our recently acquired Isolaz and Isolaz Pro systems and use of our treatment tips, our financial performance will be adversely affected.

We may not be able to achieve or sustain profitability even if we are able to generate significant revenue.

We incurred a loss of \$11.2 million and \$16.4 million in the year ended December 31, 2009 and 2008, respectively. In the past, we have expanded our business and increased our expenses in order to grow revenue. We will have to increase our revenue while effectively managing our expenses in order to achieve sustained profitability. Our failure to achieve or sustain profitability could negatively impact the market price of our common stock.

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We may not be successful in selling and marketing our new products.

The commercial success of the products and technologies we develop will depend upon the acceptance of these products by physicians and their patients. It is difficult for us to predict how successful recently introduced products and procedures including the Thermage CPT system and Fraxel re:store Dual system, or products we are currently developing, will be over the long term. If the products we develop do not gain market acceptance, our revenues and operating results will suffer. In addition, we expect to face significant competition, in some cases from companies that are more established, market more widely known products and have greater resources than we do. We may not be able to differentiate our new products sufficiently from our competitors' products to achieve significant market penetration. As a result of these factors, we may incur significant sales and marketing expenses for our new products without achieving commercial success, which could harm our business and our competitive position.

In addition, as new or enhanced products are introduced, we must successfully manage the transition from older products in order to minimize disruption in customers' ordering patterns, avoid excessive levels of older product inventories, and ensure that enough supplies of new products can be delivered to meet customer demand.

The failure of our systems to meet patient expectations or the occurrence of unpleasant side effects from the Thermage, Fraxel and our recently acquired Isolaz and Isolaz Pro procedures could impair our financial performance.

Our future success depends upon patients having a positive experience with the Thermage, Fraxel and our recently acquired Isolaz and Isolaz Pro procedures in order to increase physician demand for our products, as a result of both individual patients' repeat business and as a result of word-of-mouth referrals. We believe that patients may be dissatisfied with the Thermage, Fraxel and our recently acquired Isolaz and Isolaz Pro procedures if they find it to be too painful. Furthermore, patients may experience temporary swelling or reddening of the skin as a procedure side effect. In rare instances, patients may receive burns, blisters, skin discoloration or skin depressions. Experiencing excessive pain or any of these side effects or adverse events could discourage a patient from having a Thermage, Fraxel and our recently acquired Isolaz and Isolaz Pro procedure or discourage a patient from having additional procedures or referring Thermage and Fraxel procedures to others. In order to generate repeat and referral business, we also believe that patients must be satisfied with the effectiveness of the procedures. Results obtained from a Thermage, Fraxel and our recently acquired Isolaz and Isolaz Pro procedure are subjective and may be subtle. A Thermage, Fraxel and our recently acquired Isolaz and Isolaz Pro treatment may produce results that may not meet patients' expectations. If patients are not satisfied with the procedure or feel that it is too expensive for the results obtained, our reputation and future sales will suffer.

The conditions of our secured term loan contain certain financial covenants with respect to our performance and other covenants that restrict our activities. If we are unable to comply with these covenants, we would have to negotiate an amendment to the loan agreement or the lender could accelerate the repayment of our indebtedness.

Our secured term loan contains certain financial covenants which require us to maintain specified levels of positive EBITDA and tangible net worth (both as defined in the loan agreement) each fiscal quarter. We are also subject to restrictive covenants, including among others covenants that restrict our ability to incur additional indebtedness, to dispose of assets, to effect certain corporate transactions, including specified mergers or acquisitions, and to pay dividends. The loan agreement generally provides for customary events of default, including among others non-payment defaults, covenant defaults, and a default in the event a material adverse change occurs. There is no assurance that we will be able to comply with our financial covenants. Upon the occurrence of an event of default under the term loan, the lender will be entitled to acceleration of all obligations under the loan agreement and an obligation to repay all obligations in full and such event of default could result in an increase to the applicable interest rate of 5.00%. Any acceleration in the repayment of our indebtedness could adversely affect our business.

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We may face problems with our acquisition of Aesthera Corporation.

