PATHEON INC
Form 10-12G/A
April 13, 2011
Table of Contents

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1

TO

FORM 10

GENERAL FORM FOR REGISTRATION OF SECURITIES

Pursuant to Section 12(b) or (g) of the Securities Exchange Act of 1934

PATHEON INC.

(Exact name of registrant as specified in its charter)

Canada	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4721 Emperor Boulevard, Suite 200	
Durham, NC	**27703**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code: **(919) 226-3200**

Copies to:

Eric W. Evans	**Jason L. Martinez, Esq.**
Chief Financial Officer	**Smith, Anderson, Blount,**
Patheon Inc.	**Dorsett, Mitchell & Jernigan L.L.P.**
4721 Emperor Boulevard, Suite 200	**P.O. BOX 2611**
Durham, NC 27703	**Raleigh, NC 27602-2611**
Telephone: (919) 226-3200	**Telephone: (919) 821-1220**

Securities to be registered pursuant to Section 12(b) of the Act: **None.**

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

Restricted Voting Shares

(Title of Class)

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

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

Table of Contents

TABLE OF CONTENTS

Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This registration statement contains statements that we believe are forward-looking statements. These statements reflect management s expectations regarding our future growth, results of operations, performance (both operational and financial) and business prospects and opportunities. Where possible, words such as plans, expects or does not expect, budget, forecasts, anticipates or does not anticipate, b intends and similar expressions or statements that certain actions, events or results may, could, would, might or will be taken, occur or be achieved, have been used to identify these forward-looking statements. Although the forward-looking statements contained in this registration statement reflect management s current assumptions based upon information currently available to management and based on assumptions that management believes to be reasonable, we cannot be certain that actual results will be consistent with these forward-looking statements. Current material assumptions relate to foreign exchange rates, customer volumes and regulatory compliance. A number of factors could cause actual results, performance or achievements to differ materially from the results expressed or implied in the forward-looking statements, including those listed in Item 1A. Risk Factors of this registration statement. These factors should be considered carefully, and readers should not place undue reliance on the forward-looking statements. Forward-looking statements necessarily involve significant known and unknown risks, assumptions and uncertainties that may cause our actual results, performance, prospects and opportunities in future periods to differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include, among other things: customer demand for our services; supply arrangements; exposure to complex production issues; global economic environment; international operations and foreign currency fluctuations; competition; credit and customer concentration; rapid technological change; dependence upon key management personnel and executives; pension plans; derivative financial instruments; divestitures and restructurings; impacts of acquisitions; the existence of a significant shareholder; substantial financial leverage; interest rate risks; regulatory matters affecting manufacturing and pharmaceutical development services; potential environmental, health and safety liabilities; product liability claims; and intellectual property. See Item 1A. Risk Factors. Although we have attempted to identify important risks and factors that could cause actual actions, events or results to differ materially from those described in forward-looking statements, there may be other factors and risks that cause actions, events or results not to be as anticipated, estimated or intended. There can be no assurance that forward-looking statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, as noted above, readers should not place undue reliance on forward-looking statements. These forward-looking statements are made as of the date of this registration statement and, except as required by law, we assume no obligation to update or revise them to reflect new events or circumstances.

General

All references to $ or dollars in this registration statement are to U.S. dollars unless otherwise indicated.

Item 1. Business.

Overview

We are a leading provider of commercial manufacturing outsourcing services (CMO) and outsourced pharmaceutical development services (PDS) to the global pharmaceutical industry. We believe we are the world s second-largest CMO provider and the world s largest PDS provider based on calendar year 2009 revenues provided by PharmSource, a provider of pharmaceutical outsourcing business information. We offer a wide range of services from developing drug candidates at the pre-formulation stage through the launch, commercialization and production of approved drugs. During the fiscal year ended October 31, 2010 (fiscal 2010), we provided services to approximately 300 customers throughout the world, including 19 of the world s 20 largest pharmaceutical companies, six of the world s 10 largest biotechnology companies and five of the world s 10 largest specialty pharmaceutical companies. In fiscal 2010, we manufactured 10 of the top 100 selling drug compounds in the world based on revenues for the products reported by Evaluate Pharma, a provider of pharmaceutical industry data, and our products were distributed in approximately 60 countries. We are also

Table of Contents

currently developing nine of the top 100 developmental stage drugs in the world on behalf of our customers based on projected potential revenues for the products reported by Evaluate Pharma.

Our CMO business focuses primarily on prescription products in sterile dosage forms and solid, semi-solid and liquid conventional dosage forms. We have also developed a wide range of specialized capabilities in high potency, controlled substances and sustained release products. Our PDS business provides a broad range of development services, including finished dosage formulation across approximately 40 dosage forms, clinical trial packaging and associated analytical services. We have established our position as a market leader by leveraging our scale, global reach, specialized capabilities, broad service offerings, scientific expertise and track record of product quality and regulatory compliance to provide cost-effective solutions to our customers.

Company History

The heritage of our company dates back to 1974, when we established Custom Pharmaceuticals Ltd., a contract manufacturing business, in Fort Erie, Canada. We increased our contract manufacturing capabilities in 1982 by building a new manufacturing facility in Burlington, Canada, and from 1994 through 2002, we continually expanded our contract manufacturing capabilities by building or acquiring facilities in Canada, Europe and the United States and entered into the PDS business.

