COOPER COMPANIES INC
Form 10-K
December 26, 2006
Table of Contents

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF

THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED OCTOBER 31, 2006

COMMISSION FILE NO. 1-8597

THE COOPER COMPANIES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-2657368**
(State or other jurisdiction of incorporation)	**(I.R.S. Employer Identification No.)**
6140 Stoneridge Mall Road, Suite 590	
Pleasanton, California	**94588**
(Address of principal executive offices)	**(Zip Code)**

925-460-3600

(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, $.10 par value, and associated rights	**New York Stock Exchange**

Securities registered pursuant to Section 12(g) of the Act:

None

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

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, 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 or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act (check one).

Large accelerated filer x Accelerated filer ¨ Non-accelerated filer ¨

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

On November 30, 2006, there were 44,296,628 shares of the registrant s common stock held by non-affiliates with aggregate market value of $2.4 billion on April 30, 2006, the last day of the registrant s most recently completed second fiscal quarter.

Number of shares outstanding of the registrant s common stock, as of November 30, 2006: 44,982,833

Documents Incorporated by Reference:

Document	Part of Form 10-K
Portions of the Proxy Statement for the Annual Meeting of Stockholders scheduled to be held March 20, 2007	Part III

Table of Contents

THE COOPER COMPANIES, INC. AND SUBSIDIARIES

Annual Report on Form 10-K

for the Fiscal Year Ended October 31, 2006

Table of Contents

Table of Contents

PART I

Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements as defined by the Private Securities Litigation Reform Act of 1995. These include certain statements about the integration of the Ocular Sciences, Inc. (Ocular) business, our capital resources, performance and results of operations. In addition, all statements regarding anticipated growth in our revenue, anticipated market conditions, planned product launches and results of operations are forward-looking. To identify these statements look for words like believes, expects, may, will, should, could, seeks, intends, plans, estimates or anticipates and similar words or phrases. Discussions of strategy, plans or intentions often conta forward-looking statements. Forward-looking statements necessarily depend on assumptions, data or methods that may be incorrect or imprecise and are subject to risks and uncertainties. These include the risk that acquired businesses will not be integrated successfully into CooperVision (CVI) and CooperSurgical (CSI), including the risk that The Cooper Companies, Inc. (Cooper, the Company, we or similar pronouns) may not continue to realize anticipated benefits from its cost-cutting measures and inherent in accounting assumptions made in the acquisitions; the risks that CVI s new products will be delayed or not occur at all, or that sales will be limited following introduction due to manufacturing constraints or poor market acceptance; risks related to implementation of information technology systems covering the Company s businesses and any delays in such implementation or other events which could result in management having to report a material weakness in the effectiveness of the Company s internal control over financial reporting in its 2006 annual report on Form 10-K; risks with respect to the ultimate validity and enforceability of the Company s patent applications and patents and the possible infringement of the intellectual property of others; and the impact of the NeoSurg Technologies, Inc., Inlet Medical, Inc. and Lone Star Medical Products, Inc. acquisitions on CSI s and the Company s revenue, earnings and margins.

Events, among others, that could cause our actual results and future actions of the Company to differ materially from those described in forward-looking statements include major changes in business conditions, a major disruption in the operations of our manufacturing or distribution facilities, new competitors or technologies, significant delays in new product introductions, the impact of an undetected virus on our computer systems, acquisition integration delays or costs, increases in interest rates, foreign currency exchange exposure, investments in research and development and other start-up projects, variations in stock option expenses caused by stock price movement or other assumptions inherent in accounting for stock options, dilution to earnings per share from acquisitions or issuing stock, worldwide regulatory issues, including product recalls and the effect of healthcare reform legislation, cost of complying with corporate governance requirements, changes in tax laws or their interpretation, changes in geographic profit mix effecting tax rates, significant environmental cleanup costs above those already accrued, litigation costs including any related settlements or judgments, the adverse effects of natural disasters on patients, practitioners and product distribution, cost of business divestitures, changes in expected utilization of recognized net operating loss carry forwards, the requirement to provide for a significant liability or to write off a significant asset, including impaired goodwill, changes in accounting principles or estimates and other events described in our Securities and Exchange Commission filings, including the Business and Risk Factors sections in this Annual Report on Form 10-K for the fiscal year ended October 31, 2006. We caution investors that forward-looking statements reflect our analysis only on their stated date. We disclaim any intent to update them except as required by law.

Table of Contents

Item 1. *Business*.

The Cooper Companies, Inc. (Cooper or the Company), a Delaware corporation organized in 1980, develops, manufactures and markets healthcare products, primarily medical devices through its two business units, CooperVision, Inc. (CVI) and CooperSurgical, Inc. (CSI).

CVI develops, manufactures and markets a broad range of contact lenses for the worldwide vision correction market. Its leading products are disposable spherical and specialty contact lenses.

CVI is a leading manufacturer of toric lenses, which correct astigmatism, multifocal lenses for presbyopia (blurring near vision due to advancing age), cosmetic lenses that change or enhance the appearance of the color of the eye and spherical lenses that correct the most common visual defects. CVI s products are primarily manufactured at its facilities located in the United Kingdom, Puerto Rico and Norfolk, Virginia. CVI distributes products out of Rochester, New York, and the United Kingdom and various smaller international distribution facilities.

CSI develops, manufactures and markets medical devices, diagnostic products and surgical instruments and accessories used primarily by gynecologists and obstetricians. CSI s products are primarily manufactured and distributed at its facility in Trumbull, Connecticut.

