COOPER COMPANIES INC
Form 8-K
June 20, 2003

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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 20, 2003

THE COOPER COMPANIES, INC.
(Exact name of registrant as specified in its charter)

Delaware	1-8597	94-2657368
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

6140 Stoneridge Mall Road, Suite 590, Pleasanton, California 94588
(Address of principal executive offices)

(925) 460-3600
(Registrant's telephone number, including area code)

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ITEM 5. Other Events.

On June 20, 2003, The Cooper Companies, Inc. announced that it completed its offering of $100 million of 2 5/8% convertible senior debentures due 2023 in a private placement. A copy of the press release regarding this event is being filed as an exhibit to this report. Nothing in this report shall be deemed to constitute an offer to sell or the solicitation of an offer to buy any securities.

ITEM 7. Financial Statements, Pro Forma Financial Information and Exhibits.

(c) Exhibits.

Exhibit No.	Description

99.1	Press Release dated June 20, 2003

ITEM 9. Regulation FD Disclosure.

In connection with the proposed offering described in Item 5 of this report, the Company anticipates disclosing to prospective purchasers of the debentures the information set forth below, which is furnished herein for informational purposes and should not be deemed filed under the Securities Exchange Act of 1934, as amended.

RISKS RELATED TO US AND 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. Numerous companies develop, manufacture and market contact lenses. Many competitors in the contact lens business have substantially greater financial resources and larger research and development and sales forces than CooperVision. Furthermore, many of these competitors offer a greater range of contact lenses, plus a variety of other eyecare products, including lens care products and ophthalmic pharmaceuticals, which may give them a competitive advantage in marketing their lenses to high volume contract accounts. To a lesser extent, CooperVision also competes with manufacturers of eyeglasses and other forms of vision correction. There can be no assurance that we will not encounter increased competition in the future, or that a successful entry into CooperVision'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. CooperSurgical 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.

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

Our growth strategy involves expanding our operations to numerous foreign jurisdictions and a significant portion of our current operations is conducted and located outside the United States. We have manufacturing and distribution sites in two major regions: North America and Europe. Approximately 37% of our net sales for the fiscal year ended October 31, 2002 and approximately 39% of our net sales for the six months ended April 30, 2003 were derived from the sale of products outside the United States. Further, we believe that sales outside the U.S. 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 U.S.;

- compliance with U.S. Department of Commerce export controls;

- tax rates in some foreign countries may exceed those of the U.S. and foreign earnings may be subject to withholding requirements or the imposition of tariffs, exchange controls or other restrictions;

- compliance with a variety of foreign regulatory regimes;

- 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;

- the difficulties associated with managing a large organization spread throughout various countries;

- the risk that foreign governments may adopt regulations or take other actions that would have a direct or indirect adverse impact on our business and market opportunities;

- the difficulty of enforcing agreements and collecting receivables through some foreign legal systems; fluctuations in currency exchange rates;

- the potential difficulty in enforcing intellectual property rights in some foreign countries; and

- the difficulties associated with gaining market share in Japan.

As we continue to expand our business globally, our success will depend, in large part, on our ability to anticipate and effectively manage these and other risks associated with our international operations. However, any of these factors could adversely affect our international operations and, consequently, our operating results.

Acquisitions we may make may involve numerous risks.

We have a history of making acquisitions, which have significantly contributed to our growth in recent years. As part of our growth strategy, particularly at CooperSurgical, we intend to continue to consider acquiring complementary technologies, products and businesses. Although we regularly engage in discussions with respect to possible acquisitions and joint ventures, we do not currently have any understandings, commitments or agreements relating to any material acquisitions. Future acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt and contingent liabilities and an increase in amortization and/or write-offs of goodwill and other intangible assets, which could have a material adverse effect upon our business, financial condition and results of operations. Risks we could face with respect to acquisitions include:

- difficulties in the integration of the operations, technologies, products and personnel of the acquired company;
- risks of entering markets in which we have no or limited prior experience;
- potential loss of employees;
- an inability to identify and consummate future acquisitions on favorable terms or at all;
- diversion of management's attention away from other business concerns;
- expenses of any undisclosed or potential liabilities of the acquired company; and
- expense, including restructuring expenses, to shut-down our own locations and/or terminate our employees.

