SIRONA DENTAL SYSTEMS, INC.
Form 10-K
December 04, 2008
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

x Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended September 30, 2008

or

¨ Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from to

Commission file number 000-22673

Sirona Dental Systems, Inc.

(Exact name of registrant as specified in charter)

Delaware (State or other jurisdiction of incorporation or organization)		11-3374812 (I.R.S. Employer Identification No.)
30-30 47th Avenue, Suite 500, Long Island City, New York (Address of principal executive offices)	11101 (Zip Code)	(718) 937-5765 (Telephone No.)

Securities Registered Pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common stock, par value $0.01 per share	The NASDAQ Stock Market LLC (NASDAQ Global Select Market)

Securities Registered Pursuant to Section 12(g) of the Act:

None

(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer x	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ¨ No x

The aggregate market value of Common Stock held by non-affiliates of the registrant as of March 31, 2008 the last business day of the registrant s most recently completed second fiscal quarter was approximately $455,560,685. Such aggregate market value is computed by reference to the closing sale price of the Common Stock on such date.

As of December 1, 2008, the number of shares outstanding of the Registrant s Common Stock, par value $.01 per share, was 54,865,995.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant s definitive proxy statement for its 2009 annual meeting of stockholders, which is expected to be filed with the Securities and Exchange Commission not later than January 28, 2009 are incorporated by reference into Part III of this report on Form 10-K. In the event such proxy statement is not filed by January 28, 2009 the required information will be filed as an amendment to this report on Form 10-K no later than that date.

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FORWARD-LOOKING STATEMENTS

This Form 10-K Annual Report contains forward-looking statements that involve risk and uncertainties. All statements, other than statements of historical facts, included in this Annual Report regarding the Company, its financial position, products, business strategy and plans and objectives of management of the Company for future operations, are forward-looking statements. When used in this Annual Report, words such as anticipate, believe, estimate, expect, intend, objectives, plans and similar expressions, or the negatives thereof or variations thereon comparable terminology as they relate to the Company, its products or its management, identify forward-looking statements. Such forward-looking statements are based on the beliefs of the Company s management, as well as assumptions made by and information currently available to the Company s management. Actual results could differ materially from those contemplated by the forward-looking statements as a result of various factors, including, but not limited to, those contained in Management s Discussion and Analysis of Financial Condition and Results of Operations in Item 7 of this Annual Report and the Risk Factors set forth in Item 1A of this Annual Report. All forward looking statements speak only as of the date of this Annual Report and are expressly qualified in their entirely by the cautionary statements included in this report. The Company undertakes no obligation to update or revise forward-looking statements which may-be made to reflect events or circumstances that arise after the date made or to reflect the occurrence of unanticipated events other than required by law.

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PART I

ITEM 1. BUSINESS

Overview

Sirona Dental Systems, Inc. (Sirona or the Company) is a leading manufacturer of high-tech dental equipment. Sirona focuses on developing innovative systems and solutions for dentists globally. Sirona provides a broad range of advanced products in each of four primary areas:

- Dental CAD/CAM Systems;
- Imaging Systems;
- Treatment Centers; and
- Instruments.

Sirona distributes its products globally to dental practices, clinics and laboratories through an international network of distributors. The distributors typically offer both dental equipment and consumables, and, therefore, have regular contact with the ultimate end-users.

Sirona s revenue for the year ended September 30, 2008 was $757.1 million. Sirona sells its products globally, with the U.S. market contributing 29.2% of revenue, or $220.9 million, the German market contributing $153.8 million or 20.3%, and the rest of the world contributing 50.5% of revenue, or $382.4 million.

History

The history of Sirona dates back to the establishment of Reiniger, Gebbert & Schall, which introduced the first electrical drill machine in 1882. In 1925, the Company became part of Siemens & Halske Group and in 1934 launched the smallest x-ray in the world, enabling dental x-rays for the first time. In 1956, Siemens introduced the Sirona brand for a treatment center and in 1958 the group developed the first ball-bearing turbine for dental drills.

In 1997, funds advised by the financial sponsor, Permira, acquired the dental business (Sirona) from Siemens in a leveraged buy-out transaction. Following the transaction, Sirona substantially increased its international sales and intensified its focus on product innovation. In November 2003, Permira sold Sirona to the Scandinavian financial sponsor, EQT, and management in a leveraged buy-out transaction that closed on February 16, 2004. On April 30, 2005, funds managed by Madison Dearborn Partners, a private equity firm, and Sirona s management entered into an agreement to acquire Sirona in a leveraged buy-out transaction that closed on June 30, 2005.

On September 25, 2005, Schick Technologies, Inc. (Schick) entered into an Exchange Agreement with Sirona Holdings Luxco S.C.A. (Luxco) and Sirona Holding GmbH (Sirona Holding) providing for the issuance of 36,972,480 shares of Schick common stock to Luxco in exchange for Luxco s entire economic interest in Sirona Holding, which consisted of all of the issued and outstanding share capital of Sirona Holding and the existing indebtedness of Sirona Holding owed to Luxco in the principal amount of Euro 151.0 million ($182 million) plus accrued interest (the Exchange). On June 20, 2006, the Exchange closed and Schick, a Delaware corporation formed in 1997, was renamed Sirona Dental Systems, Inc. Even though Sirona Holding became a subsidiary of Schick upon the completion of the Exchange, Sirona Holding was deemed the acquiring corporation for accounting purposes because Luxco received a controlling ownership interest in the Company, Sirona Holding s designees constitute a majority of the members of the Company s board of directors and Sirona Holding s senior management represent a majority of the senior management of the Company.