We completed our last major acquisition in fiscal 2005, with the acquisition of MOVA Pharmaceutical Corporation (MOVA), a leading U.S. prescription pharmaceutical contract manufacturer located in Puerto Rico. During 2006 and 2007, we determined that the carrying value of MOVA s intangible assets, long-lived depreciable assets and goodwill were impaired as a result of the suspension of production of a major product due to concerns over product shelf life and the decline of another major product as a result of the approval by the U.S. Food and Drug Administration (the FDA) of a generic version of the product, which culminated in a significant increase in losses reported by the Puerto Rico operations, and the completion of a long-range plan that showed a significant reduction in earnings relative to prior forecasts. The impairment charges associated with these write-downs were $78.0 million for intangible assets, $52.0 million for long-lived depreciable assets and $172.5 million for goodwill. Following the acquisition of MOVA and associated impairments, we shifted our focus from external expansion to reviewing opportunities to improve our financial stability and operational efficiencies.

In 2006 and 2007, we conducted a review of strategic and financial alternatives that resulted in a $150,000,000 investment in us by JLL Partners Inc., a New York private equity firm (JLL Partners), and a refinancing of our North American indebtedness. As a result of this investment, an affiliate of JLL Partners received two series of preferred stock, one of which it converted into restricted voting shares in 2009 and the other of which entitles it to elect up to three members of our Board of Directors (our Board). See Item 6. Executive Compensation Compensation Committee Interlocks and Insider Participation Arrangements with JLL. Affiliates of JLL Partners currently beneficially own approximately 56% of our restricted voting shares.

In 2007, we announced a plan to restructure our Canadian network of six pharmaceutical manufacturing facilities to align with our strategy of focusing on developing and manufacturing prescription, rather than over-the-counter, products. To improve capacity utilization and profitability at our Whitby facility, we began decommissioning our York Mills facility and transferring all services undertaken at that site to, primarily, our Whitby facility. In the fiscal year ended October 31, 2008 (fiscal 2008), we sold our Niagara-Burlington operations to Pharmetics Inc.

In fiscal 2008, we announced a plan to restructure our Puerto Rican operations. In January 2009, we closed our Carolina facility in Puerto Rico and are marketing the remaining assets for sale. Later in 2009, we announced our intention to consolidate our two remaining Puerto Rico operations into our manufacturing site in Manatí and ultimately close or sell our plant in Caguas. The consolidation is expected to continue beyond the end of calendar year 2012.

In November 2008, we opened a U.S. headquarters in Research Triangle Park, North Carolina. In 2008, we also opened a new early phase development facility in Milton Park, in Oxfordshire, United Kingdom, and a new European headquarters in Zug, Switzerland, near Zurich.

Table of Contents

In November 2009, we completed the PDS facility inside our existing commercial manufacturing site in Ferentino, Italy. The expansion doubled PDS manufacturing capabilities for clinical batches. This area, which was designed for future expansion, was set up specifically for the scale-up of products for clinical use following the completion of development activities on site.

In January 2010, we began construction to expand our manufacturing facility in Bourgoin, France to include a pharmaceutical development center offering a full range of solid dose services as part of our PDS business. The construction was completed during the first quarter of the fiscal year ending October 31, 2011 (fiscal 2011).

On April 23, 2010, we completed the issuance of $280 million, 8.625% senior secured notes, due April 15, 2017 (the Notes), in a private placement to certain qualified institutional buyers. We used the net proceeds of $268.5 million to repay all of our indebtedness under our then existing senior secured term loan and asset-based revolving credit facility (ABL), to repay certain other indebtedness and to pay expenses and fees. We are using the remaining proceeds for general corporate purposes. Concurrently, we entered into an amended and restated $75 million ABL. As a result of this amendment, the ABL now matures in 2014.

Our Segments

Although we were historically organized and managed as a single business segment providing commercial manufacturing and pharmaceutical development services, due to the continued growth in our operations and a change in our executive management structure, in fiscal 2008 we organized ourselves into two operating segments: CMO and PDS. In addition, we categorize certain selling, general and administrative costs and foreign exchange gains and losses under a separate segment reporting line item referred to as corporate costs. In fiscal 2010, our CMO and PDS segments accounted for 81.2% and 18.8% of our total revenues, respectively. Financial information about these segments and information regarding net sales and long-lived assets attributable to operations in Canada, the United States, Europe and other countries is contained in Note 16 Segmented Information of our consolidated financial statements beginning on page F-1 of this registration statement. Additional financial information about our segments is contained in Item 2. Financial Information Management s Discussion and Analysis. For a discussion of risks attendant to our foreign operations, please see Item 1A. Risk Factors Risks Related to our Business and Industry.

The illustration below sets forth the various stages of the drug development and manufacturing process; shaded processes are services that we provide.

Note: API: Active Pharmaceutical Ingredient

PAI: Pre-Approval Inspection(s)

Table of Contents

Commercial Manufacturing

We believe we are the world s second-largest CMO provider with an approximate 5% global market share in 2009 based on calendar year 2009 revenues provided by PharmSource. We operate nine facilities located throughout North America and Europe. We manufacture various sterile dosage forms, as well as solid, semi-solid and liquid conventional dosage forms. Our sterile dosage forms include aseptically (sterile) filled and terminally sterilized liquids and powders in ampoules, vials, bottles and pre-filled syringes and sterile lyophilized (freeze-dried) products in both vials and ampoules. Conventional dosage forms include both coated and uncoated compressed tablets, hard shell gelatin capsules, powders, ointments, creams, gels, syrups, suspensions, solutions and suppositories. Currently, our capacity utilization is higher for our facilities for sterile dosage forms than for conventional dosage forms. We further differentiate ourselves by offering specialized capabilities relating to high potency, controlled substance and sustained release products. In fiscal 2010, our CMO segment generated 81.2% of our total revenues.

Set forth below is a table illustrating our various dosage forms.