CVI and CSI each operate in highly competitive environments. Competition in the medical device industry involves the search for technological and therapeutic innovations in the prevention, diagnosis and treatment of disease. Both of Cooper s businesses compete primarily on the basis of product quality and differentiation, technological benefit, service and reliability.

COOPERVISION

We estimate that the worldwide soft contact lens market will grow about 5 percent during calendar 2006 to about $4.8 billion annually. In the Americas, which we estimate is about 41 percent of the worldwide market, we estimate that revenue will grow about 7 percent to $2.0 billion, and in Europe, which we estimate is about 28 percent of the market, we estimate that revenue will grow about 3 percent to $1.3 billion. We estimate that Japan and Asia Pacific countries, about $1.5 billion or 31 percent of the world market, will grow about 3 percent.

The contact lens market has two major segments. The spherical lens segment, which we estimate is about $3.6 billion in calendar 2006, includes lenses that correct uncomplicated near- and farsightedness. We estimate that products recommended for one day of wear (single-use lenses) account for about 40 percent of spherical lens revenue. The specialty lens segment, which we estimate at $1.2 billion in calendar 2006, includes lenses that meet special needs of contact lens patients: toric, cosmetic and multifocal lenses. CVI offers both specialty lenses and spherical lenses.

To compete successfully in the numerous niches of the contact lens market, companies must offer differentiated products that are priced competitively and manufactured efficiently. CVI believes that it is the only contact lens manufacturer to use three different manufacturing processes to produce its lenses: lathing, cast molding and FIPS, a cost-effective combination of lathing and molding. This manufacturing flexibility provides CVI with competitive advantage by:

Producing high, medium and low volumes of lenses made with a variety of materials for a broader range of market niches than competitors serve: single-use, two-week, monthly and quarterly

Table of Contents

disposable sphere and toric lenses and custom toric lenses for patients with a high degree of astigmatism.

Offering a wider range of lens parameters, leading to a higher successful fitting rate for practitioners and better visual acuity for patients.

In addition, CVI believes that its lenses provide superior comfort through its use of the lens edge technology provided under the patents covered by its Edge Patent License described under Patents, Trademarks and Licensing Agreements.

Cooper s Proclear® line of spherical, multifocal and toric lenses, are manufactured with omafilcon A, a material that incorporates a proprietary phosphorylcholine technology that helps enhance tissue-device compatibility. Proclear® lenses are the only lenses with FDA clearance for the claim may provide improved comfort for contact lens wearers who experience mild discomfort or symptoms relating to dryness during lens wear. Mild discomfort relating to dryness during lens wear is a condition that often causes patients to discontinue contact lens wear.

In many geographic markets, it is our belief that favorable demographic trends in younger cohorts; an increase in the reported incidence of myopia due in part to the recently described computer vision syndrome ; lower contact lens wearer drop out rates as technology improves and a continuing shift in practitioner preferences from low-featured commodity lenses to higher-value specialty and single-use lenses support a favorable world market outlook, including a trend, primarily in the United States, to fitting silicone hydrogel lenses, which, as measured by their dk/t score, supply a higher level of oxygen to the cornea than traditional hydrogel lenses.

CVI has yet to develop sufficient manufacturing capabilities to compete in the market for silicone hydrogel lenses, which we estimate accounts for 22 percent or $1 billion of the worldwide contact lens market.

Historically, CVI has shown strength in the specialty lens segments which include toric lenses, cosmetic lenses and multifocal lenses. CVI estimates that specialty lenses currently account for about 25 percent or $1.2 billion of the worldwide contact lens market.

To participate in these market trends, CVI continues to leverage the January 6, 2005, acquisition of Ocular Sciences, Inc. (Ocular) giving it access to new technologies, particularly patented silicone hydrogel and single-use lens technologies, new geographic markets, particularly Japan and Germany, and higher volume manufacturing processes, particularly the Gen II manufacturing platform (Gen II).

With the Ocular acquisition, CVI gained a significant presence in the largest segment of the contact lens market: spherical lenses that correct the most common types of visual defects; near- and farsightedness uncomplicated by more complex visual defects. We estimate that spherical lenses account for about 75 percent of the world market for contact lenses.

Contact Lens Products

CVI s core product lines include specialty lenses which are toric, cosmetic and multifocal lenses plus phosphorylcholine (PC) Technology spherical lenses, silicone hydrogel spherical lenses and single-use lenses. Worldwide, CVI s specialty lens revenue grew 9 percent in fiscal 2006 over fiscal 2005. Sales of CVI s toric lenses, grew 11 percent in fiscal 2006 and now account for about 35 percent

Table of Contents

of its soft lens revenue and disposable toric lenses grew 16 percent in fiscal 2006. We estimate that the worldwide toric market will grow about 11 percent in calendar 2006. CVI s PC Technology products its line of spherical, toric and multifocal products, including Biomedics XC , that incorporate PC Technology grew 29 percent in fiscal 2006.

We estimate that the market for spherical contact lenses will grow 4 percent worldwide during calendar 2006 driven in part by the acceptance of newer silicone hydrogel lenses. We estimate that worldwide silicone hydrogel revenue will increase about 53 percent to $1.1 billion during calendar 2006, approximately two-thirds of which will be generated in the United States. CVI began a limited launch of its Biofinity brand of silicone hydrogel spherical contact lenses in Europe, the United States and selected markets in Asia-Pacific, in fiscal 2006 and continues to develop its manufacturing capabilities to participate in this market. CVI s reported spherical revenue grew 2 percent in fiscal 2006 to $422.2 million. Single-use sphere revenue grew 21 percent in fiscal 2006 and now represents 12 percent of CVI s soft lens revenue.