Schick s business was founded in 1992 and it completed an initial public offering of its common stock on July 1, 1997. Our common stock is currently traded publicly on the NASDAQ Global Select Market. In

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connection with the Exchange, the Company changed its trading symbol to SIRO from SCHK. Previously, from September 16, 1999 through December 20, 2005, Schick s common stock was traded on the Over-the-Counter (OTC) Bulletin Board under the trading symbol SCHK.

Industry/Products

Overview

The global dental market encompasses the diagnosis, treatment and prevention of disease and ailments of the teeth, gums and supporting bone. This market has enjoyed steady growth over the past years, driven by a number of factors, including an increased desire for aesthetics, a demographic shift towards an aging population coupled with a desire to retain tooth structure later in life, growth in disposable income, a desire for more convenience on the part of both dentists and patients, a shift towards private pay, a greater need for dental preventative care and technological innovation.

The global dental market has been impacted by technological developments that allow a dentist to increase productivity. This is particularly important in markets where demand for dental services is increasing and the number of dentists remains relatively fixed. In addition, technological developments allow dentists to offer higher quality treatment to patients. We believe that the high-tech end of the dental market is growing at a faster pace than the overall dental market and that this trend will continue over time.

Recent technological advancements in the dental equipment industry include 3D radiography, digital radiography, CAD/CAM technology, intra oral cameras and periodontic instruments.

Dental equipment comprises the whole working environment of a dentist or dental technician, including the dentist s chair, lights, imaging systems and dental CAD/CAM systems, instruments, as well as practice furniture and other dental or laboratory equipment. Investments in dental equipment are capital intensive and the average product life cycle ranges between 10 20 years (shorter for instruments), depending on the nature and quality of the dental equipment.

Dental consumables comprise all materials and consumables utilized by the dental technician, oral surgeon, orthodontist or dentist in their daily work. These include precious metal alloys or ceramics and orthodontics, as well as other filling and impression materials.

Products

Our principal products can be generally classified into the following categories: Dental CAD/CAM Systems, Imaging Systems, Treatment Centers and Instruments.

Set forth below is a brief description of each of our segments. See Note 22 to our consolidated financial statements for revenues and gross profit by segment for each of the last three fiscal years, and assets by segment, at September 30, 2008 and 2007.

Dental CAD/CAM Systems

Dental CAD/CAM Systems address the worldwide market for dental restorations, which includes several types of restorations, such as inlays, onlays, veneers, crowns, bridges, copings and bridge frameworks made from ceramic, metal or composite blocks. The global market for dental restorations can be divided into two sub-segments: hand-made in-mouth filings and out-of-mouth pre-shaped restorations. CAD/CAM-produced ceramic restorations represent a small but growing part of the out-of-mouth restoration market. Although the number of out-of-mouth restorations prepared with CAD/CAM systems has increased over the last three years, the number of dental practitioners and dental laboratories using CAD/CAM technology worldwide is still low. For example, Sirona estimates that market penetration in the United States is approximately 9%, and in Germany approximately 11%.

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Sirona pioneered the application of high-tech CAD/CAM techniques to the traditional lab-based restoration process with the commercialization of the CEramic REConstruction, or CEREC, method. Sirona s CEREC system is an in-office application which enables the dentist to produce high quality restorations from ceramic material and insert them into the patient s mouth during a single appointment. CEREC represents an advantageous substitute for the traditional out-of-mouth pre-shaped restoration method, which requires a dentist to send a model of the damaged tooth to a dental laboratory, and therefore multiple patient visits. The system consists of an imaging unit and a milling unit. The imaging unit scans the damaged area, captures the image of the tooth or teeth requiring restoration and proposes the specifications for the restoration. The milling unit then mills the ceramic restoration to the required specifications based upon the captured image. The result is a biocompatible, non-metallic, natural-looking restoration made of durable, high-quality ceramic materials completed in a single treatment session. Independent studies indicate that CEREC ceramic restorations, in addition to the benefit of appearing natural-looking, are as durable as gold and can replace conventional restoration materials for most procedures. In fiscal year 2003, Sirona launched its CEREC 3 product, which has been periodically updated, including enhanced software applications. In fiscal year 2007, Sirona launched its next generation milling unit, the MC XL, as well as new Biogeneric software. The MC XL produces a high quality, precisely fitted restoration in half the time that the classic CEREC milling unit requires. The MC XL s fine tolerances are especially appreciated by doctors who demand the most precise restoration possible. Both the MC XL and the classic milling unit are compatible with all CEREC 3 units, allowing a smooth transition to the new technology for existing CEREC owners who wish to upgrade. Additionally, Sirona offers a service contract on its CEREC product which includes software updates and upgrades on a when-and-if-available basis and maintenance on software-related hardware.

In addition to CEREC, Sirona also offers the products inLab and inEos for dental laboratories. These products are designed to improve efficiency and reduce costs for the dental lab. inLab scans the model received from the dentist and mills the ceramic restoration, such as crown copings, bridge frameworks from ceramic or composite blocks, to the specifications of the captured image. In fiscal year 2007, Sirona launched its next generation inLab unit, the inLab MC XL. The new unit features a modern, elegant design with solid, heavy-duty construction. Milling performance and precision has been optimized and milling time as been considerably reduced. The inEos scanner, which was launched in 2005, is a high speed scanner which produces 3D digital images from a single tooth up to a jaw, directly from the plaster model. The inEos product has scanning times of less than 10 seconds, a significant factor which enhances productivity.

In 2004, Sirona started its central restoration service business for copings and bridge-frameworks in Germany and expanded service to the United States in 2006. This service allows dental labs to scan a plaster model received from the dentist and transmit the digital image directly to Sirona via the internet, where the bridge or coping is created at a central manufacturing site, with the final product shipped directly to the lab.

