Cardium Therapeutics, Inc.
Form 10KSB
March 15, 2007
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-KSB

ANNUAL REPORT

under Section 13 or 15(d)

of the Securities Exchange Act of 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2006

000-14136

(Commission file number)

CARDIUM THERAPEUTICS, INC.

(Name of small business issuer in its charter)

Delaware	**27-0075787**
(State of incorporation)	**(IRS Employer Identification No.)**
3611 Valley Centre Drive, Suite 525	
San Diego, California 92130	**(858) 436-1000**
(Address of principal executive offices)	**(Issuer s telephone number)**

Securities registered under Section 12(b) of the Exchange Act:

None

Securities registered under Section 12(g) of the Exchange Act:

Common Stock, $0.0001 par value per share

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

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will be contained, to the best of Cardium s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. x

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

Cardium s revenues for its most recent fiscal year ended December 31, 2006 were $756,137.

The aggregate market value of Cardium s common stock held by non-affiliates of Cardium as of March 9, 2007 was approximately $103,264,612 (based on the closing sale price of $3.10 reported by Nasdaq on March 9, 2007). For this purpose, all of Cardium s officers and directors and their affiliates were assumed to be affiliates of Cardium.

As of March 9, 2007, 40,914,425 shares of Cardium s common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III (Items 9, 10, 11, 12 and 14) of this Form 10-KSB incorporates by reference portions of Cardium s definitive proxy statement for its Annual Meeting of Stockholders to be held June 6, 2007, to be filed on or before April 30, 2007.

Transitional Small Business Disclosure Format (Check one): ¨ Yes x No

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SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS

Certain statements in this report, including information incorporated by reference, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934, and the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect current views about future events and financial performance based on certain assumptions. They include opinions, forecasts, intentions, plans, goals, projections, guidance, expectations, beliefs or other statements that are not statements of historical fact. Words such as may, will, should, could, would, expects, plans, believes, anticipates, intends, estimates, ap projects, or the negative or other variation of such words, and similar expressions may identify a statement as a forward-looking statement. Any statements that refer to projections of our future financial performance, our anticipated growth and trends in our business, our goals, strategies, focus and plans, and other characterizations of future events or circumstances, including statements expressing general optimism about future operating results and the development of our products, are forward-looking statements. Forward-looking statements in this report may include statements about:

future financial and operating results;

the timing, conduct and outcome of discussions with regulatory agencies, regulatory submissions and clinical trials;

the performance of Generx, Innercool Therapies Celsius Control System, Excellarate, and other product candidates and their potential to attract development partners and/or generate revenues;

our beliefs and opinions about the safety and efficacy of our products and product candidates and the results of our clinical studies and trials;

the development or commercialization of competitive products or medical procedures;

our development of new products and product candidates;

our growth, expansion and acquisition strategies, the success of such strategies, and the benefits we believe can be derived from such strategies;

the outcome of litigation matters;

our intellectual property rights and those of others, including actual or potential competitors;

the ability to enter into acceptable relationships with one or more contract manufacturers or other service providers on which we may depend and the ability of such contract manufacturers or other service providers to manufacture biologics or devices or to provide services of an acceptable quality on a cost-effective basis;

our personnel, consultants and collaborators;

operations outside the United States;

current and future economic and political conditions;

overall industry and market performance;

the impact of accounting pronouncements;

management s goals and plans for future operations; and

other assumptions described in this report underlying or relating to any forward-looking statements.

The forward-looking statements in this report speak only as of the date of this report and caution should be taken not to place undue reliance on any such forward-looking statements. Forward-looking statements are subject to certain events, risks, and uncertainties that may be outside of our control. When considering forward-

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looking statements, you should carefully review the risks, uncertainties and other cautionary statements in this report as they identify certain important factors that could cause actual results to differ materially from those expressed in or implied by the forward-looking statements. These factors include, among others, the risks described under Item 6 and elsewhere in this report, as well as in other reports and documents we file with the United States Securities and Exchange Commission (SEC).

Unless the context requires otherwise, all references in this report to the Company, Cardium, we, our, and us refer to Cardium Therapeutics, and, as applicable, Innercool Therapies, Inc., Tissue Repair Company and our other wholly-owned subsidiaries.

PART I

ITEM 1. DESCRIPTION OF BUSINESS

Overview

We are a medical technology company primarily focused on the development and commercialization of novel biologic therapeutics and medical devices for cardiovascular and ischemic disease. Since we were initially funded in October 2005, we have made three strategic acquisitions and assembled a portfolio of innovative late-stage cardiovascular and regenerative medicine product candidates, together with medical devices having U.S. Food and Drug Administration (FDA) clearances that are marketed and sold through our direct sales force. We have established a pipeline of innovative products that are divided into three companies, Cardium Biologics, InnerCool Therapies, and Tissue Repair Company.

As our current products and product candidates become successfully advanced, we intend to continue to pursue opportunistic acquisitions designed to enhance long-term stockholder value. At the same time, as technologies and product candidates are advanced and businesses are built-up, further developed and mature, we may consider various corporate development transactions to enhance and monetize stockholder value such as corporate partnerings, spin-out transactions and equity distribution.

Cardium Biologics Non-Surgical Approaches to Treating Heart Disease

Schering Transaction

In October 2005, we acquired a portfolio of interventional cardiology growth factor therapeutics from Schering AG Group, Germany (Schering). This portfolio included the following three product candidates: (1) Generx (alferminogene tadenovec), is a late-stage DNA-based growth factor therapeutic that is being developed as a one-time treatment to promote and stimulate the growth of collateral circulation in the hearts of patients with ischemic conditions such as recurrent angina; (2) Corgentin, a next-generation pre-clinical product candidate, is a DNA-based therapeutic based on myocardial produced insulin-like growth factor-I which could be developed for administration in an acute care setting by interventional cardiologists as a treatment for heart attack patients immediately following percutaneous coronary intervention. Corgentin is designed to enhance myocardial healing in and around the infarct zone when used as an adjunct to existing vascular-directed pharmacologic and interventional therapies; and (3) Genvascor, a pre-clinical, DNA-based therapeutic, based on endothelial nitric oxide synthase (eNOS) intended to induce the localized and sustained production of nitric oxide directed at mediating the effects of multiple growth factors to enhance neovascularization and increased blood flow for the treatment of patients with critical limb ischemia due to advanced peripheral arterial occlusive disease.

Under the terms of the transaction, we paid Schering a $4 million fee, and will pay a $10 million milestone payment upon the first commercial sale of each resulting product. We also are obligated to pay the following royalties to Schering: (i) 5% on net sales of an FGF-4 based product such as Generx, and/or (ii) 4% on net sales of other products developed based on technology transferred to us by Schering.

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Market Data for Heart Disease and Angina

According to the World Heart Federation, heart disease is the world s leading cause of death.

Over 13 million men and women in the United States suffer from heart disease.

Angina, a serious and debilitating heart condition usually associated with heart disease, is a growing health problem with over 6 million Americans suffering from chronic angina and an additional 400,000 new diagnoses each year.

The U.S. Census Bureau projects that the over 55 population, the group most at risk for angina, will increase by approximately 70% over the next 30 years.

An estimated 2 million patients in the U.S. suffer from recurrent angina, a chronic condition in patients with heart disease who are receiving maximal drug therapy and have already undergone one or more mechanical interventions.

Current Treatments for Heart Disease and Angina

Based on the current practice of medicine, angina due to heart disease is treated using one or more of three approaches: (1) chronic drug therapy; (2) percutaneous coronary intervention (angioplasty and stenting); and (3) coronary artery bypass graft surgery.

Currently available drugs to treat angina include beta-blockers, calcium channel blockers, long-acting nitrates, and metabolic modulators. These drugs increase cardiovascular blood flow by vasodilation and decrease the heart s demand for oxygen by reducing the metabolic load. This reduced cardiac workload is achieved by lowering heart rate, blood pressure and/or the strength of the heart s contraction. Hemodynamic and other side effects can limit or prevent the use of currently available drugs in patients whose blood pressure or cardiac function is already decreased. These limiting effects can be particularly pronounced when anti-anginal drugs are used in combination. In addition, co-morbidities such as reactive airway disease, congestive heart failure and diabetes also complicate treatment with existing anti-anginal drugs because these conditions may cause patients to be more vulnerable to known side effects of these therapies. Adverse effects include lower extremity edema associated with calcium channel blockers, impotence and depression associated with beta-blockers, and headaches associated with nitrates. Consequently, for some patients and physicians, presently available medical treatments may not relieve angina and have unacceptable side effects. Importantly, for many chronic angina patients, currently available therapies may provide variable or incomplete relief. Despite the widespread use of these therapies, up to three-fourths of symptomatic patients have recurrent or persistent anginal symptoms. Many patients, even those on multiple drugs, continue to experience angina attacks.

Of the major interventions performed for treating severe heart disease in the United States, namely percutaneous coronary intervention (PCI or angioplasty) and coronary artery bypass graft (CABG) surgeries, more than one million procedures are performed annually and more than two-thirds of these are performed on men. While angioplasty and stenting or CABG surgeries can be used to mechanically open or surgically bypass blockages of the large epicardial blood vessels that surround the myocardium, neither angioplasty nor CABG are believed to be capable of also addressing blockages or flow limitations affecting the mid-sized to smaller blood vessels that are located deeper within the heart muscle. These deeper blood vessels, which form the underlying coronary microcirculation, are directly responsible for conveying oxygenated blood into close proximity with the adjacent heart tissue. In addition, microcirculatory impedance or resistance to flow at the downstream level can contribute substantially to reducing overall blood flow through the myocardium which may be a contributory cause of ischemia in patients with heart disease. In that regard, many patients continue to experience angina even after surgical and other interventions have been performed to mechanically open or bypass accessible portions of the large upstream blood vessels that initially conduct blood flow into the heart.

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Cardiovascular-Directed Growth Factors Generx

Generx (alferminogene tadenovec) is the lead product candidate in a new class of cardiovascular biologics that is being developed to leverage the body s natural healing processes in response to repeated ischemic stress (insufficient blood flow and myocardial oxygen supply due to coronary heart disease). The natural biologic response to repeated transient ischemia is angiogenesis, the growth of new collateral blood vessels, which is orchestrated by a complex and not fully understood cascade involving many myocardial-derived growth factors. These newly formed vessels can effectively augment blood flow and oxygen delivery to parts of the patient s heart downstream from a blockage in a coronary artery. In many patients however, including those with recurrent angina, coronary collateral vessel formation is insufficient to meet the heart s needs during stress. Currently available anti-anginal drugs, which may provide symptomatic relief, are generally designed to alter the oxygen demand of the heart muscle or dilate vessels to temporarily relieve angina. Generx is an angiogenic therapeutic that is designed to promote the heart s natural response of collateral growth and to increase blood flow in the microcirculation.

The Technology and Science of Generx

Our intracoronary approach to deliver Generx to the heart relies on a cellular receptor-driven adenovector system to carry DNA into heart cells to stimulate the localized production of FGF-4 angiogenic proteins intended to promote the growth of microvascular circulation in ischemic regions of the heart to improve blood flow and correspondingly relieve anginal pain due to coronary artery disease. Our technique of intracoronary infusion of the adenovector encoding the FGF-4 gene results in direct delivery into the heart s extensive internal network of coronary circulation. This delivery method takes advantage first of the unique anatomy of the coronary circulation designed by nature for highly efficient oxygen and nutrient extraction, and second of the high concentration of cell surface receptors in the heart that are available for high-yield, first pass adenovector uptake. Our approach thus allows for the targeted and selective delivery of the biologic product throughout the heart. Growth factors like FGF-4 are normally secreted locally and are effective only in the local microenvironment, only a fraction of a millimeter from where they are secreted, in response to ischemia or stress. Delivery of Generx throughout the heart using our intra-coronary method therefore allows for the stimulation of collateral blood vessel growth throughout ischemic areas of the heart.