The risks associated with acquisitions could have a material adverse effect upon our business, financial condition and results of operations. We cannot assure you that we will be successful in consummating future acquisitions on favorable terms or at all.

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 Proclear aspheric and multifocal, and, therefore, the market acceptance and customer demand for these products are uncertain. The development of a market for our products may be impacted by many factors, some of which are out of our control, including:

- acceptance of our products by eyecare practitioners;
- the cost competitiveness of our products;
- consumer reluctance to try a new product;
- regulatory requirements;
- consumer perception of our new products; and
- the emergence of newer and more competitive products.

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 niche areas of the healthcare industry in which CooperVision and CooperSurgical compete. Although our focus is on products that will be marketable immediately or in the short 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 meaningful. There can be no assurance that our new products will be successful in the marketplace and, as a result, justify the expense involved in their development and approval. In addition, there can be no assurance that new products or technologies will not be developed that could lead to the obsolescence of one or more of our products, which could have a material adverse effect on our business, financial condition, or results of operations.

We manufacture a significant portion of the products we sell and we face risks associated with manufacturing operations.

CooperVision and CooperSurgical manufacture a significant portion of the products they sell. As a result, any prolonged disruption in the operations of our manufacturing facilities, whether due to technical or labor difficulties, destruction of or damage to any facility or other reasons, could have a material adverse effect on our business, financial condition and results of operations.

We are vulnerable to interest rate risk with respect to our debt.

We are subject to interest rate risk in connection with the issuance of variable and fixed-rate debt. In order to maintain our desired mix of fixed-rate and variable-rate debt, we may use interest rate swap agreements and exchange fixed and variable-rate interest payment obligations over the life of the arrangements, without exchange of the underlying principal amounts. We cannot assure you that we will be successful in structuring such swap agreements to effectively manage our risks. If we are unable to do so, we may be adversely affected in our business, earnings and financial condition.

Exchange rate fluctuations could adversely affect our financial results.

As a result of our international operations, we expect to generate an increasing portion of our revenue and incur a significant portion of our expenses in currencies other than U.S. dollars. Although we may enter into foreign exchange agreements with financial institutions to reduce our exposure to fluctuations in foreign currency values relative to our debt or receivables obligations, these hedging transactions, if entered into, will not eliminate that risk entirely. In addition, to the extent we are unable to match revenue received in foreign currencies with costs paid in the same currency, exchange rate fluctuations could have a negative impact on our financial condition and results of operations. Additionally, because our consolidated financial results are reported in dollars, if we generate sales or earnings in other currencies the translation of those results into dollars can result in a significant increase or decrease in the amount of those sales or earnings. As a result of our worldwide operations, currency exchange rate fluctuations tend to affect our results of operations and financial position.

If we do not retain our key personnel and attract and retain other highly skilled employees our business could suffer.

If we fail to recruit and retain the necessary personnel, our business and our ability to obtain new customers, develop new products and provide acceptable levels of customer service could suffer. The success of our business is heavily dependent on the leadership of our key management personnel. Our success also depends on our ability to recruit, retain and motivate highly skilled sales, marketing and engineering personnel. Competition for these persons in our industry is intense and we may not be able to successfully recruit, train or retain qualified personnel.

Our intellectual property may be misappropriated or subject to claims of infringement.

We consider our intellectual property rights, including patents, trademarks and licensing agreements, to be an integral component of our business. We attempt to protect our intellectual property rights through a combination of patent, trademark, copyright and trade secret laws, as

well as licensing agreements and third-party nondisclosure and assignment agreements. Our failure to obtain or maintain adequate protection of our intellectual property rights for any reason could have a material adverse effect on our business, results of operations and financial condition.

We have applied for patent protection in the U.S. relating to certain existing and proposed processes and products. We cannot assure you that any of our patent applications will be approved. The patents we own could be challenged, invalidated or circumvented by others and may not be of sufficient scope or strength to provide us with any meaningful protection or commercial advantage. Patent applications in the U.S. are maintained in secrecy for a period of time, which may last until patents are issued, and since publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries by several months, we cannot be certain that we will be the first creator of inventions covered by any patent application we make or the first to file patent applications on such inventions. Further, we cannot assure you that we will have adequate resources to enforce our patents.