In 2008, we expanded our CEREC offering through the introduction of CEREC Connect. CEREC Connect is a web based service that allows the digital impression acquired through the CEREC acquisition unit to be transferred electronically to InLab laboratories. The laboratories can use this data to create final restorations. Many restorations produced by a laboratory can be produced through the CEREC Connect system eliminating the need to take a physical impression in these cases.

The Dental CAD/CAM Systems segment contributed 31%, 32% and 35% to Sirona s revenue for the fiscal years ended September 30, 2008, 2007 and 2006, respectively.

Imaging Systems

Imaging Systems comprise a broad range of equipment for diagnostic imaging in the dental practice, using both film-based and digital technologies. Sirona has developed a comprehensive range of imaging systems for panoramic and intra-oral applications. This allows the dentist to accommodate the patient in a more efficient manner.

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Intra-oral x-ray equipment uses image-capture devices (film or sensor), which are inserted into the mouth behind the diagnostic area, and typically take images of one or two teeth. Panoramic x-ray equipment produces images of the entire jaw structure by means of an x-ray tube and an image capture device, which rotates around the head.

In 2004, Sirona introduced its next generation of digital panoramic x-ray systems, the Orthophos XG line. The flagship model, the Orthophos XG Plus, provides specialists, orthodontists, oral surgeons and implantologists with over 30 programs and a wide variety of diagnostic possibilities. Other models of the family include the Orthophos XG 5, which is designed for general dental practitioners, and the basic model Orthophos XG 3.

As a result of the Exchange, Sirona expanded its imaging system product line to include Schick s CDR (computed digital radiography) system, the leading intra-oral digital imaging system in the United States. Schick s product line includes an imaging sensor based on CMOS technology and the Schick Pan, a digital panoramic unit.

In fiscal year 2007, Sirona introduced its GALILEOS Comfort 3-D imaging unit. Today, three-dimensional imaging is offering the field of dentistry previously undreamed-of diagnostic and therapeutic options in the fields of surgery, prosthetics, orthodontics, and restorative dentistry. GALILEOS was created to bring these options to life and integrate them efficiently into routine dental practices. In July 2008 Sirona launched GALILEOS Compact, which is specifically tailored to meet the needs of the general practitioner and also has the ability to display traditional 2-D panoramic digital images.

The Imaging Systems segment contributed 34%, 34% and 26% to Sirona s revenue for the fiscal years ended September 30, 2008, 2007 and 2006, respectively, making this segment the largest contributor to Sirona s revenue in fiscal year 2008 and 2007.

Treatment Centers

Treatment Centers comprise a broad range of products from basic dentist chairs to sophisticated chair-based units with integrated diagnostic, hygiene and ergonomic functionalities, as well as specialist centers used in preventative treatment and for training purposes. Sirona offers specifically configured products to meet the preferences of dentists within each region in which it operates. Sirona s treatment center configurations and system integration are designed to enhance productivity by creating a seamless workflow within the dental practice. Sirona s centers therefore allow the dentist to both improve productivity and increase patient satisfaction, significant factors in adding value to his or her practice. In October 2004, Sirona acquired one of the leading Chinese manufacturers of basic treatment centers, located in Foshan (South China). These basic products will be manufactured both for the domestic Chinese market and for export markets.

In July 2008, Sirona launched its new TENEO Treatment Center, which combines industry-leading technology with a timeless design that provides both patient and dentist with the ultimate in convenience and comfort.

The Treatment Centers segment contributed 22%, 22% and 25% to Sirona s revenue for the fiscal years ended September 30, 2008, 2007 and 2006, respectively.

Instruments

Sirona offers a wide range of instruments, including handheld and power-operated handpieces for cavity preparation, endodontics, periodontology and prophylaxis. The instruments are supplemented by multi-function tips, supply and suction hoses, as well as care and hygiene systems for instrument preparation. Sirona s instruments are often sold as packages in combination with treatment centers. During the last two years, Sirona introduced several new products, including:

SIROLaser, a versatile, compact, convenient diode laser that can be used in endodontics, periodontology and oral surgery;

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PerioScan, an all-in-one ultrasonic scaling unit, enabling both diagnosis and treatment of dental calculus with a single device; and

SIROEndo, a root canal preparation unit that can be attached to any treatment center.

Sirona intends to continue to strengthen the position of its Instruments segment as a diversified supplier of high-quality, reliable, user-friendly and cost-efficient dental instruments.

The Instruments segment contributed 13%, 12% and 14% to Sirona s revenue for the fiscal years ended September 30, 2008, 2007 and 2006, respectively.

Manufacturing and Suppliers

Our main manufacturing and assembly activities are located in Bensheim, approximately 60 kilometers south of Frankfurt am Main, Germany. We also operate smaller manufacturing sites in New York, Italy, Denmark and China. All of our facilities are in good condition.

All of our manufacturing facilities maintain a Quality Management System that is registered to ISO 9001:2000 and ISO 13485:2003. Our New York and Bensheim facilities also maintain a Device Establishment Registration with the United States Food and Drug Administration.

Manufacturing consists primarily of assembly, systems integration and testing. We generally outsource manufacturing of parts and components used in the assembly of our products but own the design and tools used by our key component suppliers. We do, however, manufacture most of the precision parts used for our instruments and we also operate an Electronic Center, for the supply of electronic boards and components.

We purchase various components for our products from a number of outside suppliers. We currently have established relationships with approximately 1,300 suppliers, of which we view approximately 390 as key suppliers. Each supplier is selected according to stringent quality criteria, which are reviewed regularly. In general, we do not believe we are dependent on one or a small group of suppliers and believe we could locate alternative suppliers if needed. Some of our suppliers, however, are single source in order to allow for enhanced quality assurance and potential for joint product development. The need to replace one of our single source suppliers could cause a disruption in our ability to timely deliver certain of our products. The Company is dependent upon a limited number of suppliers for critical components. If these suppliers delay or discontinue the manufacture of these components, the Company may experience delays in shipments, increased costs and cancellation of orders for its products. See ITEM 1A Risk Factors.

