

McCarley James L
Form 4
February 01, 2011

FORM 4 UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

OMB APPROVAL

OMB Number: 3235-0287
Expires: January 31, 2005
Estimated average burden hours per response... 0.5

Check this box if no longer subject to Section 16. Form 4 or Form 5 obligations may continue. See Instruction 1(b).

STATEMENT OF CHANGES IN BENEFICIAL OWNERSHIP OF SECURITIES

Filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, Section 17(a) of the Public Utility Holding Company Act of 1935 or Section 30(h) of the Investment Company Act of 1940

(Print or Type Responses)

1. Name and Address of Reporting Person *
McCarley James L

2. Issuer Name and Ticker or Trading Symbol
RTI INTERNATIONAL METALS INC [RTI]

5. Relationship of Reporting Person(s) to Issuer

(Check all applicable)

(Last) (First) (Middle)

3. Date of Earliest Transaction (Month/Day/Year)
01/28/2011

____ Director _____ 10% Owner
 Officer (give title below) _____ Other (specify below)
EVP - Operations

C/O RTI INTERNATIONAL METALS, INC., 1550 CORAOPOLIS HEIGHTS ROAD, SUITE 500

(Street)

4. If Amendment, Date Original Filed(Month/Day/Year)

6. Individual or Joint/Group Filing(Check Applicable Line)
 Form filed by One Reporting Person
 Form filed by More than One Reporting Person

PITTSBURGH, PA 15101-2973

(City) (State) (Zip)

Table I - Non-Derivative Securities Acquired, Disposed of, or Beneficially Owned

1. Title of Security (Instr. 3)	2. Transaction Date (Month/Day/Year)	2A. Deemed Execution Date, if any (Month/Day/Year)	3. Transaction Code (Instr. 8)	4. Securities Acquired (A) or Disposed of (D) (Instr. 3, 4 and 5)	5. Amount of Securities Beneficially Owned Following Reported Transaction(s) (Instr. 3 and 4)	6. Ownership Form: Direct (D) or Indirect (I) (Instr. 4)	7. Nature of Ownership (Instr. 4)
			Code	V	Amount	(A) or (D)	Price
Common Stock	01/28/2011		A		6,027	A	\$ 0 <u>(1)</u>
					6,458	(2)	D

Reminder: Report on a separate line for each class of securities beneficially owned directly or indirectly.

Persons who respond to the collection of information contained in this form are not required to respond unless the form displays a currently valid OMB control number.

SEC 1474 (9-02)

Edgar Filing: McCarley James L - Form 4

Table II - Derivative Securities Acquired, Disposed of, or Beneficially Owned (e.g., puts, calls, warrants, options, convertible securities)

1. Title of Derivative Security (Instr. 3)	2. Conversion or Exercise Price of Derivative Security	3. Transaction Date (Month/Day/Year)	3A. Deemed Execution Date, if any (Month/Day/Year)	4. Transaction Code (Instr. 8)	5. Number of Derivative Securities (A) or Disposed of (D) (Instr. 3, 4, and 5)	6. Date Exercisable and Expiration Date (Month/Day/Year)	7. Title and Amount of Underlying Securities (Instr. 3 and 4)	8. Amount or Number of Shares
Employee Stock Option	\$ 28.47	01/28/2011		A	6,027	<u>(3)</u> 01/28/2021	Common Stock	6,027

Reporting Owners

Reporting Owner Name / Address	Relationships			
	Director	10% Owner	Officer	Other
McCarley James L C/O RTI INTERNATIONAL METALS, INC. 1550 CORAOPOLIS HEIGHTS ROAD, SUITE 500 PITTSBURGH, PA 15101-2973			EVP - Operations	

Signatures

James L. McCarley by Chad Whalen,
Attorney-in-Fact

02/01/2011

___Signature of Reporting Person Date

Explanation of Responses:

- * If the form is filed by more than one reporting person, see Instruction 4(b)(v).
- ** Intentional misstatements or omissions of facts constitute Federal Criminal Violations. See 18 U.S.C. 1001 and 15 U.S.C. 78ff(a).
- (1) Award of restricted stock made to a reporting person exempt under Rule 16b-3.
- (2) Includes 431 shares acquired by the reporting person pursuant to the Company's Employee Stock Purchase Plan since the last reportable transaction.
- (3) Employee stock options which shall vest in three ratable installments on January 27, 2012; January 28, 2013, and 2014.

Note: File three copies of this Form, one of which must be manually signed. If space is insufficient, see Instruction 6 for procedure. Potential persons who are to respond to the collection of information contained in this form are not required to respond unless the form displays a currently valid OMB number. "2%"> **PART I** 1 Item 1: Business 1 Item 1A: Risk Factors 22 Item 1B: Unresolved Staff Comments 36 Item 2: Properties 36 Item 3: Legal Proceedings 36 **PART II** 37 Item 5: Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities 37 Item 6: Selected Financial Data 39 Item 7: Management's Discussion and Analysis of Financial Condition and Results of Operations 39 Item 7A: Quantitative and Qualitative Disclosures About Market Risks 53 Item 8: Financial Statements and Supplemental Data 53 Item 9: Changes in and Disagreements with

Accountants on Accounting and Financial Disclosure 53 Item 9A: Controls and Procedures 54 Item 9B:
Other Information 54 **PART III** 55 **PART IV** 56 Item 15: Exhibits, Financial Statement Schedules
56 SIGNATURES 61 EX-10.11 EX-10.12 EX-10.13 EX-10.15 EX-10.26 EX-23.1 EX-31.1 EX-31.2 EX-32.1

Table of Contents

Part I

Item 1: Business

BUSINESS

Our Company

We are a growing specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. Our primary target markets are hospital acute care and gastroenterology, which are characterized by relatively concentrated physician prescriber bases that we believe can be penetrated effectively by relatively small, targeted sales forces. Cumberland is dedicated to providing innovative products which improve quality of care for patients and address poorly met medical needs.

Our product portfolio includes Acetadote® (*acetylcysteine*) Injection for the treatment of acetaminophen poisoning, Caldolor® (*ibuprofen*) Injection, the first injectable treatment for pain and fever approved in the United States, and Kristalose® (*lactulose*) for Oral Solution, a prescription laxative. We market and sell our products through our dedicated hospital and gastroenterology sales forces in the United States, which together comprised more than 100 sales representatives and managers as of March 1, 2011. We are also partnering our products to reach international markets. Net revenues for the years ended December 31, 2010, 2009 and 2008 were \$45.9 million, \$43.5 million and \$35.1 million, respectively.

We have both product development and commercial capabilities, and believe we can leverage our existing infrastructure to support our expected growth. Our management team consists of pharmaceutical industry veterans experienced in business development, product development, commercialization and finance. Our business development team identifies, evaluates and negotiates product acquisition, in-licensing and out-licensing opportunities. Our product development team develops proprietary product formulations, manages our clinical trials, prepares all regulatory submissions and manages our medical call center. Our quality and manufacturing professionals oversee the manufacture of our products. Our marketing and sales professionals are responsible for our commercial activities, and we work closely with our third party distribution partner to ensure availability and delivery of our products.

We have been profitable since 2004, generating sufficient cash flows to fund our development and marketing programs. In 2009, we completed an initial public offering of our common stock to help facilitate our further growth. Our strategy includes maximizing the potential of our existing products and continuing to expand our portfolio of differentiated products. Our current products are approved for sale in the United States, and we are working with overseas partners to bring them to international markets. We also look for opportunities to expand into additional patient populations through new product indications, whether through our own clinical studies or by supporting investigator-initiated studies at reputable research institutions. We actively pursue opportunities to acquire additional late-stage development product candidates as well as marketed products in our target medical specialties. Further, we are supplementing these growth strategies with the early-stage drug development activities of Cumberland Emerging Technologies (CET), our majority-owned subsidiary. CET partners with universities and other research organizations to develop promising, early-stage product candidates, which Cumberland Pharmaceuticals has the opportunity to commercialize.

We were incorporated in 1999 and have been headquartered in Nashville, Tennessee since inception. Our website address is www.cumberlandpharma.com. We make available through our website, free of charge, our annual reports on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K and any amendments, as well as

other documents, as soon as reasonably practicable after

Table of Contents

Part I

their filing with the U.S. Securities and Exchange Commission, or SEC. These filings are also available to the public at www.sec.gov.

Our Strategy

Maximize sales of Acetadote and Kristalose

Since its launch in June 2004, we have consistently grown product sales for Acetadote, our injectable treatment for acetaminophen poisoning. Net revenue from Acetadote sales grew from \$18.8 million in 2007 to \$35.1 million in 2010, a compound annual growth rate of 23%. In 2009, we expanded our hospital sales force in preparation for the launch of Caldolor, and are also leveraging this expansion to support Acetadote sales. In early 2011, we received FDA approval for a new formulation of Acetadote and have subsequently launched that new product. We are working to secure patent protection for this new formulation, which we believe could provide us with long term protection for the product.

Kristalose competes in the high growth U.S. prescription laxatives market which, based on data from IMS Health, had sales of approximately \$373 million in 2009. After acquiring exclusive U.S. rights to Kristalose in April 2006, we assembled an experienced, dedicated sales force and designed a new marketing program, re-launching the product in September 2006. We inherited this product on a downtrend and have been successful in halting that decline and moving toward growth by enhancing brand awareness and highlighting the product's many positive, competitive attributes.

Successfully commercialize Caldolor

We believe Caldolor, injectable ibuprofen, currently represents our most significant product opportunity based on the large potential markets for intravenous treatment of pain and fever, as well as clinical results for the product to date. In September 2009, we began marketing the product in the U.S. through our expanded hospital sales force. During 2010, we focused on obtaining formulary approval and stocking of the product at U.S. hospitals and other medical facilities. Beginning in the first quarter of 2011, we began working to increase that stocking as well as drive use of the product in those facilities. We hold international patent rights for Caldolor and, in connection with certain current and potential future international partners, are working to seek regulatory approval for and market Caldolor outside of the U.S.

Continue to build a high-performance sales organization to address our target markets

We believe that continuing to build our sales infrastructure will help drive prescription volume and product sales. We currently utilize two distinct sales teams to address our primary target markets: a hospital sales force for the acute care market and a field sales force for the gastroenterology market.

Hospital market: We promote Acetadote and Caldolor through our dedicated hospital sales team of 72 representatives and managers. This team addresses hospitals across the U.S., and is comprised of sales professionals with substantial experience in the hospital market. According to IMS Health, U.S. hospitals accounted for approximately \$31 billion, or 10%, of U.S. pharmaceutical sales in 2009. However, IMS also reports that only 2% of approximately \$21 billion total pharmaceutical industry promotional spending was focused on hospital-use drugs in 2009. The majority of promotional spending is directed toward large, outpatient markets on drugs intended for chronic use rather than short-term, hospital use. We believe the hospital market is underserved and highly concentrated, and that it can be penetrated effectively by a small, dedicated sales force without large-scale promotional activity.

Gastroenterology market: We promote Kristalose through a dedicated field sales force addressing a targeted group of physicians who are responsible for a majority of total retail Kristalose prescriptions nationally. By investing in our marketing program, we believe that we will be able to increase market share for Kristalose and that we will be equipped to promote any further gastroenterology product

2

Table of Contents**Part I**

additions as well. Because the market for gastrointestinal diseases is broad in patient scope, yet relatively narrow in physician base, we believe it provides product opportunities but can be penetrated with a modest sales force.

Expand our product portfolio by acquiring rights to additional products and late-stage product candidates

In addition to our product development activities, we are also seeking to acquire products or late-stage development product candidates to continue to build a portfolio of complementary products. We focus on under-promoted, FDA-approved drugs as well as late-stage development products that address poorly met medical needs, which we believe helps mitigate our exposure to risk, cost and time associated with drug discovery and research. We plan to continue to target products that are competitively differentiated, have valuable trademarks or other intellectual property, and allow us to leverage our existing infrastructure. We also plan to explore opportunities to seek approval for new uses of existing pharmaceutical products.

Develop a pipeline of early-stage products through CET

In order to build our product pipeline, we are supplementing our acquisition and late-stage development activities with the early-stage drug development activities of CET, our majority-owned subsidiary. CET partners with universities and other research organizations to develop promising, early-stage product candidates, and Cumberland Pharmaceuticals has the opportunity to negotiate rights to further develop and commercialize them.

Our Products

Our key products include:

Product	Indication	Delivery	Status
Acetadote®	Acetaminophen Poisoning	Injectable	Marketed
Caldolor®	Pain and Fever	Injectable	Marketed
Kristalose®	Chronic and Acute Constipation	Oral Solution	Marketed

Acetadote®

Acetadote® is an intravenous formulation of N-acetylcysteine, or NAC, indicated for the treatment of acetaminophen poisoning. Acetadote, which has been available in the United States since Cumberland's 2004 introduction of the product, is currently used in hospital emergency departments to prevent or lessen potential liver damage resulting from an overdose of acetaminophen, a common ingredient in many over-the-counter pain relief and fever-reducing products. Acetaminophen continues to be the leading cause of poisonings reported by hospital emergency rooms in the United States, and Acetadote has become a standard of care for treating this potentially life-threatening condition.

Originally approved in January 2004, Acetadote received FDA approval as an orphan drug, which provided seven years of marketing exclusivity from date of approval. In connection with the FDA's approval of Acetadote, we committed to certain post-marketing activities for the product. Our first Phase IV commitment (pediatric) was completed in 2004 and resulted in the FDA's 2006 approval of expanded labeling for Acetadote for use in pediatric patients. Our second Phase IV commitment (clinical) was completed in 2006 and resulted in further revised labeling for the product with FDA approval of additional safety data in 2008. We completed our third and final Phase IV commitment (manufacturing) for Acetadote in 2010, which has culminated in the approval and launch of a new, next

generation formulation of the product.

In October 2010, we submitted a supplemental new drug application (sNDA) to the FDA for approval of a new formulation of Acetadote designed to replace the original formulation. The new formulation,

Table of Contents

Part I

which is the result of the aforementioned Phase IV commitment made to the FDA, addresses the FDA's safety concerns and contains no ethylene diamine tetracetic acid or other stabilization and chelating agents and is preservative-free. In January 2011, we received FDA approval and commenced U.S. launch activities for this new Acetadote product. The original formulation has been removed from FDA reference materials and we no longer manufacture it. We have filed a patent application with the U.S. Patent and Trademark Office to protect the proprietary new formulation.

In March 2010, we submitted another sNDA to the FDA for the use of Acetadote in patients with non-acetaminophen acute liver failure. The sNDA included data from a clinical trial led by investigators at the University of Texas Southwestern Medical Center indicating that acute liver failure patients treated with Acetadote have a significantly improved chance of survival without a transplant. The study showed that these patients can also survive a significant number of days longer without transplant, which would provide patients requiring transplant increased time for a donor organ to become available.

Acute liver failure is associated with a high mortality rate and frequent need for liver transplantation. Approximately half of acute liver failure cases are caused by acetaminophen poisoning while the other half result from a variety of causes including hepatitis and alcohol. Currently, transplantation of the liver is the only treatment for patients with liver failure not caused by acetaminophen overdose.

In May 2010, the FDA officially accepted the sNDA and granted a priority review with a response expected in September 2010. In August 2010, we announced that the FDA extended its review of the sNDA by three months, resulting in a new Prescription Drug User Fee Act (PDUFA) goal date in December 2010. In December, we received a Complete Response Letter from the FDA indicating that the agency had completed its review of the application and had identified additional items that must be addressed prior to approving the new indication. We are in discussions with the FDA to gain clarity on a pathway to approval for this indication to treat a critically ill patient population with few treatment alternatives. In addition to expanded labeling for Acetadote, we have requested additional exclusivity for the product in association with the potential new indication.

We are also supporting a number of investigator-initiated studies to explore other potential indications for Acetadote.

Market for Acetadote

Acetaminophen is one of the most widely used drugs for oral treatment of pain and fever in the U.S. and can be found in many common over-the-counter products and prescription narcotics. Though safe at recommended doses, the drug can cause liver damage with excessive use. According to the American Association of Poison Control Centers National Poison Data System, acetaminophen poisoning was the leading cause of toxic drug ingestions reported to U.S. poison control centers in 2008. In a study published in 2005 that examined acute liver failure, researchers concluded that acetaminophen poisoning was responsible for acute liver failure in over half the patients examined in 2003, up from 28% in 1998. While an estimated 48% of cases were due to the accidental use over several days, causing chronic liver failure, an estimated 44% of the cases were intentional overdoses, causing acute liver failure. According to the FDA, four grams of acetaminophen is the daily maximum dosage recommended for adults. Ingesting just eight grams of acetaminophen a day can cause serious complications, especially in people, whose livers are stressed by virus, medication or alcohol. When used in conjunction with opiates, acetaminophen can offer effective pain relief after surgery or injury; however, patients taking acetaminophen/opiate combination drugs on a chronic basis often eventually require increasing amounts to achieve the same level of pain relief, which can also lead to liver failure. In January 2011, the FDA initiated a campaign to heighten awareness of the potential toxicity associated with

acetaminophen and announced that it is asking manufacturers of prescription

4

Table of Contents

Part I

acetaminophen combination products to limit the maximum amount of acetaminophen in these products to 325 mg per tablet in an effort to reduce adverse events.