Targeted delivery of the adenovector containing the DNA encoding FGF-4 throughout the heart muscle is believed to efficiently and safely program the heart to produce and secrete angiogenic FGF-4 proteins, which stimulate the natural angiogenic healing process. Compared with other methods for DNA transfer, the adenovector encoding FGF-4 is taken up with high efficiency by cells in the heart. The transfected heart cells then transcribe the FGF-4 gene into messenger RNA, and translate that RNA into FGF-4 protein, with a signal sequence to cause its secretion. The adenovector DNA encoding growth FGF-4 expresses FGF-4 protein for a period of several weeks. This limited production is beneficial for therapeutic angiogenesis since new blood vessels, once initiated, tend to develop and remain in areas of need such as ischemic areas of the heart muscle. The adenovector encoding FGF-4 is not incorporated into the transfected cell s chromosomes; therefore it does not integrate or cause any disruption in the cell s own DNA-encoded genes. Generx, in combination with ischemic stress (angina), is therefore designed to promote collateral vessel growth precisely when and where it is needed. Generx is being developed as a one-time intracoronary administration to improve the underlying physiology in patients with recurrent angina.

We believe that our angiogenic therapeutic approach differs markedly from other potential angiogenic therapies currently at various stages of development, and that our approach offers several advantages over competitors. Our intracoronary delivery technique utilizes a standard diagnostic catheter, a commonly used tool of all interventional cardiologists. The intracoronary catheter approach also offers the potential for a broader distribution of therapeutic material throughout the heart. Additionally, our delivery method is designed to allow for the use of angiogenic therapy as an adjunctive treatment along with percutaneous intracoronary intervention (angioplasty and stent). Our approach to the treatment of heart disease uses a standard cardiac catheter to

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gradually infuse an angiogenic adenovector into the coronary circulation. The intracoronary route of delivery is readily accessible from outside of the heart. It also directly supplies the underlying heart muscle, as well as the coronary endothelium, to which adenovectors can bind and from which blood vessels grow in the process of angiogenesis. Cardiac infusion catheters and the intracoronary delivery route are also beneficial because they are routinely used by cardiologists for performing standard diagnostic procedures such as angiography.

Adenovectors are one of the most widely studied DNA delivery vehicles in human clinical trials. In the context of heart disease, angiogenic adenovectors are believed to be particularly useful as biologics in that they do not integrate into the human genome but can bind to and remain in the heart for a sufficient period of time to promote the development of new blood vessels. Adenovectors are also considered to be significantly more efficient than naked plasmid DNA for gene transfer. Naturally occurring biological receptors for adenovectors are believed to facilitate their binding to a broad area of heart muscle supplied by the infused coronary circulation.

Generx Clinical Data Meta-Analysis and Phase III Protocol

In June 2006, we reported our recently completed meta-analysis findings of the clinical studies conducted by the Schering AG Group, Germany. Based on this analysis, positive effects following intracoronary angiogenic therapy in both men and women with heart disease were observed. The data was presented at the American Society of Gene Therapy (ASGT) 9th Annual Meeting in Baltimore, Maryland. Timothy D. Henry, M.D., FACC, an interventional cardiologist and Professor of Medicine at the Minneapolis Heart Institute presented the data at a Special Cardiovascular Session entitled *Modulating Cardiac Phenotype: From Basic Mechanism to Clinical Trials.* As reported, several positive findings have emerged from a review of the AGENT clinical data, which relates to our lead product candidate, Generx (Ad5FGF-4).

The AGENT clinical studies involved 663 patients with angina who were enrolled at more than one hundred leading medical centers in the U.S., Canada, Europe and South America. All of the AGENT clinical studies were conducted in a randomized, placebo-controlled and double-blind manner so that neither patients nor their doctors knew whether a patient had received a one-time infusion of Generx or a placebo.

As reported at the ASGT meeting, there was a statistically significant reduction in anginal severity among the Generx patients compared to placebo at 6 months as measured by CCS Class (Canadian Cardiovascular Society), a widely used functional assessment for patients experiencing angina pectoris (chest pain associated with heart disease which can severely limit patients daily activities). Longer-term patient follow-up showed that the observed improvements with respect to anginal class were maintained even a year after patients had received a one-time infusion of Generx.

It was further reported that among more exercise-limited patients in the AGENT-3 study (including both men and women over 55 who had previously been unable to exercise for more than 5 minutes on the exercise treadmill test (ETT)), there was a significant improvement in the primary endpoint of ETT duration in the group receiving Generx as compared to the placebo group. These improvements in exercise capacity were statistically significant with respect to the primary endpoint as measured 12 weeks following intracoronary administration; and a subsequent patient follow-up showed that the differences between the Generx and placebo groups were even greater after 6 months.

In addition it was observed that a protocol-specified subgroup analysis by gender in AGENT-3 revealed a significant increase in the primary endpoint of ETT duration among women with angina, an improvement that was also maintained 6 months after the one-time infusion of Generx. Additional data from the subgroup meta-analysis of all women participating in the AGENT-3 and AGENT-4 clinical studies showed that Generx had a statistically significant effect on improvements in overall exercise treadmill time, time to onset of angina during ETT, exercise time to 1 mm ST-segment depression on electrocardiogram, and CCS Class, each as compared to the placebo control group.

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As reported previously and as seen in other studies involving exercise treadmill testing, a substantial placebo response, which may be further accentuated by accompanying exercise or lifestyle changes, was observed among healthier patients. The occurrence of such a placebo response, particularly one affecting exercise capacity, tends to limit drug versus placebo distinctions among more exercise-competent subgroups when using the treadmill test. In line with those observations, the meta-analysis of the AGENT-3 and AGENT-4 studies showed that among a subgroup of patients, particularly men who were younger and more capable of exercise, there was a substantial placebo response. Among women, who have generally been under-represented in cardiovascular clinical trials despite a high incidence of heart disease, the observed placebo response was substantially less and the apparent treatment effect was therefore greater even when women with less severe forms of angina were included. Among both men and women, when patients were more exercise-limited to begin with, the placebo response was relatively limited. Importantly, the group of exercise-limited patients that had received Generx experienced a substantial improvement in exercise time on ETT whereas the placebo group did not, a difference that was both statistically significant and maintained over time.

As summarized by the AGENT clinical investigators in the abstract presented at the ASGT, the results of this meta-analysis suggest that Ad5FGF-4 may have a clinically meaningful and measurable effect on ETT and other measures of angina in women with recurrent angina, and potentially in both men and women that are older than 55 and have limited exercise capacity.

Generx to Advance to Phase 3 Following Meetings with FDA

In December 2006, we announced that Generx is to be advanced to a Phase 3 clinical trial in women as a potential treatment for myocardial ischemia (insufficient blood flow within the heart muscle), following an end-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA). As reported, Generx is the first and only DNA-based cardiovascular therapeutic to be advanced to Phase 3, and is believed to be the only current Phase 3 product candidate for the potential treatment of stable angina, a chronic medical condition affecting millions of patients in the U.S. and elsewhere.

The potential for Generx to bring about sustained improvements in blood flow and heart function, as compared to medications for symptom relief such as anti-anginals, also led the FDA to indicate that changes on an electrocardiogram (ECG) that are diagnostic of myocardial ischemia would constitute both an objective and acceptable primary efficacy endpoint for a proposed product indication of treating myocardial ischemia. Data from the completed AGENT-3 and AGENT-4 studies indicated that women receiving Generx showed a statistically significant improvement with respect to their ischemia as measured by time to ST segment changes on ECG (the primary efficacy endpoint now accepted by FDA for the Phase 3 study), as well as related improvements in overall exercise treadmill time (ETT), time to onset of angina during ETT, and improvements in angina class, each as compared to the placebo control group.

Following discussions with FDA, improvements in myocardial blood flow within the affected heart muscle will also be measured directly by SPECT perfusion imaging (single photon emission computed tomography) as a secondary efficacy endpoint. SPECT perfusion was the focus of the AGENT-2 mechanism of action study (Grines *et al*., *JAM Coll Cardiol* 2003; 42:1339-47). Improvements in myocardial blood flow observed in the AGENT-2 study, which included both men and women, were similar in magnitude to improvements reported in the literature for patients who have undergone revascularization procedures (coronary artery bypass graft surgery or angioplasty).

This Phase 3 clinical study (AWARE), which is expected to be underway in the first half of 2007, will be a randomized, placebo-controlled, double blind trial in approximately 300 women at multiple medical centers in the U.S. An additional follow-up study of Generx in men with recurrent angina due to myocardial ischemia is expected to commence later. Our therapeutic approach to the treatment of cardiovascular heart disease has been the focus of the most widely-conducted clinical studies for Angiogenic Gene Therapy (AGENT-1 through

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AGENT-4), which to date have involved 663 patients at more than one hundred U.S., European and other medical centers.

Additional Cardiovascular Product Candidates

Product Candidate for Heart Attack Corgentin [Ad5IGF-I]

Corgentin, our lead pre-clinical product candidate, is a next-generation DNA-based therapeutic based on myocardial produced insulin-like growth factor-I (ad5IGF-I). We will seek to advance the current standard of care for heart attack patients through the development of Corgentin to enhance myocardial healing in and around the infarct zone when used as an adjunct to existing vascular-directed pharmacologic and interventional therapies. As currently envisioned, Corgentin would be developed as a potential treatment to be administered to heart attack patients immediately following reperfusion. The objective of this treatment approach is focused on enhancing myocardial repair and restoration of heart cells that have been injured as a result of the heart attack. Today s current standard of care is vascular-directed, focusing on restoring blood flow, while Corgentin would seek to broaden treatment to include a cardiomyocyte-directed therapy to prevent further damage to and to help repair cells that have been injured as a result of the heart attack. To further confirm the utility of the Corgentin approach and establish its commercialization potential, we are planning additional pre-clinical studies in the porcine acute myocardial infarction model, closely mimicking the clinical setting. If confirmatory, we may seek to initiate clinical studies on our own or with a corporate development partner.

Product Candidate for Peripheral Vascular Disease Genvascor [Ad5eNOS]

As part of our acquisition of cardiovascular growth factor therapeutic assets from the Schering AG Group, Germany, we also secured the rights to Genvascor, a pre-clinical, DNA-based, endothelial nitric oxide synthase (eNOS) therapeutic. This product candidate is being designed to induce production of nitric oxide directed at mediating the effects of multiple growth factors to enhance neovascularization and increased blood flow for the treatment of patients with critical limb ischemia due to advanced peripheral vascular disease. We may seek to develop additional pre-clinical information through sponsored studies and, if confirmatory, we may consider the further development of Genvascor either alone or through a corporate collaboration.

Innercool Therapies Temperature Control for Preventing Ischemic Injury

Innercool Therapies Transaction

In March 2006, we acquired the technologies and products of InnerCool Therapies, Inc., a San Diego-based medical technology company in the emerging field of therapeutic hypothermia, which is designed to rapidly and controllably cool the body in order to reduce cell death and damage following acute ischemic events such as cardiac arrest or stroke, and to potentially lessen or prevent associated injuries such as adverse neurological outcomes. InnerCool s Celsius Control System has now received regulatory clearance in the U.S., Europe and Australia. We plan to accelerate the commercialization of the Celsius Control System and broaden and expand its therapeutic hypothermia technology into other medical indications and applications. Since the acquisition by Cardium, InnerCool s sales force has been expanded, a new cGMP manufacturing facility has been secured to increase production capabilities, and a next-generation console for the Celsius Control System has been developed for a planned 2007 launch.

In connection with the transaction, we issued to the seller 2,500,000 shares of our common stock. In addition, as part of the acquisition, we agreed to (i) deliver to the seller $5 million in cash or shares of our common stock, at our election, if net sales revenue from certain of InnerCool s products acquired in the acquisition equals or exceeds $20 million in any one calendar year beginning with 2006 and ending December 31, 2011; (ii) assume certain liabilities of InnerCool Therapies in the aggregate amount of approximately $580,000; and (iii) pay certain transaction costs associated with the acquisition and amounts that may be payable to former employees of the seller for accrued and unpaid vacation, in the aggregate, equal to

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approximately $170,000, as well as certain audit fees and other expenses of approximately $100,000. The acquisition was recorded based on our then-current common stock price of $2.35 per share.