Sales and Marketing

Our sales and marketing efforts are directed through regional managers who oversee our sales professionals. These professionals work closely with our distribution partners to maximize the efficiency and productivity of their sales efforts. Our marketing initiatives are focused on highlighting Sirona s leading role as a high-tech systems provider and industry innovator. In order to promote our brand and increase client loyalty, our distribution partners are supported through wide ranging advertising activities. In addition, we are a key presenter at all major dental exhibitions, which are critical forums for raising brand awareness and new product introductions. Lastly, our product information is actively made available to business publications, dentists, journals, professional organizations and dental schools and our website (www.Sirona.com) is an important interactive platform for end-users as well as for distributors.

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Distribution

Sirona distributes its products globally to dental practices, clinics and laboratories through an international network of more than 300 distributors. See Note 22 to our consolidated financial statements for a description of our net sales and long-lived assets by geographic region for the last three fiscal years. Because distributors typically cover both dental equipment and consumables, they have regular contact with the dentist and are therefore optimally positioned to identify new equipment sale opportunities. Sirona s primary distributors in the United States are Patterson Companies and Henry Schein, two of the world s largest dental distributors. Outside of the United States, Henry Schein is the company s largest distributor, and, along with Pluradent, primarily distributes for Sirona in Europe. Patterson Companies and Henry Schein accounted for 27% and 15%, respectively, of Sirona s worldwide revenue for the twelve months ended September 30, 2008. Sirona distributes elsewhere through a well developed network of independent regional distributors. Sirona works closely with its distributors by training their technicians and sales representatives with respect to its products. With over 5,500 sales and service professionals trained each year, Sirona is able to ensure high standards of quality in after-sale service and the best marketing of its products. The success of Sirona s products is evidenced by their importance to its distribution partners, and such products are in many cases are among their best selling offerings.

On April 27, 1998, Sirona and Patterson Companies entered into an exclusive distribution agreement (the Distribution Agreement) pursuant to which Patterson was appointed as the exclusive distributor of Sirona s CEREC CAD/CAM products within the United States and Canada. Under the terms of the Distribution Agreement, Patterson s exclusivity was to terminate on September 30, 2007. On June 30, 2005, Sirona and Patterson entered into an amendment of the Distribution Agreement which extended Patterson s exclusivity from October 1, 2007 through September 30, 2017. As consideration for the extension of its exclusivity, Patterson agreed to make a one-time payment to Sirona in the amount of $100 million (the Exclusivity Fee). In July 2005, Patterson paid the Exclusivity Fee, in its entirety, to Sirona. The full amount of the Exclusivity Fee was recorded as deferred income and is being recognized on a straight-line basis commencing on October 1, 2007. In the event of termination of the Distribution Agreement (a) due to force majeure, (b) by Patterson due to Sirona s insolvency, or (c) by Sirona as a result of a failure by Patterson to meet its performance obligations, Sirona would be required to refund to Patterson a portion of the Exclusivity Fee as liquidated damages. The amount of the Exclusivity Fee required to be refunded declines by $15 million per year in each of fiscal 2008 through 2012 and by $5 million per year thereafter. In the event of termination by Patterson due to a breach by Sirona of its exclusivity obligations, the unearned portion of the Exclusivity Fee (as determined on a straight-line basis beginning in fiscal 2008) must be refunded to Patterson as liquidated damages. The extension did not modify or alter the underlying provisions of the companies agreement through 2007, including the performance criteria necessary to maintain the exclusivity. The performance criteria are benchmark thresholds which afford Sirona the opportunity to abandon the exclusivity or to terminate the agreement with Patterson, but do not create minimum purchase obligations under a take-or-pay arrangement.

In April 2000, Schick and Patterson entered into an exclusive distribution agreement covering the United States and Canada; and as of May 1, 2000, Schick began marketing and selling its CDR dental products in the United States and Canada through Patterson. This contract was amended in July 2005 and March 2007 and is due to expire on December 31, 2009 but provides that the parties will meet before expiration of the term to discuss additional renewals of three years.

Competition

Competition in the global dental market is fragmented by both geography and products. We compete with a variety of companies, including large international companies as well as smaller companies that compete regionally or on a more narrow product line. Sirona competes on the basis of its comprehensive and innovative product line and its global distribution network.

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Research and Development

Sirona commits significant resources to research and development, with a particular focus on developing products that offer new diagnostic and treatment options, while increasing user comfort and streamlining process efficiency. Sirona spent approximately $49 million, $47 million and $33 million on research and development activities in the years ended September 30, 2008, 2007 and 2006, respectively, which represented more than 6% of Sirona s total revenue in each year. Sirona employs 197 people in its global research and development departments. Sirona also cooperates in its research efforts with partners in research facilities and dental practices around the world.

Patents, Trade Secrets and Proprietary Rights

We seek to protect our intellectual property through a combination of patent, trademark and trade secret protection. We believe that our future success will depend in part on our ability to obtain and enforce patents for our products and processes, preserve our trade secrets and operate without infringing the proprietary rights of others.

Patents

We have an active corporate patent program, the goal of which is to secure patent protection for our technology. Sirona owns and maintains approximately 1,000 patents and patent applications throughout the world. The patents expire at various dates through 2025. We also license or sublicense some of the technology used in our products from third parties.

Trademarks

We generally attempt to build brand awareness of our products through the use of trademark registrations. Sirona, CEREC, Orthophos, Heliodent, inLab and CDR are some of our key registered trademarks. In addition, we have common law trademark rights in several other names we use commercially in connection with our products.