Our competitors in both the U.S. and foreign countries, many of which have substantially greater resources and have made substantial investments in competing technologies, may have applied for or obtained, or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make and sell our products. We have not conducted an independent review of patents issued to third parties. Claims that our products infringe the proprietary rights of others are more likely to be asserted after commencement of commercial sales incorporating our technology. We cannot assure you that we will not infringe on any of our competitors' patents.

Significant litigation regarding intellectual property rights exists in our industry. It is possible that third parties will make claims of infringement against us or manufacturers in connection with their use of our technology. Any claims, even those without merit, could:

- be expensive and time consuming to defend;
- cause us to cease making, licensing or using products that incorporate the challenged intellectual property;
- require us to redesign or reengineer our products, if feasible;
- divert management's attention and resources; or
- require us to enter into royalty or licensing agreements in order to obtain the right to use a necessary product, component or process.

Any royalty or licensing agreements, if required, may not be available to us on

acceptable terms or at all. A successful claim of infringement against us or our contract manufacturers in connection with the use of our technology could adversely affect our business.

We also rely on unpatented proprietary technology. It is possible that others will not independently develop the same or similar technology or otherwise obtain access to our unpatented technology. To protect our trade secrets and other proprietary information, we require employees, consultants, advisors and collaborators to enter into confidentiality agreements. We cannot assure you that these agreements will provide meaningful protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use, misappropriation or disclosure of such trade secrets, know-how or other proprietary information. If we are unable to maintain the proprietary nature of our technologies, we could be materially adversely affected.

Moreover, with respect to both existing and proposed foreign and domestic operations, we cannot assure you that changes in current or future laws or regulations or future judicial intervention would not have a material adverse effect on us. We are unable to predict the effect that any future foreign or domestic legislation or regulation may have on our existing or future business.

We rely on independent suppliers for raw materials and we could experience inventory shortages if we were required to use an alternative supplier on short notice.

We rely on independent suppliers for key raw materials, which primarily consist of various chemicals and packaging materials. Raw materials used by us 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 manufacturer on short notice.

We face an inherent risk of exposure to product liability claims.

We face an inherent risk of exposure to product liability claims in the event that the use of our products results in personal injury. We also face the risk that defects in the design or manufacture of our products might necessitate a product recall. We handle some risk with a combination of self-insurance and third- party carrier policies, which policies are subject to deductibles and limitations. One of our products is the subject of product liability claims, which arose prior to the acquisition of the manufacturer. Although we are entitled to indemnification from the seller and the products are covered by third party carrier insurance there can be no assurance that such indemnification and insurance will be adequate. There can be no assurance that we will not experience material losses due to product liability claims or recalls in the future.

We face risks related to environmental matters.

Our facilities are subject to a broad range of federal, state, local and foreign environmental laws and requirements, including those governing discharges to the

air and water, the handling or disposal of solid and hazardous substances and wastes and remediation of contamination associated with the release of hazardous substances at our facilities and offsite disposal locations. We have made, and will continue to make, expenditures to comply with such laws and requirements. Future events, such as changes in existing laws and regulations or the discovery of contamination at our facilities, may give rise to additional compliance or remediation costs that could have a material adverse effect on our business, results of operations or financial condition. Moreover, as a manufacturer of various products, we are exposed to some risk of claims with respect to environmental matters, and there can be no assurance that material costs or liabilities will not be incurred in connection with any such claims.

We are involved in a voluntary clean-up at one of our sites in the state of New York, and although the workplan submitted to the state was accepted and the clean-up is proceeding in accordance with the workplan and our expectations, there can be no assurance that the clean-up will be completed within the timeframe and cost projected, that the expected results will be

achieved, or that we will not identify alternate sources of contamination in connection with their remediation. As such, there can be no assurance that material costs or liabilities will not be incurred in connection with any such remediation.

We may be required to recognize impairment charges.

Pursuant to generally accepted accounting principles, we are required to perform impairment tests on our goodwill balance annually or at any time when events occur, which could impact the value of our business segments. Our determination of whether an impairment has occurred is based on a comparison of each of our reporting units' fair market value with its carrying value. Significant and unanticipated changes could require a provision for impairment in a future period that could substantially affect our reported earnings in a period of such change. In addition, such charges would reduce our consolidated net worth and our shareholders' equity, increasing our debt to total capitalization ratio, which may result in a default under our credit facilities.