Conventional dosage forms			
Solids	Tablets	Specialized	High potency
	Capsules	capabilities	Controlled substances
	Powders		
Semi-solids	Creams		Sustained release products
	Ointments		Soft gels
	Suppositories		Liquid filled hard shell capsules
	Gels		
Liquids	Syrups		Nasal sprays
	Solutions		
	Suspensions		
Sterile dosage forms			
	Aseptically (sterile) filled and terminally sterilized liquids and powders (in ampoules, vials, bottles and pre-filled syringes)		
	Pre-filled syringes and sterile lyophilized (freeze-dried) products (in vials and ampoules)		
	Sterile (injectable) cephalosporin powder filling		

We operate a segregated sterile (injectable) cephalosporin powder filling and lyophilisation facility in the United Kingdom. The combination of sterile cephalosporin capabilities and our 31,000 square foot lyophilisation plant dedicated to lyophilized cephalosporin products allows us to provide a full range of dosage forms for this category of antibiotics.

In fiscal 2010, we had a diverse CMO customer base with large pharmaceutical companies, specialty companies and large biotechnology companies comprising 55%, 27% and 5% of our fiscal 2010 CMO revenues, respectively, with the remainder being derived from our early stage pharmaceutical, generic and other customers.

Pharmaceutical Development Services

We believe we are the world s largest PDS provider with an approximate 10% global market share in 2009 based on calendar year 2009 revenues provided by PharmSource, offering a broad range of development services across approximately 40 different dosage forms. We operate eight development centers and one clinical trial packaging facility located throughout North America and Europe. Our PDS offerings support customers across various stages of the drug development process, including (i) pre-formulation, formulation and development of dosage forms; (ii) manufacturing of development stage products during the regulatory drug approval process, including manufacturing of pilot batches;

(iii) scale-up and technology transfer services designed to validate

Table of Contents

commercial-scale drug manufacturing processes; and (iv) development of analytical methods and delivery of analytical services. In fiscal 2010, our PDS offerings were provided to a diverse customer base with specialty companies, large pharmaceutical companies and large biotechnology companies comprising 32%, 30% and 37% of our fiscal 2010 PDS revenues, respectively, with the remaining 1% being derived from our early stage pharmaceutical, generic and other customers.

During fiscal 2010, we worked on approximately 395 projects for our customers, including eight drug candidates at the new drug application (NDA) stage. Among the projects we worked on during fiscal 2010, 87 projects were at Phase I, 93 projects were at Phase II, 85 projects were at Phase III, and 130 projects were at the pre-clinical or post-approval stage. During fiscal 2010 and 2009, we developed six products for customers that received new market approval. Since the beginning of fiscal 2001, our PDS business has developed, on behalf of our customers, 28 new molecular entities (NME) that have been approved for marketing by regulatory authorities, as well as numerous new formulations of existing NMEs. Any patent and drug approvals that we obtain, or help to obtain, belong to our customers, and we do not receive royalties or earn revenues from products or NMEs that we develop, or help to develop, other than for the development services we provide. Our development group, comprised of approximately 600 scientists and technicians, including approximately 80 holding doctoral degrees, has extensive development experience across a wide variety of pharmaceutical dosage forms. Our PDS business serves as a pipeline for future commercial manufacturing opportunities. Since most of these products are at the beginning of their patent life, these products typically present long-term manufacturing opportunities. From the beginning of fiscal 2008 through the end of fiscal 2010, we were awarded CMO contracts for 27 new products that had been developed by our PDS business. In fiscal 2010, our PDS segment generated 18.8% of our total revenues.

Performance Enhancement Initiatives

We are committed to providing quality products and services to our customers. We are undertaking a series of initiatives to reduce operating expenses and increase manufacturing efficiency, including launching the Patheon Advantage™ Lean 6 Sigma program and upgrading our information technology infrastructure. We have established a number of key performance indicators to measure the benefits of these initiatives, including on-time delivery, right first time batches and inventory turns. Over the last three fiscal years, the following initiatives were introduced:

Patheon Advantage™ is a companywide program that combines lean manufacturing practices with six sigma manufacturing to streamline operations, remove production bottlenecks, increase capacity utilization and improve performance throughout the network. All of our sites have completed their Lean 6 Sigma leadership training and at least one round of initial activities.

One Patheon™ is our global initiative to create one consistent customer interface by providing customers with consistent quotes and proposals, technical documents, invoice procedures, workflow management, ongoing performance communication and project execution.

Quick to Clinic™ is a program designed to accelerate drug development timelines for customers through rapid distribution of clinical trial materials for Phase I (First Time in Human) studies and delivery of finished drug product within four months from receipt of active pharmaceutical ingredients (API). To this end, our Milton Park (U.K.) and Whitby (Canada) facilities are designated as delivery centers.

Quick to Market™ offers accelerated transfer of commercially available products from our customers or their supplier s manufacturing plants to our facilities.

The Patheon Performance Guarantee, launched in June 2009, is a new term to be added to commercial manufacturing contracts for customers with critical supply requirements that guarantees, in writing, delivery performance and legacy of quality. If we fail to perform as guaranteed, we provide the customer discounts on future services. The average on-time, in-full delivery across our entire network was approximately 93% in fiscal 2010.

Table of Contents

We have developed a four-year information technology master plan that sets the overall direction for systems and services for our business. It centers on the development of strategic information technology assets that will drive competitive advantages for our business and includes both the addition of new information technology assets and the enhancement of existing information technology assets.

Successful implementation of these initiatives has enabled us to improve our performance as measured by key performance indicators, including increasing our frequency of on-time, in-full delivery of customer orders across our entire network from 85% in the first quarter of fiscal 2008 to approximately 93% in the first quarter of fiscal 2011.