In addition to growing Biofinity manufacturing capacity, capabilities and sales, CVI continues to compete against silicone hydrogel products with its PC Technology and single-use products, and with traditional hydrogel products utilizing advanced design technologies.

CVI Fiscal 2006 Revenue Growth by Geographic Segment

CVI s worldwide revenue grew 5 percent in fiscal 2006 over fiscal 2005 with the Americas region up 3 percent and now representing 48 percent of its worldwide revenue; Europe up 9 percent and representing 37 percent of its worldwide revenue and the Asia-Pacific region up 4 percent and representing 15 percent of its worldwide revenue.

Americas

Americas revenue growth slowed due to a 1 percent decline in spherical revenue in fiscal 2006 over fiscal 2005 caused primarily by a market shift to silicone hydrogel spherical lenses. Overall revenue growth was driven by sales of toric lenses, which grew 6 percent and multifocal lenses, which grew 34 percent.

Europe

European revenue growth was driven by sales of toric lenses, which grew 20 percent in fiscal 2006 over fiscal 2005, single-use lenses, which grew 29 percent and multifocal lenses, which grew 38 percent. CVI estimates that it is the second largest contact lens supplier in Europe, with direct business units in France, Germany, Holland, Hungary, Italy, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Asia Pacific

Japan is the second largest contact lens market in the world after the United States, and soft lens popularity continues to grow. CVI estimates that the total market for soft contact lenses in Japan and the Pacific Rim today is about $1.5 billion, compared to an estimated $2.0 billion in the Americas. The Japanese market is largely made up of single-use lenses, which we estimate represents about 57 percent of the market.

We believe that the incidence of nearsightedness in Japan is one of the highest in the world and based on our experience about half of those with astigmatism are potential candidates for toric lenses. We

Table of Contents

expect that the Japanese toric segment, currently a smaller percentage of the total market than it is in the United States, will grow rapidly as newer generations of toric lenses are introduced.

Asia Pacific revenue growth was driven by sales of single-use product, which grew 18 percent in fiscal 2006 over fiscal 2005 and represented 54 percent of CVI s sales in Japan.

CVI Competition

A number of manufacturers compete in the worldwide market for contact lenses. CVI s three largest competitors are Johnson & Johnson s Vistakon division (Vistakon), CIBA Vision (owned by Novartis AG) and Bausch & Lomb Incorporated.

The contact lens market is highly competitive. CVI s primary competitors in the spherical lens market are Bausch & Lomb, CIBA Vision and Vistakon. Recent trends in the spherical lens market include a shift towards silicone hydrogel lenses, primarily in the United States, and toward single-use lenses. CVI s primary competitors currently control almost all of the silicone hydrogel market as CVI continues to develop its silicone hydrogel manufacturing capabilities. Silicone hydrogel products, while essential to CVI s long-term success, are not expected to begin to contribute revenue growth until the second half of 2007.

In the specialty lens market, CVI s primary toric competitors are Bausch & Lomb and Vistakon. Toric lens manufacturers compete to provide the highest possible level of visual acuity and patient satisfaction by offering a wide range of lens parameters, superior wearing comfort and a high level of customer service, both for patients and contact lens practitioners. CVI believes that its three manufacturing processes yield a wider range of toric lens parameters than its competitors, providing greater choices for patient and practitioner and better visual acuity, and that it offers superior customer services, including high standards of on-time product delivery. However, there is a developing trend in the U.S. toric lens market toward silicone hydrogel products. CVI has not launched a silicone hydroge1 product and does not expect to do so until late calendar 2007 to early calendar 2008.

CVI s major competitors have greater financial resources and larger research and development budgets and sales forces. Nevertheless, CVI offers a high level of customer service through its direct sales organizations around the world and through telephone sales and technical service representatives who consult with eye care professionals about the use of the Company s lens products. CVI believes that its sales force is particularly well equipped through extensive training to meet the needs of contact lens practitioners and their customers.

CVI also competes with manufacturers of eyeglasses and with refractive surgical procedures that correct visual defects. CVI believes that it will continue to compete favorably against eyeglasses, particularly in markets where the penetration of contact lenses in the vision correction market is low, offering lens manufacturers an opportunity to gain market share. CVI also believes that laser vision correction is not a material threat to its sales of contact lenses because each modality serves a different age group. CVI believes that almost all new contact lens wearers are in their teens or twenties, while refractive surgery patients are typically in their late thirties or early forties when their vision has stabilized.

COOPERSURGICAL

Historically, many small medical device companies have supplied the women s healthcare market with a wide range of products through a fragmented distribution system. CSI s strategy is to identify and acquire selected smaller companies and product lines that will improve its existing market position or serve new clinical areas.

Table of Contents

In November 2006, CSI acquired Lone Star Medical Products, Inc. (Lone Star) advancing its expansion into the hospital segment of women s healthcare. This acquisition complements the 2005 acquisitions of Inlet Medical, Inc. (Inlet) and NeoSurg Technologies, Inc. (NeoSurg) which also address the surgical market. See Profiles of Recent Acquisitions below.

Since its beginning in 1990, CSI has successfully established a leading position among companies providing medical device products to the obstetrics and gynecology medical specialty. Since then, CSI has grown to over $120 million in revenue through a series of more than 20 acquisitions. During the past five years, CSI s revenue grew at a compounded rate of 16 percent with double-digit operating margins excluding restructuring costs and minimal capital expenditure requirements. Cooper s strong cash flow allows CSI to readily compete for available opportunities in both the office and hospital markets.