We are in the process of upgrading certain of our management information systems and there can be no assurance that there will not be excessive costs associated with such upgrade.

We are in the process of upgrading certain of our management information systems. There can be no assurance that such upgrades will not result in a disruption of our business, extensive commitment of time and other costs related to upgrading such management information systems.

Our earnings will be adversely affected if we are required to change our accounting policies with respect to the expensing of stock options.

We do not currently deduct the expense of stock option grants from our income based on the fair value method. Regulatory authorities, including the Financial Accounting Standards Board and the International Accounting Standards Board, are considering requiring companies to change their accounting policies to record

the fair value of stock options issued to employees and directors as an expense. Many companies have or are in the process of voluntarily changing their accounting policies to expense the fair value of stock options. Stock options are an important component of our employee compensation package. If we change our accounting policy with respect to the treatment of stock option grants, our earnings would be adversely affected which in turn could have negative impact on the price of our common stock and the debentures.

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

Technological developments in the eyecare industry, such as new surgical procedures or medical devices, may adversely affect the demands for our products. Corneal refractive surgical procedures such as Lasik surgery and the development of new pharmaceutical products may decrease 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 optical business.

Risks relating to government regulation.

FDA regulations

Our products and operations are subject to extensive and rigorous regulation by the U.S. Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), and its implementing regulations, guidances, and standards. The FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, promotion, distribution, and production of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. The FDA also regulates the export of medical devices manufactured in the United States to international markets. Any violations of these laws and regulations could result in a material adverse effect on our business, financial condition and results of operations. In addition, if there is a change in law, regulation or judicial interpretation, we may have to change our business practices, which could have a material adverse effect on our business, financial condition and results of operations.

Under the FFDCA, medical devices are classified into one of three classes -- Class I, Class II or Class III -- depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. We have products in each class.

Class I devices are those for which safety and effectiveness can be assured by adherence to FDA's general regulatory controls for medical devices, which include compliance with the applicable portions of the FDA's Quality System Regulation ("QSR"), facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials (the "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 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 recently enacted Medical Device User Fee and Modernization Act of 2002, 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. When a 510(k) is required, the manufacturer must submit to the FDA a premarket notification submission demonstrating that the device is "substantially equivalent" to either: a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or to another commercially available, similar device which was subsequently cleared through the 510(k) process.

If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device. By regulation, the FDA is required to clear a 510(k) within 90-days of submission of the application. As a practical matter, clearance often takes longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. If the FDA determines that the device, or its intended use, is not "substantially equivalent" to a preamendment or other commercially available device, the FDA will place the device, or the particular use of the device, into Class III, and the device sponsor must then fulfill much more rigorous premarketing requirements.

A Class III product is a product which has a new intended use, or uses 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.

Submission and FDA approval of a premarket approval application ("PMA") is required before marketing of a Class III product can proceed. As with 510(k) submissions, unless subject to an exemption, PMA submissions are subject to user fees. The PMA process is much more demanding than the 510(k) premarket notification process. A PMA, which is intended to demonstrate that the device is safe and effective, must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities, and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, once the FDA determines that the application is sufficiently complete to permit a substantive review, the FDA will accept the application for review. The FDA, by statute and by regulation, has 180-days to review an "accepted" PMA, although the review of an application more often occurs over a significantly longer period of time, and can take up to several years. In approving a PMA or clearing a 510(k) application, the FDA may also require some form of post-market surveillance when necessary to protect the public health or to provide additional safety and effectiveness data for the

device. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients.

The soft contact lenses that we currently market have received FDA clearance through the 510(k) process or approval through the PMA process. In addition, we have made modifications to our products that we do not believe require the submission of new 510(k) modifications or PMA supplements. We cannot confirm, however, that the FDA will agree with any of our determinations not to submit new 510(k) notifications or PMA supplements for these changes, that the FDA will not require us to cease sales and distribution while seeking clearances of 510(k) notifications and approvals of PMA supplements for the changes, or that we will obtain such clearances and approvals, if required, in a timely manner or at all.