On February 26, 2010, we completed our acquisition of Aesthera Corporation, or Aesthera, a developer, manufacturer and marketer of light-based aesthetic treatment systems. We cannot be certain that the acquisition of Aesthera will be successful or that we will realize the anticipated benefits of the acquisition. In particular, we may not be able to realize the strategic and operational benefits and objectives we had anticipated, including, greater revenue and market opportunities, maintaining industry leadership and consistent profitability. In addition, the demand for our combined product offerings may fluctuate and we may face increased competition into the markets for our products. Any of these factors and the following factors, as well as the inability to realize the long-term anticipated efficiencies and synergies of the acquisition of Aesthera, may have a material adverse effect on our business, operating results and financial condition. These factors may include:

the potential disruption of the combined company's ongoing business and diversion of management resources;

the possibility that the business cultures are not compatible;

the difficulty of incorporating acquired products, technology and rights into the combined company's products and services;

unanticipated expenses related to integration of operations;

the impairment of relationships with employees and customers as a result of any integration of new personnel;

potential unknown liabilities associated with the acquired business and technology;

potential periodic impairment of goodwill and intangible assets acquired; and

potential inability to retain, integrate and motivate key personnel.

Any acquisitions that we make could disrupt our business and harm our financial condition.

Our growth strategy includes evaluation of potential strategic acquisitions of complementary businesses, products or technologies. We may also consider joint ventures and other collaborative projects. We have incurred integration costs related to the acquisition of Reliant. We may incur similar expenses in future periods as we complete our integration plan in connection with our acquisition of Aesthera Corporation, as well as expenses associated with evaluation of other potential strategic transactions. Such expenditures could negatively impact our financial performance in future periods.

We may not be able to successfully integrate the combined business, products or technologies. In addition, the integration of such acquisition and management of any collaborative project may divert management's time and resources from our core business and disrupt our operations. If we decide to expand our product offerings, we may spend time and money on projects that do not increase our revenue. Any cash acquisition we pursue would diminish funds available to us for other uses, and any stock acquisition would dilute our stockholders' ownership. While we from time to time evaluate potential collaborative projects and acquisitions of businesses, products and technologies, and anticipate continuing to make these evaluations, we have no present understandings, commitments or agreements with respect to any other acquisitions or collaborative projects.

We may fail to effectively build and manage our sales force or to market and distribute our products.

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We rely on a direct sales force to sell our products in the United States and in certain international regions. As the Company grows, we expect to grow or realign our sales organization to meet our anticipated sales objectives. There are significant risks involved in building and managing our sales organization, including risks related to our ability to:

hire qualified individuals as needed;

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provide adequate training for the effective sale of our products; and

retain and motivate our sales employees.

In addition, sales to non-traditional practitioners of aesthetic procedures is a key element of our growth strategy. However, our sales force historically has sold primarily to dermatologists and plastic surgeons. Also, our systems compete with products that are well-established in the market. Accordingly, it is difficult for us to predict how well our sales force will perform. Our failure to adequately address these risks could have a material adverse effect on our ability to sell our products, causing our revenue to be lower than expected and harming our results of operations.

We may be required to raise additional capital and/or debt financing on unfavorable terms.

Our future liquidity requirements may increase beyond currently expected levels if we fail to achieve sustained profitability or if unanticipated expenses or other uses of cash arise. In order to meet our liquidity needs, we may be required to seek additional equity and/or debt financing. Additional financing may not be available on a timely basis on terms acceptable to us, or at all, particularly in the short-term due to the current credit and equity market funding environments. The availability of financing will depend, in part, on market conditions, and the outlook for our company. Any future equity financing would result in substantial dilution to our stockholders. If we raise additional funds by issuing debt, we may be subject to limitations on our operations, through debt covenants or other restrictions. If adequate funds are not available, we may have to delay development of new products or reduce marketing, customer support or other resources devoted to our products. In addition, if we are unable to obtain financing as needed, we may come into breach of our outstanding loan covenants. Any of these factors could harm our business and financial condition.

We are involved in intellectual property litigation, which could be costly and time consuming, and may impact our future business and financial performance.

We advised Alma Lasers Ltd. and Alma Lasers, Inc. (together Alma) as early as February 2006 that Alma's Accent product infringed numerous Thermage patents. On April 26, 2007 Alma filed a lawsuit against us in the United States District Court for the District of Delaware requesting a declaratory judgment that Alma's Accent product does not infringe our patents and that our patents are invalid. We believe that we have meritorious defenses in this action and intend to defend the action vigorously. On June 20, 2007, we filed patent infringement counterclaims against Alma in the United States District Court for the District of Delaware asserting that Alma's AccentXL and Harmony systems infringe ten of our U.S. patents. The counterclaims were amended on December 10, 2007 to include a claim of infringement of an eleventh patent. In addition to damages and attorney fees, we are asking the Court to enjoin Alma from further infringement. During May, June and July 2008, Alma filed with the United States Patent and Trademark Office requests that all of the 11 patents asserted by us be reexamined. The United States Patent and Trademark Office has made rejections of some claims in each of these 11 patents. We believe the United States Patent and Trademark Office will reaffirm the validity of our patents. Although we do not believe the final disposition of these matters will have a material adverse effect on our financial statements and future cash flows, our intellectual property has not been tested at trial. If we initiate litigation to protect our rights, we run the risk of having our patents invalidated, which would undermine our competitive position.