Market for Women s Healthcare

Based on U.S. Census estimates, CVI expects patient visits to United States obstetricians and gynecologists (Ob/Gyns) to increase over the next decade. Driving this growth is a large group of women of childbearing age and a rapidly growing middle-aged population with emerging gynecologic concerns. Consistent with an aging population, menopausal problems abnormal bleeding, incontinence and osteoporosis are expected to increase, while pregnancy, contraceptive management and general

examinations are expected to remain relatively stable. The trend toward delaying the age of childbearing to the mid-thirties and beyond will likely drive increasing treatment for infertility.

While general medical practitioners play an important role in women s primary care, the Ob/Gyn specialist is the primary market for associated medical devices.

Some significant features of this market are:

- Patient visits are for annual checkups, cancer screening, menstrual disorders, vaginitis (inflammation of vaginal tissue), treatment of abnormal Pap smears, osteoporosis (reduction in bone mass), the management of menopause, pregnancy and reproductive management.

- Osteoporosis and incontinence have become frequent diagnoses as the female population ages. Early identification and treatment of these conditions will both improve women s health and help reduce overall costs of treatment.

- Sterilization is a frequently performed surgical procedure.

- Ob/Gyns traditionally provide the initial evaluation for women and their partners who seek infertility assistance. Ovulatory drugs and intrauterine insemination (IUI) are common treatments of these cases along with embryo transfer procedures.

CSI s 2006 Revenue Growth

During 2006, CSI revenue grew 15 percent to $124.8 million, representing 15 percent of Cooper s revenue. Its operating margin was 12 percent for the fiscal year, including a $7.5 million or 6% charge for acquired in-process research and development, compared to last year s 16 percent.

CSI Competition

CSI focuses on selected segments of the women s healthcare market, supplying high quality diagnostic products and surgical instruments and accessories. In some instances, CSI offers all of the items

Table of Contents

needed for a complete procedure. The market segments in which CSI competes remains fragmented, typified by smaller technology-driven firms that generally offer only one or two product lines. Most are privately owned or divisions of public companies including some owned by companies with greater financial resources than Cooper.

Competitive factors in these segments include technological and scientific advances, product quality, price, customer service and effective communication of product information to physicians and hospitals. CSI believes that it competes successfully against these companies with its superior sales and marketing, the technological advantages of its products and by developing and acquiring new products, including those used in new medical procedures. As CSI expands its product line, it also offers to train medical professionals in their appropriate use.

CSI is expanding its presence in the significantly larger hospital and outpatient surgical procedure market. This market is dominated by larger competitors such as Johnson & Johnson s Ethicon Endo-Surgery and Ethicon Women s Health and Urology companies, Boston Scientific, Gyrus and ACMI. These competitors have well established positions within the operating room environment. CSI believes its relationship with gynecologic surgeons and focus on devices specific to gynecology surgery will facilitate in its successful expansion within the surgical market.

PROFILES OF RECENT ACQUISITIONS

Ocular Sciences, Inc.

On January 6, 2005, Cooper acquired all of the outstanding common stock of Ocular, a global manufacturer and marketer of soft contact lenses, primarily spherical and daily disposable contact lenses that are brand and product differentiated by distribution channel. The aggregate consideration paid for the stock of Ocular was about $1.2 billion plus transaction costs. Cooper paid $605 million in cash and issued approximately 10.7 million shares of its common stock to Ocular stockholders and option holders. Under the terms of the acquisition, each share of Ocular common stock was converted into the right to receive 0.3879 of a share of Cooper common stock and $22.00 in cash without interest, plus cash for fractional shares. Outstanding Ocular stock options were redeemed in exchange for a combination of cash and Cooper stock for the spread between their exercise prices and the value of the merger consideration immediately prior to closing.

Inlet Medical, Inc.

On November 1, 2005, Cooper purchased Inlet, a manufacturer of trocar closure systems and pelvic floor reconstruction procedure kits. Inlet offers a cost-effective trocar wound closure system and supplies procedure kits for the treatment of pelvic support problems. We paid $25.8 million in cash for Inlet and anticipate paying an additional amount of approximately $12.3 million related to an earn-out provision in the agreement based on revenue and operating profit achievements through October 31, 2006.

NeoSurg Technologies, Inc.

On November 21, 2005, Cooper acquired NeoSurg for $21.6 million in cash. NeoSurg has developed a patented combination reusable and disposable trocar access system to compete in the market for trocars, which we estimate is $285 million within the estimated $2.9 billion market

for laparoscopic surgical devices.

CSI introduced the redesigned NeoSurg product line of reusable and disposable trocar access systems used in laparoscopic surgery to gynecologists in November 2006. CSI believes that NeoSurg s technology will offer surgeons a superior product to existing disposable trocars while giving hospital

Table of Contents

and surgery centers the opportunity to realize significant cost reduction. The small disposable tips used in the NeoSurg system can significantly reduce hospital costs compared to existing systems offered by competitors.

Lone Star Medical Products, Inc.

On November 2, 2006, CSI acquired all of the outstanding shares of Lone Star for $27.2 million in cash. Lone Star is a manufacturer of medical devices that improve the management of the surgical site, most notably the *Lone Star Retractor System*, which places a retraction ring around the surgical incision providing greater exposure of the surgical field. While this system is used in a wide variety of surgical procedures, gynecological surgery represents 40% of its use and urology 30%.

RESEARCH AND DEVELOPMENT

Cooper employs 107 people in its research and development and manufacturing engineering departments, primarily in CVI. External specialists in lens design, formulation science, polymer chemistry, microbiology and biochemistry support product development and clinical research for CVI products. CVI s research and development activities include programs to develop silicone hydrogel products, product lines utilizing PC Technology and expansion of single-use product lines. CSI conducts research and development in-house and also employs external surgical specialists, including members of its surgical advisory board. CSI s research and development activities were for newly acquired laparoscopic surgical devices and for upgrading and redesign of many CSI osteoporoses, in-vitro fertilization, incontinence and assisted reproductive technology products and other obstetrical and gynecological product development activities.