NAC is widely accepted as the standard of care for acetaminophen overdose. According to *The Medical Letter on Drugs and Therapeutics*, NAC is virtually 100% effective in preventing severe liver damage, renal failure and death if administered within eight to ten hours of the overdose. Throughout Europe and much of the rest of the world, NAC has been available in an injectable formulation for over 25 years. Until the 2004 approval of Acetadote, however, the only FDA-approved form of NAC available in the U.S. was an oral preparation. Many U.S. hospitals prepared an off-label, IV form of NAC from the oral solution to treat patients suffering from acetaminophen poisoning. For a number of these patients, an IV product is the only reasonable route of administration due to nausea and vomiting associated with oral administration. Given this market dynamic, we concluded that a medical need existed for an FDA-approved, injectable formulation of NAC for the U.S. market.

Competitive Advantages

We believe Acetadote offers clinical benefits relative to oral NAC including ease of administration, minimizing nausea and vomiting associated with oral NAC, accurate dosage control, shorter treatment protocol and reduction in overall cost of acetaminophen overdose management. Acetadote makes NAC administration easier to tolerate for patients and easier to administer for medical providers.

Acetadote also offers a significant cost benefit to both patient and hospital by reducing treatment regimen, usually from three days to one day. An independently conducted study of Acetadote as a cost-saving treatment for acetaminophen poisoning was published in the December 2009 issue of the peer-reviewed *Journal of Medical Economics*. The study concludes that Acetadote is a less costly treatment regimen than oral NAC in all evaluated scenarios. The cost differential between the use of oral NAC and Acetadote was shown to range between \$881 and \$2,259, and was primarily attributable to the time required to complete recommended treatment. Under approved therapeutic protocols, the oral product requires 72 hours to administer compared to 21 hours for Acetadote. Consequently, the use of Acetadote results in shorter hospital stays, resulting in substantial cost disparity between the treatments.

Caldolor®

Caldolor, our intravenous formulation of ibuprofen, was the first injectable product approved in the United States for the treatment of both pain and fever. The FDA approved Caldolor for marketing in the United States in June 2009 following a priority review. The product is indicated for use in adults for the management of mild to moderate pain, for the management of moderate to severe pain as an adjunct to opioid analgesics, and for the reduction of fever.

In September 2009, we successfully implemented the U.S. launch of Caldolor, with more than 100 experienced sales professionals promoting the product across the country. Caldolor is stocked at the major wholesalers serving hospitals nationwide, and is available in 400mg and 800mg vials. We are focused on securing formulary approval and stocking nationally for Caldolor. Our sales group is highly focused on meeting with members of hospital pharmacy and therapeutic committees to secure placement on committee agendas to continue growing widespread formulary approval.

Beginning in 2011, we are reaching out to a wider audience within hospitals to drive pull-through sales of Caldolor in facilities that have added the product to formulary. Our sales professionals are equipped with marketing documents which highlight key differentiating factors including the product's ability to be safely dosed not only post-operatively

but also at induction of anesthesia. We supported the publication of Caldolor clinical data in 2010, with results from those trials appearing in peer-reviewed journals as well as being presented at appropriate medical meetings around the country.

Table of Contents

Part I

We have worldwide commercial rights to Caldolor. We market Caldolor in the United States through our existing hospital sales force, and are partnering with third parties to reach markets outside the United States.

The Market for Caldolor

Therapeutic agents used to treat pain are known as analgesics. Physicians prescribe injectable analgesics for hospitalized patients who have high levels of pain, require rapid pain relief or cannot take oral analgesics. According to IMS, the U.S. market for injectable analgesics exceeded \$329 million, or 671 million units, in 2009. This market consists principally of generic opioids and the NSAID ketorolac.

Injectable opioids such as morphine, meperidine, hydromorphone and fentanyl accounted for approximately 622 million units sold in 2009. While opioids are widely used for acute pain management, they are associated with a variety of side effects including sedation, nausea, vomiting, constipation, headache, cognitive impairment, reduced GI motility and respiratory depression. Respiratory depression, if not monitored closely, can be deadly. Opioid-related side effects can warrant dosing limitations, which may reduce overall effectiveness of pain relief. Side effects from opioids can cause a need for further medication or treatment, and can increase lengths of stay in post-anesthesia care units as well as overall hospital stay, which can lead to increased costs for hospitals and patients.

Despite a poor safety profile, use of ketorolac, the only non-opioid injectable analgesic available in the U.S., has grown from approximately 38 million units in 2004, or 5% of the market, to approximately 48 million units in 2009, or 7% of the market, according to IMS Health. The FDA warns that ketorolac should not be used in various patient populations that are at-risk for bleeding, as a prophylactic analgesic prior to major surgery or for intra-operative administration when stoppage of bleeding is critical.

Caldolor is one of only two U.S.-approved injectable treatments for fever, with the other being an injectable acetaminophen product. Significant fever, generally defined as a temperature of greater than 102 degrees Fahrenheit, can cause hallucinations, confusion, convulsions and death. Hospitalized patients are subject to increased risk for developing fever, especially from exposure to infectious agents. Patients with endotracheal intubation, sedation, reduced gastric motility, nausea or recent surgery are frequently unable to ingest, digest, absorb, or tolerate oral products to reduce fever. Treatment for these patients ranges from rectal delivery of medication to physical cooling measures such as tepid baths, ice packs and cooling blankets.

Clinical Development Overview

We acquired from Vanderbilt University an exclusive, worldwide license to clinical trial data on the use of intravenous ibuprofen for treatment of hospitalized patients with severe sepsis syndrome, a complex inflammatory condition often resulting in high fever due to infection. Published in the *New England Journal of Medicine*, this data indicated that intravenous ibuprofen was effective in reducing high fever in critically ill patients who were largely unable to receive oral medication. Based upon data generated from this study, we met with the FDA to determine the requirements for gaining FDA approval of intravenous ibuprofen through a 505(b)(2) application. Following discussion with and recommendations by the FDA, we implemented a development program for Caldolor that was designed to obtain approval for a dual indication for the product management of pain and reduction of fever. We performed extensive formulation work resulting in a patented, proprietary product and conducted a number of clinical studies evaluating the safety and efficacy of Caldolor for treatment of pain and fever.

Table of Contents**Part I**

More than 1,400 subjects, including over 800 receiving IV Ibuprofen, were studied in seven clinical trials supporting our new drug application (NDA) filing. Below is a summary of the clinical trials that supported the NDA and that are currently described in our package insert:

Study name	Number of subjects	Setting	Study results
Pharmacokinetic Study	36	Healthy volunteers	Similar PK parameters between oral and Caldolor
Adult Safety Study	12	Healthy volunteers	Safe and well-tolerated IV infusion of Caldolor
Sepsis Study IND 32803 ⁽¹⁾	455	Hospitalized patients with severe sepsis	Significant and sustained reduction of temperature in patients with high fever ($p < 0.01$) ⁽³⁾
Adult Malaria Fever Study	60	Hospitalized adult malaria patients	Significant reduction in temperature over 24 hours of treatment ($p = 0.002$)
Phase III Adult Fever Study ⁽²⁾	120	Hospitalized adult febrile patients	Significant, dose-dependent, reduction in temperature supporting 400mg dose ($p = 0.0003$)
Phase III Adult Dose Ranging Pain Study ⁽²⁾	406	Hospitalized adult abdominal and orthopedic post-operative patients	Dose-dependent, morphine sparing effect (22%) supporting 800mg dose Significant reduction in pain intensity scores (VAS) ⁽⁴⁾ over 24 hours of treatment ($p = 0.001$)
Phase III Adult Abdominal Hysterectomy Pain Study ⁽²⁾	319	Hospitalized adult abdominal hysterectomy patients	Significant, morphine-sparing effect (19%, $p < 0.001$) Significant reduction in pain intensity scores (VAS) over 24 hours of treatment ($p = 0.011$)
Total	1,408		

(1) Study data licensed from Vanderbilt University; Cumberland report filed 2003

- (2) Pivotal Study
- (3) P-value <0.05 represents statistical significance
- (4) Visual Analog Scale

Additional Studies

Adult Orthopedic Pain Study: We initiated a Phase III pain study in post-operative adult patients who had undergone orthopedic surgical procedures. Patients, all with access to patient controlled analgesia (PCA) with morphine, were randomized to also receive either 800mg of Caldolor (multi-modal therapy) or placebo treatment (standard therapy) four times daily for up to five days. The first dose in this study

Table of Contents

Part I

was administered prior (pre-operatively) to the surgical procedure. The primary endpoint was reduction in patient pain intensity scores using VAS measured with movement.

We enrolled 185 patients in the safety population. There was a significant reduction in pain intensity scores using VAS. Patients receiving Caldolor reported a 26% greater reduction in pain intensity after 24 hours ($p < 0.001$; with movement Area Under the Curve of VAS) compared to placebo. 24 hours after the first dose of Caldolor was administered patients receiving Caldolor reported a 32% greater reduction in pain at rest ($p < 0.001$ at rest AUC-VAS) compared to placebo. In this study, we also investigated the efficacy of Caldolor in reducing morphine use by patients receiving the 800mg dose. There was a significant reduction in morphine use by those receiving 800mg of Caldolor after surgery and through hour 24.

Adult Burn Study: We conducted a multicenter, randomized, double-blind, placebo-controlled trial at five U.S. and international clinical sites, including hospital burn units and burn centers, to evaluate the safety and efficacy of Caldolor in treating fever and pain in hospitalized burn patients. Patients were administered 800mg of Caldolor every six hours for five consecutive days. The study raised no safety concerns and the medication was well tolerated. There was no difference in adverse effects between patients who received a placebo and those receiving Caldolor. The study evaluated 61 adult burn patients with second or third degree burns covering more than 10 percent total body surface area. Other participant criteria included an anticipated hospital stay of more than 72 hours and temperatures of 38.0 degrees Celsius (100.4 degrees Fahrenheit) or greater. Statistical significance was achieved for the primary endpoint of reducing fever in burn patients over the first 24 hours of treatment.

Adult Pharmacokinetics Study: We conducted a randomized, double-blind, placebo-controlled, single dose crossover study of the pharmacokinetics, safety and tolerability of Caldolor in healthy adult volunteers. Twelve subjects were randomized in equal proportions to receive a single dose of 800mg Caldolor, administered over five to seven minutes, and oral placebo administered concurrently, followed by a wash-out period of a single dose of 800mg oral ibuprofen and intravenous placebo given concurrently. There were no serious adverse events nor any adverse events classified as moderate or severe. The most common adverse event, which was classified as mild, was infusion site pain in three subjects. The results of the study indicate that the mean C_{max} of Caldolor was approximately twice that of the oral dose and the median T_{max} for Caldolor was 6.5 minutes compared to 1.5 hours for the oral product. The AUC was similar between the two products. Results from the trial demonstrate the effects of decreasing infusion time for Caldolor from the current package insert guideline of no less than 30 minutes to an infusion time of five to seven minutes.

Phase IV Required Pediatric Assessment

The required pediatric assessment for the Caldolor NDA was deferred until 2011 for the treatment of fever and until 2012 for the management of pain. Two clinical studies are currently underway to address the Phase IV requirements. By conducting pediatric clinical studies and supplying requested data to the FDA, Cumberland has the opportunity to obtain up to an additional six months of marketing exclusivity for Caldolor. If results of these trials are not favorable, we would not be eligible for additional pediatric exclusivity; however, unfavorable pediatric results would not impact marketing status for use in adults.

No additional Phase IV commitments were assigned by the FDA.

Safety Summary

Extensive use and worldwide literature support the strong safety profile of oral ibuprofen. Building on the oral safety profile, we have assembled an integrated IV ibuprofen safety database combining data from our clinical trials as well as previously published study data. We used this data to support our

8

Table of Contents

Part I

NDA filing and will continue to use and update the data as a part of our ongoing safety evaluation. In addition, this data will be used by our sales force and in our marketing materials to promote Caldolor.

In clinical trials supporting our proposed indications, no serious adverse events have been directly attributed to Caldolor. The number and percentage of all patients in pivotal studies who reported treatment emergent adverse events was comparable between IV ibuprofen and placebo treatment groups. Additionally, there have been no safety related differences between Caldolor and placebo involving side effects sometimes observed with oral NSAIDs, such as changes in renal function, bleeding events or gastrointestinal disorders.

Kristalose®

Kristalose is a prescription laxative administered orally for the treatment of constipation. An innovative, dry powder crystalline formulation of lactulose, Kristalose is designed to enhance patient compliance and acceptance. We acquired exclusive U.S. commercialization rights to Kristalose in 2006, assembled a new dedicated field sales force and re-launched the product in September 2006 under the Cumberland brand. We direct our sales efforts to physicians who are the most prolific writers of prescription laxatives, including gastroenterologists, pediatricians, internists and colon and rectal surgeons.

Market for Kristalose

Constipation is a common condition in the U.S., affecting approximately 20% of the population each year. While many occurrences are non-recurring, a significant number are chronic in nature and require some treatment to control or resolve. Constipation treatments are sold in both the over-the-counter (OTC) and prescription segments. The prescription laxative market has historically consisted of a few highly promoted brands including MiraLax® (polyethylene glycol 3350), which is now being sold as an OTC product, and Amitiza®, as well as several generic forms of liquid lactulose. According to data from IMS Health, the prescription laxative market had sales of approximately \$373 million in 2009.

Competitive Advantages

Kristalose is the only prescription-strength laxative available in pre-measured powder packets, making it very portable. The drug dissolves quickly in four ounces of water, offering patients a virtually tasteless, grit-free and calorie-free alternative to liquid lactulose treatments. We believe that Kristalose has competitive advantages over competing prescription laxatives, such as fewer potential side effects and contraindications as well as lower cost. There are no age limitations or length of use restrictions for Kristalose, and it is the only osmotic prescription laxative still sampled to physicians.

In 2009, we completed a multicenter, randomized, open label, crossover patient preference study evaluating Kristalose compared to similar products in liquid forms. Over a 14-day period, 50 patients with a recent diagnosis of chronic constipation were administered both Kristalose and liquid lactulose in a crossover study. Patient preference was measured through survey responses collected at the end of the study. Overall, more patients preferred Kristalose, noting portability as a key differentiating feature. More patients also preferred the taste of Kristalose as well as the consistency compared to the syrup formulations. There was no significant difference in adverse effects between patients who took Kristalose and those taking liquid lactulose. We are also exploring opportunities to expand into new indications with Kristalose.

Early-stage product candidates

Our pre-clinical product candidates are being developed through CET, our 85%-owned subsidiary. Cumberland Pharmaceuticals negotiates rights to develop and commercialize CET product candidates, and in conjunction with research institutions has obtained nearly \$1 million in grant funding from the National Institutes of Health to support the development of these programs.

Table of Contents

Part I

Four of the more advanced CET development programs are:

- Ø In collaboration with Vanderbilt University, we are currently developing a new palliative treatment for fluid buildup in the lungs of cancer patients. The product candidate is a protein therapeutic being designed to treat pleural effusion, a condition which occurs when cancer spreads to the surface of the lung and chest cavity, causing fluid to accumulate and patients to suffer shortness of breath and chest pain. An estimated 100,000 patients are affected by this condition each year. Vanderbilt University researchers believe they have found a method of treating this condition which may involve less pain, a higher success rate and faster healing time, resulting in significantly shorter hospital stays.
- Ø In collaboration with the University of Mississippi, we are developing a highly purified, injectable anti-infective used to treat fungal infections in immuno-compromised patients. This product candidate's active ingredient is currently FDA-approved in a different formulation, and while it is the therapeutic of choice for infectious disease specialists in treating such fungal infections, it can produce serious side effects related to renal toxicity, often resulting in dosage limitations or discontinued use. University of Mississippi researchers have developed what they believe is a purer and safer form of the anti-infective.
- Ø In collaboration with the University of Tennessee, we are currently developing a novel asthma therapeutic designed to prevent remodeling of airway smooth muscle to reduce asthmatic reaction in pediatric patients. Airway remodeling occurs when the cells or muscles that line the airway become inflamed and can result in decreased lung function. University of Tennessee researchers believe they have found a treatment that can reduce, or even prevent, asthma attacks in children.
- Ø CET previously entered into an agreement with Vanderbilt University to develop a novel treatment to improve renal function in patients with hepatorenal syndrome, a condition where kidneys fail suddenly due to cirrhosis of the liver. The product candidate may reduce renal blood flow in association with acute kidney failure. In the third quarter of 2010, Cumberland Pharmaceuticals entered into an option agreement with CET to assume the rights and responsibilities associated with the product candidate. We have commenced product manufacturing and submitted an investigational new drug application for the clinical evaluation of this product candidate.