Market Data

Cardiac Arrest:

In the United States, an estimated 500,000 people experience cardiac arrest each year, of which approximately 150,000 survive and are treated with advanced care.

Outside the United States, it is estimated that approximately 900,000 people experience cardiac arrest each year, of which 200,000 survive and are treated with advanced care.

The American Heart Association recently revised its guidelines to recommend the use of therapeutic cooling as part of the critical care procedures for patients with an out-of-hospital cardiac arrest following ventricular fibrillation.

Heart Attack or Acute Myocardial Infarction (AMI):

In the United States, an estimated 865,000 people experience a new or recurrent heart attack each year.

An estimated 325,000 people in the U.S., and approximately 375,000 people outside the United States, receive emergency angioplasty or anti-clotting treatment as first-line care following a heart attack.

Stroke:

In the United States, approximately 700,000 people experience a stroke each year, and a comparable number of patients are affected outside the United States.

The American Stroke Association has identified the treatment of stroke victims with therapeutic hypothermia as a promising area of research.

Cardiothoracic Surgery:

Approximately 500,000 patients in the U.S., and 300,000 patients outside the United States, undergo cardiothoracic surgery each year.

Major medical societies, such as the American Society of PeriAnesthesia Nurses, American Society of Anesthesiologists, American Association of Nurse Anesthetists and Association of Perioperative Registered Nurses have issued specific guidelines for temperature management during cardiothoracic surgeries.

Achieving or Maintaining Normal Body Temperature:

Potential applications for achieving or maintaining normal body temperature or normothermia include warming trauma patients whose temperatures have dropped below normal due to extensive blood loss and subsequent fluid replacement therapy, cooling heat stroke victims, re-warming patients with accidental hypothermia caused by exposure, and warming burn victims whose temperatures are below normal due to exposure in the intensive care unit.

Treatment of Acute Ischemic Conditions Using Temperature Modulation

Numerous articles have been published in scientific and medical journals describing the usefulness of therapeutic cooling, which is designed to protect endangered cells, prevent tissue death and preserve organ function following events associated with severe deprivation such as stroke or cardiac arrest. Therapeutic

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hypothermia is believed to work by protecting critical tissues and organs such as the brain, heart and kidneys following acute ischemic or inflammatory events, by lowering metabolism and preserving cellular energy stores, thereby potentially stabilizing cellular structure and preventing or reducing injuries at the cellular, tissue and organ level. Two international clinical trials on hypothermia after cardiac arrest published in The New England Journal of Medicine demonstrated that induced hypothermia reduced mortality and improved long-term neurological function. Based on these results, the American Heart Association (AHA) and the International Liaison Committee on Resuscitation (ILCOR) issued new guidelines recommending that cardiac arrest victims be treated with cooling or induced hypothermia. The AHA guidelines now recommend the use of therapeutic cooling as part of the critical care procedures for patients with an out-of-hospital cardiac arrest following ventricular fibrillation.

Traditional Approaches to Temperature Modulation External Cooling and Warming

Clinicians currently manage patient temperature primarily by using cooling and warming blankets, ice packs and other external measures. These low technology approaches rely on cooling or warming the patient from outside the body and are often ineffective, cumbersome and labor intensive. Significant limitations include the following.

Surface cooling and warming products are often slow and ineffective at achieving and maintaining target body temperatures. Because the skin acts as an insulator opposing external changes in temperature, surface cooling and warming products are not able to reach therapeutic temperatures quickly and are incapable of precisely maintaining temperatures within desired ranges. This often results in wide temperature fluctuations and sustained periods during which patients are at dangerous temperature levels. Conventional products offer limited user control, thereby requiring medical staff to manually maintain and physically monitor patient temperatures on a continuous basis.

Because conventional temperature management products do not consistently maintain therapeutic target body temperatures, patients are at risk for brain and other organ damage. Surface cooling devices can also cause shivering, which increases metabolic demands, deprives organs of oxygen and causes increased intracranial pressure. Shivering is normally treated with sedatives or narcotics, potentially leading to additional complications. Extended use of these external devices can also create skin rashes, skin damage, patient hygiene problems and infection around wound sites.

External temperature management devices require extensive coverage of the patient s body, imposing obstacles for physicians and nurses to run tests, administer medication, draw blood, treat wounds and manage patient hygiene and provide other routine care. In addition, these devices are difficult to administer to patients with external trauma due to the need to keep wound sites accessible for treatment.

Endovascular Temperature Control the InnerCool Celsius Control System

Endovascular cooling, provided by InnerCool s Celsius Control System, is believed to offer more rapid and precise temperature control and ease of administration which are believed to be important requirements for the potential treatment of patients presenting with acute ischemic stroke in a hospital setting. In addition, it offers the ability to cool conscious patients without the need to anesthetize them, avoiding a potentially confounding factor.

InnerCool s Celsius Control System is currently being used in surgical and intensive care hospital units. The Celsius Control System is designed to rapidly and controllably cool the body in order to reduce cell death and damage following acute ischemic events such as cardiac arrest or stroke, and to potentially lessen or prevent associated injuries such as adverse neurological outcomes.

InnerCool s approach to therapeutic hypothermia is based on a single-use flexible metallic catheter and a fully integrated endovascular cooling system, which allows for rapid and controlled cooling and re-warming. InnerCool s Celsius Control System integrates a number of desirable features including a slim catheter profile, a highly efficient

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flexible metallic heat transfer element, a built-in temperature monitoring sensor, and a programmable console capable of rapidly and controllably inducing, maintaining and reversing therapeutic cooling.

InnerCool s Celsius Control System has received FDA 510(k) clearance for use in inducing, maintaining and reversing mild hypothermia in neurosurgical patients, both in surgery and in recovery or intensive care. The system has also received FDA clearance for use in cardiac patients in order to achieve or maintain normal body temperatures during surgery and in recovery/intensive care, and as an adjunctive treatment for fever control in patients with cerebral infarction and intracerebral hemorrhage. InnerCool has also received a CE mark allowing the Celsius Control System to be marketed in the European Community, and a TGA approval allowing the system to be marketed in Australia.

The Celsius Control System is now being used at a number of leading U.S. medical centers, including those at Stanford University, Cornell, Columbia, the University of Michigan, Harborview Medical Center, San Francisco General Hospital, the University of California Medical Centers at San Diego and San Francisco, and at medical centers in Australia and Sweden.

Studies for additional indications with InnerCool s Celsius Control System are expected to be conducted in collaboration with the National Institutes of Health, AHA and others. Potential future applications of the technology include endovascular cooling for cardiac arrest, acute ischemic stroke and myocardial infarction (heart attack), and acute traumatic injury.

Therapeutic Hypothermia for Stroke the ICTuS-L Study

The ICTuS-L study is sponsored by the National Institute of Neurological Disorders (NINDS), one of the National Institutes of Health (NIH). The NINDS sponsors and conducts research to learn about the healthy brain and to discover and disseminate information on ways to prevent, cure and treat neurological neuromuscular disorders and stroke. The NINDS leads the federal government s medical research effort to fight stroke. It funds research studies at universities, medical schools and hospitals across the country and conducts its own research on the grounds of the NIH campus in Bethesda, Maryland, as well as at the NIH Stroke Center at Suburban Hospital, Bethesda.

Positive Effects of Hypothermia Following Heart Attack

In October 2006, InnerCool announced preclinical data demonstrating a new and expanded benefit of early rapid cooling for the potential treatment of acute myocardial infarction (heart attack), as presented at the Transcatheter Cardiovascular Therapeutics (TCT) 2006 Annual Meeting in Washington, DC. Innercool also announced their plans for a new clinical study to further assess the safety and potential usefulness of early cooling for heart attack patients, which is expected to be co-sponsored in Sweden and to begin within the next several months.

The research reported at TCT was conducted by a team of interventional cardiologists led by Drs. Goran Olivecrona and David Erlinge at the Lund University Hospital, Sweden. In the recently completed study in a preclinical porcine heart attack model, researchers evaluated rapid cooling, induced by a combination of cold saline infusion along with InnerCool Therapies endovascular Celsius Control System, prior to or coincident with percutaneous coronary intervention (PCI) procedures, which are used to restore blood flow in the heart. The data showed that cooling prior to PCI reduced overall infarct size (reflecting tissue damage) by an additional 40%. These findings strongly support the use of early rapid cooling in planned clinical studies, and suggest that InnerCool s endovascular cooling system may have the potential to enable interventional cardiologists to dramatically reduce tissue damage following a heart attack.

Based on these findings, InnerCool plans to sponsor a study on the use of early rapid cooling following heart attack, which is expected to be co-sponsored and conducted by the interventional cardiology center at Lund University Hospital, Sweden. The planned study will be a randomized human clinical trial designed to evaluate the potential use of InnerCool s hypothermia system in the treatment of heart attack patients. This study will

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randomize approximately twenty patients who present within six hours of their heart attack for PCI alone or PCI plus the new early rapid cooling protocol. The hypothermia arm will include iced saline infusion plus use of the InnerCool Celsius Control System catheter prior to reperfusion in patients undergoing PCI. The trial will employ cardiac magnetic resonance imaging (MRI) to provide an accurate assessment of the damage to the heart within days of the injury. The trial is expected to begin by early 2007 and to complete enrollment and treatment within about six months.

Benefits of Inducing Hypothermia During Aneurysm Surgery

In September 2006, Michael K. Morgan, M.D. reported on his direct experience and the benefits of the Celsius Control System in inducing hypothermia in cerebral vascular surgery patients at the Neurosurgical Society of Australasia (NSA) Annual Scientific Meeting in Cairns, Australia. It was reported by Dr. Morgan, a noted vascular neurosurgeon and Professor and Dean of the School of Advanced Medicine, Macquarie University, Sydney, that he had conducted retrospective review of over 600 aneurysms over a seven-year period, and found that patients with aneurysms greater than 12 millimeters are more likely to have over 20 minutes of temporary occlusion times. Temporary occlusion of arteries in the brain during aneurysm repair in such patients exposes the brain to ischemia (localized lack of oxygen), which can have negative consequences in terms of neurologic outcomes.

Dr. Morgan reported on the safety, efficient cooling and beneficial outcomes achieved utilizing InnerCool s Celsius Control System in an open-label cohort of 26 patients with 33 aneurysms, and reported that based on his experience and the clinical data reviewed, aneurysms greater than 12 millimeters frequently require prolonged temporary occlusion times. It was also reported that the ability of InnerCool s Celsius Control System to safely and effectively cool patients with aneurysms provides an important new tool for protecting the brain from ischemic injury, especially in patients such as these who are at higher risk for tissue damage due to the prolonged lack of blood flow, and that, in addition to achieving positive outcomes, there were no clinically significant catheter-related complications. The specifics of these findings are expected to be published in a neurosurgical journal.

Tissue Repair Company Healing Chronic Wounds

Tissue Repair Company Transaction

In August 2006, we obtained the rights to develop various technologies and products now part of the Tissue Repair Company (TRC), a San Diego-based biopharmaceutical company focused on the development of growth factor therapeutics for the potential treatment of chronic diabetic wounds. TRC s lead product candidate, Excellarate, is a DNA-activated collagen gel for topical treatment formulated with an adenovector delivery carrier encoding human platelet-derived growth factor-B (PDGF-B). Excellarate is initially being developed as a single administration for the treatment of non-healing diabetic foot ulcers.

The Excellarate topical gel is designed to stimulate angiogenesis and granulation tissue formation through the recruitment and proliferation of chemotactic cells such as monocytes and fibroblasts, which are necessary for the stimulation of a variety of wound healing processes. Other potential applications for TRC s Gene Activated Matrix (GAM) technology include therapeutic angiogenesis (cardiovascular ischemia, peripheral arterial disease) and orthopedic products, including hard tissue (bone) and soft tissue (ligament, tendon, and cartilage) repair. We have entered into a contract manufacturing agreement to produce Excellarate for clinical studies, and we plan to initiate a Phase 2b clinical study for Excellarate during the second half of 2007.