Litigation related to infringement and other intellectual property claims, with or without merit, is unpredictable, can be expensive and time-consuming and could divert management's attention from our core business. If we lose this kind of litigation, a court could require us to pay substantial damages, and prohibit us from using technologies essential to our products, any of which would have a material adverse effect on our business, results of operations and financial condition. We do not know whether necessary licenses would be available to us on satisfactory terms, or whether we could redesign our products or processes to avoid infringement.

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Our industry has been characterized by frequent intellectual property litigation. Our competitors or other patent holders may assert that our products and the methods we employ are covered by their patents. If our products or methods are found to infringe, we could be prevented from marketing them. In addition, we do not know whether our competitors or potential competitors have applied for, or will apply for or obtain, patents that will prevent, limit or interfere with our ability to make, use, sell, import or export our products. Competing products may also appear in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, we could be prevented from marketing our products in one or more countries.

In addition, we may hereafter become involved in litigation to protect our trademark rights associated with our company name or the names used with our products. Names used with our products and procedures may be claimed to infringe names held by others or to be ineligible for proprietary protection. If we have to change the name of our company or products, we may experience a loss in goodwill associated with our brand name, customer confusion and a loss of sales.

We are involved in litigation relating to our acquisition of Reliant Technologies, Inc., which could be costly and time consuming.

On December 21, 2009, a complaint was filed in the Santa Clara County Superior Court by three former stockholders of Reliant Technologies, Inc. against Reliant and certain former officers and directors of Reliant in connection with our acquisition of Reliant, which closed on December 23, 2008. The complaint purports to be brought on behalf of the former common stockholders of Reliant. As a result of the acquisition, a successor entity to Reliant, Reliant Technologies, LLC, became our wholly-owned subsidiary. Eric Stang and Leonard DeBenedictis are among the defendants named in the complaint. Messrs. Stang and DeBenedictis are members of our board of directors, and Mr. DeBenedictis is our Chief Technology Officer. The principal claim, among others, is that Reliant violated the California Corporations Code by failing to obtain the vote from a majority of holders of Reliant's common stock prior to the consummation of the acquisition. The complaint also purports to challenge disclosures made by Reliant in connection with its entry into the acquisition and that the defendants failed to maximize the value of Reliant for the benefits of Reliant's common stockholders. We believe that this suit is without merit, and we intend to vigorously defend it. Although we do not expect that the final disposition of this litigation will have a material adverse effect on our financial results, we may have to devote certain personnel and resources to resolve this litigation.

Intellectual property rights may not provide adequate protection for our products, which may permit third parties to compete against us more effectively.

We rely on a combination of patent, copyright, trademark and trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. As of December 31, 2009, we had 74 issued U.S. patents, 73 pending U.S. patent applications, 52 issued foreign patents and 72 pending foreign patent applications, some of which foreign applications preserve an opportunity to pursue patent rights in multiple countries. Some of our system components are not, and in the future may not be, protected by patents. Additionally, our patent applications may not issue as patents or, if issued, may not issue in a form that will be advantageous to us. Any patents we obtain may be challenged, invalidated or legally circumvented by third parties. Consequently, competitors could market products and use manufacturing processes that are substantially similar to, or superior to, ours. 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 generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. Moreover, we do not have patent rights in all foreign countries in which a market may exist, and where we have applied for foreign patent rights, the laws of many foreign countries will not protect our intellectual property rights to the same extent as the laws of the United States.

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In addition, competitors could purchase our systems and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If our intellectual property is not adequately protected so as to protect our market against competitors' products and methods, our competitive position could be adversely affected, as could our business.

Performing clinical studies on, and collecting data from, the Thermage or Fraxel procedures is inherently subjective, and we have limited data regarding the efficacy of our systems. If future data is not positive or consistent with our prior experience, rates of physician adoption will likely be harmed.