BUSINESS DEVELOPMENT

Since inception, we have had an active business development program focused on acquiring rights to marketed products and product candidates that fit our strategy and target markets. We source our business development leads through our senior executives and our international network of pharmaceutical and medical industry insiders. These opportunities are reviewed and considered on a regular basis by a multi-disciplinary team of our managers against a list of selection criteria. We have historically focused on product opportunities with relatively low acquisition, development and commercialization costs, employing a variety of deal structures.

We intend to continue to build a portfolio of complementary, niche products largely through product acquisitions and late-stage product development. Our primary targets are under-promoted, FDA-approved drugs with existing brand recognition and late-stage development product candidates that address unmet medical needs in the hospital acute care and gastroenterology markets. We believe that by focusing mainly on approved or late-stage products, we can minimize the significant risk, cost and time associated with drug development.

Through CET, we are collaborating with a growing list of reputable research institutions. Our business development team is responsible for identifying appropriate CET product candidates and negotiating with our university partners to secure rights to these candidates. Although we believe that these collaborations may be important to our business in the future, they are not material to our business at this time.

10

Table of Contents

Part I

CLINICAL AND REGULATORY AFFAIRS

We have in-house capabilities for the management of our clinical, professional and regulatory affairs. Our team develops and manages our clinical trials, prepares regulatory submissions, manages ongoing product-related regulatory responsibilities and manages our medical information call center. Team members have been responsible for devising the regulatory and clinical strategies and obtaining FDA approvals for Acetadote and Caldolor.

Clinical development

Our clinical development personnel are responsible for:

- Ø creating clinical development strategies;
- Ø designing and monitoring our clinical trials;
- Ø creating case report forms and other study-related documents;
- Ø overseeing clinical work contracted to third parties; and
- Ø overseeing CET grant funding proposals.

Regulatory and quality affairs

Our internal regulatory and quality affairs team is responsible for:

- Ø preparing and submitting NDAs and fulfilling post-approval marketing commitments;
- Ø maintaining investigational and marketing applications through the submission of appropriate reports;
- Ø submitting supplemental applications for additional label indications, product line extensions and manufacturing improvements;
- Ø evaluating regulatory risk profiles for product acquisition candidates, including compliance with manufacturing, labeling, distribution and marketing regulations;
- Ø monitoring applicable third-party service providers for quality and compliance with current Good Manufacturing Practices, Good Laboratory Practices, and Good Clinical Practices, and performing periodic audits of such vendors; and
- Ø maintaining systems for document control, product and process change control, customer complaint handling, product stability studies and annual drug product reviews.

Professional and medical affairs

Our clinical and regulatory team provides in-house, medical information support for our marketed products. This includes interacting directly with healthcare professionals to address any product or medical inquiries through our medical information call center. Prior to the launch of Caldolor, we expanded our medical affairs staff to support inquiries from medical professionals regarding the appropriate use of Caldolor as well as to support the efforts of our expanded hospital sales force. In addition to coordinating the call center, our clinical/regulatory group generates medical information letters, provides informational memos to our sales forces and assists with ongoing training for the sales forces.

SALES AND MARKETING

Our sales and marketing team has broad industry experience in selling branded pharmaceuticals. Our sales and marketing professionals manage our dedicated hospital and gastroenterology sales forces, including more than 100 sales representatives and district managers, direct our national marketing

Table of Contents

Part I

campaigns and maintain key national account relationships. In January 2007, we converted our hospital sales force, which had previously been contracted to us by Cardinal Health Inc., or Cardinal, to Cumberland employees through our wholly-owned subsidiary, Cumberland Pharma Sales Corp.

Our gastroenterology-focused team was formed in September 2006 with our re-launch of Kristalose and is a field sales force addressing high prescribers of laxatives. This gastroenterology sales force was previously contracted to us by Ventiv Commercial Services, LLC, or Inventiv. In September 2010, we converted the field sales force to Cumberland employees as we had previously done with our hospital force.

Our sales and marketing executives conduct ongoing market analyses to evaluate marketing campaigns and promotional programs. The evaluations include development of product profiles, testing of the profiles against the needs of the market, determining what additional product information or development work is needed to effectively market the products and preparing financial forecasts. We utilize professional branding and packaging as well as promotional items to support our products, including direct mail, sales brochures, journal advertising, educational and reminder leave-behinds, patient educational pieces and product sampling. We also regularly attend targeted trade shows to promote broad awareness of our products. Our National Accounts group is responsible for key large buyers and related marketing programs. This group supports sales and marketing efforts by maintaining relationships with our wholesaler customers as well as with third-party payors such as Group Purchasing Organizations, Pharmacy Benefit Managers, Hospital Buying Groups, state and federal government purchasers and influencers and health insurance companies.

International sales and marketing

We have licensed to third parties the right to distribute certain products outside the U.S. We have granted Alveda Pharmaceuticals Inc., or Alveda, an exclusive license to distribute Caldolor in Canada subject to receipt of regulatory approval. Alveda is obligated to make payments to us of up to \$1,000,000 Canadian upon Caldolor's achieving specified regulatory milestones in Canada and to pay us a royalty based on Canadian sales of Caldolor. This license terminates five years after regulatory approval is obtained in Canada for the later of the fever or pain indications.

In December 2009, we announced that we entered into an exclusive partnership with DB Pharm Korea Co. Ltd., a Korean-based pharmaceutical company, for the commercialization of Caldolor in South Korea. Under the terms of the agreement, DB Pharm Korea is responsible for obtaining any regulatory approval for the product and handling ongoing regulatory requirements, product marketing, distribution and sales in Korea. We maintain responsibility for product formulation, development and manufacturing. Under the agreement, Cumberland will receive up to \$500,000 in upfront and milestone payments as well as a transfer price, and we will receive royalties on any future sales of Caldolor in South Korea.

In October 2009, we announced that we entered into an exclusive partnership with Phebra Pty Ltd., or Phebra, an Australian-based specialty pharmaceutical company, for the commercialization of Caldolor in Australia and New Zealand. Phebra has responsibility for obtaining any regulatory approval for the product, and for handling all ongoing regulatory requirements, product marketing, distribution and sales in the territories. We will maintain responsibility for product formulation, development and manufacturing. Under the terms of the agreement, Cumberland will receive up to \$500,000 in upfront and milestone payments as well as a transfer price, and we will receive royalties on any future sales of Caldolor in those territories.

We also granted Phebra an exclusive license to market and distribute Acetadote in Australia, New Zealand, and Southeast Asia, subject to the receipt of regulatory approval. Phebra is obligated to make payments to us of up to \$325,000 upon Phebra's achieving specified milestones as well as royalty

12

Table of Contents

Part I

payments. In April 2010, the Therapeutic Goods Administration granted approval for the commercialization of Acetadote in Australia and in October 2010, Phebra commenced with the Australian launch of the product. This introduction of Acetadote in Australia marked the introduction of Cumberland's products into international markets. In addition to Australia, Phebra has exclusive marketing rights to Acetadote for New Zealand and has obtained marketing approval in that country.

MANUFACTURING AND DISTRIBUTION

We partner certain non-core, capital-intensive functions, including manufacturing and distribution. Our executives are experienced in these areas and manage these third-party relationships with a focus on quality assurance.

Manufacturing

Our key manufacturing relationships include:

- Ø In July 2000, we established an international manufacturing alliance with a predecessor to Hospira Australia Pty. Ltd., or Hospira. Hospira sources active pharmaceutical ingredients, or APIs, and manufactures Caldolor for us under an agreement that expires in June 2014, subject to early termination upon 45 days prior notice in the event of uncured material breach by us or Hospira. The agreement will automatically renew for successive three-year terms unless Hospira or we provide at least 12 months prior written notice of non-renewal. Under the agreement, we pay Hospira a transfer price per unit of Caldolor supplied. In addition, we reimburse Hospira for agreed-upon development, regulatory and inspection and audit costs.
- Ø Bioniche Teoranta, or Bioniche, sources APIs and has manufactured our Acetadote product for sale in the U.S. at its FDA-approved manufacturing facility in Ireland. Our relationship with Bioniche began in January 2002. Bioniche manufactures and packages Acetadote for us, and we purchase Acetadote from Bioniche pursuant to an agreement that we are currently renegotiating.
- Ø Inalco S.p.A. and Inalco Biochemicals, Inc., or collectively Inalco, from which we licensed exclusive U.S. commercialization rights to Kristalose in April 2006, source APIs and supply us with the product under an agreement that expires in 2021. The agreement renews automatically for successive three-year terms unless we or Inalco provide written notice of intent not to renew at least 12 months prior to expiration of a term. Either we or Inalco may terminate this agreement upon at least 45 days prior written notice in the event of uncured material breach. Under the agreement, we are required to pay Inalco a transfer price per unit of Kristalose supplied and a percentage royalty in the low to mid single-digits throughout the term of the agreement based on our net sales of Kristalose. We are required to purchase minimum quantities of Kristalose. In 2010, Inalco sold its facility that manufactured the API for Kristalose, resulting in shipping delays and possible increases in supply prices. We are currently in discussions with Inalco regarding these price increases, as well as an amendment to the Inalco agreement.
- Ø We entered into an agreement with Bayer Healthcare, LLC, or Bayer, in February 2008 for the manufacture of Caldolor and Acetadote. The agreement expires in February 2013, subject to early termination upon 30 days prior written notice in the event of uncured material breach by us or Bayer. The agreement will automatically renew for successive one-year terms unless Bayer or we provide at least six months prior written notice of non-renewal. Under the agreement, we pay Bayer a transfer price per each unit of Caldolor or Acetadote supplied. In addition,

we pay Bayer for agreed upon development costs.

Table of Contents

Part I

Distribution

Like many other pharmaceutical companies, we employ an outside third-party logistics contractor to facilitate our distribution efforts. Since August 2002, Specialty Pharmaceutical Services, or SPS, (formerly CORD Logistics, Inc.) has exclusively handled all aspects of our product logistics efforts, including warehousing, shipping, customer billing and collections. SPS is a division of Cardinal. SPS's main facility is located outside of Nashville, Tennessee, with more than 325,000 square feet of space and a well-established infrastructure. In 2008, SPS opened a second, distribution-only facility in Reno, Nevada, with an additional 88,000 square feet of space. We began utilizing this facility for distribution to certain locations in the second half of 2008. We maintain ownership of our finished products until sale to our customers.

INTELLECTUAL PROPERTY

We seek to protect our products from competition through a combination of patents, trademarks, trade secrets, FDA exclusivity and contractual restrictions on disclosure. Proprietary rights, including patents, are an important element of our business. We seek to protect our proprietary information by requiring our employees, consultants, contractors and other advisors to execute agreements providing for protection of our confidential information upon commencement of their employment or engagement. We also require confidentiality agreements from entities that receive our confidential data or materials.

Acetadote

Acetadote was approved by the FDA in January 2004 as an orphan drug for the intravenous treatment of acetaminophen overdose. As an orphan drug, we were entitled to seven years of marketing exclusivity for the treatment of this approved indication, which expired in January 2011. In January 2011, we received FDA approval for our next generation, new formulation of Acetadote, for which we have applied for patent protection through U.S. patent application No. 11/209,804, as well as through international application No. PCT/US06/20691, both of which are directed to acetylcysteine compositions, methods of making the same and methods of using the same. In addition, we have an exclusive, worldwide license to NAC clinical data from Newcastle Master Misericordiae Hospital in Australia. We have no expected outstanding payment obligations pursuant to this contract.

Caldolor

We are the owner of U.S. Patent No. 6,727,286, which is directed to ibuprofen solution formulations, methods of making the same, and methods of using the same, and which expires in 2021. This U.S. patent is associated with our completed international application No. PCT/US01/42894. We have filed for international patent protection in association with this PCT application in various countries, some of which have been allowed and some of which remain pending.

In 2009, we also filed the first of several new patent applications for Caldolor. Part of an ongoing initiative to protect the value of our intellectual property, the new applications address our proprietary method of dosing intravenous ibuprofen.

We have an exclusive, worldwide license to clinical data for intravenous ibuprofen from Vanderbilt University, in consideration for royalty and other payment obligations related to Caldolor.

In addition, we received three years marketing exclusivity upon receipt of FDA approval for Caldolor. We intend to seek further exclusivity from the FDA upon completion of successful pediatric clinical trials for the product.

Table of Contents

Part I

Kristalose

We are the exclusive licensee of U.S. Patent No. 5,480,491 owned by Inalco relating to Kristalose, directed to a process for preparation of crystalline lactulose. Related license rights include an exclusive license to use related Inalco know-how and the Kristalose trademark to manufacture, market and distribute Kristalose in the U.S. Under our agreement with Inalco, Inalco is solely responsible for prosecuting and maintaining both the patents and know-how that we license from them. Our license expires in 2021 and is subject to earlier termination for material breach. Our payment obligations under this agreement are described under Manufacturing and Distribution Manufacturing.

COMPETITION

The pharmaceutical industry is characterized by intense competition and rapid innovation. Our continued success in developing and commercializing pharmaceutical products will depend, in part, upon our ability to compete against existing and future products in our target markets. Competitive factors directly affecting our markets include but are not limited to:

- Ø product attributes such as efficacy, safety, ease-of-use and cost-effectiveness;
- Ø brand awareness and recognition driven by sales and marketing and distribution capabilities;
- Ø intellectual property and other exclusivity rights;
- Ø availability of resources to build and maintain developmental and commercial capabilities;
- Ø successful business development activities;
- Ø extent of third-party reimbursements; and
- Ø establishment of advantageous collaborations to conduct development, manufacturing or commercialization efforts.

A number of our competitors possess research and development and sales and marketing capabilities as well as financial resources greater than ours. These competitors, in addition to emerging companies and academic research institutions, may be developing, or in the future could develop, new technologies that could compete with our current and future products or render our products obsolete.

Acetadote

Acetadote is our injectable formulation of NAC for the treatment of acetaminophen overdose. NAC is accepted worldwide as the standard of care for acetaminophen overdose. Despite the availability of injectable NAC outside the United States, Acetadote, to our knowledge, is the only injectable NAC product approved in the U.S. to treat acetaminophen overdose. Our competitors in the acetaminophen overdose market are those companies selling orally administered NAC including, but not limited to, Geneva Pharmaceuticals, Inc., Bedford Laboratories division of Ben Venue Laboratories, Inc., Roxane Laboratories, Inc. and Hospira Inc.

Caldolor

Caldolor is marketed for the treatment of pain and fever, primarily in a hospital setting. A variety of other products address the acute pain market:

- Ø Morphine, the most commonly used product for the treatment of acute, post-operative pain, is manufactured and distributed by several generic pharmaceutical companies.
- Ø DepoDur[®] is an extended release injectable formulation of morphine that is marketed by EKR Therapeutics, Inc.

Table of Contents

Part I

- Ø Other generic injectable opioids, including fentanyl, meperidine and hydromorphone, address this market.
- Ø Ketorolac (brand name Toradol®), an injectable NSAID, is also manufactured and distributed by several generic pharmaceutical companies.
- Ø Ofirmev®, an injectable acetaminophen product, was approved by the FDA in 2010.

We are aware of other product candidates in development to treat acute pain including injectable NSAIDs, novel opioids, new formulations of existing therapies and extended release anesthetics. We believe non-narcotic analgesics for the treatment of post-surgical pain are the primary potential competitors to Caldolor.

In addition to the injectable analgesic products above, many companies are developing analgesics for specific indications such as migraine and neuropathic pain, oral extended-release forms of existing narcotic and non-narcotic products, and products with new methods of delivery such as transdermal. We are not aware of any approved injectable products indicated for the treatment of fever in the U.S. other than Caldolor and Ofirmev. There are, however, numerous drugs available to physicians to reduce fevers in hospital settings via oral administration to the patient, including ibuprofen, acetaminophen, and aspirin. These drugs are manufactured by numerous pharmaceutical companies.

Kristalose

Kristalose is a dry powder crystalline prescription formulation of lactulose indicated for the treatment of constipation. The U.S. constipation therapy market includes various prescription and OTC products. The prescription products which we believe are our primary competitors are Amitiza® and liquid lactuloses. Amitiza is indicated for the treatment of chronic idiopathic constipation in adults and is marketed by Sucampo Pharmaceuticals Inc. and Takeda Pharmaceutical Company Limited. Liquid lactulose products are marketed by a number of pharmaceutical companies.