Under the terms of the TRC transaction, we paid $1 million in cash and assumed approximately $120,000 in liabilities. If TRC advances the Excellarate product candidate to a Phase 2 clinical study, TRC would be obligated to pay a product advancement milestone of $1 million. TRC has the right to return the assets and product rights at anytime prior to the milestone payment and it would have no further obligation under the agreement. If TRC successfully commercializes Excellarate, TRC would pay royalties based on worldwide net sales of such product. The royalty rate would be 10% minus any applicable third party royalties (including a royalty to the University of Michigan under a license agreement assumed by Tissue Repair Company), and would also be subject to a development cost-recovery offset, which could be deducted at the rate of $5 million per year from any applicable royalty obligations. The

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deduction for third party royalties would apply until worldwide net sales exceeded $100 million per year. The cost-recovery offset would apply until TRC recovered 50% of its associated product development costs. TRC would also have a right to buy out the ongoing royalty obligation based on a one-time payment of 30% of net sales for the fifth calendar year or the first year in which sales exceeded $250 million. If pre-specified milestones relating to the commercial development of Excellarate are not satisfied, and we do not elect to return the assets to the seller, then we would issue to the seller stock purchase warrants to purchase up to an aggregate of 2 million shares of our Common Stock (one 500,000 share allotment for each of up to four missed events) at an exercise price of $4.00 per share. The seller could also require TRC to return certain product rights if TRC failed to meet the Excellarate development milestones by more than six months, excluding delays caused by defined product-related limitations.

Chronic Wound Market

An estimated 12.5 million patients worldwide suffer from chronic wounds with the industrialized countries making up 8 million, of which the U.S. totals approximately 3.7 million.

Over 800,000 patients in the U.S. develop diabetic foot ulcers annually.

Approximately 1.7 million patients suffer from pressure wounds, 1 million from diabetic foot ulcers and 1 million from venous status ulcers.

Diabetic ulcers cost the U.S. healthcare system approximately $5 billion per year with treatment and subsequent lower limb amputations adding an addition $1 billion per year.

Of the approximately 15 million diabetic patients approximately 15 to 20 percent of this patient population will go on to suffer at least one chronic foot ulcer and of those 6 percent will be hospitalized due to infection or other ulcer-related complications.

Diabetes is the leading cause of non-traumatic lower extremity amputations and approximately 14 to 24 percent of patients with diabetes who develop foot ulcers eventually have an amputation.

Current Treatment Approaches for Chronic Wounds

There are several treatment modalities currently used for severe chronic ulcers in diabetic patients, including topical dressings, off-loading, debridement and skin grafts. Regranex® Gel (becaplermin), which is marketed by Johnson & Johnson s Ethicon Wound Management Division, is considered to be the only FDA-approved prescription medicine to treat such wounds. Regranex® Gel is a recombinant human platelet-derived growth factor (rrPDGF-BB) protein that is used as an adjunct with other current treatment modalities described above and is used to treat lower extremity diabetic neuropathic ulcers. Based on Regranex® Gel s instructions for use, an estimated 70 administrations and 70 wound cleanings and redressings would be required over a 10-week treatment period (once daily administration followed by a subsequent wound cleaning and redressing without gel).

Gene Activated Matrix (GAM) Technology

We believe that patient compliance can be a major factor preventing or limiting improved medical outcomes, particularly when repeated administrations are required at a wound site. Gene Activated Matrix technology is designed to provide a therapeutic level of protein synthesis at a particular site in the body and can be used in soft tissue such as skin, ligament, tendons and cartilage, as well as hard tissue such as bone. The technology is distinctive in that it is an immobilized form of local gene delivery that allows for control of gene uptake. GAM consists of a biocompatible matrix comprising a gene or DNA vector encoding a growth factor or other therapeutic protein.

For tissue repair, the application method involves placement of a GAM gel directly onto a wound site. TRC s studies have shown that proliferative cells in the body can migrate into the GAM, take up the immobilized vector and gene and then transiently express the

encoded therapeutic protein. Compared with topical applications of proteins, this *in situ* expression method significantly prolongs the availability of therapeutic protein to the cells

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involved in tissue repair. TRC s GAM technology may have potential utility in several clinical indications where protein therapeutics have had limited success, including treatment of dermal wounds (such as diabetic foot ulcers), therapeutic angiogenesis (pharmacologically inducing new blood vessel growth), and orthopedic products for repair of various tissues, including hard tissue (bone) and soft tissue (ligament, tendon, cartilage).

Tissue Repair Product Candidate Excellarate

Excellarate is being developed as a next-generation treatment to leverage the established medical utility of PDGF-B, and to simplify treatment by stimulating the body s own localized and sustained production of PDGF-B at the wound site over a 6- to 12-day period following a single dose administration. We believe that a one-time administration or in more severe cases several once-a-week administrations of the Excellarate topical gel, which is designed to mediate a sustained cellular-release of PDGF-B at the injury site, could substantially simplify the treatment regimen, thus potentially enhancing patient compliance and improving medical outcomes.

Excellarate is a DNA-activated collagen gel for topical treatment formulated with an adenovector delivery carrier encoding human platelet-derived growth factor-B (PDGF-B). Excellarate is initially being developed as a single administration for the treatment of non-healing, neuropathic diabetic foot ulcers. The Excellarate topical gel, a type of Gene Activated Matrix , is designed to stimulate angiogenesis and granulation tissue formation through the recruitment and proliferation of chemotactic cells such as monocytes and fibroblasts, which are necessary for the stimulation of a variety of wound healing processes.

Excellarate has been evaluated in an initial multi-center Phase 1/2 clinical trial that evaluated preliminary safety and included an assessment of healing in 15 patients having diabetic foot ulcers that did not heal using conventional techniques. Based on the data obtained, Excellarate appeared to be safe and well tolerated in patients with diabetic foot ulcers. In addition, in the 12 patients that completed the treatment protocol and follow-up, over 80% of the patients exhibited complete closure of previously non-healing wounds by 14 weeks. Single dose applications were administered in 70% of the patients and the remaining patients received a weekly dose application over a four-week period. Based on the prior pre-clinical and toxicology database, and results from the Phase 1/2 clinical study, we anticipate that Excellarate may be advanced into a randomized, double-blind, placebo-controlled, multi-center Phase 2b clinical study commencing in the second half of 2007.

Business Strategy

Strategic Goals

Building upon our core products and product candidates, our strategic goal is to develop a portfolio of medical products at various stages of development and secure additional financial resources to commercialize these products in a timely and effective manner. The key elements of our strategy are to:

- Initiate the Phase 3 AWARE clinical study for Generx in the first half of 2007;
- initiate a Phase 2b clinical study for Excellarate in the second half of 2007;
- accelerate the commercialization of Innercool s Celsius Control System and, at the same time, broaden and expand our therapeutic hypothermia technology into other medical indications and applications;
- leverage our financial resources and focused corporate infrastructure through the use of contract manufacturers to produce clinical supplies and a contract research organization to manage or assist planned clinical studies;
- advance the pre-clinical development of Corgentin and potentially seek partnering opportunities for the Corgentin and Genvascor product candidates;

broaden and expand our product base and financial resources through other corporate development transactions in an attempt to enhance stockholder value, which could include acquiring other medical-related companies or product opportunities and/or securing additional capital; and

monetize the economic value of our product portfolio by establishing strategic collaborations at appropriate valuation inflection points.

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Strategic Business Transactions

We were initially formed as a Delaware corporation in December 2003 by Christopher J. Reinhard, our Chairman, President and Chief Executive Officer, and Tyler M. Dylan, Ph.D., our Chief Business Officer and General Counsel, to acquire certain technology and product rights from Schering AG Group, Germany relating to certain growth factor therapeutics that were initially developed by Collateral Therapeutics Inc. (Collateral) in partnership with Schering. Mr. Reinhard was a co-founder and executive officer of Collateral and Dr. Dylan was General Counsel of Collateral. In 2002, following a six year strategic research and development collaboration and successful Phase 2 clinical studies of Generx, Schering acquired Collateral for approximately $160 million.

As part of a strategic refocusing in 2004, Schering divested its cardiovascular small molecule drugs and biologics under clinical development, including Generx. Mr. Reinhard and Dr. Dylan subsequently negotiated a transaction to acquire Schering s portfolio of cardiovascular growth factor therapeutics formally co-developed with Collateral. In October 2005, we completed a private equity financing concurrent with a merger transaction with a small public company raising $30 million to support our acquisition of Schering s portfolio of growth factor therapeutics. Since we were initially funded, a little more than a year ago, we have made three acquisitions described above and which are summarized below.

As set forth in the summary schedule below, we estimate that approximately $270 million has been invested by sellers and their affiliates in connection with the businesses, product candidates and technology in our three completed acquisitions. Based on the terms negotiated by our management team, these assets have been acquired at an average purchase price (as measured by upfront cash, equity, assumed debt and product success milestones) of approximately 10% on capital invested by corporate pharmaceutical partners, venture capital firms and other investors.

Summary of Strategic Acquisitions

Acquisition	Estimated Capital Invested (by sellers and affiliates)	Acquisition Price plus Milestones (excluding royalties)	Price/Invested Capital
Cardium Biologics Cardiovascular Growth Factor Therapeutics	~ $200 Million	$4 Million Cash plus potential $10 Million Milestone upon product success (Product Sales)	7%
InnerCool Therapies Endovascular Temperature Control Systems	~ $50 Million	~ $6 Million Equity plus potential $5 Million Milestone upon product success (Sales > $20 Million); No royalties	22%
Tissue Repair Company DNA-Activated Matrices for Wounds	~ $20 Million	~ $1 Million Cash plus $1 Million Clinical Milestone (Phase 2 advancement)	10%
Total	~ $270 Million	~ $27 Million	10%

	Up-front payments: ~$11 Million (incl. equity)	4%

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We plan to continue to build our business through internal development and external acquisitions. As an emerging public company, we have initially focused on acquiring undervaluled opportunities having unrealized value but which we believe have potential for significant future growth and development or partnering prospects when combined with the value-added skills and perspectives of our experienced management team.

As our current products and product candidates become successfully advanced, we intend to continue to pursue opportunistic acquisitions designed to enhance long-term stockholder value. At the same time, as technologies and product candidates are advanced and businesses are built-up, further developed and mature, we may consider various corporate development transactions to enhance and monetize stockholder value such as corporate partnerings, spin-out transactions and equity distribution.

Government Regulation

New drugs and biologics, including gene therapy and other DNA-based products, are subject to regulation under the federal Food, Drug, and Cosmetic Act. In addition, biologics are also regulated under the Public Health Service Act. We believe that the pharmaceutical products we are attempting to develop will be regulated either as biological products or as new drugs. Both statutes and their corresponding regulations govern, among other things, the testing, manufacturing, distribution, safety, efficacy, labeling, storage, record keeping, advertising and other promotional practices involving biologics or new drugs. FDA approval or other clearances must be obtained before clinical testing, and before manufacturing and marketing, of biologics and drugs. Obtaining FDA approval has historically been a costly and time-consuming process. Different regulatory regimes are applicable in other major markets.

In addition, any gene therapy and other DNA-based products we develop will require regulatory approvals before human trials and additional regulatory approvals before marketing. New biologics are subject to extensive regulation by the FDA and the Center for Biological Evaluation and Research and comparable agencies in other countries. Currently, each human-study protocol is reviewed by the FDA and, in some instances, the National Institutes of Health, on a case-by-case basis. The FDA and the National Institutes of Health have published guidance documents with respect to the development and submission of gene therapy protocols.

To commercialize our product candidates, we must sponsor and file an investigational new drug (IND) application and be responsible for initiating and overseeing the human studies to demonstrate the safety and efficacy and, for a biologic product, the potency, which are necessary to obtain FDA approval of any such products. For our newly sponsored investigational new drug applications, we will be required to select qualified investigators (usually physicians within medical institutions) to supervise the administration of the products, and we will be required to ensure that the investigations are conducted and monitored in accordance with FDA regulations and the general investigational plan and protocols contained in the IND application.