Cooper-sponsored research and development expenditures during the fiscal years ended October 31, 2006, 2005 and 2004 were $27 million excluding a write-off of $7.5 million of purchased in-process research and development related to NeoSurg, $22.9 million excluding a write-off of $20 million of purchased in-process research and development related to Ocular and $6.5 million, respectively, representing 3%, 3% and 1% of net sales in each fiscal year. During fiscal 2006, CVI represented 87% and CSI represented 13% of the total expenditures, net of acquired in-process research and development. We did not participate in any customer-sponsored research and development programs.

GOVERNMENT REGULATION

Medical Device Regulation

Our products are medical devices subject to extensive regulation by the United States Food and Drug Administration (FDA) in the United States and other regulatory bodies abroad. FDA regulations govern, among other things, medical device design and development, testing, manufacturing, labeling, storage, recordkeeping, premarket clearance or approval, advertising and promotion, and sales and distribution. Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either prior 510(k) clearance or prior premarket approval (PMA) from the FDA. A majority of the medical devices we currently market have received FDA clearance through the 510(k) process or approval through the PMA process. Because we cannot be assured that any new products we develop, or any product enhancements, will be subject to the shorter 510(k) clearance process, significant delays in the introduction of any new products or product enhancements may occur. For example, to qualify our new silicone hydrogel contact lens products for extended wear use, more extensive

premarket testing and approval would be required.

Device Classification

The FDA classifies medical devices into one of three classes Class I, II, or III depending on the degree of risk associated with each medical device and the extent of control needed to ensure its safety

Table of Contents

and effectiveness. Both CVI and CSI develop and market medical devices under different levels of FDA regulation depending on the classification of the device. Class III devices, such as flexible and extended wear contact lenses, require extensive premarket testing and approval, while Class I and II devices require substantially lower levels of regulation.

Class I devices are those for which safety and effectiveness can be assured by adherence to the FDA s general regulatory controls for medical devices, which include compliance with the applicable portions of the FDA s Quality System Regulation, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials (General Controls). Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below.

Class II devices are subject to the FDA s General Controls, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification procedure. Pursuant to the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), as of October 2002 unless a specific exemption applies, 510(k) premarket notification submissions are subject to user fees. Certain Class II devices are exempt from this premarket review process.

Class III devices are those devices which have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device. The safety and effectiveness of Class III devices cannot be assured solely by the General Controls and the other requirements described above. These devices almost always require formal clinical studies to demonstrate safety and effectiveness and must be approved through the premarket approval process described below. Premarket approval applications (and supplemental premarket approval applications) are subject to significantly higher user fees under MDUFMA than are 510(k) premarket notifications.

510(k) Clearance Pathway

When we are required to obtain a 510(k) clearance for a device that we wish to market, we must submit a premarket notification to the FDA demonstrating that the device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for the submission of premarket approval applications. By regulation, the FDA is required to respond to a 510(k) premarket notification within 90 days of submission of the notification. As a practical matter, clearance can take significantly longer. If the FDA determines that the device, or its intended use, is not substantially equivalent to a previously-cleared device or use, the FDA will place the device, or the particular use of the device, into Class III.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that changes its intended use, will require a new 510(k) clearance or could require premarket approval. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer s determination. If the FDA disagrees with a manufacturer s determination that a new clearance or approval is not required for a particular modification, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or premarket approval is obtained. Also, in these circumstances, we may be subject to significant regulatory fines or penalties. We have made and plan to continue to make additional product enhancements and modifications to our devices that we believe do not require new 510(k) clearances.

Table of Contents

Premarket Approval Pathway

A PMA application must be submitted if the device cannot be cleared through the 510(k) premarket notification procedures. The PMA process is much more demanding than the 510(k) premarket notification process. A PMA application must be supported by extensive data including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA s satisfaction the safety and effectiveness of the device.

After a PMA application is complete, the FDA begins an in-depth review of the submitted information. The FDA, by statute and regulation, has 180 days to review an accepted PMA application, although the review generally occurs over a significantly longer period of time, and can take up to several years. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with the Quality System Regulation (QSR). New PMA applications or PMA application supplements are required for significant modifications to the manufacturing process, labeling and design of a device that is approved through the premarket approval process. Premarket approval supplements often require submission of the same type of information as a premarket approval application, except that the supplement is limited to information needed to support any changes from the device covered by the original premarket approval application, and may not require as extensive clinical data or the convening of an advisory panel.

Clinical Trials

A clinical trial is almost always required to support a PMA application and is sometimes required for a 510(k) premarket notification. These trials generally require submission of an application for an investigational device exemption (IDE) to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for more abbreviated investigational device exemption requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by both the FDA and the appropriate institutional review boards at the clinical trial sites. All of Cooper s currently marketed products have been cleared by all appropriate regulatory agencies, and Cooper has no product currently being marketed under an IDE.

Continuing FDA Regulation

After a device is placed on the market, numerous regulatory requirements apply. These include: the QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures during the manufacturing process; labeling regulations, which prohibit the promotion of products for unapproved, or off-label uses and impose other restrictions on labeling; and medical device reporting, regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA to determine our compliance with the QSR and other regulations.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions: fines, injunctions, and civil penalties; recall

Table of Contents

or seizure of our products; operating restrictions, suspension of production; refusing our request for 510(k) clearance or premarket approval of new products; withdrawing 510(k) clearance or premarket approvals that are already granted; and criminal prosecution.