Customers

In fiscal 2010, we provided services to approximately 300 customers throughout the world, including 19 of the world s 20 largest pharmaceutical companies, six of the world s 10 largest biotechnology companies and five of the world s 10 largest specialty pharmaceutical companies. We are also currently developing on behalf of our customers nine of the 100 top developmental stage drugs in the world, based on the potential revenues for the products reported by EvaluatePharma®. During fiscal 2010, no single customer accounted for more of 10.0% of our total revenues in our CMO business or PDS business. In fiscal 2010, our top 20 customers in our CMO segment accounted for approximately 81% of our CMO revenues. As described above, in June 2009, we launched a new performance guarantee initiative designed to enhance our service to customers. The Patheon Performance Guarantee was added as a new feature in CMO contracts for customers with critical supply requirements.

We have recently entered into several master service agreements with customers that contemplate long-term multi-product and multi-site commercial manufacturing and/or PDS, including a seven-year manufacturing agreement that led to construction of a new manufacturing facility within one of our existing sites with significant financing from the customer, a five-year master supply agreement with a global pharmaceutical company to provide development and manufacturing services and carve-out arrangements at certain of our facilities under which sizeable parts of our current production have been transferred to us from facilities owned by our customers that were slated for closure or downsizing. These arrangements are part of a trend towards developing broader and longer-term relationships with our customers.

Our CMO customers typically provide a yearly forecast of anticipated product demand. Customers also deliver firm purchase orders, typically three months prior to scheduled production, after which time they may adjust contract quantities or delivery dates within certain limits, provided that we are reimbursed for any expenses incurred in connection with such adjustment. Upon delivery to us of a customer purchase order confirming the quantity and delivery date, the order is scheduled for production. Our CMO customer contracts, typically with multi-year terms, formalize the standard business arrangements outlined above, including production based on the delivery of firm purchase orders. In addition, the contracts typically provide for six to 18 months advance notice for the transfer or discontinuance of any product. The customer assumes liability for all material commitments made in accordance with purchase orders. We maintain the right to pass on price increases to the customer over and above some predetermined minimum percentage. The actual revenues generated by our major customer agreements are based on volumes that are determined by market demands for the customer s product from time to time.

Our PDS business provides services on a fee-for-service basis. We typically respond to a customer request and prepare a quotation which, if accepted, typically forms the basis of the contract with the customer. Our PDS contracts typically require us to perform development services within a designated scope. Frequently, the continuation of our work on a particular project will depend on various factors such as research results and the customer s needs.

Sales and Marketing

Our global sales and marketing group is responsible for generating new business for our CMO and PDS businesses. Our sales team is broken into two distinct groups territory-based sales executives and key account

Table of Contents

executives. Each of our territory-based sales teams is responsible for seeking potential customers and generating sales to all customers within its territory that are not named as a key account. Our North America territory-based sales team is comprised of 20 team members and covers the United States and Canada. We also have a territory-based sales team covering Europe and Japan, which is comprised of nine members. In addition, we have six global key account executives who act as our primary interface with our most significant accounts; currently approximately 35 of our customers have key account status. Despite the functional and geographical delineation of our sales teams, each sales team or executive seeks to generate sales in both our CMO and PDS segments across our entire network. Determination of which site, or sites, will perform specific services is dictated by the nature of the customer s product, our capabilities and customer preferences.

The projects of our existing customers are managed by site-based project managers and business managers, who also play an integral role in the sales process by ensuring that the existing projects are meeting customers expectations. Our sales executives work closely with the site-based teams to understand our customers projects and evolving needs, enabling the sales executives and site-based teams to obtain additional work on existing projects and to identify new projects.

Our sales team is supported by global marketing, sales operations and business intelligence groups located at our U.S. headquarters in Research Triangle Park, North Carolina, and regional support resources in Europe.

Supply Arrangements

For our contract manufacturing operations, we are required to source various APIs, excipients, raw materials and packaging components from third-party suppliers and/or our actual customers. Our customers specify these components, raw materials and packaging materials in line with their product registration files, and, in some cases, they specify the actual supplier from whom we must purchase these inputs. In most cases, our customers manage the sourcing and physical delivery of the API to us at no cost. We generally source and procure all other input materials from established local or regional suppliers specialized towards serving the pharmaceutical sector.

Supply arrangements are an inherent part of our ability to produce products for our customers in a timely manner and thus create a degree of dependence that could negatively impact revenues if such supply is interrupted. Such interruptions can be either localized to a specific supplier issue or as a result of wider supply interruptions due to natural disasters or international disruptions caused by geopolitical issues or other events. See Item 1A. Risk Factors Risks Related to Our Business and Industry. We work closely with suppliers at both a local and corporate level to establish clear supply agreements that set forth the supply relationship expectations and the legal terms and conditions of the agreements, including potential liabilities for supply interruption situations. These agreements are critical to our ability to manage and mitigate risk across our supply chain.

Competition

We operate in a market that is highly competitive. We compete to provide CMO and PDS to pharmaceutical companies around the world.

Our competition in the CMO market includes full-service pharmaceutical outsourcing companies; contract manufacturers focusing on a limited number of dosage forms; contract manufacturers providing multiple dosage forms; and large pharmaceutical companies offering third-party manufacturing services to fill their excess capacity. In addition, in Europe, there are a large number of privately owned, dedicated outsourcing companies that serve only their local or national markets. Also, large pharmaceutical companies have been seeking to divest portions of their manufacturing capacity, and any such divested businesses may compete with us in the future. We compete primarily on the basis of the security of supply (quality, regulatory compliance and financial stability), service (on-time delivery and manufacturing flexibility) and cost-effective manufacturing (prices and a commitment to continuous improvement).