The FDA receives reports on the progress of each phase of testing, and it may require the modification, suspension, or termination of trials if an unwarranted risk is presented to patients. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. The IND application process can thus result in substantial delay and expense. Human gene therapy products, a primary area in which we are seeking to develop products, are a new category of therapeutics. Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the trial period, the number of patients the FDA will require to be enrolled in the trials to establish the safety, efficacy and potency of human gene therapy products, or that the data generated in these studies will be acceptable to the FDA to support marketing approval.

After the completion of trials of a new drug or biologic product, FDA marketing approval must be obtained. If the product is regulated as a biologic, the Center for Biological Evaluation and Research will require the submission and approval, depending on the type of biologic, of either a biologic license application or a product license application and a license application before commercial marketing of the biologic. If the product is

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classified as a new drug, we must file a new drug application with the Center for Drug Evaluation and Research and receive approval before commercial marketing of the drug. The new drug application or biologic license applications must include results of product development, laboratory, animal and human studies, and manufacturing information. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the new drug application or biologic license applications for filing and, even if filed, that any approval will be granted on a timely basis, if at all. In the past, new drug applications and biologic license applications submitted to the FDA have taken, on average, one to two years to receive approval after submission of all test data. If questions arise during the FDA review process, approval can take more than two years.

Notwithstanding the submission of relevant data, the FDA may ultimately decide that the new drug application or biologic license application does not satisfy its regulatory criteria for approval and may require additional studies. In addition, the FDA may condition marketing approval on the conduct of specific post-marketing studies to further evaluate safety and effectiveness. Rigorous and extensive FDA regulation of pharmaceutical products continues after approval, particularly with respect to compliance with current good manufacturing practices (GMPs), reporting of adverse effects, advertising, promotion and marketing. Discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions.

Ethical, social and legal concerns about gene therapy, genetic testing and genetic research could result in additional regulations restricting or prohibiting the processes we or our suppliers may use. Federal and state agencies, congressional committees and foreign governments have expressed interest in further regulating biotechnology. More restrictive regulations or claims that our products are unsafe or pose a hazard could prevent us from commercializing any such products.

The approval and/or clearance for marketing of medical devices, such as those being developed by our Innercool Therapies subsidiary, is also subject to extensive controls by health regulatory and other authorities. Although some devices can be cleared for marketing pursuant to a procedure referred to as an FDA 501(k) clearance, other devices and/or indications may require additional clinical studies and may be subject to even more extensive regulatory and other controls.

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

We are also subject to a variety of other regulations in the United States, including those relating to bioterrorism, taxes, labor and employment, import and export, and intellectual property.

To the extent we have operations outside the United States, any such operations would be similarly regulated by various agencies and entities in the countries in which we operate. The regulations of these countries may conflict with those in the United States and may vary from country to country. In markets outside the United States, we may be required to obtain approvals, licenses or certifications from a country s ministry of health or comparable agency before we begin operations or the marketing of products in that country. Approvals or licenses may be conditioned or unavailable for certain products. These regulations may limit our ability to enter certain markets outside the United States.

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Competition

The pharmaceutical, biotechnology and medical device industries are intensely competitive. Our products and any product candidates developed by us would compete with existing drugs, therapies and medical devices or procedures and with others under development. There are many pharmaceutical companies, biotechnology companies, medical device companies, public and private universities and research organizations actively engaged in research and development of products for the treatment of cardiovascular and related diseases, and/or products for temperature control therapy. Many of these organizations have financial, technical, research, clinical, manufacturing and marketing resources that are greater than ours. If a competing company develops or acquires rights to a more efficient, more effective, or safer competitive therapy for treatment of the same or similar diseases we have targeted, or one that offers significantly lower costs of treatment, our business, financial condition and results of operations could be materially adversely affected. In view of the relatively early stage of the industry, we believe that the most significant competitive factor in the field of gene therapy and biologics is the effectiveness and safety of a product candidate, as well as its relative safety, efficacy and cost as compared to other products, product candidates or approaches that may be useful for treating a particular disease condition.

We believe that our product development programs will be subject to significant competition from companies using alternative technologies, as well as to increasing competition from companies that develop and apply technologies similar to ours. Other companies may succeed in developing products earlier than we do, obtaining approvals for these products from the FDA more rapidly than we do or developing products that are safer, more effective or less expensive than those under development or proposed to be developed by us. We cannot assure you that research and development by others will not render our technology or product candidates obsolete or non-competitive or result in treatments superior to any therapy developed by us, or that any therapy developed by us will be preferred to any existing or newly developed technologies.

We are aware of products currently under development by competitors targeting the same or similar cardiovascular and vascular diseases as our Generx product development. These include biologic treatments using forms of genes and therapeutic proteins. For example, Corautus Genetics, Inc., pursuant to a development agreement with Boston Scientific, has initiated a clinical study to evaluate a non-viral delivery of vascular endothelial growth factor-2 (VEGF-2) DNA in the form of naked plasmid for the direct injection into the heart muscle of patients with severe angina. They are conducting a Phase 2 clinical study with plans to enroll patients with Class III or IV angina that are not suitable for traditional revascularization procedures. Additionally, GenVec, Inc. announced the initiation of a Phase 2 clinical study of BioByPass Angiogen, which uses Vascular Endothelial Growth Factor-121 (VEGF-121) as a treatment for patients with severe coronary artery disease. This study will reportedly evaluate the effects of ETT time, heart function and quality of life in patients. Angiogen will apparently be administered to patients using direct injection into heart muscle using a guidance system (NOGA). GenVec previously announced a research collaboration with Cordis Corporation, a Johnson & Johnson company, to utilize the NOGA guidance delivery for its Angiogen product. We will also face competition from entities using other traditional methods, including new drugs and mechanical therapies, to treat cardiovascular and vascular disease.

In the areas of temperature control therapy, as practiced by our Innercool Therapies subsidiary, there are a number of actual or potential competitive approaches including alternative endovascular approaches based on inflatable balloon devices, such as the CoolGard thermal regulating system developed by Alsius Corporation, and the Reprieve system being developed by Radiant Medical Inc. Alsius is currently marketing its CoolGard device, although it has recalled a number of units. Radiant is studying its Reprieve device in COOL MI, an international study reportedly designed to demonstrate that lowering a patient s body temperature in connection with treatment of a heart attack can reduce subsequent damage to the heart and that earlier, faster and deeper cooling results in a clinically significant reduction in heart damage. Other approaches being developed for therapeutic cooling include the use of specialized cooling pads such as those employed in the Artic Sun system being developed by Medivance, and other devices such as cooling blankets and helmets.

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Manufacturing Strategy

To leverage our experience and available financial resources, except as noted below with respect to Innercool Therapies, we do not plan to develop company-owned and operated manufacturing facilities. We plan to outsource all product manufacturing to a contract manufacturer of clinical drug products that operates at a manufacturing facility in compliance with current good manufacturing practices (GMPs). We may also seek to refine the current manufacturing process and final product formulation to achieve improvements in storage temperatures and the like.

Our management team already has experience with production of Adenovirus vector (Adenovector), DNA-based therapies, which is believed to be useful in understanding the unique requirements of our business. Schering, using their experience in the production of clinical grade, DNA-based drug products, has developed an adenovector manufacturing process employing the use of master viral banks and master cell banks. Technical transfer of process materials and methodologies from Schering to Cardium is expected to take place, combining the expertise of both companies.

The FDA has established guidelines and standards for the development and commercialization of molecular and gene-based drug products i.e.: *Guidance for Industry CMC for Human Gene Therapy INDs November 2004, Sterile Drug Products Produced by Aseptic Processing September 2004, Human Somatic Cell Therapy and Gene Therapy March 1998, PTC in the Characterization of Cell Lines Used to Produce Biologicals July 1993*. These industry guidelines, among others, provide essential oversight with regard to process methodologies, product formulations and quality control standards to ensure the safety, efficacy and quality of these drug products.

In January 2006, we entered into a Production Service Agreement with Molecular Medicine BioServices, Inc., pursuant to which Molecular Medicine will manufacture our lead product candidate, Generx, for late-stage clinical development. The agreement is due to expire upon completion of the project, which is anticipated to be completed in 2007. We may terminate the agreement at any time in our discretion by giving Molecular Medicine 60 days notice of termination. Molecular Medicine may terminate the agreement at any time in its discretion by giving us 180 days written notice. Either party may terminate the agreement upon a material breach by the other party, subject to certain cure periods.

The disposable portions of Innercool s products, the catheter and administrative set, are currently assembled at our facilities in San Diego. The console s cooling sub-assembly is currently purchased from a single vendor, although we believe there are several vendors that could supply this component. Innercool currently integrates this sub-assembly with additional software, printed circuit boards, electrical isolation, and a user interface in order to create the final product. We are currently considering improvements to the Innercool console that are designed to enhance functionality and/or manufacturability.

Innercool s manufacturing operations are required to comply with certain quality assurance regulations. Specifically, Innercool must adhere to the FDA quality system regulations, comply with ISO 13485 requirements and maintain our CE mark. We believe Innercool s operations meet such requirements.

Marketing and Sales

Our product candidates must undergo testing and development in clinical trials and pre-clinical studies. Other than Innercool s Celsius Control System, we do not currently have any products approved for marketing nor any present capacity to market and sell products that could be commercially developed based on our technology. If we should obtain any such marketing approvals, we expect that we would elect to engage in marketing or sales through or in collaboration with a commercialization partner, although we are not currently involved with such a partner.

Innercool is currently selling its products into neurosurgical and neurocritical care markets. Innercool s sales force currently consists of three individuals. Representative accounts include medical centers at Stanford

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University, Cornell, Columbia, the University of Michigan, Seattle s Harborview and Swedish medical centers, San Francisco General Hospital, and the University of California medical centers at San Diego and San Francisco.

Innercool has received a CE mark allowing its products to be marketed in the European Community, and approval from the Therapeutic Goods Administration (TGA) that allows it to market its products in Australia. Innercool has used a distributorship arrangement to commence sales efforts in Australia and has opened accounts at some of the country s premier hospitals. Innercool has not commenced sales efforts in Europe and does not currently expect to do so other than through a distributorship arrangement.

Intellectual Property

As part of our acquisition of Schering s portfolio of cardiovascular growth factor therapeutic assets, pursuant to a Technology Transfer Agreement entered into between Cardium and Schering, we acquired from Schering a portfolio of methods and compositions directed at the treatment of cardiovascular diseases. We also have exclusive licenses to methods for introducing DNA to the heart and for improving heart muscle function, as well as to various biologics. Our resulting portfolio of cardiovascular product candidates and associated intellectual property include methods and genes applicable to the treatment of heart diseases, the promotion of healing, and the treatment of peripheral vascular disease. In March 2006, we also acquired a portfolio of intellectual property related to devices and methods for endovascular temperature control therapy, in connection with our acquisition of the assets of Innercool Therapies. In August 2006, we acquired the rights to various technologies and products now part of TRC including Excellarate. There can be no assurance that our intellectual property assets will be sufficient to protect our commercialization opportunities, nor that our planned commercialization activities will not infringe any intellectual property rights held or developed by third parties.

We have entered into certain collaborative and licensing arrangements in connection with each of our acquisitions. We expect to continue evaluations of the safety, efficacy and possible commercialization of our therapeutic genes and methods of gene therapy, as well as our other product candidates and technologies. On the basis of such evaluations, we may alter our current research and development programs, clinical studies, partnering or other development or commercialization activities. Accordingly, we may elect to cancel, from time to time, one or more of the following arrangements with third parties, subject to any applicable accrued liabilities and, in certain cases, termination fees. Alternatively, the other parties to such arrangements may, in certain circumstances, be entitled to terminate the arrangements. Further, the amounts payable under certain of our arrangements may depend on the number of products or indications for which any particular technology licensed under such arrangement is used by us. Thus, any statement of potential fees payable by us under each agreement is subject to a high degree of potential variation from the amounts indicated.

Our business strategy includes the establishment of research collaborations to support and supplement our discovery, pre-clinical and clinical research and development phases of the product commercialization cycle, as well as the implementation of long-term strategic partnerships with major pharmaceutical and biotechnology companies and interventional cardiology and medical device companies, to support clinical trials and product commercialization activities, including product manufacturing, marketing and distribution.