Even if regulatory approval or clearance of a medical device is granted, the FDA may impose limitations or restrictions on the uses and indications for which the device may be labeled and promoted. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. FDA regulations prohibit a manufacturer from promoting a device for an unapproved, or off-label use. Failure to comply with this prohibition on off-label promotion could result in enforcement action by the FDA, including, among other things, warning letters, fines, injunctions, consent decrees and civil or criminal penalties.

Foreign Regulation

Health authorities in foreign countries regulate Cooper s clinical trials and medical device sales. The regulations vary widely from country to country. Even if the FDA has approved a product, the regulatory agencies in each country must approve new products before they may be marketed there.

These regulatory procedures require a considerable investment in time and resources and usually result in a substantial delay between new product development and marketing. If the Company does not maintain compliance with regulatory standards or if problems occur after marketing, product approval may be withdrawn.

In addition to FDA regulatory requirements, the Company also maintains ISO 9000 certification and CE mark approvals for its products. A CE mark is an international symbol of adherence to certain standards and compliance with applicable European medical device requirements. These quality programs and approvals are required by the European Medical Device Directive and must be maintained for all products intended to be sold in the European market. In order to maintain these quality benchmarks, the Company is subjected to rigorous biannual reassessment audits of its quality systems and procedures.

Other Health Care Regulation

We may be subject to various federal, state and foreign laws pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state healthcare programs, including Medicare, Medicaid, Veterans Administration health programs and TRICARE. While we believe that our operations are in material compliance with such laws, because of the complex and far-reaching nature of these laws, there can be no assurance that we would not be required to alter one or more of our practices to be in compliance with these laws. In addition, health care reform proposals have been formulated by the legislative and administrative branches of the federal and state governments. Additionally, there may also be changes that could affect coverage and reimbursement for our products from governmental and other third-party payors. These changes could affect our business, revenues, profitability and results of operations. If there is a change in law, regulation or administrative or judicial interpretation, we may have to change our business practices or our existing business practices could be challenged as unlawful.

Anti-Kickback and Fraud Laws

Our operations may be subject to federal and state anti-kickback laws. Certain provisions of the Social Security Act, which are commonly known collectively as the Medicare Fraud and Abuse Statute,

Table of Contents

prohibit persons from knowingly and willfully soliciting, receiving, offering or providing remuneration directly or indirectly to induce either the referral of an individual, or the furnishing, recommending or arranging for a good or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid. The definition of remuneration under this statute has been broadly interpreted to include anything of value, including such items as gifts, discounts, waiver of payments and providing anything at less than its fair market value. Many states have adopted prohibitions similar to the Medicare Fraud and Abuse Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not only by the Medicare and Medicaid programs.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) created new prohibitions on: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing or attempting to execute a scheme or artifice to defraud any healthcare benefit program, including private payers. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation in connection with the delivery of or payment for healthcare benefits, items or services. This statute applies to any health benefit plan, not just Medicare and Medicaid. Additionally, HIPAA granted expanded enforcement authority to the U.S. Department of Health and Human Services (HHS) and the U.S. Department of Justice (DOJ) and provided enhanced resources to support the activities and responsibilities of the Office of Inspector General (OIG) and DOJ by authorizing large increases in funding for investigating fraud and abuse violations relating to healthcare delivery and payment. In addition, HIPAA mandates the adoption of standards for the electronic exchange of health information.

Physician Self-Referral Laws

We may also be subject to federal and state physician self-referral laws. Federal physician self-referral legislation (commonly known as the Stark Law) prohibits, subject to certain exceptions, physician referrals of Medicare and Medicaid patients to an entity providing certain designated health services if the physician or an immediate family member has any financial relationship with the entity. The Stark Law also prohibits the entity receiving the referral from billing any good or service furnished pursuant to an unlawful referral, and any person collecting any amounts in connection with an unlawful referral is obligated to refund such amounts. Various states have corollary laws to the Stark Law, including laws that require physicians to disclose any financial interest they may have with a healthcare provider to their patients when referring patients to that provider. Both the scope and exceptions for such laws vary from state to state.

False Claims Laws

Under separate statutes, submission of claims for payment or causing such claims to be submitted that are not provided as claimed may lead to civil money penalties, criminal fines and imprisonment, and/or exclusion from participation in Medicare, Medicaid and other federally funded state health programs. These false claims statutes include the federal False Claims Act, which prohibits the knowing filing of a false claim or the knowing use of false statements to obtain payment from the federal government. When an entity is determined to have violated the False Claims Act, it must pay three times the actual damages sustained by the government, plus mandatory civil penalties of between $5,500 and $11,000 for each separate false claim. Suits filed under the False Claims Act, known as qui tam actions, can be brought by any individual on behalf of the government and such individuals (known as relators or, more commonly, as whistleblowers) may share in any amounts paid by the entity to the government in fines or settlement. In addition, certain states have enacted laws modeled

Table of Contents

after the federal False Claims Act. Qui tam actions have increased significantly in recent years causing greater numbers of healthcare companies to have to defend a false claim action, pay fines or be excluded from the Medicare, Medicaid or other federal or state healthcare programs as a result of an investigation arising out of such action.

RAW MATERIALS

CVI s raw materials primarily consist of various chemicals and packaging materials. There are alternative supply sources for all of our raw materials other than our silicone hydrogel material. Asahikasei Aime Co. Ltd. (Asahi) is our sole supplier of the material used to make our silicone hydrogel contact lens products, comfilcon A. If Asahi fails to supply sufficient material on a timely basis or at all for any reason, we may suffer a disruption in the supply of our silicone hydrogel contact lens products and may need to switch to an alternative supplier in accordance with our agreement with Asahi.