There are several hundred OTC products used to treat constipation marketed by numerous pharmaceutical and consumer health companies. MiraLax® (polyethylene glycol 3350), previously a prescription product, was indicated for the treatment of constipation and manufactured and marketed by Braintree Laboratories, Inc. Under an agreement with Braintree, Schering-Plough introduced MiraLax as an OTC product in February 2007.

GOVERNMENT REGULATION

Pharmaceutical companies are subject to extensive regulation by national, state, and local agencies in countries in which they do business. The manufacture, distribution, marketing and sale of pharmaceutical products is subject to government regulation in the U.S. and various foreign countries. Additionally, in the U.S., we must follow rules and regulations established by the FDA requiring the presentation of data indicating that our products are safe and efficacious and are manufactured in accordance with cGMP regulations. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market our products and we may be criminally prosecuted. We and our manufacturers and clinical research organizations may also be subject to regulations under other federal, state and local laws, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act, the Clean Air Act and import, export and customs regulations as well as the laws and regulations of other countries.

Table of Contents

Part I

FDA Approval Process

The steps required to be taken before a new prescription drug may be marketed in the U.S. include:

- Ø completion of pre-clinical laboratory and animal testing;
- Ø the submission to the FDA of an investigational new drug application, or IND, which must be evaluated and found acceptable by the FDA before human clinical trials may commence;
- Ø performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use; and
- Ø submission and approval of an NDA.

The sponsor of the drug typically conducts human clinical trials in three sequential phases, but the phases may overlap. In Phase I clinical trials, the product is tested in a small number of patients or healthy volunteers, primarily for safety at one or more dosages. In Phase II clinical trials, in addition to safety, the sponsor evaluates the efficacy of the product on targeted indications, and identifies possible adverse effects and safety risks in a patient population. Phase III clinical trials typically involve testing for safety and clinical efficacy in an expanded population at geographically-dispersed test sites.

The FDA requires that clinical trials be conducted in accordance with the FDA's good clinical practices (GCP) requirements. The FDA may order the partial, temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The institutional review board (IRB), or ethics committee (outside of the U.S.), of each clinical site generally must approve the clinical trial design and patient informed consent and may also require the clinical trial at that site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

The results of the pre-clinical and clinical trials, together with, among other things, detailed information on the manufacture and composition of the product and proposed labeling, are submitted to the FDA in the form of an NDA for marketing approval. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has ten months in which to complete its initial review of a standard NDA and respond to the applicant. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months of the PDUFA goal date. If the FDA's evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the FDA may issue an approval letter. The FDA may also issue an approvable letter setting forth further conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug for certain indications. According to the FDA, the median total approval time for NDAs approved during calendar year 2004 was approximately 13 months for standard applications. If the FDA's evaluations of the NDA submission and the clinical and manufacturing procedures and facilities are not favorable, it may refuse to approve the NDA and issue a not-approvable letter. The time and cost of

completing these steps and obtaining FDA approval can vary dramatically depending on the drug. However, to complete these steps for a novel drug can take many years and cost millions of dollars.

Table of Contents

Part I

Section 505(b)(2) New Drug Applications

As an alternate path for FDA approval of new indications or new formulations of previously-approved products, a company may file a Section 505(b)(2) NDA, instead of a stand-alone or full NDA. Section 505(b)(2) of the FDC Act was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendments. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Some examples of products that may be allowed to follow a 505(b)(2) path to approval are drugs which have a new dosage form, strength, route of administration, formulation or indication.

We successfully secured FDA approvals for Acetadote in January 2004 and for Caldolor in June 2009 pursuant to the 505(b)(2) pathway. Upon approval of a full or 505(b)(2) NDA, a drug may be marketed only for the FDA-approved indications in the approved dosage forms. Further clinical trials are necessary to gain approval for the use of the product for any additional indications or dosage forms. The FDA may also require post-market reporting and may require surveillance programs to monitor the side effects of the drug, which may result in withdrawal of approval after marketing begins.

Special Protocol Assessment Process

The special protocol assessment, or SPA, process generally involves FDA evaluation of a proposed Phase III clinical trial protocol and a commitment from the FDA that the design and analysis of the trial are adequate to support approval of an NDA, if the trial is performed according to the SPA and meets its endpoints. The FDA's guidance on the SPA process indicates that SPAs are designed to evaluate individual clinical trial protocols primarily in response to specific questions posed by the sponsors. In practice, the sponsor of a product candidate may request an SPA for proposed Phase III trial objectives, designs, clinical endpoints and analyses. A request for an SPA is submitted in the form of a separate amendment to an IND, and the FDA's evaluation generally will be completed within a 45-day review period under applicable PDUFA goals, provided that the trials have been the subject of discussion at an end-of-Phase II and pre-Phase III meeting with the FDA, or in other limited cases.

On June 14, 2004, we submitted a request for SPA of our Caldolor Phase III clinical study. During a meeting with the FDA on September 29, 2004, the FDA confirmed that the efficacy data from our study of post-operative pain with a positive outcome was considered sufficient to support a 505(b)(2) application for the pain indication. Final determinations by the FDA with respect to a product candidate, including as to the scope of its labeling, are made after a complete review of the applicable NDA and are based on the entire data in the application.

Orphan Drug Designation

The Orphan Drug Act of 1983, or Orphan Drug Act, encourages manufacturers to seek approval of products intended to treat rare diseases and conditions with a prevalence of fewer than 200,000 patients in the U.S. or for which there is no reasonable expectation of recovering the development costs for the product. For products that receive orphan drug designation by the FDA, the Orphan Drug Act provides tax credits for clinical research, FDA assistance with protocol design, eligibility for FDA grants to fund clinical studies, waiver of the FDA application fee, and a period of seven years of marketing exclusivity for the product following FDA marketing approval. Acetadote received Orphan Drug designation in October 2001 and was approved by the FDA for the intravenous treatment of moderate to severe acetaminophen overdose in January 2004. As an orphan drug, Acetadote was entitled to marketing exclusivity until

January 2011 for the treatment of this approved indication, and we intend to seek additional exclusivity for this product through new potential indications. This exclusivity would not prevent a product with a different formulation from competing with Acetadote, however.

Table of Contents

Part I

The Hatch-Waxman Act

The Hatch-Waxman Act provides three years of marketing exclusivity for the approval of new and supplemental NDAs, including Section 505(b)(2) NDAs, for, among other things, new indications, dosages or strengths of an existing drug, if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval of the application. It is under this provision that we received three years marketing exclusivity for Caldolor upon receipt of FDA approval in June 2009.

Recent Health Care Legislation

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act, or PPACA. On March 30, 2010, the Health Care and Education Reconciliation Act of 2010, or HCERA, was enacted into law, which modified the revenue provisions of the PPACA. The PPACA as amended by the HCERA constitutes the healthcare reform legislation. The following highlights certain provisions of the legislation that may affect us.

Pharmaceutical Industry Fee

Beginning in calendar-year 2011, an annual fee will be imposed on pharmaceutical manufacturers and importers that sell branded prescription drugs to specified government programs (e.g., Medicare Part D, Medicare Part B, Medicaid, Department of Veterans Affairs programs, Department of Defense programs and TRICARE). The annual fee will be allocated to companies based on their previous calendar-year market share using sales data that the government agencies that purchase the pharmaceuticals will provide to the Treasury Department. Although we participate in governmental programs that would subject us to this fee, our sales volume in such programs is less than \$10 million, with the first \$5 million of sales being exempt from the fee. We do not anticipate this fee will have a material impact on our results of operations.

Medicaid Rebate Rate

We currently provide rebates for Kristalose sold to Medicaid beneficiaries. Effective January 1, 2010, the rebate increased from eleven percent to thirteen percent of the average manufacturer price. Our sales of Kristalose under the Medicaid program have been increasing. We expect the increased rebate percentage will impact our net revenue for Kristalose by less than \$0.1 million for the year ended December 31, 2011.

Federal Grant Funding

The legislation established a fifty-percent nonrefundable investment tax credit or grant for qualified investments in qualifying therapeutic discovery projects. The provision allocated \$1 billion during the two-year period (2009-2010) for the program. The credit is available only to companies with 250 or fewer employees. The qualified investment for any tax year is the aggregate amount of the costs paid or incurred in that year for expenses necessary for and directly related to the conduct of the qualifying therapeutic discovery project. We submitted applications for four of our research projects prior to the deadline of July 21, 2010. In November 2010, we received a response from the Internal Revenue Service indicating approval for funding. We received grants of approximately \$0.9 million based on actual 2009 and 2010 expenditures.

Other Regulatory Requirements

Regulations continue to apply to pharmaceutical products after FDA approval occurs. Post-marketing safety surveillance is required in order to continue to market an approved product. The FDA also may, in its discretion, require post-marketing testing and surveillance to monitor the effects of approved

Table of Contents

Part I

products or place conditions on any approvals that could restrict the commercial applications of these products.

If we seek to make certain changes to an FDA-approved product, such as promoting or labeling a product for a new indication, making certain manufacturing changes or product enhancements or adding labeling claims, we will need FDA review and approval before the change can be implemented. While physicians may use products for indications that have not been approved by the FDA, we may not label or promote the product for an indication that has not been approved. Securing FDA approval for new indications or product enhancements and, in some cases, for manufacturing and labeling claims, is generally a time-consuming and expensive process that may require us to conduct clinical trials under the FDA's IND regulations. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all. In addition, adverse experiences associated with use of the products must be reported to the FDA, and FDA rules govern how we can label, advertise or otherwise commercialize our products. In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid or other federally financed health care programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal health care programs. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product.

Outside of the U.S., our ability to market our products will also depend on receiving marketing authorizations from the appropriate regulatory authorities. The foreign regulatory approval process includes all of the risks associated with the FDA approval process described above. The requirements governing the conduct of clinical trials and marketing authorization vary widely from country to country.

ENVIRONMENTAL MATTERS

We are subject to federal, state, and local environmental laws and regulations and we believe that our operations comply with such regulations. We anticipate that the effects of compliance with federal, state and local laws and regulations relating to the discharge of materials into the environment will not have any material effect on our capital expenditures, earnings or competitive position.

SEASONALITY

There are no significant seasonal aspects to our business.

BACKLOG

Due to the relatively short lead-time required to fill orders for our products, backlog of orders is not considered material to our business.

20

Table of Contents

Part I

EMPLOYEES

As of March 1, 2011, we had 131 full-time employees. In addition, we believe that utilizing experienced, independent contractors and consultants is a cost-efficient and effective way to accomplish our goals and a number of individuals have provided or are currently providing services to us pursuant to agreements between the individuals or their employers and us. None of our employees are represented by a collective bargaining unit. We believe that we have positive relationships with our employees.

Table of Contents

Part I

Item 1A: Risk Factors

You should carefully consider the risk factors described below and throughout this report, which could materially affect our business. There are also risks that are not presently known or not presently material, as well as the other information set forth in this report that could materially affect our business. In addition, in our periodic filings with the SEC, press releases and other statements, we discuss estimates and projections regarding our future performance and business outlook. By their nature, such forward-looking statements involve known and unknown risks, uncertainties and other factors that in some cases are out of our control. For a further discussion of forward-looking statements, please refer to the section entitled Special Note Regarding Forward-Looking Statements. These factors could cause our actual results to differ materially from our historical results or our present expectations and projections. These risk factors and uncertainties include, but are not limited to the following:

RISKS RELATED TO OUR BUSINESS

An adverse development regarding our products could have a material and adverse impact on our future revenues and profitability.

A number of factors may impact the effectiveness of our marketing and sales activities and the demand for our products, including:

- Ø The prices of our products relative to other drugs or competing treatments;
- Ø Any unfavorable publicity concerning us, our products, or the markets for these products such as information concerning product contamination or other safety issues in either of our product markets, whether or not directly involving our products;
- Ø Perception by physicians and other members of the healthcare community of the safety or efficacy of our products or competing products;
- Ø Regulatory developments related to our marketing and promotional practices or the manufacture or continued use of our products;
- Ø Changes in intellectual property protection available for our products or competing treatments;
- Ø The availability and level of third-party reimbursement for sales of our products; and
- Ø The continued availability of adequate supplies of our products to meet demand.

If demand for our products weaken, our revenues and profitability will likely decline. Known adverse effects of our marketed products are documented in product labeling, including the product package inserts, medical information disclosed to medical professionals and all marketing-related materials. At this time, no unforeseen or serious adverse effects outside of those specified in current product labeling have been directly attributed to our approved products.

If any manufacturer we rely upon fails to produce our products in the amounts we require on a timely basis, or fails to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may be unable to meet demand for our products and may lose potential revenues.

We do not manufacture any of our products, and we do not currently plan to develop any capacity to do so. Our dependence upon third parties for the manufacture of products could adversely affect our profit margins or our ability to develop and deliver products on a timely and competitive basis. If for any reason we are unable to obtain or retain third-party manufacturers on commercially acceptable terms, we may not be able to sell our products as planned. Furthermore, if we encounter delays or

Table of Contents

Part I

difficulties with contract manufacturers in producing our products, the distribution, marketing and subsequent sales of these products could be adversely affected.

Caldolor is manufactured at Hospira Australia Pty. Ltd.'s facility in Australia and Bayer's facility in Kansas. Beginning in early 2011, Acetadote is manufactured primarily at Bayer's facility in Kansas and Bioniche's manufacturing plant in Ireland is an alternative manufacturing source for Acetadote. The active pharmaceutical ingredient for Kristalose is manufactured at a single facility in Italy. If any one of these facilities is damaged or destroyed, or if local conditions result in a work stoppage, we could suffer an inability to meet demand for our products. Kristalose is manufactured through a complex process involving trade secrets of the manufacturer; therefore, it would be particularly difficult to find a new manufacturer of Kristalose on an expedited basis. As a result of these factors, our ability to manufacture Kristalose may be substantially impaired if the manufacturer is unable or unwilling to supply sufficient quantities of the product.

In addition, all manufacturers of our products and product candidates must comply with current good manufacturing practices, referred to as cGMP, enforced by the FDA through its facilities inspection program. These requirements include quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our products may be unable to comply with cGMP requirements and with other FDA, state and foreign regulatory requirements.

We have no control over our manufacturers' compliance with these regulations and standards. If our third-party manufacturers do not comply with these requirements, we could be subject to:

- Ø fines and civil penalties;
- Ø suspension of production or distribution;
- Ø suspension or delay in product approval;
- Ø product seizure or recall; and
- Ø withdrawal of product approval.

We are dependent on a variety of other third parties. If these third parties fail to perform as we expect, our operations could be disrupted and our financial results could suffer.

We have a relatively small internal infrastructure. We rely on a variety of third parties, other than our third-party manufacturers, to help us operate our business. Other third parties on which we rely include:

- Ø Cardinal Health Specialty Pharmaceutical Services, a logistics and fulfillment company and business unit of Cardinal, which warehouses and ships our marketed products; and
- Ø Vanderbilt University and the Tennessee Technology Development Corporation, co-owners with us of CET, and the universities that collaborate with us in connection with CET's research and development programs.

If these third parties do not continue to provide services to us, or collaborate with us, we might not be able to obtain others who can serve these functions. This could disrupt our business operations, increase our operating expenses or otherwise adversely affect our operating results.

Competitive pressures could reduce our revenues and profits.

The pharmaceutical industry is intensely competitive. Our strategy is to target differentiated products in specialized markets. However, this strategy does not relieve us from competitive pressures, and can entail distinct competitive risks. Certain of our competitors do not aggressively promote their products in our markets. An increase in promotional activity in our markets could result in large shifts in market share, adversely affecting us.

Table of Contents

Part I

Our competitors may sell or develop drugs that are more effective and useful and less costly than ours, and they may be more successful in manufacturing and marketing their products. Many of our competitors have significantly greater financial and marketing resources than we do. Additional competitors may enter our markets.

The pharmaceutical industry is characterized by constant and significant investment in new product development, which can result in rapid technological change. The introduction of new products could substantially reduce our market share or render our products obsolete. The selling prices of pharmaceutical products tend to decline as competition increases, through new product introduction or otherwise, which could reduce our revenues and profitability.

Governmental and private health care payors have recently emphasized substitution of branded pharmaceuticals with less expensive generic equivalents. An increase in the sales of generic pharmaceutical products could result in a decrease in revenues of branded pharmaceuticals. While there are no generic equivalents competing with our products at this time, in the future we could face generic competition.

The commercial launch of Caldolor is subject to many internal and external challenges and if we cannot overcome these challenges in a timely manner, our future revenues and profits could be materially and adversely impacted.