Table of Contents

Our competition in the PDS market includes a large number of laboratories that offer only a limited range of developmental services, generally at a small scale; providers focused on specific technologies and/or dosage forms; and a few fully integrated companies that can provide the full complement of services necessary to develop, scale-up and manufacture a wide range of dosage forms. We also compete in the PDS market with major pharmaceutical and chemical companies, specialized contract research organizations, research and development firms, universities and other research institutions. We may also compete with the internal operations of pharmaceutical companies that choose to source PDS internally. We compete primarily on the basis of scientific expertise, knowledge and experience in dosage form development, availability of a broad range of equipment, on-time delivery of clinical materials, compliance with current good manufacturing practices (cGMPs), regulatory compliance, cost effective services and financial stability.

Some of our competitors may have substantially greater financial, marketing, technical or other resources than we do. Additional competition may emerge and may, among other things, result in a decrease in the fees paid for our services.

One of the many factors affecting competition is the current excess capacity within the pharmaceutical industry of facilities capable of manufacturing drugs in solid and semi-solid dosage forms. Thus, customers currently have a wide range of supply alternatives for these dosage forms. Another factor causing increased competition is that a number of companies in Asia, particularly India, have been entering the CMO and PDS sectors over the past few years, have begun obtaining approval from the FDA for certain of their plants and have acquired additional plants in Europe and North America. One or more of these companies may become a significant competitor to us.

Employees

As of March 31, 2011, we had approximately 3,800 employees. National works councils are active at all of our facilities in the United Kingdom, France and Italy consistent with local labor laws. There is no union representation at any of our North American sites. Our management believes that we generally have a good relationship with our employees around the world and the works councils that represent a portion of our European employee base.

Intellectual Property

We rely on a combination of trademark, patent, trade secret and other intellectual property laws of the United States and other countries. We have applied in the United States and in certain foreign countries for registration of a limited number of trademarks and patents, some of which have been registered or issued. Also, many of the formulations used by us in manufacturing products to customer specifications are subject to patents or other intellectual property rights owned by or licensed to the relevant customer. Further, we rely on non-disclosure agreements and other contractual provisions to protect our intellectual property rights and typically enter into mutual confidentiality agreements with customers that own or are licensed users of patented formulations.

We have developed and continue to develop knowledge and expertise (know-how) and trade secrets in the provision of services in both our PDS and CMO businesses. Our know-how and trade secrets may not be patentable, but they are valuable in that they enhance our ability to provide high-quality services to our customers.

To the extent that we determine that certain aspects of the service provided by our CMO and PDS businesses are innovative and patentable, we have filed and pursued, and plan to continue to file and pursue, patent applications to protect such inventions, as well as applications for registration of other intellectual property rights, as appropriate. However, we do not consider any particular patent, trademark, license, franchise or concession to be material to our overall business.

Table of Contents

Regulatory Matters

We are required to comply with the regulatory requirements of various local, state, provincial, national and international regulatory bodies having jurisdiction in the countries or localities where we manufacture products or where our customers products are distributed. In particular, we are subject to laws and regulations concerning research and development, testing, manufacturing processes, equipment and facilities, including compliance with cGMPs, labeling and distribution, import and export, and product registration and listing. As a result, most of our facilities are subject to regulation by the FDA, as well as regulatory bodies of other jurisdictions, such as the European Medicines Agency of the European Union (the EMEA) and/or the National Health Surveillance Agency in Brazil (the NHSA), depending on the countries in which our customers market and sell the products we manufacture and/or package on their behalf. We are also required to comply with environmental, health and safety laws and regulations, as discussed in Environmental Matters. These regulatory requirements impact many aspects of our operations, including manufacturing, developing, labeling, packaging, storage, distribution, import and export and record keeping related to customers products. Noncompliance with any applicable regulatory requirements can result in government refusal to approve (i) facilities for testing or manufacturing products or (ii) products for commercialization. The FDA and other regulatory agencies can delay, limit or deny approval for many reasons, including:

- Changes to the regulatory approval process, including new data requirements, for product candidates in those jurisdictions, including the United States, in which we or our customers may be seeking approval;
- A product candidate may not be deemed to be safe or effective;
- The ability of the regulatory agency to provide timely responses as a result of its resource constraints; and
- The manufacturing processes or facilities may not meet the applicable requirements.

In addition, if new legislation or regulations are enacted or existing legislation or regulations are amended or are interpreted or enforced differently, we may be required to obtain additional approvals or operate according to different manufacturing or operating standards or pay additional product or establishment user fees. This may require a change in our research and development and manufacturing techniques or additional capital investments in our facilities.

Our pharmaceutical development and manufacturing projects generally involve products that must undergo pre-clinical and clinical evaluations relating to product safety and efficacy before they are approved as commercial therapeutic products. The regulatory authorities having jurisdiction in the countries in which our customers intend to market their products may delay or put on hold clinical trials, delay approval of a product or determine that the product is not approvable. The FDA or other regulatory agencies can delay approval of a drug if our manufacturing facility is not able to demonstrate compliance with cGMPs, pass other aspects of pre-approval inspections or properly scale up to produce commercial supplies. The FDA and comparable government authorities having jurisdiction in the countries in which our customers intend to market their products have the authority to withdraw product approval or suspend manufacture if there are significant problems with raw materials or supplies, quality control and assurance or the product we manufacture is adulterated or misbranded.