Raw materials used by CSI are generally available from more than one source. However, because some products require specialized manufacturing procedures, we could experience inventory shortages if we were required to use an alternative supplier on short notice.

MARKETING AND DISTRIBUTION

In the United States, CVI markets its products through its field sales representatives, who call on optometrists, ophthalmologists, opticians, optical chains and distributors. CVI augments its U.S. sales and marketing efforts with e-commerce, telemarketing and advertising in professional journals. In Australia, Brazil, Canada, France, Germany, Holland, Hungary, Italy, Japan, Korea, Malaysia, Norway, Portugal, Singapore, South Africa, Spain, Sweden, Switzerland, Taiwan and the United Kingdom, CVI primarily markets its products through its field sales representatives. In other countries, CVI uses distributors and has given some of them the exclusive right to market its products.

CSI s products are marketed by a network of field sales representatives and distributors. In the United States, CSI augments its sales and marketing activities with e-commerce, telemarketing, direct mail and advertising in professional journals.

PATENTS, TRADEMARKS AND LICENSING AGREEMENTS

Cooper owns or licenses a variety of domestic and foreign patents, which, in total, are material to its overall business. The names of certain of Cooper s products are protected by trademark registrations in the United States Patent and Trademark Office and, in some cases, also in foreign trademark offices. Applications are pending for additional trademark and patent registrations. Cooper aggressively protects its intellectual property rights.

No individual patent or license is material to the Company or either of its principal business units other than:

Our Patent License Agreement dated as of December 2, 1997, between Cooper and Geoffrey Galley, Albert Moreland, Barry Bevis and Ivor Atkinson entered into in connection with the Company s acquisition of Aspect Vision Care Limited (the Edge Patent License). This agreement extends until the patents expire in January 2010 and relates to patents used by CVI to produce a contact lens edge that provides superior comfort to the wearer. The edge forms a part of CVI s

Table of Contents

products (both spherical and toric lenses) that are manufactured using a cast molding technology in the CVI s Hamble, England, Norfolk, Virginia and Juana Diaz, Puerto Rico, facilities.

Our license related to products manufactured by CVI using the proprietary phosphorylcholine (PC Technology) patents that we received in connection with the Company s acquisition of Biocompatibles Eye Care, Inc. Our Proclear® Compatibles brand of spherical, multifocal and toric soft contact lenses are manufactured using this PC Technology . This license term extends until the patents expire.

In addition to trademarks and patent licenses, the Company owns certain trade secrets, copyrights, know-how and other intellectual property.

DEPENDENCE ON CUSTOMERS

Neither of our business units depends to any material extent on any one customer or any one affiliated group of customers.

GOVERNMENT CONTRACTS

Neither of our business units is materially subject to profit renegotiation or termination of contracts or subcontracts at the election of the United States government.

BACKLOG

Backlog is not a material factor in either of Cooper s business units.

SEASONALITY

CVI s contact lens sales in its first fiscal quarter, which runs from November 1 through January 31, are typically lower than subsequent quarters, as patient traffic to practitioners offices is relatively light during the holiday season.

COMPLIANCE WITH ENVIRONMENTAL LAWS

Federal, state and local provisions that regulate the discharge of materials into the environment, or relate to the protection of the environment, do not currently materially affect Cooper s capital expenditures, earnings or competitive position.

WORKING CAPITAL

Cooper has not required any material working capital arrangements in the past five years.

FINANCIAL INFORMATION ABOUT BUSINESS SEGMENTS, GEOGRAPHIC AREAS, FOREIGN OPERATIONS AND EXPORT SALES

The information required by this item is included in Note 13. Business Segment Information of our Financial Statements and Supplementary Data and Item 1A. Risk Factors Risks Relating to Our Business, included in this report.

EMPLOYEES

On October 31, 2006, the Company had about 7,500 employees. The Company believes that its relations with its employees are good.

Table of Contents

NEW YORK STOCK EXCHANGE CERTIFICATION

We submitted our 2006 annual Section 12(a) CEO certification with the New York Stock Exchange. The certification was not qualified in any respect. Additionally, we filed with the Securities and Exchange Commission as exhibits to our Annual Report on Form 10-K for the year ended October 31, 2006, the CEO and CFO certifications required under Section 302 of the Sarbanes-Oxley Act of 2002.

AVAILABLE INFORMATION

The Cooper Companies, Inc. Internet address is http://www.coopercos.com. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, along with all other reports and amendments filed with or furnished to the Securities and Exchange Commission (SEC) are publicly available free of charge on our Web site as soon as reasonably practicable. The public may read and copy these materials at the SEC s Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a Web site that contains such reports, proxy and information statements and other information whose Internet address is http://www.sec.gov. The Company s Corporate Governance Principles, Ethics and Business Conduct Policy and charters of each committee of the Board of Directors are also posted on the Company s Web site. The information on the Company s Web site is not part of this or any other report we file with, or furnish to, the SEC.

Table of Contents

Item 1A. ***Risk Factors.***

Our business faces significant risks. These risks include those described below and may include additional risks and uncertainties not presently known to us or that we currently deem immaterial. Our business, financial condition and results of operations could be materially adversely affected by any of these risks, and the trading prices of our common stock or convertible debentures could decline. These risks should be read in conjunction with the other information in this report.

Risks Relating to Our Business

We operate in the highly competitive healthcare industry and there can be no assurance that we will be able to compete successfully.