Caldolor represents a substantial portion of our future growth. Caldolor was approved by the FDA in June 2009, and we started commercializing Caldolor in the United States in September 2009. The commercial success of Caldolor is dependent on many third-parties, including physicians, pharmacists, hospital pharmacy and therapeutics committees, or P&T committees, suppliers and distributors, all of whom we have little or no control over. We expect Caldolor to be administered primarily to hospitalized patients who are unable to receive oral therapies for the treatment of pain or fever. Before we can distribute Caldolor to any new hospital customers, Caldolor must be approved for addition to the hospitals' formulary lists by their P&T committees. A hospital's P&T committee generally governs all matters pertaining to the use of medications within the institution, including review of medication formulary data and recommendations of drugs to the medical staff. We cannot guarantee that we will be successful in getting the approvals we need from enough P&T committees to be able to optimize hospital sales of Caldolor. Even if we obtain hospital approval for Caldolor, we must still convince individual hospital physicians to prescribe Caldolor repeatedly. Because Caldolor is a new drug with little track record, any mistakes made in the timely supply of Caldolor, education about how to properly administer Caldolor or any unexpected side effects that develop from use of the drug, may lead physicians to not accept Caldolor as a viable treatment alternative.

In addition to the extensive external efforts required, the commercial success of Caldolor also depends on our ability to coordinate supply, distribution, marketing, sales and education efforts. Internally, the successful commercialization of Caldolor depends on our ability to maintain a well-trained, qualified sales force, to equip our sales force with effective supportive materials, to target appropriate markets and to accurately price Caldolor. In addition, as Caldolor is a newly marketed drug, our sales force will need to be credible and persuasive in order to convince physicians and pharmacists in target markets to use Caldolor. If we are unable to provide our sales force with convincing supportive materials, such as clinical papers, sales literature and formulary kits, they may not be able to sell Caldolor in sufficient quantities. We must also target the right hospitals across the United States. Any failure in sales force coverage could limit our ability to generate market acceptance for Caldolor. We also have set a price for Caldolor that we believe hospitals and other purchasers are willing to pay, but that will also generate sufficient profits. If we have set a price for Caldolor that hospitals consider too high, we may need to subsequently reduce the price for Caldolor. If we have set

the initial price for Caldolor too low, we may not generate adequate profits and may not be able to raise the price of the drug in the future.

Table of Contents

Part I

Any attempt by us to expand the potential market for Caldolor is subject to limitations.

In its June 2009 Caldolor approval letter, the FDA required us to conduct two additional Phase IV pediatric studies by 2011 and 2012, respectively. If the results of these Phase IV clinical studies are not favorable, we may not be able to expand the market for Caldolor to children ages 1-16. We may also experience delays associated with these required Phase IV clinical studies potentially resulting from, among other factors, difficulty enrolling pediatric patients. Such delays could impact our ability to obtain an additional six months of FDA exclusivity.

In addition, we have only obtained regulatory approval to market Caldolor in the United States. In foreign jurisdictions such as Canada, New Zealand, South Korea, Southeast Asia and Australia we have licensed the right to market Caldolor to third parties. These third parties are responsible for seeking regulatory approval for Caldolor in their respective jurisdictions. We have no control over these third parties and cannot be sure that marketing approval for Caldolor will be obtained outside the United States.

Our future growth depends on our ability to identify and acquire rights to products. If we do not successfully identify and acquire rights to products and successfully integrate them into our operations, our growth opportunities may be limited.

We acquired rights to Caldolor, Acetadote and Kristalose. Our business strategy is to continue to acquire rights to FDA-approved products as well as pharmaceutical product candidates in the late stages of development. We do not plan to conduct basic research or pre-clinical product development, except to the extent of our investment in CET. As compared to large multi-national pharmaceutical companies, we have limited resources to acquire third-party products, businesses and technologies and integrate them into our current infrastructure. Many acquisition opportunities involve competition among several potential purchasers including large multi-national pharmaceutical companies and other competitors that have access to greater financial resources than we do. With future acquisitions, we may face financial and operational risks and uncertainties. We may not be able to engage in future product acquisitions, and those we do complete may not be beneficial to us in the long term.

If we are unable to maintain and build an effective sales and marketing infrastructure, we will not be able to commercialize and grow our products and product candidates successfully.

As we grow, we may not be able to secure sales personnel or organizations that are adequate in number or expertise to successfully market and sell our products. This risk would be accentuated if we acquire products in areas outside of hospital acute care and gastroenterology, since our sales forces specialize in these areas. If we are unable to expand our sales and marketing capability or any other capabilities necessary to commercialize our products and product candidates, we will need to contract with third parties to market and sell our products. If we are unable to establish and maintain adequate sales and marketing capabilities, we may not be able to increase our product revenue, may generate increased expenses and may not continue to be profitable.

If governmental or third-party payors do not provide adequate reimbursement for our products, our revenue and prospects for continued profitability may be limited.

Our financial success depends, in part, on the availability of adequate reimbursement from third-party healthcare payors. Such third-party payors include governmental health programs such as Medicare and Medicaid, managed care providers and private health insurers. Third-party payors are increasingly challenging the pricing of medical products

and services, while governments continue to propose and pass legislation designed to reduce the cost of healthcare. Adoption of such legislation could further limit reimbursement for pharmaceuticals.

Table of Contents

Part I

For example, in March 2010, the U.S. government passed into law and enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, Health Care Reform Act). Among other provisions, the Health Care Reform Act calls for an increase in certain Medicare drug rebates paid by pharmaceutical manufacturers and an industry fee imposed on pharmaceutical manufacturers according to the individual manufacturer's relative percentage of total industry sales to specified government programs. At this time no assurances can be given that these measures, or any other measures included in the Health Care Reform Act, will not have an adverse effect on our revenues in the future. Furthermore, future cost control initiatives, legislation, and regulations could decrease the price that we would receive for any products, which would limit our revenue and profitability.

Also, reimbursement practices of third-party payors might preclude us from achieving market acceptance for our products or maintaining price levels sufficient to realize an appropriate return on our investment in product acquisition and development. If we cannot obtain adequate reimbursement levels, our business, financial condition and results of operations would be materially and adversely affected.

Formulary practices of third-party payors could adversely affect our competitive position.

Many managed health care organizations are now controlling the pharmaceutical products listed on their formulary lists. Having products listed on these formulary lists creates competition among pharmaceutical companies which, in turn, has created a trend of downward pricing pressure in our industry. In addition, many managed care organizations are pursuing various ways to reduce pharmaceutical costs and are considering formulary contracts primarily with those pharmaceutical companies that can offer a full line of products for a given therapy sector or disease state. Our products might not be included on the formulary lists of managed care organizations, and downward pricing pressure in our industry generally could negatively impact our operations.

Continued consolidation of distributor networks in the pharmaceutical industry as well as increases in retailer concentration may limit our ability to profitably sell our products.

We sell most of our products to large pharmaceutical wholesalers, who in turn sell to, thereby supplying, hospitals and retail pharmacies. The distribution network for pharmaceutical products has become increasingly consolidated in recent years. Further consolidation or financial difficulties could also cause our customers to reduce the amounts of our products that they purchase, which would materially and adversely affect our business, financial condition and results of operations.

Our CET joint initiative may not result in our gaining access to commercially viable products.

Our CET joint initiative with Vanderbilt University and Tennessee Technology Development Corporation is designed to help us investigate, in a cost-effective manner, early-stage products and technologies. However, we may never gain access to commercially viable products from CET for a variety of reasons, including:

- Ø CET investigates early-stage products, which have the greatest risk of failure prior to FDA approval and commercialization;
- Ø In some programs, we do not have pre-set rights to product candidates developed by CET. We would need to agree with CET and its collaborators on the terms of any product licensed to, or acquired by, us;

Ø We rely principally on government grants to fund CET's research and development programs. If these grants were no longer available, we or our co-owners might be unable or unwilling to fund CET operations at current levels or at all;

26

Table of Contents

Part I

- Ø We may become involved in disputes with our co-owners regarding CET policy or operations, such as how best to deploy CET assets or which product opportunities to pursue. Disagreement could disrupt or halt product development; and
- Ø CET may disagree with one of the various universities with which CET is collaborating on research. A disagreement could disrupt or halt product development.

We depend on our key personnel, the loss of whom would adversely affect our operations. If we fail to attract and retain the talent required for our business, our business will be materially harmed.

We are a relatively small company, and we depend to a great extent on principal members of our management and scientific staff. If we lose the services of any key personnel, in particular, A.J. Kazimi, our Chief Executive Officer, it could have a material adverse effect on our business prospects. We currently have a key man life insurance policy covering the life of Mr. Kazimi. We have entered into agreements with each of our employees that contain restrictive covenants relating to non-competition and non-solicitation of our customers and suppliers for one year after termination of employment. Nevertheless, each of our officers and key employees may terminate his or her employment at any time without notice and without cause or good reason, and so as a practical matter these agreements do not guarantee the continued service of these employees. Our success depends on our ability to attract and retain highly qualified scientific, technical and managerial personnel and research partners. Competition among pharmaceutical companies for qualified employees is intense, and we may not be able to retain existing personnel or attract and retain qualified staff in the future. If we experience difficulties in hiring and retaining personnel in key positions, we could suffer from delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect operating results.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product or product candidate and may have to limit its commercialization.

We face an inherent risk of product liability lawsuits related to the testing of our product candidates and the commercial sale of our products. An individual may bring a liability claim against us if one of our product candidates or products causes, or appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we may incur substantial liabilities. Liability claims may result in:

- Ø decreased demand for our products;
- Ø injury to our reputation;
- Ø withdrawal of clinical trial participants;
- Ø significant litigation costs;
- Ø substantial monetary awards to or costly settlement with patients;
- Ø product recalls;

Ø loss of revenue; and

Ø the inability to commercialize our product candidates.

We are highly dependent upon medical and patient perceptions of us and the safety and quality of our products. We could be adversely affected if we or our products are subject to negative publicity. We could also be adversely affected if any of our products or any similar products sold by other companies prove to be, or are asserted to be, harmful to patients. Also, because of our dependence upon medical and patient perceptions, any adverse publicity associated with illness or other adverse effects resulting

Table of Contents

Part I

from the use or misuse of our products or any similar products sold by other companies could have a material adverse impact on our results of operations.

We have product liability insurance that covers our clinical trials and the marketing and sale of our products up to a \$10 million annual aggregate limit, subject to specified deductibles. Our current or future insurance coverage may prove insufficient to cover any liability claims brought against us.

Because of the increasing costs of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise.

Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.%

2006

16.3 2000 20.9

2005

13.3 1999 8.7

2004

29.2 1998 -6.8

2003

54.3 1997 20.5

2002

-12.5

TOP 10 POSITIONS

% of Net Assets Applicable
to Common Stockholders

Australian Government 7.5% Bond

5.4%

New Zealand Government 6.00% Bond

4.6

South Africa Government 10.00% Bond

3.5	
Unit Corporation	
3.4	
Metal Management	
3.3	
Trican Well Service	
3.3	
Reliance Steel & Aluminum	
3.3	
Thor Industries	
3.2	
Schnitzer Steel Industries Cl. A	
3.1	
Lincoln Electric Holdings	
3.0	

PORTFOLIO SECTOR BREAKDOWN

% of Net Assets Applicable
to Common Stockholders

Natural Resources	
26.7%	
Industrial Products	
21.6	
Consumer Products	
13.1	
Industrial Services	
9.7	
Technology	
6.2	

Financial Intermediaries

4.7

Health

4.7

Financial Services

1.5

Bonds

13.5

Cash and Cash Equivalents

13.4

Royce Focus Trust

Manager's Discussion

A dynamic first half and relatively stable second half added up to a very successful year for Royce Focus Trust (FUND) on both an absolute and relative basis. **For the calendar year, FUND gained 12.2% on a net asset value (NAV) basis and 3.0% on a market price basis, both results well ahead of its small-cap benchmark, the Russell 2000, which lost 1.6% in 2007.** After posting impressive first-half returns—up 15.9% on a net asset value (NAV) basis and 8.6% on a market price basis, versus the Russell 2000's gain of 6.5%, for the same period—the Fund managed well amid the third quarter's volatility. FUND was up 0.4% on an NAV basis and down 5.3% on a market price basis while its benchmark declined 3.1%.

The fourth quarter saw more widespread losses in the market as a whole, though small-cap stocks continued to be among the hardest hit. The Russell 2000 lost 4.6% between October and December, while the Fund was down 3.6% on an NAV basis and up 0.1% on a market price basis. The portfolio's down-market strength can best be seen in its performance from the small-cap peak on 7/13/07 through 12/31/07, when it lost 7.4% on an NAV basis and 7.8% on a market price basis while the Russell 2000 fell 9.9%.

From the previous small-cap market peak on 3/9/00 through 12/31/07, FUND returned 237.2% on an NAV basis and 305.2% on a market price basis, versus a 39.5% result for the small-cap index. The Fund

GOOD IDEAS THAT WORKED
2007 Net Realized and Unrealized
Investment Return*

\$3,691,814

also handily outpaced the Russell 2000 during the bullish phase from the small-cap market trough on 10/9/02 through 12/31/07, gaining 254.5% on an NAV basis and 277.9% on a market price basis, while the Russell 2000 was up 149.5% for the same period. These strong market cycle results played a major role in FUND's outperformance of the benchmark over calendar-based periods. On both an NAV and market price basis, the Fund's limited portfolio of primarily small-cap stocks beat the index for the one-, three-, five-, 10- year and since-inception of our management (11/1/96) periods ended 12/31/07. **FUND's NAV average annual total return since the inception of our management was 14.2%.**

Although five sectors posted net losses, declines on a dollar basis were small. At the individual holding level, KKR Financial disappointed. The firm is run by experienced investment bankers whose business plan appealed to our contrarian nature when we first heard it in spring 2007. KKR Financial was ready for the calamitous collapse of the subprime

Schnitzer Steel Industries Cl. A	
IPSCO	3,396,454
Florida Rock Industries	2,290,728
Chaparral Steel	2,085,186
Woodward Governor	2,075,208

*Includes dividends

Important Performance and Risk Information

All performance information reflects past performance, is presented on a total return basis and reflects the reinvestment of distributions. Past performance is no guarantee of future results. Current performance may be higher or lower than performance quoted. Returns as of the recent month-end may be obtained at www.roycefunds.com. The market price of the Fund's shares will fluctuate, so that shares may be worth more or less than their original cost when sold. The Fund normally invests primarily in small-cap companies, which may involve considerably more risk than investing in a more diversified portfolio of larger-cap companies. Standard deviation is a statistical measure within which a fund's total returns have varied over time. The greater the standard deviation, the greater a fund's volatility.

Performance and Portfolio Review

market and related credit crunch. They held ample highest-grade mortgage paper with which to weather the predicted storm. What the firm—and we—failed to account for was how difficult life would be even for parties holding high-quality debt in the current environment. Their mortgage holdings were suddenly devalued and the company’s levered positions only exacerbated its difficulties. In the otherwise-profitable precious metals and mining industry within the Natural Resources sector, Gammon Gold also showed net losses for the year. Lower-than-expected production at this early stage producer seemed to keep investors away in 2007. We sold some shares in October before purchasing more shares in November, mostly content to wait for operational improvements.

The Fund’s strongest dollar-based net gains came from the Industrial Products sector, which more than tripled the net gain of the next best-performing sector, Natural Resources. Each of the Fund’s top five performers—and seven of its top ten—were Industrial Products holdings. After posting stronger-than-expected fiscal third-quarter earnings in July, the share price of recycling and scrap metal business Schnitzer Steel Industries began to soar, though it moved a little

GOOD IDEAS AT THE TIME 2007 Net Realized and Unrealized Investment Loss*

KKR Financial	\$2,108,348
Gammon Gold	1,823,204
Knight Capital Group Cl. A	1,346,523
Arkansas Best	1,137,072
Winnebago Industries	1,098,220

*Net of dividends

closer to earth in the fourth quarter. We trimmed our position from September through December. Canadian steel production and fabrication company IPSCO first attracted our attention in 2004 with its pristine balance sheet, strong history of earnings and high returns on capital. It was also the target of the urge to merge. Earlier this year, several larger firms began looking at the firm as a potential acquisition, with Swedish business SSAB finally closing the deal in May. We sold our shares between April and May. We first began to buy shares of construction aggregates company Florida Rock Industries in other Royce-managed portfolios more than 20 years ago and have had a position in FUND’s portfolio since 1998. In February 2007, the company was acquired by a larger competitor at a substantial premium. We finished selling our stake in April.

Edgar Filing: McCarley James L - Form 4

¹Royce & Associates assumed investment management responsibility for the Fund on 11/1/96.