We believe that in order to significantly grow our business, we will need to conduct future clinical studies of the effectiveness of our Thermage and Fraxel systems. Clinical studies of aesthetic treatments are subject to a number of limitations. First, these studies do not involve well-established objective standards for measuring the effectiveness of treatment. Subjective, before and after, evaluation of the extent of change in the patient's appearance, performed by a medical professional or by the patient, is the most common method of evaluating effectiveness. A clinical study may conclude that a treatment is effective even if the change in appearance is subtle and not long-lasting. Second, as with other non-invasive or minimally invasive energy-based devices, the effect of the Thermage and Fraxel procedures vary from patient to patient and can be influenced by a number of factors, including the area of the body being treated, the age and skin laxity of the patient and operator technique.

We have not conducted any head-to-head clinical studies that compare results from treatment with our systems to surgery or treatment with other aesthetic devices. Without head-to-head studies against competing alternative treatments, which we have no current plans to conduct, potential customers may not find clinical studies of our technology sufficiently compelling to purchase our Thermage and Fraxel systems. If we decide to pursue additional studies in the future, they could be expensive and time consuming, and the data collected may not produce favorable or compelling results. If the results of such studies do not meet physicians' expectations, our Thermage and Fraxel systems may not become widely adopted, physicians may recommend alternative treatments for their patients, and our business may be harmed.

To successfully market and sell our systems internationally, we must address many issues with which we have limited experience.

International sales accounted for 54% of our revenue for the year ended December 31, 2009 and 48% of our revenue for each of the years ended December 31, 2008 and 2007. We believe that a significant portion of our business will continue to come from international sales through increased penetration in countries where we currently sell our products, combined with expansion into new international markets. However, international sales are subject to a number of risks, including:

difficulties in staffing and managing our international operations;

difficulties in penetrating markets in which our competitors' products are more established;

reduced or no protection for intellectual property rights in some countries;

export restrictions, trade regulations and foreign tax laws;

regulation of the sale of the hydrofluorocarbon used with our ThermoCool system;

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fluctuating foreign currency exchange rates;

foreign certification and regulatory clearance or approval requirements;

difficulties in developing effective marketing campaigns for unfamiliar, foreign countries;

dependence on third-party distributors in some territories;

customs clearance and shipping delays;

political and economic instability;

preference for locally produced products;

business interruption resulting from transitioning to direct sales from international distributors in certain international regions;
and

difficulties in getting distributors to relinquish regulatory documentation.

If one or more of these risks were realized, it could require us to dedicate significant resources to remedy the situation, and if we are unable to find a solution, our revenue may decline.

To market and sell our products internationally, we depend on distributors, and they may not be successful.

We currently depend primarily on third-party distributors to sell and service our products internationally and to train our international customers, and if these distributors terminate their relationships with us or under-perform we may be unable to maintain or increase our level of international revenue. We will also need to engage additional international distributors to grow our business and expand the territories in which we sell our systems. Distributors may not commit the necessary resources to market, sell and service our products to the level of our expectations. If current or future distributors do not perform adequately, or if we are unable to engage distributors in particular geographic areas, our revenue from international operations will be adversely affected. In addition, from time to time, legal disputes arise when we wish to discontinue a distributor relationship in a given territory or otherwise feel a distributor is not performing adequately. Such disputes have led to legal proceedings that are costly to litigate and that could result in outcomes that are not favorable to us.

New legislation regarding healthcare reform may affect our revenue and financial condition.

The U.S. government is currently considering and may in the future consider healthcare policies and proposals intended to curb rising costs, including those that could significantly affect both private and public reimbursement for healthcare services. State and local governments, as well as a number of foreign governments, are also considering or have adopted similar types of policies. Such policies and proposals include changes that would change the dynamics of the health care industry, including having the federal or one or more state governments assume a larger role in the health care system such as competing with private health insurers, imposing new taxes on health insurers, or restructuring of the Medicare or Medicaid programs. It is unclear which, if any, of the various U.S. healthcare reforms currently being discussed and/or proposed might be enacted by the U.S. Congress and signed into law. We are unable to predict what healthcare reform legislation or regulations, if any, will be enacted in the U.S.; whether other healthcare legislation or regulations affecting our business may be proposed or enacted in the future; what effect any legislation or regulation would have on our business; or the effect ongoing uncertainty about these matters will have on the purchasing decisions of our customers.

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We compete against companies that have more established products, longer operating histories and greater resources, which may prevent us from achieving significant market penetration or increased operating results.