Some of our manufactured products are listed as controlled substances. Controlled substances are those products that present a risk of substance abuse. In the United States, these types of products are classified by the U.S. Drug Enforcement Agency (the DEA) as Schedule II, III, and IV substances under the Controlled Substances Act of 1970. The DEA classifies substances as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Scheduled substances are subject to DEA regulations relating to manufacturing, storage, distribution, import and export and physician prescription procedures. For example, scheduled drugs are subject to distribution limits and a higher level of recordkeeping requirements. Furthermore, the total amount of controlled substances for

Table of Contents

manufacture or commercial distribution is limited by the DEA and allocated through quotas. Our quotas or our customers quotas, if any, may not be sufficient to meet commercial demand or to economically produce the product.

Entities must be registered annually with the DEA to manufacture, distribute, dispense, import, export and conduct research using controlled substances. State controlled substance laws also require registration for similar activities. In addition, the DEA requires entities handling controlled substances to maintain records, file reports, follow specific labeling and packaging requirements and provide appropriate security measures to control against diversion of controlled substances. If we fail to follow these requirements, we may be subject to significant civil and/or criminal penalties and possibly a revocation of one of our DEA registrations.

Products containing controlled substances may generate significant public health and safety issues, and in such instances, federal or state authorities can withdraw or limit the marketing rights or regulatory approvals for these products. For some scheduled substances, the FDA may require us or our customers to develop product attributes or a risk evaluation and mitigation strategy to reduce the inappropriate use of the products, including the manner in which they are marketed and sold, so as to reduce the risk of diversion or abuse of the product. Developing such a program may be time-consuming and could delay approval of product candidates containing controlled substances. Such a program or delays of any approval from the FDA could adversely affect our business, results of operations and financial condition.

Audits are an important means by which prospective and existing customers gain confidence that our operations are conducted in accordance with applicable regulatory requirements. In fiscal 2010, our facilities and development centers were audited by 187 separate customer audit teams, representing both prospective and existing customers. These audits contribute to our ongoing improvement of our manufacturing and development practices. In addition to customer audits, we, like all commercial drug manufacturers, are subject to audits by various regulatory authorities. In fiscal 2010, 22 such audits by regulatory authorities were conducted at our sites in North America and Europe, involving multiple products. Responses to audit observations were accepted and product approval was granted, with the exception of three inspections that are still pending. It is not unusual for regulatory agencies or customers to request further clarification and/or follow-up on the responses we provide.

Environmental Matters

Our operations are subject to a variety of environmental, health and safety laws and regulations in each of the jurisdictions in which we operate. These laws and regulations govern, among other things, air emissions, wastewater discharges, the handling and disposal of hazardous substances and wastes, soil and groundwater contamination and employee health and safety. We are also subject to laws and regulations governing the destruction and disposal of raw materials and non-compliant products, the handling of regulated material that is included in our offerings and the disposal of our offerings at the end of their useful life. These laws and regulations have increasingly become more stringent, and we may incur additional expenses to ensure compliance with existing or new requirements in the future. Any failure by us to comply with environmental, health and safety requirements could result in the limitation or suspension of our operations. We also could incur monetary fines, civil or criminal sanctions, third-party claims or cleanup or other costs as a result of violations of or liabilities under such requirements. In addition, compliance with environmental, health and safety requirements could restrict our ability to expand our facilities or require us to acquire costly pollution control equipment, incur other significant expenses or modify our manufacturing processes.

Our manufacturing facilities, in varying degrees, use, store and dispose of hazardous substances in connection with their processes. At some of our facilities, these substances are stored in underground storage tanks or used in refrigeration systems. Some of our facilities, including those in Puerto Rico, have been utilized over a period of years as manufacturing facilities, with operations that may have included on-site landfill or other waste disposal activities and have certain known or potential conditions that may require remediation in the future, and several of these have undergone remediation activities in the past by former owners or operators.

Table of Contents

Some of our facilities are located near third-party industrial sites and may be impacted by contamination migrating from such sites. A number of our facilities use groundwater from onsite wells for process and potable water, and if these onsite sources became contaminated or otherwise unavailable for future use, we could incur expenses for obtaining water from alternative sources. In addition, our operations have grown through acquisitions, and it is possible that facilities that we have acquired may expose us to environmental liabilities associated with historical site conditions that have not yet been discovered. Some environmental laws impose liability for contamination on current and former owners and operators of affected sites, regardless of fault. If remediation costs or potential claims for personal injury or property or natural resource damages resulting from contamination arise, they may be material and may not be recoverable under any contractual indemnity or otherwise from prior owners or operators or any insurance policy. Additionally, we may not be able to successfully enforce any such indemnity or insurance policy in the future. In the event that new or previously unknown contamination is discovered or new cleanup obligations are otherwise imposed at any of our currently or previously owned or operated facilities, we may be required to take additional, unplanned remedial measures and record charges for which no reserves have been recorded.

Seasonality

Revenues from some of our CMO and PDS operations have traditionally been lower in our first fiscal quarter, being the three months ending January 31. We attribute this trend to several factors, including (i) the reassessment by many customers of their need for additional product in the last quarter of the calendar year in order to use existing inventories of products; (ii) the lower production of seasonal cough and cold remedies in the first fiscal quarter; (iii) limited project activity towards the end of the calendar year by many small pharmaceutical and biotechnology customers involved in PDS projects in order to reassess progress on their projects and manage cash resources; and (iv) the Patheon-wide facility shutdown during a portion of the traditional holiday period in December and January.

Research and Development

We have not spent any material amount in the last three fiscal years on company-sponsored research and development activities.

Item 1A. Risk Factors.
Risks Related to Our Business and Industry

We are dependent on our customers spending on and demand for our manufacturing and development services. A reduction in spending or demand could have a material adverse effect on our business.

The amount of customer spending on pharmaceutical development and manufacturing, particularly the amount our customers choose to spend on outsourcing these services, has a large impact on our sales and profitability. Consolidation in the pharmaceutical industry may impact such spending as customers integrate acquired operations, including research and development departments and manufacturing operations.