Schering Agreement

We entered into an agreement with Schering covering the transfer or license of certain assets and technology relating to (i) methods of gene therapy for the treatment of cardiovascular disease (including methods for the delivery of genes to the heart or vasculature and the use of angiogenic and/or non-angiogenic genes for the potential treatment of diseases of the heart or vasculature); (ii) therapeutic genes that include fibroblast growth factors (including FGF-4); insulin-like growth factors (including IGF-I); and potentially other related biologics (including mutant eNOS), and (3) other technology and know-how, including manufacturing and formulation technology, as well as data relating to the clinical development of Generx and corresponding FDA regulatory

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matters. Under this agreement, we paid Schering a $4 million up front fee in October 2005 and would be required to pay a $10 million milestone payment upon the first commercial sale of each resulting product. We also may be obligated to pay the following royalties to Schering: (i) 5% on net sales of an FGF-4 based product such as Generx; or (ii) 4% on net sales of other products developed based on technology transferred to us by Schering. We are also obligated to reimburse Schering for patent expenses, including the expenses of any interference or other proceedings, accrued on or after April 1, 2005 in connection with the transferred technologies.

University of California License Agreement

In September 1995, Collateral Therapeutics entered into an agreement with the Regents of the University of California (Regents) pursuant to which the Regents granted to Collateral Therapeutics an exclusive license (with the right to sublicense) in the United States, and in foreign countries where the respective patent rights exist, to certain technology relating to angiogenic gene therapy, based on scientific discovery research conducted at a laboratory at the University of California. In June 1997, Collateral Therapeutics and the Regents entered into an exclusive license agreement (with the right to sublicense) in the United States, and in foreign countries where the respective patent rights exist, for certain technology relating to angiogenic gene therapy for congestive heart failure.

As part of the Schering transaction, we acquired Collateral Therapeutics rights and corresponding obligations under the September 1995 agreement, which in connection with the Schering transaction was amended, among other things, to include the technology previously covered by the June 1997 agreement. The agreement as amended may be canceled by us at any time on 60 days notice, following which we would continue to be responsible only for obligations and liabilities accrued before termination. Under the agreement, we are obligated to pay (1) an annual royalty fee of 2% based on net sales of products incorporating the technology licensed under the agreement, and (2) a minimum annual royalty fee (which may be offset against the net sales-based royalty fee) of $150,000 for 2009, $200,000 for 2010, $250,000 for 2011, $300,000 for 2012, $400,000 for 2013 and $500,000 for 2014 and thereafter. We also are obligated to reimburse the Regents for ongoing patent expenses incurred in connection with the licensed technologies. We are obligated to make a milestone payment to the Regents of $200,000 payable on the earlier to occur of the beginning of Phase II/III clinical trials in the United States or December 31, 2008.

The above agreement provides us with exclusive rights (subject to any license rights of the U.S. government) to develop and commercialize technology covered by patent applications that have been filed in the United States and in foreign countries. Under the terms of the agreement, we are required to diligently proceed with the development and commercialization of the products covered by the licensed patents. To demonstrate our diligence, we are required to attain certain developmental milestones on or before deadlines set forth in the licenses. If and after we receive marketing approval of the products, we will be required to market the products in the United States within six months thereafter. If there is a material breach of any of these agreements, which material breach remains uncured for 60 days, the breached agreement could be terminated by the Regents.

New York University Research and License Agreement

In March 1997, Collateral Therapeutics entered into an agreement with New York University (NYU) pursuant to which NYU granted to Collateral Therapeutics an exclusive worldwide license (with the right to sublicense) to certain technology covering development, manufacture, use and sale of gene therapy products based on FGF-4 for the treatment of coronary artery disease, peripheral vascular disease and congestive heart failure. This agreement was also assumed by us in connection with the Schering transaction and amended in certain respects pursuant to an agreement with NYU. Upon assumption, this agreement as amended provides us with exclusive rights in such fields to develop and commercialize technology covered by the issued patent and patent applications that have been filed in the United States and in foreign countries. Pursuant to the agreement, we are obligated to pay NYU license fees through the completion of the first full year of sales of licensed product equal to $50,000 per year. We also are obligated to reimburse NYU for ongoing patent expenses incurred in

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connection with the licensed technologies. Should licensed products under the agreement reach the stage of filing of a product license application (PLA) and PLA approval or foreign equivalent thereof, we could be obligated to pay up to an aggregate amount of approximately $1.8 million for each product in milestone payments. In addition, beginning in the year in which we complete one full year of sales of licensed products and continuing thereafter until the agreement terminates or expires, we could also be obligated to pay annual royalty fees equal to the greater of $500,000 or 3% on net sales of products incorporating the technology licensed under the agreement. Under the license agreement, we are required to pursue development and commercialization of the licensed products. If there is a material breach of this agreement that remains uncured for 60 days (or 30 days in the case of unpaid amounts due), the breached agreement could be terminated by NYU.

Yale University License Agreement

In September 2000, Schering entered into an agreement with Yale University pursuant to which Yale University granted to Schering an exclusive worldwide license (with the right to sublicense) to certain technology covering development, manufacture, use and sale of gene therapy products based on a phosphomimetic mutant of human endothelial nitric oxide synthase (eNOS) for the treatment of all cardiovascular diseases. As part of the Schering transaction, we assumed this agreement with Yale University and as such will be obligated to pay an annual license fee of $15,000, and make certain milestone payments during the development of the licensed products as follows: (i) $150,000 upon filing the first investigational new drug application for the first licensed product in any one of the United States, Japan or a country in the European Union; (ii) $825,000 upon treating the first patient in the second clinical trial in any one of the United States, Japan or a country in the European Union; (iii) $900,000 upon filing first Biologics License Application (BLA) or new drug application in the United States; (iv) $1.5 million upon the first commercial sale of a licensed product; and (v) $3 million upon the first $10 million in net sales. If we achieve sales of licensed products, we would be required to pay a minimum royalty of $50,000 per year that is credited to an annual sales royalty equal to 4% of the first $250 million of net sales, 5% of the next $250 million of net sales and 6% of net sales in excess of $500 million. Under the terms of this agreement, we are obligated to reimburse Yale University for ongoing patent expenses incurred in connection with the licensed technologies. If there is a material breach of this agreement that remains uncured for 60 days, the breached agreement could be terminated by Yale.

SurModics License Agreement

In connection with the Innercool Therapies acquisition, a Master License Agreement with SurModics, Inc., dated December 1, 1999, was assigned to and assumed by Innercool Therapies, Inc. (SurModics License). Pursuant to the terms of the SurModics License, SurModics grants to Innercool a worldwide license with respect to medical products that are surface-treated with photo-reactive polyvinylpyrrolidone, photo-reactive heparin, diphoto diquat (photo-reactive crosslinking compound) or any combination of such photo-reactive reagents, under SurModics trade secrets and other technical information relating to the surface-treatment of medical devices and which SurModics has the right to transmit to others, as well as certain patent applications and patents. In connection with the SurModics License, Innercool is obligated to pay SurModics a royalty equal to the greater of: (A) earned royalties calculated as a percentage of net sales of licensed products sold in each calendar year (the percentage used in each calculation during each calendar year is based on the cumulative net sales of licensed product in the calendar year as follows: 2.5% on the first $15 million of net sales; 2.25% on the next $15 million; and 2.0% on net sales over $30 million); or (B) quarterly minimum royalties that increase on an annual basis. Quarterly minimum royalties for 2006 were $20,000. In addition, Innercool grants to SurModics a noncancelable, nonexclusive, sublicensable, worldwide license to make, have made, use and sell products and processes covered by any Innercool latent reactive chemical patent, to the extent such manufacture, sale or use is covered by any claim of any patent that SurModics has the right to license or may have licensed to others, and SurModics agrees to pay to Innercool 5% of the royalties SurModics receives from its sublicensees based on sales of products that but for such sublicenses would infringe Innercool s patents. Each license granted under the SurModics License extends until expiration of the last to expire patent rights covering the applicable product or for 15 years following the first bona fide commercial sale of such product, whichever is longer. The SurModics

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License may be terminated by Innercool upon 90 days advance notice and by SurModics in the event of any material breach or default by Innercool upon 30 days advance notice.

University of Michigan License Agreement

In August 2006, as part of the Tissue Repair Company transaction, we acquired Tissue Repair Company s rights to an exclusive license with the University of Michigan for certain technology upon which Excellarate is based. We are obligated to reimburse the University of Michigan for patent expenses under the licensed technology and we may be obligated to pay royalties of 2 3.5 % on net sales of products based on the technology such as the product candidate Excellarate.

Employees

As of December 31, 2006, we employed 56 full-time employees. We expect to hire approximately nine additional employees during the next 12 months. Our employees are not represented by a collective bargaining agreement and we have not experienced any work stoppages as a result of labor disputes. We believe our relationship with our employees is good. We also rely on various consultants and advisors to provide services to us.

ITEM 2. DESCRIPTION OF PROPERTY

The table below summarizes our facilities. We believe our facilities are adequate to meet our operating requirements for the foreseeable future.

Location	Nature of Use	Square Feet	How Held	Monthly Base Rent	Lease Expiration Date
3611 Valley Centre Drive Suite 525 San Diego, CA USA	Corporate headquarters (Principal executive offices)	5,727	Leased	$ 22,335[1]	October 31, 2007[2]
6740 Top Gun St. San Diego, CA USA	Office, Research Development, Production and Related Uses[3]	29,706	Leased	$ 36,538[4]	January 19, 2013[5]
3931 Sorrento Valley Blvd. San Diego, CA USA	Office, Research and Development and Related Uses[6]	24,000[6]	Leased	$ 25,200[7]	October 31, 2007

1 In addition to base rent, we are also required to pay our proportionate share of operating and tax expenses for the office park in which our space is located.

2 The lease contains two options, the first for an additional term of one year and the second for an additional term of two years. The second option is subject to a third party right of first refusal.

3 This facility is used by Innercool Therapies, Inc., and Tissue Repair Company, each a wholly-owned subsidiary.

4 Monthly base rent through May 20, 2007. Monthly base rent increases to approximately $40,103 beginning May 21, 2007 and to $41,506 beginning January 20, 2008. In addition to base rent, we are also required to pay our proportionate share of operating and tax expenses for the office park in which our space is located.

5 The lease contains and option allowing us to cancel the last two years of the lease for a one time fee of $75,000 if we provide written notice of our intent to exercise the option no later than July 20, 2010 and an option to cancel only the last year of the lease for a one time fee of $50,000 if we give written notice no later than September 20, 2011. The lease contains an option to renew the lease for an additional six year period, provided the lessor does not elect to sell the property at the end of the current lease term.

6 This facility is used by Innercool Therapies, Inc., approximately 17,700 square feet are subleased to a third party.

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[7] In addition to base rent, we are also obligated to pay the landlord s operating expenses associated with the facility. We receive approximately $20,500 in offsetting monthly rent from the third party sublesee plus the sublesee s pro rate share of the landlord s operating expenses.

We do not intend to invest directly in real estate, real estate mortgages or interests in real estate. We have an investment policy that governs the investment of any surplus funds we may have from time to time. Under this policy, we may invest in certain securities that meet the credit and maturity requirements set forth in the policy, including securities of federal agencies, corporate obligations, municipal notes and money market funds. An investment in such securities may result in an indirect investment in real estate, real estate mortgages or interests in real estate.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in various investigations, claims and legal proceedings that arise in the ordinary course of our business. These matters may relate to intellectual property, employment, tax, regulation, contract or other matters. The resolution of these matters as they arise will be subject to various uncertainties and, even if such claims are without merit, could result in the expenditure of significant financial and managerial resources.