The aesthetics market is highly competitive and dynamic, and is marked by rapid and substantial technological development and product innovations. Demand for our products could be diminished by equivalent or superior products and technologies offered by competitors. Specifically, our products compete against a variety of offerings in the aesthetics market, including laser and other light-based medical devices, pharmaceutical products such as Botox, filler injections, chemical peels, microdermabrasion, liposuction, cosmetic surgical procedures and less invasive surgical solutions such as implanted sutures. Our closest competitors are makers of laser and other light-based devices, which include companies such as Alma Lasers, Cutera, Cynosure, Lumenis, Lutronic, Palomar Medical Technologies, Sciton and Syneron Medical.

Competition in the aesthetics market could result in price-cutting, reduced profit margins and loss of market share, any of which would harm our business, financial condition and results of operations. Our ability to compete effectively depends upon our ability to distinguish our company and our products from our competitors and their products, and on such factors as:

safety and effectiveness;

product pricing;

success of our marketing initiatives;

compelling clinical data;

intellectual property protection;

quality of customer support; and

development of successful distribution channels, both domestically and internationally.

Some of our competitors have more established products and customer relationships than we do, which could inhibit our market penetration efforts. For example, we have encountered, and expect to continue to encounter, situations where, due to pre-existing relationships, potential customers decided to purchase additional products from our competitors. Potential customers also may need to recoup the cost of expensive products that they have already purchased from our competitors and thus may decide not to purchase our products, or to delay such purchase. If we are unable to achieve continued market penetration, we will be unable to compete effectively and our business will be harmed.

In addition, some of our current and potential competitors have significantly greater financial, research and development, manufacturing, and sales and marketing resources than we have. Our competitors could utilize their greater financial resources to acquire other companies to gain enhanced name recognition and market share, as well as new technologies or products that could effectively compete with our existing product line. Given the relatively few competitors currently in the market, any business combination could exacerbate any existing competitive pressures, which could harm our business.

Competition among providers of devices for the aesthetics market is characterized by rapid innovation, and we must continuously develop new products or our revenue may decline.

While we attempt to protect our products through patents and other intellectual property rights, there are few barriers to entry that would prevent new entrants or existing competitors from developing products that compete directly with ours. As we continue to create market demand for non-surgical, non-invasive or minimally invasive treatments, competitors will enter the market with other products making similar or superior claims. We expect that any competitive advantage we may enjoy from our current and future innovations may diminish over time, as companies

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successfully respond to our, or create their own, innovations. Consequently, we believe that we will have to continuously innovate and improve our products and technology to compete successfully. If we are unable to innovate successfully, our systems could become obsolete and our revenue will decline as our customers purchase competing products.

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Our products may have undetected and unforeseen design flaws, and may experience failures particularly when first introduced, or at any time during their lifecycle. Any product recall as a result of flaws or failures could result in the loss of or delays in market acceptance of our products and adversely affect our business and reputation. Correcting defects can be time consuming. Any significant returns or warranty claims could result in significant additional costs to us and could adversely affect our results of operations.

Negative publicity regarding our Thermage, Fraxel or future procedures could harm demand, which would adversely affect sales and our financial performance.

We have in the past experienced, and expect that in the future we will experience, negative media exposure. Such publicity may present negative individual physician or patient experience regarding the safety or effectiveness of our procedures. Competitors could attempt to use such publicity to harm our reputation and disrupt current or potential future customer relationships. While, to date, we have not observed a material impact on our quarterly financial results of operations from negative publicity, future results could be negatively impacted. Additionally, while we believe that obtaining positive publicity is important to our success, and it is an important component of our marketing efforts, we have also not observed a material impact on our quarterly financial results of operations from positive publicity.

Our reputation and competitive position may be harmed not only by negative media exposure, but also by other publicly-available information suggesting that our procedures are not safe. For example, we file adverse event reports with the FDA that are publicly available on the FDA's website if our product may have caused or contributed to a serious injury or malfunctioned in a way that would likely cause or contribute to a serious injury if it were to recur. Competitors may attempt to harm our reputation by pointing to isolated injuries that have been reported or publicized, or by claiming that their product is superior because they have not filed as many adverse event reports with the FDA. Such negative publicity and competitor behavior could harm our reputation and our future sales.

Our manufacturing operations and those of our key manufacturing subcontractors are dependent upon third-party suppliers, making us vulnerable to supply shortages and price fluctuations, which could harm our business.