When FDA approval of a Class I, Class II or Class III device requires human clinical trials, and if the device presents a "significant risk" (as defined by the FDA) to human health, the device sponsor is required to file an investigational device exemption ("IDE") application with the FDA and obtain IDE approval prior to commencing human clinical trials. If the device is considered a "non-significant" risk, IDE submission to FDA is not required. Instead, only approval from the Institutional Review Board overseeing the clinical trial is required. Human clinical trials are generally required in connection with approval of Class III devices and may be required for Class I and II devices. The FDA, and the Institutional Review Board at each institution at which a clinical trial is being performed, may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk. There can be no assurances that we will be able to secure 510(k) and PMA clearances and approvals for our new medical devices, or that FDA will not suspend, modify, or revoke existing clearances and approvals for products currently being marketed by the Company. If this were to occur, it could have a material adverse effect on our business, financial condition, and results of operations.

After FDA permits a device to enter commercial distribution, numerous regulatory requirements apply. These include: the QSR, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process; labeling regulations; the FDA's general prohibition against promoting products for unapproved or "off-label" uses; and the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to reoccur. The FDA has broad post-market, regulatory and enforcement powers. Failure to comply with the applicable U.S. medical device regulatory requirements could result in, among other things, warning letters, fines, injunctions, consent decrees, civil penalties, repairs, replacements, refunds, recalls or seizures of products (which would result in the cessation or reduction of our production volume), total or partial suspension of production, the FDA's refusal to grant future premarket clearances or approvals, withdrawals or suspensions of current product applications, and criminal prosecution. If any of these events were to occur, they could have a material adverse effect on our business, financial

condition and results of operations.

From time to time we voluntarily recall a product. For example, we are currently involved in two recalls. On August 1, 2002 we initiated a voluntary recall of a uterine manipulator-injector device. There can be no assurance that the product will not cause serious injury in the future as a result of products remaining in use despite the recall. We are currently working to replace these products and do not expect the cost of this recall to be material. We also intend to issue a recall of specific batches of one of our contact lens products due to mislabeling resulting from a software error in the labeling process. We do not believe these mislabeled products pose a serious health or safety risk and believe that the cost of the recall will be approximately $400,000.

In addition, we acquired Ackrad Laboratories, Inc. on May 21, 2002. Prior to the acquisition on December 6, 1995, Ackrad had entered into a FDA Consent Decree of Permanent Injunction due to violations of FDA Good Manufacturing Practice (GMP) regulations, including failure to have adequate validation of device manufacturing and sterilization processes. Both Ackrad and we have instituted corrective actions to address the GMP deficiencies and we believe we are in substantial compliance with FDA's GMP regulations.

Healthcare reform

In recent years, an increasing number of legislative initiatives have been introduced or proposed in Congress and in state legislatures that could effect major changes in the healthcare system, either nationally or at the state level. Among the proposals under consideration are price controls on hospitals, insurance market reforms to increase the availability of group health insurance to small businesses, requirements that all businesses offer health insurance coverage to their employees and the creation of a government health insurance plan or plans that would cover all citizens. There continue to be efforts at the federal level to introduce various insurance market reforms, expanded fraud and abuse and anti- referral legislation and further reductions in Medicare and Medicaid coverage and reimbursement. A broad range of both similar and more comprehensive healthcare reform initiatives is likely to be considered at the state level. It is uncertain which, if any, of these or other proposals will be adopted. We cannot predict the effect such reforms or the prospect of their enactment may have on our business.

Retail optics industry

Our success depends to a significant extent upon the success of our customers in the retail optical industry. These customers are subject to a variety of federal, state and local laws, regulations and ordinances. The state and local legal requirements vary widely among jurisdictions and are subject to frequent change. Furthermore, numerous healthcare-related legislative proposals have been made in recent years in the Congress and in various state legislatures. The potential impact of these proposals with respect to the business of our customers is uncertain, and we cannot assure you that that the proposals, if adopted, would not have a material adverse impact on our revenues, business, financial condition and results of operations.