As of March 9, 2007, neither Cardium nor its subsidiaries were a party to any material pending legal proceeding nor was any of their property the subject of any material pending legal proceeding. We anticipate, however, that we will be regularly engaged in various patent prosecution and related matters in connection with the technology we develop and/or license. To the extent we are not successful in defending against any adverse claims concerning our technology, we could be compelled to seek licenses from one or more third parties who could be direct or indirect competitors and who might not make licenses available on terms that we find commercially reasonable or at all. In addition, any such proceedings, even if decided in our favor, involve lengthy processes, are subject to appeals, and typically result in substantial costs and diversion of resources.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

We did not submit any matters to our stockholders for a vote during the fourth quarter ended December 31, 2006.

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PART II

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market Information

Our common stock trades on both the Over-the-Counter Bulletin Board (OTCBB) and the Pink Sheets under the symbol CDTP. Below are the high and low closing prices of our common stock as reported by Nasdaq for each quarter of the years ended December 31, 2006 and 2005:

	2006		2005	
	High	Low	High	Low
First Quarter	$ 3.94	$ 1.95	$ 0.15	$ 0.15
Second Quarter	$ 3.23	$ 2.00	$ 0.46	$ 0.15
Third Quarter	$ 2.60	$ 1.85	$ 1.51	$ 0.46
Fourth Quarter	$ 3.40	$ 2.75	$ 2.35	$ 0.61

The information above reflects inter-dealer prices, without retail mark-up, mark down or commissions, may not represent actual transactions and should not be deemed to reflect an established public trading market for our common stock. The high and low closing prices shown for the first three quarters of 2005, and the low closing price shown for the fourth quarter of 2005, are for shares of common stock of Aries Ventures before the reverse merger with Cardium in October 2005. Until February 27, 2006, our common stock traded solely on the Pink Sheets.

Holders

As of March 9, 2007, there were approximately 405 stockholders of record of our common stock.

Dividends

During the last two years ended December 31, 2006 and 2005, no dividends were declared or paid on our common stock. We do not anticipate paying a dividend in the foreseeable future, as we are in our development stage and expect to sustain losses over the next several years. To the extent we do have earnings, we intend to retain any earnings to help provide funds for the development of our product candidates, the implementation of our business strategy and for our future growth.

In preparation for and in connection with the reverse merger between Aries Ventures and Cardium in October 2005, a one-time, non-dividend, cash distribution of approximately $0.43 per share was made to the stockholders of record holding, immediately prior to the close of the reverse merger, approximately two million shares of common stock of Aries Ventures.

Recent Sales of Unregistered Securities

Other than as previously reported on our Current Reports on Form 8-K filed with the SEC on October 26, 2005, March 14, 2006, and August 15, 2006, during the years ended December 31, 2006, 2005, and 2004, we did not sell any unregistered securities.

Repurchases

During the fourth quarter of 2006, we did not repurchase any shares of our common stock, nor were any repurchases made on our behalf.

ITEM 6. MANAGEMENT S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

The following is a discussion of our intended plan of operation during the next 12 months. You should carefully review the risks described under this Item 6 and elsewhere in this report, which identify certain

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important factors that could cause our plan of operation, future financial condition and results of operations to vary.

Plan of Operation

We are a medical technology company primarily focused on the development and commercialization of novel biologic therapeutics and medical devices for cardiovascular and ischemic disease. Building upon our core products and product candidates, our strategic goal is to develop a portfolio of medical products at various stages of development and secure additional financial resources to commercialize these products in a timely and effective manner. The key elements of our strategy are to:

- initiate the Phase 3 AWARE clinical study for Generx in the first half of 2007;
- initiate a Phase 2b clinical study for Excellarate in the second half of 2007;
- accelerate the development and sales of Innercool s Celsius Control System and, at the same time, broaden and expand our therapeutic hypothermia technology into other medical indications and applications;
- leverage our financial resources and focused corporate infrastructure through the use of contract manufacturers to produce clinical supplies and a contract research organization to manage or assist planned clinical studies;
- advance the pre-clinical development of Corgentin and potentially seek partnering opportunities for the Corgentin and Genvascor product candidates;
- broaden and expand our product base and financial resources through other corporate development transactions in an attempt to enhance stockholder value, which could include acquiring other companies or product opportunities and/or securing additional capital; and
- monetize the economic value of our product portfolio by establishing strategic collaborations at appropriate valuation inflection points.

We plan to continue to build our business through internal development and external acquisitions. As an emerging public company, we have initially focused on acquiring undervaluled opportunities having unrealized value but which we believe have potential for significant future growth and development or partnering prospects when combined with the value-added skills and perspectives of our experienced management team.

To the extent our current products and product candidates become successfully advanced, we intend to continue to pursue opportunistic acquisitions designed to enhance long-term stockholder value. At the same time, as technologies and product candidates are advanced and businesses are built-up, further developed and mature, we may consider various corporate development transactions to enhance and monetize stockholder value such as corporate partnerings, spin-out transactions and equity distribution.

We recognize that the practical realities of developing therapeutic products in the current regulatory environment require sizable financial investment. In view of this, we plan to pursue clinical development strategies intended to facilitate collaborations and partnerships for joint development of our products at appropriate valuation inflection points during their clinical development cycle.

On March 9, 2007, we completed a private placement of our common stock that resulted in net proceeds to the Company of approximately $20 million. As a result, we believe we have sufficient funds available to fund our operations for the next 12 months. However, the amount and timing of future cash requirements will depend on the amount and rate at which resources are applied to clinical trials and other activities associated with researching, developing, manufacturing, commercializing and supporting our products and product candidates, which could lead to our cash resources being consumed sooner than currently expected. If we do not have

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sufficient cash to maintain operations and fund planned programs, we would either need to reduce or slow our expenditures, which could cause a delay in the implementation or accomplishment of one or more components of our operation described above, or seek additional financing through the sale of equity securities, debt financing, and/or strategic licensing agreements. Any additional capital may not be available on terms that are desirable or acceptable to us, or at all.

More detailed information about our products, product candidates and our intended efforts to develop our products is included under Item 1 of this report.

Risk Factors

You should carefully consider the risks described below, as well as the other information in this report and in other reports and documents we file with the SEC when evaluating our business and future prospects. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects could be seriously harmed. In that event, the market price of our common stock could decline and you could lose all or a portion of the value of your investment in our stock.

Risks Related to Our Business and Industry

We are a development stage company formed in December 2003. We have incurred losses since inception and expect to incur significant net losses in the foreseeable future and may never become profitable.

We have sustained operating losses to date and will likely continue to sustain losses as we seek to accelerate our product development efforts. We expect these losses to be substantial in the early years of our operations because our product development and other costs, including significant amounts we expect to spend on development activities and clinical trials for Generx , Excellarate and other product candidates, cannot be offset by our limited revenues during our development stage. As of December 31, 2006, our accumulated deficit was approximately $24 million, and our cash equivalents were approximately $5.9 million. To date, we have generated limited revenues, consisting of revenues from sales of our InnerCool Celsius Control System and associated disposables, as well as interest income. A large portion of our expenses are fixed, including expenses related to facilities, equipment, contractual commitments and personnel. As a result, we expect our net losses from operations to continue for at least the next five years. Our ability to generate additional revenues and potential to become profitable will depend largely on our ability, alone or with potential collaborators, to efficiently and successfully complete the development of our product candidates, successfully complete pre-clinical and clinical tests, obtain necessary regulatory approvals, and manufacture and market our products. There can be no assurance that any such events will occur or that we will ever become profitable. Even if we do achieve profitability, we cannot predict the level of such profitability. If we sustain losses over an extended period of time, we may be unable to continue our business.

Our business prospects are difficult to evaluate because we are a new company and are developing complex and novel medical products.

Since we have a short operating history and our product candidates rely on complex technologies, it may be difficult for you to assess our growth, partnering and earnings potential. It is likely we will face many of the difficulties that new technology companies often face. These include, among others: limited financial resources; developing, testing and marketing new products for which a market is not yet established and may never become established; challenges related to the development, approval and acceptance of a new technology or product; delays in reaching our goals; lack of substantial revenues and cash flow; high product development costs; competition from larger, more established companies; and difficulty recruiting qualified employees for management and other positions. We will likely face these and other difficulties in the future, some of which may be beyond our control. If we are unable to successfully address these difficulties as they arise, our future growth

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and earnings will be negatively affected. We cannot be certain that our business strategies will be successful or that we will successfully address any problems that may arise.

We will need substantial additional capital to develop our products and for our future operations. If we are unable to obtain such funds when needed, we may have to delay, scale back or terminate our product development or our business.

Conducting the costly and time consuming research, pre-clinical and clinical testing necessary to obtain regulatory approvals and bring our products to market will require a commitment of substantial funds in excess of our current capital. Our future capital requirements will depend on many factors, including, among others: the progress of our current and new product development programs; the progress, scope and results of our pre-clinical and clinical testing; the time and cost involved in obtaining regulatory approvals; the cost of manufacturing our products and product candidates; the cost of prosecuting, enforcing and defending against patent claims and other intellectual property rights; competing technological and market developments; and our ability and costs to establish and maintain collaborative and other arrangements with third parties to assist in potentially bringing our products to market.

We will need to raise substantial additional capital to fund our future operations. We cannot be certain that additional financing will be available on acceptable terms, or at all. In recent years, it has been difficult for companies to raise capital due to a variety of factors, which may or may not continue. To the extent we raise additional capital through the sale of equity securities or we issue securities in connection with another transaction, the ownership position of existing stockholders could be substantially diluted. If additional funds are raised through the issuance of preferred stock or debt securities, these securities are likely to have rights, preferences and privileges senior to our common stock and may involve significant fees, interest expense, restrictive covenants and the granting of security interests in our assets. Fluctuating interest rates could also increase the costs of any debt financing we may obtain. Raising capital through a licensing or other transaction involving our intellectual property could require us to relinquish valuable intellectual property rights and thereby sacrifice long term value for short-term liquidity.

Our failure to successfully address ongoing liquidity requirements would have a substantially negative impact on our business. If we are unable to obtain additional capital on acceptable terms when needed, we may need to take actions that adversely affect our business, our stock price and our ability to achieve cash flow in the future, including possibly surrendering our rights to some technologies or product opportunities, delaying our clinical trials or curtailing or ceasing operations.

We acquired the assets and business of InnerCool Therapies, Inc. in March 2006 and rights to develop the Excellarate product candidate of the Tissue Repair Company in August 2006 and may, in the future, pursue acquisitions of other companies or product rights that, if not successful, could adversely affect our business, financial condition and results of operations.

On March 8, 2006, we completed our acquisition of the assets and business of InnerCool Therapies, Inc., a medical technology company focused on the emerging field of therapeutic hypothermia. On August 11, 2006, we acquired rights to develop the Excellarate product candidate of the Tissue Repair Company, a medical technology company focused on the development of growth factor therapeutics for the potential treatment of chronic wounds such as dermal ulcers. These businesses are subject to all of the operational risks that can affect medical technology companies, including those related to regulatory approvals and clinical studies, acceptance of technology, competing technology, intellectual property rights, profitability, suppliers and third party collaborators, adverse publicity, litigation, and retention of key personnel.

In the future, we may pursue additional acquisitions of other companies, technologies or products. Acquisitions of businesses or product rights, including the InnerCool and Tissue Repair Company transactions, involve numerous risks, including:

- our limited experience in evaluating businesses and product opportunities and completing acquisitions;

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the use of our existing cash reserves or the need to obtain additional financing to pay for all or a portion of the purchase price of such acquisitions and to support the ongoing operations of the businesses acquired;

the potential need to issue convertible debt, equity securities, stock options and stock purchase warrants to complete an acquisition, which would dilute our stockholders and could adversely affect the market price of our common stock;

potential difficulties related to integrating the technology, products, personnel and operations of the acquired company;

requirements of significant capital infusions in circumstances under which the acquired business, its products and/or technologies may not generate sufficient revenue or any revenue to offset acquisition costs or ongoing expenses;

entering markets in which we have no or limited prior direct experience and where competitors have stronger market or intellectual property positions;

disruptions to our ongoing business, diversion of resources, increases in our expenses and distraction of management s attention from the normal daily operations of our business;

the potential to negatively impact our results of operations because an acquisition may require us to incur large one-time charges to earnings, amortize or write down amounts related to goodwill and other intangible assets, or incur or assume substantial debt or liabilities, or cause adverse tax consequences, substantial depreciation or deferred compensation charges;

an uncertain sales and earnings stream, or greater than expected liabilities and expenses, associated with the acquired company, product or product rights;

failure to operate effectively and efficiently as a combined organization utilizing common information and communication systems, operating procedures, financial controls and human resources practices;

potential loss of key employees of the acquired company; and

disruptions to our relationships with existing collaborators who could be competitive with the acquired business.