Many of our customers finance their research and development spending from private and public sources. We have experienced slowdowns in our customers spending on pharmaceutical development and related services, which we believe have been primarily due to the lack or decreased availability of capital for specialty and emerging pharmaceutical companies and the consolidation within the pharmaceutical industry, which resulted in the postponement of certain projects. Any reduction in customer and potential customer spending on pharmaceutical development and related services may have a material adverse effect on our business, results of operations and financial condition.

Furthermore, demand for our CMO segment is driven, in part, by products we bring to market for our PDS customers. Due to the long lead times associated with obtaining regulatory approvals for many of these products,

Table of Contents

particularly dosage forms, and the competitive advantage that can come from gaining early approval, it is important that we maintain a sufficiently large portfolio of pharmaceutical products and such products are brought to market on a timely basis. If we experience a reduction in research and development by our customers, the decrease in activity in our PDS segment could also negatively affect activity levels in our CMO business. Any decline in demand for our services may have a material adverse effect on our business, results of operations and financial condition.

The consumers of the products we manufacture for our customers may significantly influence our business, results of operations and financial condition.

We are dependent on demand for the products we manufacture for our customers and have no control or influence over the market demand for our customers products. Demand for our customers products can be adversely affected by, among other things, delays in health regulatory approval, the loss of patent and other intellectual property right protection, the emergence of competing products, including generic drugs, the degree to which private and government drug plans subsidize payment for a particular product and changes in the marketing strategies for such products.

If the products we manufacture for our customers do not gain market acceptance, our revenues and profitability will be adversely affected. The degree of market acceptance of our customers products will depend on a number of factors, including:

- the ability of our customers to publicly establish and demonstrate the efficacy and safety of such products, including compared to competing products;
- the costs to potential consumers of using such products; and
- marketing and distribution support for such products.

If production volumes of key products that we manufacture for our customers and related revenues are not maintained, it may have a material adverse effect on our business, results of operations and financial condition. Additionally, any changes in product mix due to market acceptance of our customers products may adversely affect our margins.

Our services and offerings are highly complex, and if we are unable to provide quality and timely offerings to our customers, our business could suffer.

The services we offer are highly exacting and complex, due in part to strict regulatory requirements. A failure of our quality control systems in our business units and facilities could cause problems to arise in connection with facility operations or during preparation or provision of products, in both cases, for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials or environmental factors. Such problems could affect production of a particular batch or series of batches, requiring the destruction of products, or could halt facility production altogether. In addition, our failure to meet required quality standards may result in our failure to timely deliver products to our customers, which in turn could damage our reputation for quality and service. Any such incident could, among other things, lead to increased costs, lost revenue, reimbursement to customers for lost APIs, damage to and possibly termination of existing customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, we may be subject to regulatory actions, including product recalls, product seizures, injunctions to halt manufacture and distribution, restrictions on our operations, civil sanctions, including monetary sanctions, and criminal actions. In addition, such issues could subject us to litigation, the cost of which could be significant.

Table of Contents

Our PDS projects are typically for a shorter term than our CMO projects, and any failure by us to maintain a high volume of PDS projects, including due to lower than expected success rates of the products for which we provide services, could adversely affect our business, results of operations and financial condition.

Unlike our CMO segment, where our contracts are typically multi-year in duration, our PDS segment contracts are generally shorter in term and typically require us to provide development services within a designated scope. Since our PDS business focuses on products that are still in the developmental stages, the viability of many of our PDS projects is not certain. As a result, many of these projects fail to progress to the subsequent development phase. Even if a customer wishes to proceed with a project, the product we are developing on its behalf may fail to receive necessary regulatory approval, or other factors, such as the development of a competing product, may hinder the development of the product.

If we are unable to continue to obtain new projects from existing and new customers, our PDS segment could be adversely affected. Furthermore, although our PDS business acts as a pipeline for our CMO segment, we cannot predict the turnover rate of our PDS projects or how successful we will be in winning new projects that lead to a viable product. As such, an increase in the turnover rate of our PDS projects may negatively affect our CMO segment at a later time. In addition, the discontinuation of a project as a result of our failure to satisfy a customer s requirements may also affect our ability to obtain future projects from the customer involved or from new customers.

Continued volatility and disruption to the global capital and credit markets and the global economy have adversely affected, and may continue to adversely affect, our business and results of operations and have adversely affected, and may continue to adversely affect, our customers and suppliers.

Recently, the global capital and credit markets and the global economy have experienced a period of significant uncertainty, characterized by the bankruptcy, failure, collapse or sale of various financial institutions and a considerable level of intervention from governments around the world. These conditions have adversely affected the demand for our products and services, which has negatively affected our business and results of operations. In addition, interest rate fluctuations, financial market volatility or credit market disruptions may limit our access to capital, and may also negatively affect our customers and our suppliers ability to obtain credit to finance their businesses on acceptable terms or at all. As a result, customers need for and ability to purchase our products or services may decrease. For example, certain of our customers have decreased their research and development spending due to their lack of access to capital. In addition, lack of access to capital may cause our suppliers to increase their prices, reduce their output or change their terms of sale. If our customers or suppliers operating and financial performance deteriorates, or if they are unable to make scheduled payments or obtain credit, our customers may not be able to pay, or may delay payment of, accounts receivable owed to us, and our suppliers may restrict credit or impose different payment terms. Any inability of our customers to pay us for our products and services or any demands by suppliers for different payment terms may adversely affect our earnings and cash flow.