There is substantial United States federal and state governmental regulation related to the prescribing of contact lenses. These regulations relate to who is permitted to prescribe and fit contact lenses, the prescriber's obligation to provide prescriptions to its patients, the length of time a prescription is valid, the ability or obligation of prescribers to prescribe lenses by brand rather than by generic equivalent or specification, and other matters. In addition, adverse regulatory or other decisions affecting eyecare practitioners, or material changes in the selling and prescribing practices for contact lenses, could have a material adverse affect on our business, operating results and financial condition. Finally, although cost controls or other requirements imposed by third party healthcare payors such as insurers and health maintenance organizations have not historically had a significant effect on contact lens prices or distribution practices, this could change in the future, and could adversely affect our business, financial condition and results of operations.

International product regulations

In many of the foreign countries in which we market our products, we are subject to regulations affecting, among other things, product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. Many of the regulations applicable to our devices and products in such countries are similar to those of the FDA. In many countries, the national health or social security organizations require our products to be qualified before they can be marketed with the benefit of reimbursement eligibility. To date, we have not experienced difficulty in complying with these regulations. Due to the movement towards harmonization of standards in the European Union, we expect a changing regulatory environment in Europe characterized by a shift from a country-by-country regulatory system to a European Union-wide single regulatory system. We cannot currently predict the timing of this harmonization. Our failure to receive, or delays in the receipt of, relevant foreign qualifications could have a material adverse effect on our business, financial condition and results of operations.

We have also implemented policies and procedures allowing us to position ourselves for the changing international regulatory environment. The ISO 9000 series of standards has been developed as an internationally recognized set of guidelines that are aimed at ensuring the design and manufacture of quality products. A company that passes an ISO audit and obtains ISO registration becomes internationally recognized as well run and functioning under a competent quality system. In certain foreign markets, it may be necessary or advantageous to obtain ISO 9000 series certification, which is in some ways analogous to compliance with the FDA's QSR requirements. The European Community promulgated rules requiring medical products to

receive a CE mark by mid-1998. A CE mark is an international symbol of adherence to certain standards and compliance with applicable European medical device requirements.

Federal privacy and transaction law and regulations

Other federal legislation will affect the manner in which we use and disclose health information. The Health Insurance Portability and Accountability Act of

1996 (HIPAA) mandates, among other things, the adoption of standards for the electronic exchange of health information that may require significant and costly changes to current practices. The U.S. Department of Health and Human Services (HHS) has released three rules to date mandating the use of new standards with respect to certain healthcare transactions and health information. The first rule requires the use of uniform standards for common healthcare transactions, including healthcare claims information, plan eligibility, referral certification and authorization, claims status, plan enrollment and disenrollment, payment and remittance advice, plan premium payments, and coordination of benefits. The second rule released by HHS imposes new standards relating to the privacy of individually identifiable health information. These standards not only require compliance with rules governing the use and disclosure of protected health information, but they also require an entity subject to HIPAA to obtain satisfactory assurances that any of its business associates to whom such information is disclosed will safeguard the information. The third rule released by HHS establishes minimum standards for the security of electronic health information. While we do not believe we are directly regulated as a covered entity under HIPAA, many of our customers are covered entities subject to HIPAA. Such customers may require us to enter into business associates agreements, which obligate us to safeguard certain health information we obtain in the course of servicing the customers, restrict the manner in which we use and disclose such information and impose liability on us for failure to meet our contractual obligations. The costs of complying with these contractual obligations and potential liability associated with failure to do so could have a material adverse effect on our business and financial condition and results of operation.

Fraud and abuse

We may be subject to various federal and state 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 its practices to be in compliance with these laws. Any violations of these laws or regulations could result in a material adverse effect on our business, financial condition and results of operations. Moreover, if there is a change in law, regulation, administrative or judicial interpretation, we may have to change our business practices or our existing business practices could be challenged as unlawful, which could have a material adverse effect on our business, financial condition and results of operations.

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, 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.

HIPAA created two new federal crimes: 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 HHS and the U.S. Department of Justice (DOJ) and provided enhanced resources to support the activities and responsibilities of the 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 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.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

THE COOPER COMPANIES, INC.

By /s/ Stephen C. Whiteford

Stephen C. Whiteford
Vice President and
Corporate Controller
(Principal Accounting Officer)

Dated: June 20, 2003

EXHIBIT INDEX

Exhibit No.	Description	Sequentially Numbered Page
99.1	Press Release dated June 20, 2003.	