²Reflects the cumulative total return experience of a continuous common stockholder who reinvested all distributions as indicated and fully participated in the primary subscription of the 2005 rights offering.

³Reflects the actual market price of one share as it traded on Nasdaq.

FUND INFORMATION AND PORTFOLIO DIAGNOSTICS	
Fund Net Assets	\$166 million
Symbol Market Price NAV	FUND XFUNX
Net Leverage [□]	2%
Turnover Rate	62%
Average Market Capitalization [*]	\$1,290 million
Weighted Average P/E Ratio ^{**}	12.4x
Weighted Average P/B Ratio	2.4x
Weighted Average Portfolio Yield	4.0%
<p>[□]Net leverage is the percentage, in excess of 100%, of the total value of equity type investments, divided by net assets, excluding preferred stock. [*]Geometrically calculated ^{**}The Fund's P/E ratio calculation excludes companies with zero or negative earnings (10% of portfolio holdings as of 12/31/07).</p>	
CAPITAL STRUCTURE	
Publicly Traded Securities Outstanding at 12/31/07 at NAV or Liquidation Value	
18.6 million shares of Common Stock	\$166 million
6.00% Cumulative Preferred Stock	\$25 million
RISK/RETURN COMPARISON	
Five-Year Period Ended 12/31/07	

	Average Annual Total Return	Standard Deviation	Return Efficiency*
FUND (NAV)	24.15%	15.56	1.55
Russell 2000	16.25	14.44	1.13

*Return Efficiency is the average annual total return divided by the annualized standard deviation over a designated time period.

History Since Inception

The following table details the share accumulations by an initial investor in the Funds who reinvested all distributions (including fractional shares) and participated fully in primary subscriptions for each of the rights offerings. Full participation in distribution reinvestments and rights offerings can maximize the returns available to a long-term investor. This table should be read in conjunction with the Performance and Portfolio Reviews of the Funds.

History	Amount Invested	Purchase Price*	Shares	NAV Value**	Market Value**
Royce Value Trust					
11/26/86 Initial Purchase	\$ 10,000	\$ 10.000	1,000	\$ 9,280	\$ 10,000
10/15/87 Distribution \$0.30		7.000	42		
12/31/87 Distribution \$0.22		7.125	32	8,578	7,250
12/27/88 Distribution \$0.51		8.625	63	10,529	9,238
9/22/89 Rights Offering	405	9.000	45		
12/29/89 Distribution \$0.52		9.125	67	12,942	11,866
9/24/90 Rights Offering	457	7.375	62		
12/31/90 Distribution \$0.32		8.000	52	11,713	11,074
9/23/91 Rights Offering	638	9.375	68		
12/31/91 Distribution \$0.61		10.625	82	17,919	15,697
9/25/92 Rights Offering	825	11.000	75		
12/31/92 Distribution \$0.90		12.500	114	21,999	20,874
9/27/93 Rights Offering	1,469	13.000	113		
12/31/93 Distribution \$1.15		13.000	160	26,603	25,428
10/28/94 Rights Offering	1,103	11.250	98		
12/19/94 Distribution \$1.05		11.375	191	27,939	24,905
11/3/95 Rights Offering	1,425	12.500	114		
12/7/95 Distribution \$1.29		12.125	253	35,676	31,243
12/6/96 Distribution \$1.15		12.250	247	41,213	36,335
1997 Annual distribution total \$1.21		15.374	230	52,556	46,814
1998 Annual distribution total \$1.54		14.311	347	54,313	47,506
1999 Annual distribution total \$1.37		12.616	391	60,653	50,239
2000 Annual distribution total \$1.48		13.972	424	70,711	61,648
2001 Annual distribution total \$1.49		15.072	437	81,478	73,994
2002 Annual distribution total \$1.51		14.903	494	68,770	68,927
1/28/03 Rights Offering	5,600	10.770	520		
2003 Annual distribution total \$1.30		14.582	516	106,216	107,339
2004 Annual distribution total \$1.55		17.604	568	128,955	139,094
2005 Annual distribution total \$1.61		18.739	604	139,808	148,773
2006 Annual distribution total \$1.78		19.696	693	167,063	179,945
2007 Annual distribution total \$1.85		19.687	787		
12/31/07	\$ 21,922		8,889	\$ 175,469	\$ 165,158

Royce Micro-Cap Trust

Edgar Filing: McCarley James L - Form 4

12/14/93	Initial Purchase	\$ 7,500	\$ 7,500	1,000	\$ 7,250	\$ 7,500
10/28/94	Rights Offering	1,400	7,000	200		
12/19/94	Distribution \$0.05		6,750	9	9,163	8,462
12/7/95	Distribution \$0.36		7,500	58	11,264	10,136
12/6/96	Distribution \$0.80		7,625	133	13,132	11,550
12/5/97	Distribution \$1.00		10,000	140	16,694	15,593
12/7/98	Distribution \$0.29		8,625	52	16,016	14,129
12/6/99	Distribution \$0.27		8,781	49	18,051	14,769
12/6/00	Distribution \$1.72		8,469	333	20,016	17,026
12/6/01	Distribution \$0.57		9,880	114	24,701	21,924
2002	Annual distribution total \$0.80		9,518	180	21,297	19,142
2003	Annual distribution total \$0.92		10,004	217	33,125	31,311
2004	Annual distribution total \$1.33		13,350	257	39,320	41,788
2005	Annual distribution total \$1.85		13,848	383	41,969	45,500
2006	Annual distribution total \$1.55		14,246	354	51,385	57,647
2007	Annual distribution total \$1.35		13,584	357		

12/31/07 **\$ 8,900** **3,836** **\$ 51,709** **\$ 45,802**

Royce Focus Trust

10/31/96	Initial Purchase	\$ 4,375	\$ 4,375	1,000	\$ 5,280	\$ 4,375
12/31/96					5,520	4,594
12/5/97	Distribution \$0.53		5,250	101	6,650	5,574
12/31/98					6,199	5,367
12/6/99	Distribution \$0.145		4,750	34	6,742	5,356
12/6/00	Distribution \$0.34		5,563	69	8,151	6,848
12/6/01	Distribution \$0.14		6,010	28	8,969	8,193
12/6/02	Distribution \$0.09		5,640	19	7,844	6,956
12/8/03	Distribution \$0.62		8,250	94	12,105	11,406
2004	Annual distribution total \$1.74		9,325	259	15,639	16,794
5/6/05	Rights offering	2,669	8,340	320		
2005	Annual distribution total \$1.21		9,470	249	21,208	20,709
2006	Annual distribution total \$1.57		9,860	357	24,668	27,020
2007	Annual distribution total \$2.01		9,159	573		

12/31/07 **\$ 7,044** **3,103** **\$ 27,679** **\$ 27,834**

Beginning with the 1997 (RVT), 2002 (RMT) and 2004 (FUND) distributions, the purchase price of distributions is * a weighted average of the distribution reinvestment prices for the year.

Other than for initial purchase, values are stated as of December 31 of the year indicated, after reinvestment of ** distributions.

18 | 2007 Annual Report to Stockholders

Distribution Reinvestment and Cash Purchase Options

Why should I reinvest my distributions?

By reinvesting distributions, a stockholder can maintain an undiluted investment in the Fund. The regular reinvestment of distributions has a significant impact on stockholder returns. In contrast, the stockholder who takes distributions in cash is penalized when shares are issued below net asset value to other stockholders.

How does the reinvestment of distributions from the Royce closed-end funds work?

The Funds automatically issue shares in payment of distributions unless you indicate otherwise. The shares are generally issued at the lower of the market price or net asset value on the valuation date.

How does this apply to registered stockholders?

If your shares are registered directly with a Fund, your distributions are automatically reinvested unless you have otherwise instructed the Funds' transfer agent, Computershare, in writing. A registered stockholder also has the option to receive the distribution in the form of a stock certificate or in cash if Computershare is properly notified.

What if my shares are held by a brokerage firm or a bank?

If your shares are held by a brokerage firm, bank, or other intermediary as the stockholder of record, you should contact your brokerage firm or bank to be certain that it is automatically reinvesting distributions on your behalf. If they are unable to reinvest distributions on your behalf, you should have your shares registered in your name in order to participate.

What other features are available for registered stockholders?

The Distribution Reinvestment and Cash Purchase Plans also allow registered stockholders to make optional cash purchases of shares of a Fund's common stock directly through Computershare on a monthly basis, and to deposit certificates representing your Fund shares with Computershare for safekeeping. The Funds' investment adviser is absorbing all commissions on optional cash purchases under the Plans through December 31, 2008.

How do the Plans work for registered stockholders?

Computershare maintains the accounts for registered stockholders in the Plans and sends written confirmation of all transactions in the account. Shares in the account of each participant will be held by Computershare in non-certificated form in the name of the participant, and each participant will be able to vote those shares at a stockholder meeting or by proxy. A participant may also send other stock

certificates held by them to Computershare to be held in non-certificated form. There is no service fee charged to participants for reinvesting distributions. If a participant elects to sell shares from a Plan account, Computershare will deduct a \$2.50 fee plus brokerage commissions from the sale transaction. If a nominee is the registered owner of your shares, the nominee will maintain the accounts on your behalf.

How can I get more information on the Plans?

You can call an Investor Services Representative at (800) 221-4268 or you can request a copy of the Plan for your Fund from Computershare. All correspondence (including notifications) should be directed to: [Name of Fund] Distribution Reinvestment and Cash Purchase Plan, c/o Computershare, PO Box 43010, Providence, RI 02940-3010, telephone (800) 426-5523.

Royce Value Trust

Schedule of Investments

	SHARES	VALUE
COMMON STOCKS □		
113.4%		
Consumer Products □ 4.9%		
Apparel, Shoes and Accessories - 1.8%		
Brown Shoe Company	15,600	\$ 236,652
Kenneth Cole Productions Cl. A	35,000	612,150
Columbia Sportswear	34,600	1,525,514
Delta Apparel ^b	580,760	4,152,434
Jos. A. Bank Clothiers ^{a,c}	5,800	165,010
K-Swiss Cl. A	110,000	1,991,000
Lazare Kaplan International ^a	103,600	842,268
Polo Ralph Lauren Cl. A	12,500	772,375
Quiksilver ^{a,c}	19,000	163,020
Skechers U.S.A. Cl. A ^{a,c}	5,500	107,305
Tandy Brands Accessories	13,200	128,700
Timberland Company Cl. A ^{a,c}	5,000	90,400
Tod's	30,000	2,091,909
Warnaco Group (The) ^{a,c}	4,900	170,520
Weyco Group	307,992	8,469,780
		21,519,037
Collectibles - 0.6%		
Leapfrog Enterprises Cl. A ^{a,c}	175,000	1,177,750
RC2 Corporation ^a	132,600	3,722,082
Russ Berrie & Company ^a	124,300	2,033,548
		6,933,380
Food/Beverage/Tobacco - 0.2%		
Hain Celestial Group ^{a,c}	37,800	1,209,600
Hershey Creamery	709	1,471,175
		2,680,775
Health, Beauty and Nutrition - 0.1%		
NutriSystem ^{a,c}	5,000	134,900
Sally Beauty Holdings ^{a,c}	194,600	1,761,130
		1,896,030

Home Furnishing and Appliances - 1.5%

Aaron Rents	4,500	86,580
DTS ^{a,c}	64,100	1,639,037
Ekornes	110,000	1,933,701
Ethan Allen Interiors	50,800	1,447,800
Hunter Douglas	23,300	1,718,519
Kimball International Cl. B	286,180	3,920,666
La-Z-Boy ^c	68,200	540,826
Lewis Group	425,000	2,849,445
Rational	14,900	3,048,318
Universal Electronics ^{a,c}	10,000	334,400

17,519,292

Household Products/Wares - 0.1%

Blyth	14,700	322,518
-------	--------	---------

Sports and Recreation - 0.6%

Beneteau	100,000	2,547,785
Coachmen Industries ^c	47,700	283,815
Monaco Coach	166,650	1,479,852
Sturm, Ruger & Company ^a	272,900	2,259,612
Thor Industries	26,100	992,061

7,563,125

Total (Cost \$49,543,275)

58,434,157

Consumer Services ^b 3.7%

Direct Marketing - 0.1%

Takkt	115,000	1,998,743
-------	---------	-----------

	SHARES	VALUE
Leisure and Entertainment - 0.1%		
Shuffle Master ^{a,c}	15,000	\$ 179,850
Media and Broadcasting - 0.1%		
Cox Radio Cl. A ^{a,c}	23,000	279,450
Discovery Holding Company Cl. B ^{a,c}	36,600	931,470
		<hr/> 1,210,920
Online Commerce - 0.1%		
FTD Group	55,000	708,400
Restaurants and Lodgings - 0.9%		
Benihana Cl. A ^{a,c}	6,600	84,150
CEC Entertainment ^{a,c}	184,300	4,784,428
Jamba ^{a,c}	18,600	68,820
Krispy Kreme Doughnuts ^{a,c}	26,400	83,424
Morgans Hotel Group ^{a,c}	90,000	1,735,200
Steak n Shake ^a	198,000	2,158,200

Edgar Filing: McCarley James L - Form 4

Tim Hortons	65,000	2,400,450
		<hr/>
		11,314,672
		<hr/>
Retail Stores - 2.3%		
America's Car-Mart ^{a,c}	95,400	1,197,270
BJ's Wholesale Club ^{a,c}	4,300	145,469
Blockbuster Cl. A ^{a,c}	27,000	105,300
Build-A-Bear Workshop ^{a,c}	10,000	139,500
Bulgari	300,000	4,174,010
CarMax ^{a,c}	50,000	987,500
Charlotte Russe Holding ^a	8,100	130,815
Children's Place Retail Stores ^a	13,670	354,463
DSW Cl. A ^{a,c}	8,700	163,212
Dress Barn (The) ^{a,c}	287,280	3,593,873
Fielmann	27,533	1,808,645
Fred's Cl. A	50,000	481,500
Gander Mountain ^{a,c}	53,300	262,769
Gymboree Corporation ^{a,c}	5,300	161,438
Hot Topic ^{a,c}	29,000	168,780
99 Cents Only Stores ^{a,c}	95,000	756,200
Pier 1 Imports ^{a,c}	1,000,000	5,230,000
Stein Mart	182,800	866,472
Tiffany & Co.	125,000	5,753,750
Urban Outfitters ^{a,c}	27,000	736,020
West Marine ^a	131,100	1,177,278
Wet Seal (The) Cl. A ^{a,c}	162,000	377,460
		<hr/>
		28,771,724
		<hr/>
Other Consumer Services - 0.1%		
Knot (The) ^{a,c}	15,000	239,100
		<hr/>
Total (Cost \$44,883,463)		44,423,409
		<hr/>
Diversified Investment Companies - 0.2%		
Closed-End Funds - 0.2%		
Central Fund of Canada Cl. A	181,500	1,967,460
		<hr/>
Total (Cost \$1,297,400)		1,967,460
		<hr/>
Financial Intermediaries - 11.7%		
Banking - 4.4%		
Ameriana Bancorp	40,000	343,200
BB Holdings ^a	289,400	1,382,312
BOK Financial	164,227	8,490,536
Banca Finnat Euramerica	210,630	268,762
Bank of N.T. Butterfield & Son	371,250	6,775,313
Bank Sarasin & Cie Cl. B	125	589,217

December 31, 2007

	SHARES	VALUE
Financial Intermediaries		
(continued)		
Banking (continued)		
Banque Privee Edmond de Rothschild	17	\$ 653,364
CFS Bancorp	265,000	3,879,600
Cadence Financial	40,300	587,977
Commercial National Financial	54,900	1,033,218
Farmers & Merchants Bank of Long Beach	1,266	8,355,600
Hawthorn Bancshares	44,400	1,110,000
Heritage Financial	12,915	257,008
HopFed Bancorp	112,500	1,658,250
Jefferson Bancshares	32,226	325,483
Mechanics Bank	200	3,610,000
Nexity Financial ^{a,c}	147,599	980,057
Old Point Financial	25,000	508,750
Timberland Bancorp ^b	469,200	5,714,856
Tompkins Financial	17,545	680,746
Vontobel Holding	12,000	581,341
W Holding Company	935,400	1,131,834
Whitney Holding	40,500	1,059,075
Wilber Corporation	103,900	909,125
Wilmington Trust	31,000	1,091,200
Yadkin Valley Financial	3,800	58,026
		52,034,850
Insurance - 3.8%		
Alleghany Corporation ^a	15,318	6,157,836
Aspen Insurance Holdings	64,000	1,845,760
Erie Indemnity Cl. A	139,900	7,259,411
Greenlight Capital Re Cl. A ^{a,c}	80,500	1,673,595
IPC Holdings	27,000	779,490
Leucadia National	44,940	2,116,674
MBIA	69,200	1,289,196
Markel Corporation ^a	7,200	3,535,920
Montpelier Re Holdings	66,000	1,122,660
NYMAGIC	85,200	1,970,676
ProAssurance Corporation ^{a,c}	38,070	2,090,804
RLI	99,724	5,663,326
Security Capital Assurance	30,000	116,700
Stewart Information Services	103,800	2,708,142
Wesco Financial	4,750	1,933,250
White Mountains Insurance Group	9,000	4,626,450
Zenith National Insurance	2,000	89,460