Trade Secrets

In addition to patent protection, we own trade secrets and proprietary know-how, which we seek to protect, in part, through appropriate agreements with employees, and, to a limited degree, employment agreements with appropriate individuals. These agreements generally allow assignment of confidential information developed by or made known to the individual by the Company during the course of the individual s relationship with the Company as confidential and not to be disclosed to third parties, except in specific limited circumstances. The agreements also generally assign to the Company all inventions conceived by the individual in the course of rendering services to the Company. However, there can be no assurance that the Company will be successful in enforcing this policy in each case, that the Company would have adequate remedies available for any breach or that the Company s trade secrets will not otherwise become known to, or independently developed by, its competitors.

Regulation

Medical Devices

Most of our products require certain forms of regulatory clearance, including, but not limited to, marketing clearance by the United States Food and Drug Administration (the FDA) in accordance with the Federal Food, Drug and Cosmetic Act, as amended (the { FD&C Act) and by our Notified Body in accordance with the European Union s Medical Device Directive 93/42/EEC (MDD).

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The FDA and MDD review process typically requires extended proceedings pertaining to product safety and efficacy. We believe that our future success will depend to a large degree upon commercial sales of improved versions of our current products and sales of new products; we will not be able to market such products in the U.S. or in the European Union without FDA or MDD clearance, respectively. There can be no assurance that any products developed by us in the future will be granted clearance by applicable regulatory authorities or that additional regulations will not be adopted or current regulations amended in such a manner as to adversely affect us.

Pursuant to the FD&C Act, the FDA regulates the introduction, manufacture, advertising, labeling, packaging, marketing and distribution of, and record-keeping for dental devices. The FDA classifies medical devices intended for human use into three classes: Class I, Class II, and Class III. The Company s products are classified by the FDA into Class I or II that renders them subject only to general controls that apply to all medical devices, in particular regulations regarding alteration, misbranding, notification, record-keeping and good manufacturing practices.

The FD&C Act further provides that, unless exempted by regulation, medical devices may not be commercially distributed in the U. S. unless they have been cleared by the FDA. There are two review procedures by which medical devices can receive such clearance. Some products may qualify for clearance under a Section 510(k) procedure, in which the manufacturer submits to the FDA a pre-market notification that it intends to begin marketing the product, and shows that the product is substantially equivalent to another legally marketed product (i.e., that it has the same intended use and that it is as safe and effective as a legally marketed device, and does not raise different questions of safety and effectiveness than does a legally marketed device). Certain Class I devices are exempt from the 510(k) pre-market notification requirement and manufacturers of such products may proceed to market without any submission to the FDA. In some cases, the 510(k) notification must include data from human clinical studies.

Marketing in the U.S. may commence once the FDA issues a clearance letter finding such substantial equivalence. According to FDA regulations, the agency has 90 days in which to respond to a Class I or II 510(k) notification. There can be no assurance, however, that the FDA will provide a timely response, or that it will reach a finding of substantial equivalence.

If a product does not qualify for the 510(k) procedure (either because it is not substantially equivalent to a legally marketed device or because it is a Class III device), the FDA must approve a Pre-Market Approval (PMA) application before marketing can begin. PMA applications must demonstrate, among other things, that the medical device is safe and effective. A PMA application is typically a complex submission that includes the results of clinical studies. Preparation of such an application is a detailed and time-consuming process. Once a PMA application has been submitted, the FDA s review process may be lengthy and include requests for additional data. By statute and regulation, the FDA may take 180 days to review a PMA application, although such time may be extended. Furthermore, there can be no assurance that the FDA will approve a PMA application.

The products that we distribute in the European Union bear the CE Mark, a European Union symbol of compliance with the MDD. In order to market our products in the member countries of the European Union, it is necessary that those products conform to the requirements of the MDD. Our Bensheim facility which is engaged in the manufacturing of Class IIa and Class IIb medical devices as defined by the MDD is ISO 13485 certified. It is also necessary that our products comply with any revisions which may be made to these standards or the MDD.

Medical devices are subject to ongoing regulatory oversight by the FDA and a Notified Body. The FD&C Act requires that all medical device manufacturers and distributors register annually with the FDA and submit a list of those medical devices which they distribute commercially. The MDD requires that Class IIa devices or higher bear a CE mark with a Notified Body Number. The FD&C Act and the MDD also requires that all

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manufacturers of medical devices comply with labeling requirements and manufacture their products and maintain their documents in a prescribed manner with respect to manufacturing, testing, and quality control activities. The FDA s Medical Device Reporting regulation and the MDD subject medical devices to post-market reporting requirements for death or serious injury, and for certain malfunctions that would be likely to cause or contribute to a death or serious injury if malfunction were to recur. In addition, the FDA and the MDD prohibit a device which has received marketing clearance from being marketed for applications for which marketing clearance has not been obtained. Furthermore, the FDA generally requires that medical devices not cleared for marketing in the U.S. receive FDA marketing clearance before they are exported, unless an export certification has been granted. The FDA and the ISO Notified Bodies regularly inspect our registered and/or certified facilities.

Failure to comply with applicable regulatory requirements can, among other consequences, result in fines, injunctions, civil penalties, suspensions or loss of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. In addition, governmental regulations may be established that could prevent or delay regulatory clearance of our products. Delays in receipt of clearance, failure to receive clearance or the loss of previously received clearance would have a material adverse effect on our business, financial condition and results of operations.