Several components and materials that comprise our products are currently manufactured by a single supplier or a limited number of suppliers. In many of these cases, we have not yet qualified alternate suppliers and rely upon purchase orders, rather than long-term supply agreements. A supply interruption or an increase in demand beyond our current suppliers' capabilities could harm our ability to manufacture our products until new sources of supply are identified and qualified. Our reliance on these suppliers subjects us to a number of risks that could harm our business, including:

interruption of supply resulting from modifications to or discontinuation of a supplier's operations;

delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's variation in a component;

a lack of long-term supply arrangements for key components with our suppliers;

inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;

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difficulty locating and qualifying alternative suppliers for our components in a timely manner;

production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications;

delay in delivery due to our suppliers prioritizing other customer orders over ours;

damage to our brand reputation caused by defective components produced by our suppliers;

increased cost of our warranty program due to product repair or replacement based upon defects in components produced by our suppliers; and

fluctuation in delivery by our suppliers due to changes in demand from us or their other customers.

Any interruption in the supply of components or materials, or our inability to obtain substitute components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers, which would have an adverse effect on our business.

If, in the future, we decide to perform additional manufacturing functions internally that we currently outsource, our business could be harmed by our limited manufacturing experience and related capabilities.

We currently perform certain value-added and proprietary manufacturing processes internally at our principal facility, and we outsource the manufacture of components, subassemblies and certain finished products to a limited number of third parties. For financial or operational purposes, we may elect to perform additional component or system manufacturing functions internally. In that event, we may face a number of challenges beyond those that we currently address in our internal assembly, inspection, testing and certification activities. Implementing complex or specialized manufacturing processes could lead to difficulties in producing sufficient quantities of manufactured items that meet our quality standards and that comply with applicable regulatory requirements in a timely and cost-effective manner. In addition, if we experience these types of internal manufacturing difficulties, it may be expensive and time consuming to engage a new or previous subcontractor or supplier to fulfill our replacement manufacturing needs. The occurrence of any of these events could harm our business.

Problems in our manufacturing processes, or those of our manufacturing subcontractors, that lead to an actual or possible malfunction in our products, may require us to recall products from customers and could disrupt our operations. Our results of operations, our reputation and market acceptance of our products could be harmed if we encounter difficulties in manufacturing that result in a recall or patient injury, and delays in our ability to fill customer orders.

We outsource the repair of key elements of some products to sole-source service subcontractors.

We outsource the repair of certain key elements of our systems to sole source contract service providers. If the operations of those service subcontractors are interrupted, we may be limited in our ability to repair equipment. Our service subcontractors are dependent on trained technical labor to effectively repair our products. In addition, our service subcontractors may be operating as medical device manufacturers and as such are required to demonstrate and maintain compliance with the FDA's Quality System Regulation, or QSR. If our service subcontractors fail to comply with the FDA's QSR, repair operations could be affected and our ability to repair certain systems may be impaired.

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We may not be able to develop an alternative cooling system that will be in compliance with changing environmental regulations in a timely or cost-effective manner.

The cooling capability of our Thermage systems relies upon a hydrofluorocarbon, or HFC, called R134a, to protect the outer layer of the skin from over-heating while our device delivers RF energy to the subcutaneous tissue. New environmental regulations phasing out certain HFCs over the next decade have been adopted or are under consideration in a number of countries, and recent European Union directives require the phase-out of certain HFCs. We have also put in place a solution for the European Union import restrictions. If we are unable to develop an alternative cooling system for our device which is not dependent on R134a in a timely or cost-effective manner, our Thermage systems may not be in compliance with environmental regulations, which could result in fines, civil penalties and the inability to sell our products in certain major international markets.

We forecast sales to determine requirements for components and materials used in our systems, and if our forecasts are incorrect, we may experience delays in shipments or increased inventory costs.

We keep limited materials, components and finished product on hand. To manage our manufacturing operations with our suppliers, we forecast anticipated product orders and material requirements to predict our inventory needs up to six months in advance and enter into purchase orders on the basis of these requirements. Our limited historical experience may not provide us with enough data to accurately predict future demand. If our business expands, our demand for components and materials would increase and our suppliers may be unable to meet our demand. If we overestimate our component and material requirements, we will have excess inventory, which would increase our expenses. If we underestimate our component and material requirements, we may have inadequate inventory, which could interrupt, delay or prevent delivery of systems to our customers. Any of these occurrences would negatively affect our financial performance and the level of satisfaction our customers have with our business.

Even though we require training for users of Thermage and Fraxel systems and do not sell our systems to non-physicians, there exists a potential for misuse, which could harm our reputation and our business.