44,979,350

Real Estate Investment**Trusts - 0.1%**

Gladstone Commercial	34,700	608,638
----------------------	--------	---------

Securities Brokers - 2.2%**Broadpoint Securities Group**

^{a,c}	200,100	236,118
----------------	---------	---------

Cowen Group ^{a,c}	32,000	304,320
----------------------------	--------	---------

Duff & Phelps Cl. A ^{a,c}	5,000	98,400
------------------------------------	-------	--------

DundeeWealth	33,300	606,988
--------------	--------	---------

E*TRADE Financial ^{a,c}	75,000	266,250
----------------------------------	--------	---------

FBR Capital Markets ^{a,c}	290,600	2,783,948
------------------------------------	---------	-----------

HQ AB	24,000	638,989
-------	--------	---------

Interactive Brokers Group Cl. A ^{a,c}	79,400	2,566,208
--	--------	-----------

Investment Technology Group ^{a,c}	30,400	1,446,736
--	--------	-----------

KBW ^{a,c}	50,000	1,279,500
--------------------	--------	-----------

Knight Capital Group Cl. A ^{a,c}	229,700	3,307,680
---	---------	-----------

LaBranche & Co ^a	137,000	690,480
-----------------------------	---------	---------

Lazard Cl. A	176,700	7,188,156
--------------	---------	-----------

SHARES VALUE

optionsXpress Holdings	53,000	\$ 1,792,460
------------------------	--------	--------------

Phatra Securities	575,000	583,832
-------------------	---------	---------

Piper Jaffray ^{a,c}	10,000	463,200
------------------------------	--------	---------

Shinko Securities	464,300	1,924,747
-------------------	---------	-----------

26,178,012

Other Financial**Intermediaries - 1.2%**

AP Alternative Assets L.P.	298,600	4,463,068
----------------------------	---------	-----------

KKR Financial	401,404	5,639,726
---------------	---------	-----------

KKR Private Equity		
--------------------	--	--

Investors LLP	105,000	1,910,503
---------------	---------	-----------

Kohlberg Capital	179,900	2,158,800
------------------	---------	-----------

14,172,097

Total (Cost \$111,770,228)

137,972,947

Financial Services**13.7%****Diversified Financial****Services - 1.3%**

AmeriCredit Corporation ^{a,c}	18,870	241,347
--	--------	---------

Centerline Holding		
--------------------	--	--

Company	59,600	454,152
---------	--------	---------

Close Brothers Group	15,000	281,921
----------------------	--------	---------

CompuCredit Corporation ^{a,c}	12,200	121,756
--	--------	---------

Encore Capital Group ^a	30,000	290,400
-----------------------------------	--------	---------

FCStone Group ^a	950	43,728
----------------------------	-----	--------

MarketAxess Holdings ^a	67,000	859,610
-----------------------------------	--------	---------

MoneyGram International	387,300	5,952,801
-------------------------	---------	-----------

Municipal Mortgage & Equity	40,300	598,052
-----------------------------	--------	---------

Ocwen Financial ^{a,c}	173,600	961,744
--------------------------------	---------	---------

	69,100	2,741,197
--	--------	-----------

Portfolio Recovery Associates		
World Acceptance <u>a,c</u>	121,700	3,283,466
		<hr/>
		15,830,174
		<hr/>
Information and Processing - 1.8%		
Deluxe Corporation	3,500	115,115
FactSet Research Systems	35,350	1,968,995
Global Payments	68,500	3,186,620
Interactive Data	134,300	4,433,243
MSCI Cl. A <u>a,c</u>	55,000	2,112,000
PRG-Schultz International <u>a,c</u>	14,420	123,579
SEI Investments	282,400	9,084,808
		<hr/>
		21,024,360
		<hr/>
Insurance Brokers - 1.3%		
Brown & Brown	115,000	2,702,500
Crawford & Company Cl. A <u>a</u>	289,200	1,012,200
Crawford & Company Cl. B <u>a</u>	162,300	673,545
eHealth <u>a</u>	25,000	802,750
Enstar Group <u>a,c</u>	7,000	856,940
Gallagher (Arthur J.) & Co.	111,200	2,689,928
Hilb Rogal & Hobbs	155,050	6,290,379
National Financial Partners	22,000	1,003,420
		<hr/>
		16,031,662
		<hr/>
Investment Management - 8.7%		
Aberdeen Asset Management	855,000	2,850,593
ADDENDA Capital	150,900	3,440,144
Affiliated Managers Group <u>a,c</u>	15,600	1,832,376
AllianceBernstein Holding L.P.	333,100	25,065,775
Anima	700,000	2,172,692
Ashmore Group	80,000	424,532
Australian Wealth Management	231,000	508,802
Azimut Holding	40,000	512,870
BKF Capital Group <u>a,c</u>	227,050	504,051

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE FINANCIAL STATEMENTS.

2007 Annual Report to Stockholders | 21

Royce Value Trust

Schedule of Investments

	SHARES	VALUE
Financial Services		
(continued)		
Investment Management		
(continued)		
Calamos Asset Management Cl. A	45,000	\$ 1,340,100
Candover Investments	21,000	744,702
CapMan Cl. B	550,000	2,607,310
Coronation Fund Managers	250,000	297,436
Deutsche Beteiligungs	90,000	2,815,084
Eaton Vance	150,200	6,820,582
Equity Trustees	19,392	536,693
Evercore Partners Cl. A	283,100	6,100,805
F&C Asset Management	150,000	571,697
Federated Investors Cl. B	161,900	6,663,804
Fiducian Portfolio Services	150,000	363,039
GAMCO Investors Cl. A	158,600	10,975,120
GP Investments BDR	85,000	3,824,908
Gimv	12,200	829,317
Highbury Financial ^{a,c}	333,350	1,500,075
JAFCO	37,300	1,221,810
MVC Capital	473,200	7,637,448
New Star Asset Management Group	93,000	327,155
Onex Corporation	50,000	1,772,633
Perpetual	10,000	582,339
RHJ International ^d	177,500	2,899,795
Rathbone Brothers	24,500	510,301
SPARX Group	6,900	3,281,794
Schroders	21,000	540,357
Trust Company	55,000	564,806
		102,640,945
Specialty Finance - 0.6%		
Credit Acceptance ^{a,c}	216,601	4,477,143
MCG Capital	138,000	1,599,420
NGP Capital Resources	50,000	781,500
		6,858,063
Total (Cost \$131,055,254)		162,385,204
Health ^e 7.6%		
Commercial Services - 1.3%		
PAREXEL International		
^{a,c}	313,700	15,151,710

Drugs and Biotech - 2.0%

Adolor Corporation ^{a,c}	172,000	791,200
Affymetrix ^{a,c}	10,000	231,400
Biovail Corporation	41,200	554,552
Endo Pharmaceuticals Holdings ^{a,c}	155,000	4,133,850
Gene Logic ^{a,c}	589,900	483,718
Genitope Corporation ^{a,c}	150,000	111,000
Human Genome Sciences ^{a,c}	90,000	939,600
K-V Pharmaceutical Cl. A ^{a,c}	51,500	1,469,810
Medicines Company (The) ^{a,c}	20,000	383,200
Millennium Pharmaceuticals ^{a,c}	100,000	1,498,000
Mylan Laboratories ^c	52,200	733,932
Myriad Genetics ^{a,c}	50,000	2,321,000
Origin Agritech ^a	28,600	189,046
Perrigo Company	191,950	6,720,170
Pharmacyclics ^{a,c}	383,000	555,350
Pharmanet Development Group ^{a,c}	10,000	392,100
QLT ^a	114,070	504,189
Sinovac Biotech ^{a,c}	27,200	139,264
Sunesis Pharmaceuticals ^{a,c}	582,000	1,146,540
VIVUS ^{a,c}	163,300	845,894
		24,143,815

	SHARES	VALUE
Health Services - 1.1%		
Albany Molecular Research ^a	85,000	\$ 1,222,300
Cross Country Healthcare ^a	30,000	427,200
Eclipsys Corporation ^{a,c}	20,000	506,200
Gentiva Health Services ^a	30,150	574,056
HMS Holdings ^{a,c}	50,000	1,660,500
Lincare Holdings ^a	52,562	1,848,080
MedQuist ^a	73,893	694,594
On Assignment ^{a,c}	375,400	2,631,554
Paramount Acquisition (Units) ^a	280,000	2,142,000
Res-Care ^{a,c}	65,460	1,646,974
		13,353,458

Medical Products and Devices - 3.0%

Allied Healthcare Products ^{a,c}	201,112	1,458,062
ArthroCare Corporation ^{a,c}	10,000	480,500
Atrion Corporation	15,750	2,008,125
Bruker BioSciences ^a	370,200	4,923,660
Coloplast Cl. B	17,000	1,459,196
CONMED Corporation ^{a,c}	81,500	1,883,465
Golden Meditech	113,600	50,339
IDEXX Laboratories ^a	158,000	9,263,540
Invacare Corporation	103,100	2,598,120
STERIS Corporation	98,600	2,843,624
Urologix ^{a,c}	445,500	516,780
Waters Corporation ^a	75,990	6,008,529
Young Innovations	62,550	1,495,571
Zoll Medical ^{a,c}	40,400	1,079,488

		36,068,999
Personal Care - 0.2%		
Nutraceutical International ^a	22,800	302,100
USANA Health Sciences ^{a,c}	38,900	1,442,412
		1,744,512
Total (Cost \$54,659,716)		90,462,494
Industrial Products [□]		
19.3%		
Automotive - 1.6%		
Copart ^{a,c}	158,100	6,727,155
ElringKlinger	20,000	2,485,463
Fuel Systems Solutions ^{a,c}	22,500	321,525
International Textile Group ^a	85,000	255,000
LKQ Corporation ^{a,c}	375,000	7,882,500
Quantam Fuel Systems Technologies Worldwide ^{a,c}	15,500	7,440
SORL Auto Parts ^{a,c}	26,700	195,444
Superior Industries International	52,000	944,840
		18,819,367
Building Systems and Components - 1.3%		
Armstrong World Industries ^{a,c}	4,100	164,451
Decker Manufacturing	6,022	207,759
Heywood Williams Group ^a	958,837	873,550
NCI Building Systems ^a	10,000	287,900
Preformed Line Products	91,600	5,450,200
Simpson Manufacturing	250,800	6,668,772
Somfy	6,000	1,756,197
		15,408,829
Construction Materials - 1.5%		
Ash Grove Cement Cl. B	50,518	12,680,018
Duratex	61,000	1,476,542
Nice	200,000	1,066,144

December 31, 2007

	SHARES	VALUE
Industrial Products		
(continued)		
Construction Materials		
(continued)		
Pretoria Portland Cement Company	300,000	\$ 1,916,049
USG Corporation ^{a,c}	25,000	894,750
		18,033,503
Industrial Components -		
1.4%		
Barnes Group	20,000	667,800
CLARCOR	83,500	3,170,495
Donaldson Company	92,800	4,304,064
GrafTech International ^{a,c}	64,790	1,150,022
PerkinElmer	135,000	3,512,700
Powell Industries ^a	92,400	4,072,068
II-VI ^a	13,500	412,425
		17,289,574
Machinery - 6.8%		
Astec Industries ^a	3,900	145,041
Baldor Electric	62,900	2,117,214
Bell Equipment	160,000	1,236,260
Burnham Holdings Cl. B	36,000	520,200
Coherent ^{a,c}	243,500	6,104,545
Diebold	73,600	2,132,928
Exco Technologies	91,000	363,281
Federal Signal	58,600	657,492
Franklin Electric	104,800	4,010,696
Graco	106,825	3,980,299
Hardinge	26,193	439,519
Haulotte Group	20,000	593,769
IDEX Corporation	54,000	1,951,020
Intermec ^{a,c}	23,000	467,130
Lincoln Electric Holdings	188,680	13,430,242
Manitou BF	65,000	2,972,798
Mueller Water Products Cl. A	72,500	690,200
Nordson Corporation	172,200	9,980,712
OSG Corporation	20,000	218,780
Pfeiffer Vacuum Technology	49,000	3,925,300
Rofin-Sinar Technologies	256,000	12,316,160
Takatori Corporation	40,000	188,640
Vacon	50,000	2,026,232
Williams Controls ^{a,c}	37,499	641,608
Woodward Governor	144,800	9,839,160

80,949,226

**Metal Fabrication and
Distribution - 1.7%**

Commercial Metals	36,600	1,077,870
CompX International Cl. A	292,300	4,273,426
Gerdau Ameristeel	61,100	868,842
Kaydon Corporation	150,800	8,224,632
Metal Management	3,500	159,355
NN	197,100	1,856,682
RBC Bearings ^{a,c}	45,000	1,955,700
Reliance Steel & Aluminum	25,920	1,404,864
§ims Group	860	20,155

19,841,526

**Miscellaneous Manufacturing
- 3.0%**

Brady Corporation Cl. A	228,400	8,014,556
Matthews International Cl. A	100,000	4,687,000
Mettler-Toledo International ^{a,c}	28,700	3,266,060
Myers Industries	30,499	441,321
Peerless Manufacturing ^a	252,600	10,404,594

	SHARES	VALUE
Raven Industries	86,200	\$ 3,309,218
§emperit AG Holding	46,275	1,688,800
Solar Integrated Technologies ^a	75,000	149,279
Synalloy Corporation	198,800	3,417,372
		<hr/> 35,378,200 <hr/>

Paper and Packaging - 0.5%

§uala Closures	300,000	1,811,654
Mayr-Melnhof Karton	36,000	3,892,304
Peak International ^a	408,400	906,648
		<hr/> 6,610,606 <hr/>

**Specialty Chemicals and
Materials - 1.3%**

Aceto Corporation	119,710	957,680
American Vanguard	26,666	462,655
Cabot Corporation	207,500	6,918,050
Calgon Carbon ^{a,c}	6,400	101,696
Fuel Tech ^{a,c}	10,000	226,500
Hawkins	206,878	3,103,170
Lydall ^a	35,500	373,460
Schulman (A.)	143,100	3,083,805
Sensient Technologies	22,000	622,160
Spartech Corporation	5,000	70,500
		<hr/> 15,919,676 <hr/>

Textiles - 0.1%

Unifi ^a	145,100	351,142
--------------------	---------	---------

Other Industrial Products - 0.1%		
Distributed Energy Systems <u>a</u>	32,000	12,800
		<hr/>
Total (Cost \$118,482,732)		228,614,449
		<hr/>
Industrial Services \square 15.2%		
Advertising and Publishing - 1.5%		
Focus Media Holding ADR <u>a,c</u>	71,900	4,084,639
Interpublic Group of Companies <u>a,c</u>	510,000	4,136,100
Lamar Advertising Cl. A	38,000	1,826,660
MDC Partners Cl. A <u>a,c</u>	60,000	584,400
Scholastic Corporation <u>a,c</u>	130,000	4,535,700
ValueClick <u>a,c</u>	45,000	985,500
Voyager Learning <u>a,c</u>	150,000	1,050,000
		<hr/>
		17,202,999
		<hr/>
Commercial Services - 5.7%		
Allied Waste Industries <u>a</u>	188,800	2,080,576
Anacomp Cl. A <u>a</u>	24,000	56,400
Animal Health International <u>a,c</u>	30,000	369,000
Canadian Solar <u>a,c</u>	50,000	1,407,500
ChinaCast Education <u>a,c</u>	5,000	34,200
Convergys Corporation <u>a,c</u>	121,000	1,991,660
Corinthian Colleges <u>a,c</u>	106,500	1,640,100
Diamond Management & Technology Consultants	80,400	584,508
First Advantage Cl. A <u>a,c</u>	5,000	82,350
Forrester Research <u>a</u>	40,300	1,129,206
Headwaters <u>a,c</u>	13,100	153,794
Hewitt Associates Cl. A <u>a</u>	208,720	7,991,889
ITT Educational Services <u>a</u>	72,000	6,139,440
Iron Mountain <u>a,c</u>	234,262	8,672,379
Landauer	117,900	6,113,115
Learning Tree International <u>a</u>	53,400	1,226,064
MPS Group <u>a</u>	564,600	6,176,724

**THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE
FINANCIAL STATEMENTS.**

2007 Annual Report to
Stockholders | 23

Royce Value Trust

Schedule of Investments

	SHARES	VALUE
Industrial Services		
(continued)		
Commercial Services		
(continued)		
MAXIMUS	127,900	\$ 4,938,219
Monster Worldwide ^a	24,800	803,520
New Horizons Worldwide ^a	228,600	365,760
Sotheby's	367,200	13,990,320
Spherion Corporation ^{a,c}	53,000	385,840
Steiner Leisure ^{a,c}	2,100	92,736
TRC Companies ^a	3,600	28,800
TeleTech Holdings ^{a,c}	8,200	174,414
Travelcenters of America ^{a,c}	2,500	31,250
Viad Corporation	9,025	285,010
Wright Express ^{a,c}	30,000	1,064,700
		68,009,474
Engineering and Construction - 1.6%		
Boskalis Westminster Comstock	40,000	2,429,948
Homebuilding Cl. A ^{a,c}	15,000	9,900
Desarrolladora Homex SAB de CV ^{a,c}	9,800	484,610
Dycom Industries ^{a,c}	35,500	946,075
EMCOR Group ^{a,c}	6,500	153,595
Fleetwood Enterprises ^a	234,300	1,401,114
Insituform Technologies Cl. A ^{a,c}	137,000	2,027,600
Integrated Electrical Services ^{a,c}	340,400	6,396,116
KBR ^a	140,000	5,432,000
		19,280,958
Food and Tobacco Processors - 0.4%		
Astral Foods	10,000	222,251
MGP Ingredients	127,400	1,200,108
Performance Food Group ^{a,c}	10,000	268,700
Seneca Foods Cl. A ^{a,c}	80,000	1,900,000
Seneca Foods Cl. B ^{a,c}	13,251	293,642

		3,884,701
<hr/>		
Industrial Distribution - 2.6%		
Central Steel & Wire	6,062	3,788,750
MSC Industrial Direct Cl. A	74,300	3,006,921
Manutan International	6,445	546,249
Ritchie Bros. Auctioneers	286,400	23,685,280
<hr/>		
		31,027,200
<hr/>		
Printing - 0.1%		
Bowne & Co.	68,100	1,198,560
<hr/>		
Transportation and Logistics - 3.3%		
Alexander & Baldwin	60,000	3,099,600
American Commercial Lines ^{a,c}	9,900	160,776
Atlas Air Worldwide Holdings ^{a,c}	20,100	1,089,822
C. H. Robinson Worldwide	80,000	4,329,600
Forward Air	269,750	8,408,107
Frozen Food Express Industries	286,635	1,691,146
Global Oceanic Carriers ^a	10,000	22,582
Hub Group Cl. A ^{a,c}	174,400	4,635,552
Landstar System	96,200	4,054,830
Patriot Transportation Holding ^a	80,300	7,406,069
UTI Worldwide	112,900	2,212,840
Universal Truckload Services ^a	115,100	2,205,316
<hr/>		
		39,316,240
<hr/>		
Total (Cost \$103,117,245)		179,920,132
<hr/>		

	SHARES	VALUE
Natural Resources □		
9.9%		
Energy Services - 5.1%		
Atwood Oceanics ^{a,c}	29,400	\$ 2,947,056
Cal Dive International ^{a,c}	50,000	662,000
Carbo Ceramics	155,200	5,773,440
Core Laboratories ^{a,c}	10,000	1,247,200
Ensign Energy Services	126,300	1,951,543
Environmental Power ^{a,c}	326,000	1,489,820
Exterran Holdings ^{a,c}	157,500	12,883,500
Global Industries ^a	54,500	1,167,390
Helix Energy Solutions Group ^{a,c}	34,226	1,420,379
Helmerich & Payne	80,600	3,229,642
ION Geophysical ^{a,c}	464,500	7,329,810
National Fuel Gas	32,500	1,517,100

Edgar Filing: McCarley James L - Form 4

Particle Drilling Technologies ^a	61,500	158,670
Pioneer Drilling ^a	6,000	71,280
SEACOR Holdings ^{a,c}	147,000	13,632,780
Superior Offshore International ^{a,c}	10,000	50,200
TETRA Technologies ^{a,c}	68,000	1,058,760
Trico Marine Services ^{a,c}	3,600	133,272
Willbros Group ^{a,c}	103,800	3,974,502
		<hr/>
		60,698,344
		<hr/>
Oil and Gas - 1.1%		
Bill Barrett ^a	50,000	2,093,500
Carrizo Oil & Gas ^{a,c}	41,700	2,283,075
Cimarex Energy	145,490	6,187,690
Falcon Oil & Gas ^a	360,000	125,842
Penn Virginia	32,880	1,434,554
PetroCorp ^{a,d}	61,400	0
PetroQuest Energy ^{a,c}	5,000	71,500
Storm Cat Energy ^{a,c}	330,800	241,484
W&T Offshore	25,000	749,000
		<hr/>
		13,186,645
		<hr/>
Precious Metals and Mining - 2.5%		
Agnico-Eagle Mines	34,000	1,857,420
Centerra Gold ^a	30,000	382,086
Etruscan Resources ^a	745,900	1,677,793
Gammon Gold ^{a,c}	198,300	1,588,383
Golden Star Resources ^{a,c}	175,000	553,000
Hecla Mining ^a	490,500	4,586,175
IAMGOLD Corporation	335,620	2,718,522
International Coal Group ^{a,c}	189,000	1,013,040
Ivanhoe Mines ^{a,c}	140,000	1,502,200
Kinross Gold ^{a,c}	110,286	2,029,262
Metorex ^a	650,000	2,065,541
Northam Platinum	500,000	2,928,081
Northgate Minerals ^a	100,000	303,000
NovaGold Resources ^a	40,000	326,400
Pan American Silver ^{a,c}	41,000	1,432,130
Randgold Resources ADR	53,000	1,967,890
Royal Gold	34,400	1,049,888
Yamana Gold	171,635	2,220,957
		<hr/>
		30,201,768
		<hr/>
Real Estate - 1.2%		
Alico	27,000	985,500
Consolidated-Tomoka Land	13,564	850,192
PICO Holdings ^{a,c}	75,200	2,528,224

December 31, 2007

	SHARES	VALUE
Natural Resources		
(continued)		
Real Estate		
(continued)		
The St. Joe Company ^c	180,100	\$ 6,395,351
Tejon Ranch Company ^{a,c}	70,000	2,859,500
		<hr/>
		13,618,767
		<hr/>
Total (Cost		
\$68,303,929)		117,705,524
		<hr/>

Technology □ 23.3%Aerospace and
Defense - 0.9%

AerCap Holdings ^{a,c}	45,000	939,150
Aerovironment ^a	2,400	58,080
Astronics Corporation ^a	52,400	2,227,000
Axsys Technologies ^{a,c}	10,000	366,500
Ducommun ^a	117,200	4,453,600
Hexcel Corporation ^{a,c}	47,500	1,153,300
Integral Systems	39,876	927,516
		<hr/>
		10,125,146
		<hr/>

Components and
Systems - 5.8%

Analogic Corporation	40,135	2,717,942
Belden	57,800	2,572,100
Benchmark Electronics ^{a,c}	208,200	3,691,386
Checkpoint Systems ^a	56,060	1,456,439
China Security & Surveillance Technology ^{a,c}	2,000	43,680
Dionex Corporation ^a	81,000	6,711,660
Electronics for Imaging ^{a,c}	25,000	562,000
Energy Conversion Devices ^{a,c}	105,500	3,550,075
Excel Technology ^{a,c}	168,500	4,566,350
Hutchinson Technology ^{a,c}	47,500	1,250,200
Imation Corporation	15,700	329,700
InFocus Corporation ^a	228,100	415,142
KEMET Corporation ^a	95,600	633,828

Edgar Filing: McCarley James L - Form 4

Methode Electronics	50,000	822,000
Nam Tai Electronics	16,500	185,955
Newport Corporation <u>a,c</u>	592,200	7,574,238
On Track Innovations <u>a,c</u>	40,000	144,000
Perceptron <u>a,c</u>	397,400	4,200,518
Plexus Corporation <u>a</u>	325,700	8,552,882
Radiant Systems <u>a,c</u>	32,500	559,975
Richardson Electronics	116,700	818,067
Smart Modular Technologies (WWH) <u>a,c</u>	13,200	134,376
TTM Technologies <u>a,c</u>	221,400	2,581,524
Technitrol	311,200	8,894,096
Teradata Corporation <u>a,c</u>	35,000	959,350
Vishay Intertechnology <u>a,c</u>	186,000	2,122,260
Zebra Technologies Cl. A <u>a</u>	76,525	2,655,418
		68,705,161

Distribution - 0.8%

Agilysys	165,125	2,496,690
Anixter International <u>a</u>	61,795	3,847,975
Tech Data <u>a,c</u>	86,500	3,262,780
		9,607,445

Internet Software and
Services - 1.3%

Arbinet-thexchange <u>a,c</u>	87,200	527,560
CDK Corporation Cl. A <u>a,c</u>	12,000	58,440
CMGI <u>a,c</u>	173,500	2,271,115
CNET Networks <u>a,c</u>	155,400	1,420,356
CryptoLogic	68,500	1,202,175

	SHARES	VALUE
CyberSource Corporation <u>a,c</u>	10,000	\$ 177,700
EarthLink <u>a,c</u>	55,200	390,264
Internap Network Services <u>a,c</u>	144,890	1,206,934
iPass <u>a,c</u>	268,400	1,089,704
j2 Global Communications <u>a,c</u>	43,420	919,201
Jupitermedia Corporation <u>a,c</u>	525,000	2,005,500
Kongzhong Corporation ADR <u>a,c</u>	8,300	50,547
Lionbridge Technologies <u>a</u>	37,500	133,125
Perficient <u>a,c</u>	10,000	157,400
RealNetworks <u>a,c</u>	256,900	1,564,521
SkyTerra Communications <u>a</u>	62,200	422,960
Stamps.com <u>a</u>	12,400	151,032
SupportSoft <u>a</u>	220,000	979,000
VeriSign <u>a,c</u>	24,800	932,728

		15,660,262
IT Services - 3.2%		
Alten ^a	64,000	2,444,611
answerthink ^a	655,000	3,170,200
BearingPoint ^{a,c}	529,100	1,497,353
Black Box	47,000	1,699,990
CACI International Cl. A ^{a,c}	10,000	447,700
CIBER ^a	10,000	61,100
Cogent		
Communications Group ^{a,c}	204,200	4,841,582
Computer Task Group ^{a,c}	101,100	559,083
Gartner ^a	213,000	3,740,280
Metavante Technologies ^{a,c}	20,000	466,400
Perot Systems Cl. A ^{a,c}	165,100	2,228,850
Sapient Corporation ^{a,c}	806,602	7,106,164
Syntel	152,679	5,881,195
TriZetto Group (The) ^{a,c}	219,800	3,817,926
Yucheng Technologies ^{a,c}	25,900	336,441
		38,298,875
Semiconductors and Equipment - 4.6%		
Actions Semiconductor		
ADR ^{a,c}	42,200	172,176
Advanced Energy		
Industries ^a	19,500	255,060
Applied Micro Circuits ^{a,c}	8,975	78,441
Axcelis Technologies ^a	135,000	621,000
BE Semiconductor		
Industries ^{a,c}	58,000	313,200
Brooks Automation ^a	15,152	200,158
CEVA ^a	31,666	385,375
Cabot Microelectronics ^a	131,200	4,711,392
Cognex Corporation	236,200	4,759,430
DSP Group ^{a,c}	115,000	1,403,000
Diodes ^a	297,450	8,944,321
Dolby Laboratories Cl. A ^a	173,900	8,646,308
Exar Corporation ^{a,c}	232,576	1,853,631
Fairchild Semiconductor		
International ^a	51,200	738,816
Himax Technologies		
ADR	121,000	516,670
Image Sensing Systems ^{a,c}	8,310	144,428
Integrated Device		
Technology ^{a,c}	23,900	270,309
International Rectifier ^{a,c}	120,000	4,076,400
Intevac ^{a,c}	57,450	835,323
Jazz Technologies		
(Units) ^a	805,000	1,408,750
Kulicke & Soffa		
Industries ^a	105,800	725,788

Edgar Filing: McCarley James L - Form 4

Maxwell Technologies ^a	21,500	177,805
Micrel	7,600	64,220
Novellus Systems ^{a,c}	12,000	330,840
ON Semiconductor ^{a,c}	19,200	170,496

**THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE
FINANCIAL STATEMENTS.**

2007 Annual Report to
Stockholders | 25

Royce Value Trust

Schedule of Investments

	SHARES	VALUE
Technology		
(continued)		
Semiconductors and Equipment (continued)		
Pericom		
Semiconductor ^{a,c}	58,000	\$ 1,084,600
Power Integrations ^{a,c}	49,000	1,687,070
Sanmina-SCI Corporation ^{a,c}	200,000	364,000
Semitool ^a	50,000	434,000
Staktek Holdings ^a	184,700	356,471
Tessera Technologies ^{a,c}	7,900	328,640
Trident Microsystems ^{a,c}	17,300	113,488
TriQuint Semiconductor ^{a,c}	27,900	184,977
Vaisala Cl. A	90,000	4,676,314
Veeco Instruments ^{a,c}	65,000	1,085,500
Vimicro International ADR ^{a,c}	270,000	1,015,200
Virage Logic ^a	100,000	835,000
		53,968,597
Software - 4.2%		
ACI Worldwide ^a	233,150	4,439,176
ANSYS ^{a,c}	100,000	4,146,000
Advent Software ^{a,c}	244,300	13,216,630
Aspen Technology ^a	27,100	439,562
Avid Technology ^{a,c}	71,000	2,012,140
BEA Systems ^{a,c}	65,610	1,035,326
Borland Software ^{a,c}	280,000	842,800
Datasul	150,000	1,586,811
Epicor Software ^{a,c}	79,900	941,222
JDA Software Group ^{a,c}	99,900	2,043,954
MSC.Software ^{a,c}	50,000	649,500
ManTech International Cl. A ^{a,c}	119,400	5,232,108
Net 1 UEPS Technologies ^{a,c}	50,000	1,468,000
Pegasystems	25,000	298,250
PLATO Learning ^a	149,642	594,079
Progress Software ^{a,c}	30,500	1,027,240
Renaissance Learning	15,000	210,000
SPSS ^a	179,600	6,449,436
Sybase ^{a,c}	82,600	2,155,034
THQ ^{a,c}	25,800	727,302
Verint Systems ^{a,c}	40,000	782,000

50,296,570

Telecommunications -
2.5%

ADTRAN	65,000	1,389,700
Adaptec ^{a,c}	2,584,100	8,734,258
Arris Group ^{a,c}	27,600	275,448
Catapult Communications ^a	87,100	657,605
China GrenTech ADR ^{a,c}	3,700	32,708
Comtech Group ^{a,c}	3,500	56,385
Covad Communications Group ^{a,c}	35,000	30,100
Foundry Networks ^{a,c}	298,600	5,231,472
Globalstar ^{a,c}	50,000	400,000
Globecomm Systems ^a	233,700	2,734,290
Golden Telecom ^{a,c}	40,000	4,038,000
IDT Corporation	108,400	856,360
IDT Corporation Cl. B Level 3 Communications ^{a,c}	401,341	1,220,077
NMS Communications ^{a,c}	380,000	615,600
Novatel Wireless ^{a,c}	4,300	69,660
Oplink Communications ^{a,c}	3,500	53,725
Sycamore Networks ^{a,c}	191,000	733,440
Tekelec ^{a,c}	8,200	102,500

	SHARES	VALUE
Tollgrade Communications ^{a,c}	20,000	\$ 160,400
UTStarcom ^{a,c}	50,000	137,500
Zhone Technologies ^{a,c}	850,000	994,500
		<hr/> 29,326,478 <hr/>
Total (Cost \$215,679,104)		<hr/> 275,988,534 <hr/>
Utilities ^b 0.2%		
CH Energy Group	44,500	1,982,030
Southern Union	11,576	339,871
		<hr/> 2,321,901 <hr/>
Miscellaneous ^e ^b 3.7%		
Total (Cost \$45,763,150)	5,071,856	<hr/> 43,453,014 <hr/>
TOTAL COMMON STOCKS		

Edgar Filing: McCarley James L - Form 4

(Cost \$946,682,909)		1,343,649,225
		<hr/>
PREFERRED STOCKS 0.2%		
Duratex	45,300	992,274
Seneca Foods Conv. ^{a,d}	85,000	1,816,875
		<hr/>
TOTAL PREFERRED STOCKS		
(Cost \$2,098,530)		2,809,149