Environmental, Health and Safety Matters

In addition to the laws and regulations discussed above, we are subject to government regulations applicable to all businesses, including, among others, regulations related to occupational health and safety, workers benefits and environmental protection. The extent of government regulation that might result from any future legislation or administrative action cannot be accurately predicted. Failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

Employees

As of September 30, 2008, the Company had 2,388 employees. The Company believes that its relations with its employees are good. No Company employees are represented by labor unions or are subject to a collective bargaining agreement in the United States. Approximately 30% of our German employees are members of the IG Metall union. We have not experienced any work stoppages due to labor disputes.

Executive Officers

See Part III, Item 10 of this Annual Report on Form 10-K Report for information about the Executive Officers of the Company.

Available Information

Information about the Company s products and services, stockholder information, press releases and filings with the Securities and Exchange Commission (SEC) can be found on the Company s Internet website at ***http://www.Sirona.com***. The information contained on our website is for informational purposes only and is not incorporated by reference into this Annual Report on Form 10-K. The Company s Annual Reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and other SEC filings, and any amendments to such reports and filings, are available free of charge at the Investor Relations section of the Company s website as soon as reasonably practical after such material is filed with, or furnished to, the SEC.

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ITEM 1A. RISK FACTORS

These risk factors may be important to understanding any statement in this Annual Report on Form 10-K or elsewhere. The following information should be read in conjunction with Management s Discussion and Analysis (MD&A), and the consolidated financial statements and related notes incorporated by reference in this report.

Our businesses routinely encounter and address risks, some of which will cause our future results to be different sometimes materially different than we presently anticipate. Discussion about the material operational risks that our businesses encounter can be found in Management s Discussion and Analysis (MD&A), in the business descriptions in Item 1 of this Form 10-K and in previous SEC filings. Below, we have described our present view of the material risks facing our business.

We must develop new products and enhancements to existing products to remain competitive.

We are currently developing new products and enhancements to existing products. We cannot assure you that we will initiate, continue with and/or succeed in our efforts to develop or enhance such products. It is expected that we will file 510(k) applications with the Food and Drug Administration, or FDA, and similar filings with governmental authorities in other countries in connection with our future products and certain of our future product enhancements. There can be no assurance that we will file applications for or obtain regulatory approval from the FDA, either in the form of a pre-market clearance or a 510(k) clearance, for any of our future products, or that in order to obtain FDA clearance, we will not be required to submit additional data or meet additional FDA requirements that may substantially delay the application process and result in substantial additional expense. In addition, such pre-marketing clearance, if obtained, may be subject to conditions on marketing or manufacturing which could impede our ability to manufacture and/or market our products. There can be no assurance that any new products will be developed by us, or if developed, will be approved by, or receive marketing clearance from, applicable domestic and/or international governmental or regulatory authorities. If we are unable to develop, obtain regulatory approval for and market new products and enhancements to existing products, our business and results of operations could be harmed.

Our business may be negatively affected if we do not continue to adapt to rapid technological change, evolving industry standards and new product introductions.

The market for our products is characterized by rapid and significant technological change, evolving industry standards and new product introductions. Our products require significant planning, design, development and testing which requires significant capital commitments and investment by us. There can be no assurance that our products or proprietary technologies will not become noncompetitive or obsolete as a result of technological change, evolving industry standards or new product introductions or that we will be able to generate any economic return on our investment in product development. If our products or technologies become noncompetitive or obsolete, our business could be negatively affected.

Our profitability would be negatively impacted by adverse general macroeconomic conditions in the geographic markets in which we sell our products.

Our profitability depends in part on the varying economic and other conditions of the global dental market, which in turn is impacted by general macroeconomic conditions in the geographic markets in which we sell our products. Growth in the global dental market over the past few years has been driven by a number of factors, including a growth in disposable income, a shift towards private pay, a greater need for dental preventative care and an increased emphasis on aesthetics. Demand for our products would be negatively impacted by a decline in the economy in general, including interest rate and tax changes, that impact the financial strength of our customers, as well as by changes in the economy in general that reduce disposable income among dental consumers in the markets we sell our products, which would in turn reduce the demand for preventative and aesthetic dental services.

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The recent disruptions in the overall world economy and financial markets could reduce disposable income among dental consumers and negatively affect the demand for dental services, which could be harmful to our financial position and results of operations. Furthermore, there can be no assurances that government responses to the disruptions in the financial markets will stabilize the markets or increase liquidity and the availability of credit for our customers. Difficult economic conditions may also result in a higher rate of losses on our accounts receivable. As a result, our business, results of operations or financial condition could be materially adversely affected.

We are dependent upon a limited number of distributors for a significant portion of our revenue and loss of these key distributors could result in a loss of a significant amount of our revenue.

Historically, a substantial portion of our revenue has come from a limited number of distributors. For example, Patterson Dental Company, Inc. accounted for 27% of revenue for the fiscal year ended September 30, 2008. In addition, 15% of our revenue for the fiscal year ended September 30, 2008 was attributable to sales to Henry Schein, Inc. It is anticipated that Patterson and Henry Schein will continue to be the largest contributors to our revenue for the foreseeable future. There can be no assurance that Patterson and Henry Schein will purchase any specified minimum quantity of products from us or that they will continue to purchase any products at all. If Patterson or Henry Schein cease to purchase a significant volume of products from us, it could have a material adverse effect on our results of operations and financial condition.

We are dependent upon a limited number of suppliers for critical components. If these suppliers delay or discontinue the manufacture of these components, we may experience delays in shipments, increased costs and cancellation of orders for our products.