While we only sell our products to licensed physicians who have met our training requirements, federal regulations allow us to sell our systems to licensed practitioners. The definition of licensed practitioners varies from state to state. As a result, our systems may be operated by licensed practitioners with varying levels of training, and in many states by non-physicians, including physician assistants, registered nurses and nurse practitioners. Thus, in some states, the definition of licensed practitioner may result in the legal use of our products by non-physicians. Outside the United States, our independent distributors sell in many jurisdictions that do not require specific qualifications or training for purchasers or operators of products. We do not supervise the procedures performed with our systems, nor can we be assured that direct physician supervision of our equipment occurs according to our recommendations. We, and our distributors, require purchasers of our products to undergo an initial training session as a condition of purchase, but do not require ongoing training. In addition, we prohibit the sale of our systems to companies that rent our systems to third parties without our approval, but cannot prevent an otherwise qualified physician from contracting with a rental company in violation of their purchase agreement with us. The use of our systems by non-physicians, as well as noncompliance with the operating guidelines set forth in our training programs, may result in product misuse and adverse treatment outcomes, which could harm our reputation and expose us to costly product liability litigation.

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Product liability suits could be brought against us due to defective design, labeling, material or workmanship, or misuse of our products, and could result in expensive and time-consuming litigation, payment of substantial damages and an increase in our insurance rates.

If our products are defectively designed, manufactured or labeled, contain defective components or are misused, we may become subject to substantial and costly litigation by our customers or their patients. Misusing our products or failing to adhere to operating guidelines could cause significant skin damage and underlying tissue damage. In addition, if our operating guidelines or product design are found to be inadequate, we may be subject to liability. We have been, continue to be and may, in the future, be involved in litigation related to the use of our products. Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizable damage awards against us. We may not have sufficient insurance coverage for all future claims. We may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, could harm our reputation in the industry and reduce product sales. Product liability claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and reducing our operating results.

After-market modifications to our treatment tips by third parties and the development of counterfeit treatment tips could reduce our sales, expose us to product liability litigation and dilute our brand quality.

Third parties have introduced adulterated after-market modifications to our treatment tips which have enabled re-use of our treatment tips in multiple procedures. Because our treatment tips are designed to withstand a finite number of firings, modifications intended to increase the number of firings could result in patient injuries caused by the use of worn-out or damaged treatment tips. In addition, third parties may seek to develop counterfeit treatment tips that are compatible with our systems and available to practitioners at lower prices than our own. If security features incorporated into the design of our systems are unable to prevent after-market modifications to our treatment tips or the introduction of counterfeit treatment tips, we could be subject to reduced treatment tip sales, product liability lawsuits resulting from the use of damaged or defective goods and damage to our reputation for providing a quality product.

We depend on skilled and experienced personnel to operate our business effectively. If we are unable to recruit, hire and retain these employees, our ability to manage and expand our business will be harmed, which would impair our future revenue and profitability.

Our success largely depends on the skills, experience and efforts of our officers and other key employees. Many of our officers and key employees do not have employment contracts with us and can terminate their employment at any time. The loss of any of our senior management team members could weaken our management expertise and harm our business.

Our ability to retain our skilled labor force and our success in attracting and hiring new skilled employees will be a critical factor in determining whether we will be successful in the future. We may not be able to meet our future hiring needs or retain existing personnel. We will face particularly significant challenges and risks in hiring, training, managing and retaining engineering and sales and marketing employees, as well as independent distributors, most of whom are geographically dispersed and must be trained in the use and benefits of our products. Failure to attract and retain personnel, particularly technical and sales and marketing personnel, would materially harm our ability to compete effectively and grow our business.

Risks Related to Regulatory Matters

If we fail to obtain and maintain necessary FDA clearances for our systems and indications, if clearances for future products and indications are delayed, not issued or rescinded or if there are federal or state level regulatory changes, our commercial operations would be harmed.

Our Thermage, Fraxel and our recently acquired Isolaz and Isolaz Pro systems are medical devices that are subject to extensive regulation in the United States by the FDA for manufacturing, labeling, sale, promotion, distribution and shipping. Before a new medical device, or a new use of or claim for an existing product, can be marketed in the United States, it must first receive either 510(k) clearance or premarket approval from the FDA, unless an exemption applies. Either process can be expensive and lengthy. The FDA's 510(k) clearance process usually takes from three to 12 months, but it can last significantly longer. The process of obtaining premarket approval is much more costly and uncertain than the 510(k) clearance process, and it generally takes from one to three years, or even longer, from the time the application is filed with the FDA.