As the contraction of the global capital and credit markets has spread throughout the broader economy, the United States and other major markets around the world have experienced very weak or negative economic growth. These recessionary conditions have impacted, and will continue to impact, consumer demand for the products we manufacture for our customers.

Our operations outside the United States and Canada are subject to a number of economic, political and regulatory risks.

We are an international company incorporated and listed in Canada with facilities and offices in seven countries. In fiscal 2010, we provided services to customers in approximately 60 countries, and nearly half of our revenues were attributable to customers outside the United States and Canada. Our operations outside the United States and Canada could be substantially affected by foreign economic, political and regulatory risks. These risks include:

- the difficulty of enforcing agreements and collecting receivables through some foreign legal systems;

Table of Contents

- fluctuations in currency exchange rates;
- customers in some foreign countries potentially having longer payment cycles;
- changes in local tax laws, tax rates in some countries that may exceed those of Canada or the United States and lower earnings due to withholding requirements or the imposition of tariffs, exchange controls or other restrictions;
- seasonal reductions in business activity;
- the credit risk of local customers and distributors;
- general economic and political conditions;
- unexpected changes in legal, regulatory or tax requirements;
- relationships with labor unions and works councils;
- the difficulties associated with managing a large global organization;
- the risk that certain governments may adopt regulations or take other actions that would have a direct or indirect adverse impact on our business and market opportunities, including nationalization of private enterprise;
- non-compliance with applicable currency exchange control regulations, transfer pricing regulations or other similar regulations; and
- violations of the Foreign Corrupt Practices Act by acts of agents and other intermediaries whom we have limited or no ability to control.

If any of these economic or political risks materialize and we have failed to anticipate and effectively manage them, we may experience adverse effects on our business and results of operations. Additionally, if we do not remain in compliance with current regulatory requirements or fail to comply with future regulatory requirements, then such non-compliance may subject us to liability and have a material adverse effect on our business and results of operations.

Fluctuations in exchange rates could have a material adverse effect on our results of operations and financial performance.

Our most significant transaction exposures arise in our Canadian operations. Prior to the refinancing in the second quarter of fiscal 2010, the balance sheet of our Canadian division included U.S. dollar denominated debt which was designated as a hedge against our investments in subsidiaries in the United States and Puerto Rico. The foreign exchange gains and losses related to the effective portion of this hedge were recorded in other comprehensive income. In the third quarter of fiscal 2010, we changed the functional currency of our corporate division in Canada to U.S. dollars, thereby eliminating the need to designate this U.S. dollar denominated debt as a hedge. In addition, approximately 80% of the revenues of the Canadian operations and approximately 15% of its operating expenses are transacted in U.S. dollars. As a result, we may experience transaction exposures because of volatility in the exchange rate between the Canadian and U.S. dollar. Based on our current U.S. denominated net inflows, as of January 31, 2011, fluctuations of +/-10% would, everything else being equal, have an annual effect on loss from continuing operations before taxes of approximately +/- $10.8 million, prior to hedging activities.

The objective of our foreign exchange risk management activities is to minimize transaction exposures and the resulting volatility of our earnings. To mitigate exchange-rate risk, we utilize foreign exchange forward contracts and collars in certain circumstances to lock in exchange rates with the objective that the gain or loss on the forward contracts and collars will approximately offset the loss or gain that results from the transaction or transactions being hedged. As of January 31, 2011, we had entered into foreign exchange forward contracts and collars to cover approximately 75% of our Canadian-U.S. dollar cash flow exposures for fiscal 2011.

Table of Contents

Translation gains and losses related to certain foreign currency denominated intercompany loans are included as part of the net investment in certain foreign subsidiaries and are included in accumulated other comprehensive income in shareholders equity. We do not currently hedge translation exposures.

While we attempt to mitigate our foreign exchange risk by engaging in foreign currency hedging activities using derivative financial instruments, we may not be successful. We may not be able to engage in hedging transactions in the future, and if we do, we may not be able to eliminate foreign currency risk, and foreign currency fluctuations may have a material adverse effect on our results of operations and financial performance.

Because a significant portion of our revenues comes from a limited number of customers, any decrease in sales to these customers could harm our business, results of operations and financial condition.

In fiscal 2010, our top 20 customers in our CMO segment accounted for approximately 80% of our CMO revenues. This customer concentration increases credit risk and other risks associated with particular customers and particular products, including risks related to market demand for customer products and regulatory and other operating risks. Disruptions in the production of major products could damage our customer relationships and adversely impact our results of operations in the future. Revenues from customers that have accounted for significant sales in the past, either individually or as a group, may not reach or exceed historical levels in any future period. The loss or a significant reduction of business from any of our major customers may have a material adverse effect on our business, results of operations and financial condition.

We operate in highly competitive markets and competition may adversely affect our business.

We operate in a market that is highly competitive. We compete to provide CMO and PDS to pharmaceutical companies around the world.

Our competition in the CMO market includes full-service pharmaceutical outsourcing companies; contract manufacturers focusing on a limited number of dosage forms; contract manufacturers providing multiple dosage forms; and large pharmaceutical companies offering third-party manufacturing services to fill their excess capacity. In addition, in Europe, there are a large number of privately owned, dedicated outsourcing companies that serve only their local or national markets. Also, large pharmaceutical companies have been seeking to divest portions of their manufacturing capacity, and any such divested businesses may compete with us in the future. We compete primarily on the basis of the security of supply (quality, regulatory compliance and financial stability), service (on-time delivery and manufacturing flexibility) and cost-effective manufacturing (prices and a commitment to continuous improvement).

Our competition in the PDS market includes a large number of laboratories that offer only a limited range of developmental services, generally at a small scale; providers focused on specific technologies and/or dosage forms; and a few fully integrated companies that can provide the full complement of