We rely on key suppliers for various critical components and procure certain components from outside sources which are sole suppliers. The availability and prices of these components may be subject to change due to interruptions in production, changing market conditions and other events. Any delays in delivery of or shortages in these components could interrupt and delay manufacturing of our products and result in the cancellation of orders for our products. In addition, these suppliers could discontinue the manufacture or supply of these components at any time. We may not be able to identify and integrate alternative sources of supply in a timely fashion or at all. Any transition to alternate suppliers may result in delays in shipment and increased expenses and may limit our ability to deliver products to our customers. If we are unable to develop reasonably-priced alternative sources in a timely manner, or if we encounter delays or other difficulties in the supply of such products and other materials from third parties, our business and results of operations may be harmed. In past years, semiconductors have been subject to significant price fluctuations.

While we have, in the past, attempted to mitigate the effects of such potential fluctuations, we cannot assure you that we will continue to do so or that we will be able to successfully mitigate the effect of future price increases on our results of operations and financial condition.

Competition in the markets for our products is intense and we may not be able to compete effectively.

Competition relating to our current products is intense and includes various companies, both within and outside of the United States. We anticipate that competition for our future products will also be intense and include various companies, both within and outside of the United States, Asia and Europe. Our competitors and potential competitors include large companies with substantially greater financial, sales and marketing, and technical resources, larger and more experienced research and development staffs, more extensive physical facilities and substantially greater experience in obtaining regulatory approvals and in marketing products than we have. In addition, we cannot assure you that our competitors are not currently developing, or will not attempt to develop, technologies and products that are more effective than those being developed by us or that would otherwise render our existing and new technology and products obsolete or noncompetitive. We may not be able to compete successfully and may lose market share to our competitors.

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Our failure to obtain issued patents and, consequently, to protect our proprietary technology, could hurt our competitive position.

Our success will depend in part on our ability to obtain and enforce claims in our patents directed to our products, technologies and processes, both in the United States and in other countries. Risks and uncertainties that we face with respect to our patents and patent applications include the following:

- the pending patent applications that we have filed, or to which we have exclusive rights, may not result in issued patents or may take longer than we expect to result in issued patents;
- the allowed claims of any patents that issue may not provide meaningful protection;
- we may be unable to develop additional proprietary technologies that are patentable;
- the patents licensed or issued to us may not provide a competitive advantage;
- other companies may challenge patents licensed or issued to us;
- disputes may arise regarding inventions and corresponding ownership rights in inventions and know-how resulting from the joint creation or use of intellectual property by us and our respective licensors; and
- other companies may design around the technologies patented by us.

If we cannot obtain or maintain approval from government agencies, we will not be able to sell our products.

We must obtain certain approvals by, and marketing clearances from, governmental authorities, including the FDA and similar health authorities in foreign countries to market and sell our products in those countries. These regulatory agencies regulate the marketing, manufacturing, labeling, packaging, advertising, sale and distribution of medical devices. The FDA enforces additional regulations regarding the safety of X-ray emitting devices. Our products are currently regulated by such authorities and certain of our new products will require approval by, or marketing clearance from, various governmental authorities, including the FDA. Various states also impose similar regulations.

The FDA review process typically requires extended proceedings pertaining to the safety and efficacy of new products. A 510(k) application is required in order to market a new or modified medical device. If specifically required by the FDA, a pre-market approval, or PMA, may be necessary. Such proceedings, which must be completed prior to marketing a new medical device, are potentially expensive and time consuming. They may delay or hinder a product s timely entry into the marketplace. Moreover, there can be no assurance that the review or approval process for these products by the FDA or any other applicable governmental authority will occur in a timely fashion, if at all, or that additional regulations will not be adopted or current regulations amended in such a manner as will adversely affect us. The FDA also oversees the content of advertising and marketing materials relating to medical devices which have received FDA clearance. Failure to comply with the FDA s advertising guidelines may result in the imposition of penalties.

We are also subject to other federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices. The extent of government regulation that might result from any future legislation or administrative action cannot be accurately predicted. Failure to comply with regulatory requirements could have a material adverse effect on our business.

Similar to the FDA review process, the EU review process typically requires extended proceedings pertaining to the safety and efficacy of new products. Such proceedings, which must be completed prior to marketing a new medical device, are potentially expensive and time consuming and may delay or prevent a product s entry into the marketplace.

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Our revenue and operating results are likely to fluctuate.

Our quarterly operating results have varied in the past and our operating results are likely to continue to fluctuate in the future. These variations result from a number of factors, many of which are substantially outside of our control, including:

- the timing of new product introductions by us and our competitors;
- timing of industry tradeshows;
- changes in relationships with distributors;
- developments in government reimbursement policies;
- changes in product mix;
- our ability to supply products to meet customer demand;
- fluctuations in manufacturing costs; and
- income tax incentives.

Our financial results may be adversely affected by fluctuations in foreign currency exchange rates.

We are exposed to currency exchange risk with respect to the U.S. Dollar in relation to the Euro, because a large portion of our revenue and expenses are denominated in Euros. While we enter into hedging arrangements to protect our business against certain currency fluctuations, these hedging arrangements from time to time do not provide comprehensive protection. We monitor changes in our exposure to exchange rate risk that result from changes in our situation. If we do not enter into effective hedging arrangements in the future, our results of operations and prospects could be materially and adversely affected.

Our hedging transactions may expose us to loss or limit our potential gains.

As part of our risk management program, we use foreign currency exchange forward contracts. While intended to reduce the effects of exchange rate fluctuations, these transactions may limit our potential gains or expose us to loss. Should our counterparties to such transactions or the sponsors of the exchanges through which these transactions are offered fail to honor their obligations due to financial distress or otherwise, we would be exposed to potential losses or might not be able to recover anticipated gains from these transactions.

We enter into the foreign currency exchange forwards as economic hedges of trade commitments or anticipated commitments denominated in currencies other than the functional currency to mitigate the effects of changes in currency rates. Although we do not enter into these instruments for trading purposes or speculation, and although our management believes all of these instruments are economically effective as hedges of underlying physical transactions, these foreign exchange commitments are dependent on timely performance by our counterparties. Their failure to perform could result in our having to close these hedges without the anticipated underlying transaction and could result in losses if foreign currency exchange rates have changed.