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Medical devices may be marketed only for the indications for which they are approved or cleared. We have obtained 510(k) clearance for various indications for our Thermage and Fraxel systems. In addition, 510(k) clearance has been obtained for various indications of our recently acquired Isolaz and Isolaz Pro systems. However, our clearances can be revoked if safety or effectiveness problems develop. We are also subject to Medical Device Reporting regulations, which require us to report to the FDA if our product causes or contributes to a death or serious injury, or malfunctions in a way that would likely cause or contribute to a death or serious injury. Our products are also subject to state regulations which are, in many instances, in flux. Changes in state regulations may impede sales. For example, federal regulations allow our systems to be sold to, or on the order of, licensed practitioners, as determined on a state-by-state basis. As a result, in some states, non-physicians may legally purchase and operate our systems. However, a state could change its regulations at any time, disallowing sales to particular types of end users. We cannot predict the impact or effect of future legislation or regulations at the federal or state levels.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

warning letters, fines, injunctions, consent decrees and civil penalties;

repair, replacement, refunds, recall or seizure of our product;

operating restrictions or partial suspension or total shutdown of production;

refusing our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to our existing products;

withdrawing 510(k) clearance or premarket approvals that have already been granted; and

criminal prosecution.

If any of these events were to occur, our business could be harmed.

If we modify our FDA-cleared devices, we may need to seek and obtain new clearances, which, if not granted, would prevent us from selling our modified product or require us to redesign our product.

Any modification to an FDA-cleared device that would significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a premarket approval. We may not be able to obtain additional 510(k) clearances or premarket approvals for new products or for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and potential future profitability. We have made modifications to our device in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified device, which could harm our operating results and require us to redesign our product.

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If we or our repair subcontractors fail to comply with the FDA's Quality System Regulation, our business would suffer.

We and our repair subcontractors are required to demonstrate and maintain compliance with the FDA's Quality System Regulation, or QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our product. The FDA enforces the QSR through periodic unannounced inspections. We have been, and anticipate in the future being, subject to such inspections. Our failure, or the failure of our repair subcontractors, to take satisfactory corrective action in response to an adverse QSR inspection could result in enforcement actions, including a public warning letter, a shutdown of our manufacturing operations, a recall of our products, civil or criminal penalties or other sanctions, which would cause our sales and business to suffer.

We may be unable to obtain or maintain international regulatory qualifications or approvals for our current or future products and indications, which could harm our business.

Sales of our products outside the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the United States. Complying with international regulatory requirements can be an expensive and time-consuming process and approval is not certain. The time required to obtain clearance or approvals, if required by other countries, may be longer than that required for FDA clearance or approvals, and requirements for such clearances or approvals may significantly differ from FDA requirements. We primarily rely upon third-party distributors to obtain all regulatory clearances and approvals required in countries outside of the United States, and these distributors may be unable to obtain or maintain such clearances or approvals. Our distributors may also incur significant costs in attempting to obtain and in maintaining foreign regulatory approvals or qualifications, which could increase the difficulty of attracting and retaining qualified distributors. If our distributors experience delays in receiving necessary qualifications, clearances or approvals to market our products outside the United States, or if they fail to receive those qualifications, clearances or approvals, we may be unable to market our products or enhancements in international markets effectively, or at all. To support the registration of products outside the United States, we must comply with and be registered to the ISO 13485: 2003-2007 Quality System Standard. Failure to adequately maintain our ISO 13485: 2003-2007 registration may adversely impact or prevent the registration of our products in some foreign countries.

Risks Related to Our Internal Control over Financial Reporting

While we believe we currently have adequate internal control over financial reporting, we are required to assess our internal control over financial reporting on an annual basis and any future adverse results from such assessment could result in a loss of investor confidence in our financial reports and have an adverse effect on our stock.

Pursuant to the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated by the Commission, we are required to maintain disclosure controls and procedures and adequate internal control over financial reporting. Under such requirements we must furnish in our Form 10-K a report by our management regarding the effectiveness of our internal control over financial reporting. The report includes, among other things, an assessment of the effectiveness of our internal control over financial reporting as of the end of our fiscal year, including a statement as to whether or not our internal control over financial reporting is effective. This assessment must include disclosure of any material weaknesses in our internal control over financial reporting identified by management. While we currently believe our internal control over financial reporting is effective, the effectiveness of our internal controls in future periods is subject to the risk that our controls may become inadequate because of changes in conditions. The effectiveness of our controls and procedures may in the future be 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 any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial information.

If we are unable to assert that our internal control over financial reporting is effective in any future period, or if and when applicable, our auditors are unable to express an opinion on the effectiveness of our internal controls, or conclude that our internal co