Each of our businesses operates within a highly competitive environment. In our soft contact lens segment, CVI faces intense competition from competitors products, in particular silicone hydrogel contact lenses, and may face increasing competition as other new products enter the market. Our major competitors in the contact lens business have substantially greater financial resources, larger research and development budgets, larger sales forces, greater market penetration and larger manufacturing volumes than CVI.

Our major competitors in the specialty contact lens business offer competitive products, newer materials plus a variety of other eye care products, including lens care products and ophthalmic pharmaceuticals, which may give them a competitive advantage in marketing their lenses. Moreover, silicone hydrogel lenses are gaining market acceptance in the specialty lens business and we are not yet able to manufacture and market our own competitive silicone hydrogel specialty products, which could erode our specialty lens market share and margins.

The market for our non-specialty, commodity contact lenses is also intensely competitive and is characterized by declining sales volumes for older product lines and growing demand for silicone hydrogel based products. Our ability to respond to these competitive pressures will depend on our ability to decrease our costs and maintain gross margins and operating results, to successfully introduce new products, including our own silicone hydrogel products, on a timely basis in markets such as the United States, Europe and Japan, and to achieve manufacturing efficiencies and sufficient manufacturing capacity and capabilities for such products. Any significant decrease in our costs per lens will depend, in part, on our ability to increase sales volume and production capabilities and/or convert certain high volume production onto our Gen II manufacturing platform (Gen II). Our failure to respond to competitive pressures in a timely manner could have a material adverse effect on our business, financial condition and results of operations.

To a lesser extent, CVI also competes with manufacturers of eyeglasses and other forms of vision correction including ophthalmic surgery. There can be no assurance that we will not encounter increased competition in the future, or that a successful entry into CVI s higher-margin specialty lens segments by a larger competitor would not have a material adverse effect on our business, financial condition or results of operations.

In the women s healthcare segment, competitive factors include technological and scientific advances, product quality, price and effective communication of product information to physicians and hospitals. CSI competes with a number of manufacturers in each of its niche markets, some of which have substantially greater financial and personnel resources and sell a much broader range of products, which may give them an advantage in marketing competitive products.

Table of Contents

Product innovations are important in the industry in which we operate, and we face the risk of product obsolescence.

Product innovations are important in the contact lens business in which CVI competes and in the niche areas of the healthcare industry in which CSI competes. Historically, we did not allocate substantial resources to new product development, but rather purchased, leveraged or licensed the technology developments of others. With the acquisition of Ocular, we are investing more in new product development, including the development of silicone hydrogel-based contact lenses. Although our focus is on products that will be marketable immediately or in the short to medium term rather than on funding longer-term, higher risk research and development projects, time commitments, the cost of obtaining necessary regulatory approval and other costs related to product innovations can be substantial. There can be no assurance that we will successfully obtain necessary regulatory approvals or clearances for our new products or that our new products will successfully compete in the marketplace and, as a result, justify the expense involved in their development and regulatory approval. In addition, our competitors may have developed or may in the future develop new products or technologies that could lead to the obsolescence of one or more of our products. Failure to stay current with our competitors with regard to new product offerings and technological changes and to offer products that provide performance that is at least comparable to competing products could have a material adverse effect on our business, financial condition, or results of operations.

If our products are not accepted by the market, we will not be able to sustain or expand our business.

Certain of our proposed products have not yet been clinically tested or commercially introduced, and we cannot assure you that any of them will achieve market acceptance or generate operating profits. We have not commercially marketed many of our planned new products, such as certain of our planned silicone hydrogel contact lens products and new contact lens products containing our patented PC Technology and have limited manufacturing capabilities for our silicone hydrogel product recently launched on a limited basis for sale in Europe, the United States and select Asia-Pacific markets. Market acceptance and customer demand for these products are uncertain. The development of a market for our products may be influenced by many factors, some of which are out of our control, including:

- limited product availability due to manufacturing constraints;
- acceptance of our products by eye care and women s healthcare practitioners;
- the cost competitiveness of our products;
- consumer reluctance to try and use a new product;
- regulatory requirements;
- the earlier release of competitive products, such as silicone hydrogel products into the market by our competitors; and
- the emergence of newer and more competitive products.

New medical and technological developments may reduce the need for our products.

Technological developments in the eye care and women s healthcare industries, such as new surgical procedures or medical devices, may limit demand for our products. Corneal refractive surgical procedures such as Lasik surgery and the development of new pharmaceutical products may decrease

Table of Contents

the demand for our optical products. If these new advances were to provide a practical alternative to traditional vision correction, the demand for contact lenses and eyeglasses may materially decrease. We cannot assure that medical advances and technological developments will not have a material adverse effect on our businesses.

Our substantial and expanding international operations are subject to uncertainties which could affect our operating results.

A significant portion of our current operations is conducted and located outside the United States, and our growth strategy involves expanding our existing foreign operations and entering into new foreign jurisdictions. We have significant manufacturing and distribution sites in North America and Europe. Approximately 50% and 49% of our net sales for the years ended October 31, 2006 and 2005, respectively, were derived from the sale of products outside the United States. Further, we believe that sales outside the United States will continue to account for a material portion of our total net sales for the foreseeable future. International operations and business expansion plans are subject to numerous additional risks, including:

- foreign customers may have longer payment cycles than customers in the United States;
- failure to comply with United States Department of Commerce export controls may result in fines and/or penalties;
- tax rates in some foreign countries may exceed those of the United States, and foreign earnings may be subject to withholding requirements or the imposition of tariffs, exchange controls or other restrictions;
- we may find it difficult to comply with a variety of foreign regulatory requirements;
- general economic and political conditions in the countries where we operate may have an adverse effect on our operations in those countries or not be favorable to our growth strategy;
- we may find it difficult to manage a large organization spread throughout various countries;