Our substantial indebtedness could have material adverse consequences for our business, cash flow, financial condition and results of operations.

We are a highly leveraged company, with total bank debt to unrelated parties of $551.6 million as of September 30, 2008. This substantial level of indebtedness, combined with our other financial obligations and contractual commitments, could have important consequences to our business. For example, it could:

increase the risk that we would be unable to generate cash sufficient to pay amounts due on our indebtedness;

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make us more vulnerable to adverse changes in general economic, industry and competitive conditions and to adverse changes in government regulation;

require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, including any indebtedness we may incur in the future, thereby reducing the availability of our cash flows to fund working capital, capital expenditures, research and development, acquisitions and other general corporate purposes;

limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operated;

place us at a competitive disadvantage compared to our competitors that have less debt; and

limit our ability to borrow additional amounts or to sell capital stock for working capital, capital expenditures, research and development, acquisitions, debt service requirements or other general corporate purposes.

Any of these factors could have a material adverse effect on us.

Restrictive covenants and conditions contained in our senior credit agreement impose significant operating and financial restrictions on our business.

Our senior credit agreement contains a number of restrictive covenants and conditions that impose significant operating and financial restrictions on our business, including restrictions on our ability to take actions that may be in the best interests of the business. These restrictions and conditions include a mandatory prepayment on a change in control or sale of all or substantially all assets, as well as significant restrictions on mergers and on any business acquisition. Other covenants limit changes to our business, lending activities, investments including joint ventures, further indebtedness, and the payment of dividends and capital share redemptions. The financial covenants require that we maintain a debt coverage ratio of consolidated total net debt to consolidated adjusted EBITDA of no more than 3.75 to 1, declining gradually to 2.50 to 1, and a cash interest coverage ratio of consolidated adjusted EBITDA to cash interest costs of 4.00 to 1 or greater. Failure to comply with these covenants will result in a default under the terms of our senior credit agreement and could result in acceleration of this indebtedness.

If we lose our key management personnel or are unable to attract and retain qualified personnel, it could adversely affect our results of operations or delay or hurt our research and product development efforts.

Our success is dependent, in part, upon our ability to hire and retain management, sales, technical, research and other personnel who are in high demand and are often subject to competing employment opportunities. It is possible that the loss of the services of one or a combination of our senior executives or key managers could have an adverse effect on our operations.

We may experience difficulties managing our growth, which could adversely affect our results of operations.

It is expected that we will grow in certain areas of our operations as we develop and, assuming receipt of the necessary regulatory approvals, market our products. We will therefore need to recruit personnel, particularly sales and marketing personnel, and expand our capabilities, which may strain our managerial, operational, financial and other resources. To compete effectively and manage our growth, we must:

train, manage, motivate and retain a growing employee base;

accurately forecast demand for, and revenue from, our product candidates; and

expand existing operational, financial and management information systems to support our development and planned commercialization activities and the multiple locations of our offices.

Our failure to manage these challenges effectively could materially harm our business.

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Because we operate in markets outside of the United States and Europe, we are subject to additional risks.

We anticipate that sales outside of the United States and Europe will continue to account for a significant percentage of our revenue. Such revenue is subject to a number of uncertainties, including but not limited to the following:

- economic and political instability;
- import or export licensing requirements;
- trade restrictions;
- longer payment cycles;
- unexpected changes in regulatory requirements and tariffs;
- fluctuations in currency exchange rates;
- potentially adverse tax consequences; and
- potentially weak protection of intellectual property rights.

These risks may impair our ability to generate revenue from our sales efforts. In addition, many countries outside of the United States and Europe have their own regulatory approval requirements for the sale of products. As a result, the introduction of new products, and our continued sale of existing products, into these markets could be prevented and/or costly and/or time-consuming, and we cannot assure you that we will be able to obtain the required regulatory approvals on a timely basis, if at all.

We may be exposed to liabilities under the Foreign Corrupt Practices Act and any determination that we violated the Foreign Corrupt Practices Act could have a material adverse effect on our business.

Our operations outside the United States are subject to the Foreign Corrupt Practices Act (the FCPA) which generally prohibits U.S. companies and their intermediaries from bribing foreign officials for the purpose of obtaining or keeping business or otherwise obtaining favorable treatment. In particular, we may be held liable for actions taken by our strategic or local partners even though such partners are foreign companies that are not subject to the FCPA. Any determination that we violated the FCPA could result in sanctions that could have a material adverse effect on our business.

We may be a party to legal actions that are not covered by insurance.

We may be a party to a variety of legal actions, such as employment and employment discrimination-related suits, employee benefit claims, breach of contract actions, tort claims, stockholder suits, including securities fraud, governmental investigations and intellectual property related litigation. In addition, because of the nature of our business, we are subject to a variety of legal actions relating to our business operations. In some cases, substantial punitive damages may be sought. Although we have maintained insurance coverage for some of these potential liabilities, we cannot assure you that such insurance coverage will continue to be available or, if available, that it can be obtained in sufficient amounts or at reasonable cost or that it will be sufficient to cover any claims that may arise. Other potential liabilities may not be covered by insurance, insurers may dispute coverage, or the amount of insurance may not be sufficient to cover the damages awarded. In addition, certain types of damages, such as punitive damages, may not be covered by insurance and/or insurance coverage for all or certain forms of liability may become unavailable or prohibitively expensive in the future.

Our profitability could suffer if third parties infringe upon our proprietary technology.

Our profitability could suffer if third parties infringe upon our intellectual property rights or misappropriate our