There can be no assurance that our InnerCool or Tissue Repair transactions, or other transactions that we may pursue, will ultimately prove successful. If we pursue an acquisition but are not successful in completing it, or if we complete an acquisition but are not successful in integrating the acquired company s employees, products or operations successfully, our business, financial condition or results of operations could be harmed.

We are an early stage company and, other than InnerCool s Celsius Control System and related disposables that are approved for limited uses, we have no other products available for sale or use. Our product candidates require additional research, development, testing, and regulatory approvals before marketing. We may be unable to develop, obtain regulatory approval or market any of our product candidates or expand the market of our existing products and technology. If our product candidates are delayed or fail, our business and stockholder value will be negatively impacted, and we may have to curtail or cease our operations.

We are in the early stage of product development and, other than InnerCool s Celsius Control System and related disposables that are approved only for limited uses, we currently do not sell any other products and may not have any other products commercially available for several years, if at all. Our product candidates, and the potential expansion of our therapeutic hypothermia products into other medical indications and

applications, require additional research and development, clinical testing and regulatory clearances before we can market them. To our knowledge, the U.S. Food and Drug Administration, or FDA, has not yet approved any gene

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therapy or similar product and there can be no assurance that it will. There are many reasons that our products and product candidates may fail or not advance beyond clinical testing, including the possibility that:

- our products and product candidates may be ineffective, unsafe or associated with unacceptable side effects;
- our product candidates may fail to receive necessary regulatory approvals or otherwise fail to meet applicable regulatory standards;
- our product candidates may be too expensive to develop, manufacture or market;
- physicians, patients, third-party payers or the medical community in general may not accept or use our products;
- our potential collaborators may withdraw support for or otherwise impair the development and commercialization of our products or product candidates;
- other parties may hold or acquire proprietary rights that could prevent us or our potential collaborators from developing or marketing our products or product candidates; or
- others may develop equivalent, superior or less expensive products.

In addition, our product candidates are subject to the risks of failure inherent in the development of biologics, gene therapy and other products based on innovative technologies. As a result, we are not able to predict whether our research, development and testing activities will result in any commercially viable products or applications. If our product candidates are delayed or we fail to successfully develop and commercialize our product candidates, or if we are unable to expand the market of our existing products or related technology, our business, financial condition or results of operations will be negatively affected, and we may have to curtail or cease our operations.

We may experience delays in our clinical trials that could adversely affect our business, financial results and commercial prospects.

To obtain regulatory approvals for new products or to expand indications for existing ones, we must, among other things, initiate and successfully complete multiple clinical trials demonstrating to the satisfaction of the FDA that our product candidates are sufficiently safe and effective for a particular indication. We are in ongoing discussions with the FDA regarding clinical trials of our Generx product candidate, and expect to soon be in discussions regarding our recently acquired Excellarate product candidate. While we expect both product candidates to be in clinical trials in 2007, there is no assurance that they will be since the timing of clinical trials is dependent on, among other things, FDA reviews, clinical site approvals, successful manufacturing of clinical materials, sufficient funding and other factors outside of our control. Furthermore, there can be no assurance that our clinical trials will in fact demonstrate to the satisfaction of the FDA and others that our products are sufficiently safe or effective.

The FDA or we may also restrict or suspend our clinical trials at any time if either believes that we are exposing the subjects participating in the trials to unacceptable health risks. We expect to continue to rely on third party clinical investigators at medical institutions and healthcare facilities to conduct and monitor our clinical trials, and, as a result, we may face additional delaying factors outside of our control. Product development costs to us and our potential collaborators will increase, and our business may be negatively impacted, if we experience delays in testing or approvals or if we need to perform more or larger clinical trials than planned, for reasons such as the following:

- the FDA or other health regulatory authorities, or institutional review boards, do not approve a clinical study protocol or place a clinical study on hold;

suitable patients do not enroll in a clinical study in sufficient numbers or at the expected rate, or data is adversely affected by trial conduct or patient drop out;

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patients experience serious adverse events, including adverse side effects of our drug candidate or device;

patients die during a clinical study for a variety of reasons that may or may not be related to our products, including the advanced stage of their disease and medical problems;

patients in the placebo or untreated control group exhibit greater than expected improvements or fewer than expected adverse events;

third-party clinical investigators do not perform the clinical studies on the anticipated schedule or consistent with the clinical study protocol and good clinical practices, or other third-party organizations do not perform data collection and analysis in a timely or accurate manner;

service providers, collaborators or co-sponsors do not adequately perform their obligations in relation to the clinical study or cause the study to be delayed or terminated;

regulatory inspections of manufacturing facilities, which may, among other things, require us or a co-sponsor to undertake corrective action or suspend the clinical studies;

the interim results of the clinical study are inconclusive or negative;

the clinical study, although approved and completed, generates data that is not considered by the FDA or others to be sufficient to demonstrate safety and efficacy; and

changes in governmental regulations or administrative actions affect the conduct of the clinical trial or the interpretation of its results.

Significant delays may adversely affect our financial results and the commercial prospects for our product candidates and delay our ability to become profitable.

If we cannot successfully complete the clinical trial process for our product candidates, or products for which we seek expanded approvals, then we will not be able to market them. Even successful clinical trials may not result in a marketable product and may not be predictive of a product s safety or efficacy in a larger and more diverse patient population.

Our Celsius Control System acquired from InnerCool Therapies has received FDA 510(k) clearance for certain specified indications but we may elect to pursue other indications, which would generally require that collaborators or we conduct additional clinical studies and/or testing. Our Generx and Excellarate product candidates are currently in the clinical stage. Other product candidates are in the pre-clinical stage and there can be no assurance they will ever advance to clinical trials. For product candidates that advance to clinical testing, we cannot be certain that a collaborator or we will successfully complete the clinical trials necessary to receive regulatory product approvals. This process is lengthy, unpredictable and expensive. To obtain regulatory approvals, a collaborative partner or we must ultimately demonstrate to the satisfaction of the FDA and others that our product candidates are sufficiently safe and effective for their proposed use.

Many factors, known and unknown, can adversely impact clinical trials and the ability to evaluate a product s safety and efficacy. Such factors may have a negative impact on our business by making it difficult to advance product candidates or by reducing or eliminating their potential or perceived value. Further, if we are forced to contribute greater financial and clinical resources to a study, valuable resources will be diverted from other areas of our business.

Clinical trials for products such as ours are often conducted with patients who have more advanced forms of a particular disease. For example, in clinical trials for our lead product candidate Generx, we expect to study patients who are not only suffering from severe forms of heart disease but are also older and much more likely to develop cancers and other serious adverse conditions. During the course of treatment, these patients

could die or suffer other adverse events for reasons that may or may not be related to the proposed product being tested. Our

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clinical trials may also be adversely impacted by patient deaths or problems that occur in other trials. However, even if unrelated to our product, such events can nevertheless adversely impact our clinical trials. As a result, our business and ability to ultimately develop and market the products and obtain revenues would suffer.

Deaths and other adverse events that occur in the conduct of clinical trials may also result in an increase in governmental regulations or litigation, and could result in delays or halts being imposed upon clinical trials, including our own. In addition, patients involved in clinical trials such as ours often have unknown as well as known health risks and pre-existing conditions. An adverse event may therefore appear to have been caused or exacerbated by the administration of study product, even if it was not actually related. Such consequences can also increase the risk that any potential adverse event in our trial could give rise to claims for damages against us, or could cause further delays or halt our clinical trial, any of which results would negatively impact us. In addition, fears regarding the potential consequences of gene therapy trials or the conduct of such trials could dissuade investigators or patients from participating in our trials, which could substantially delay or prevent our product development efforts.

Even promising results in pre-clinical studies and initial clinical trials do not ensure successful results in later clinical trials, which test broader human use of our products. Many companies in our industry have suffered significant setbacks in advanced clinical trials, despite promising results in earlier trials. Even successful clinical trials may not result in a marketable product or be indicative of the efficacy or safety of a product in the broader patient population. Many factors or variables could affect the results of clinical trials and cause them to appear more promising than they may otherwise be. Product candidates that successfully complete clinical trials could ultimately be found to be unsafe or ineffective or to have poorer risk to benefit or cost to benefit profiles as compared to other potential products or therapies.

Our ability to complete clinical trials depends on many factors, including obtaining adequate clinical supplies and having a sufficient rate of patient recruitment. For example, patient recruitment is a function of many factors, including: the size of the patient population; the proximity of patients to clinical sites; the eligibility criteria for the trial; the perceptions of investigators and patients regarding safety; and the availability of other treatment options. Even if patients are successfully recruited, we cannot be sure they will complete the treatment process. Delays in patient enrollment or treatment in clinical trials may result in increased costs, program delays, or failure, any of which can substantially affect our business or perceived value.

In addition, DNA-based therapies such as those being developed by us are relatively new and are only beginning to be tested in humans. Regulatory authorities may require us or our potential collaborators to demonstrate that our products are improved treatments relative to other therapies or may significantly modify the requirements governing gene therapies, which could result in regulatory delays or rejections that negatively impact our business. Compliance with these regulatory requirements is also time consuming and expensive. If we fail to comply with regulatory requirements, either before approval or in marketing our products after approval, we could be subject to regulatory or judicial enforcement actions. These actions could result in withdrawal of existing approvals, product recalls, injunctions, civil penalties, criminal prosecution, and enhanced exposure to product liabilities.

Ethical, social and legal concerns about gene therapy and genetic research could also result in additional regulations restricting or prohibiting our products and processes we may use. More restrictive government regulations or negative public opinion may have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates.

With respect to markets in other countries, we or a partner will also be subject to regulatory requirements governing clinical trials in those countries. Even if we complete clinical trials, we may not be able to submit a marketing application. If we submit an application, the regulatory authorities may not review or approve it in a timely manner, if at all.

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Our technologies and product candidates may have unacceptable side effects that could delay or prevent product approval.

Possible side effects of therapeutic technologies may be serious and life threatening. The occurrence of any unacceptable side effects during or after pre-clinical and clinical testing of our product candidates, or the perception or possibility that our products cause or could cause such side effects, could delay or prevent approval of our products and negatively impact our business. For example, possible serious side effects of viral vector-based gene transfer could potentially include viral or gene product toxicity resulting in inflammation or other injury to the heart or other parts of the body. In addition, the development or worsening of cancer in a patient could potentially be a perceived or actual side effect of gene therapy technologies such as our own. Furthermore, there is a possibility of side effects or decreased effectiveness associated with an immune response toward any viral vector or gene used in gene therapy. The possibility of such response may increase if there is a need to deliver the viral vector more than once.

Even if approved for marketing, our technologies and product candidates are relatively novel and unproven and they may fail to gain market acceptance.

Our ongoing business and future depends on the success of our technologies and product candidates. Gene-based therapy and endovascular temperature control therapy are new and rapidly evolving medical approaches that have not been shown to be effective on a widespread basis. Biotechnology and pharmaceutical companies have successfully developed and commercialized only a limited number of biologic-based products to date and no gene therapy has yet been successfully commercialized. Our product candidates, and the technology underlying them, are new and unproven and there is no guarantee that health care providers or patients will be interested in our products even if they are approved for use. Our success will depend in part on our ability to demonstrate sufficient clinical benefits, reliability, safety and cost effectiveness of our product candidates and technology relative to other approaches, as well as on our ability to continue to develop our product candidates to respond to competitive and technological changes. If the market does not accept our products or product candidates, when and if we are able to commercialize them, then we may never become profitable. It is difficult to predict the future growth of our business, if any, and the size of the market for our product candidates because the market and technology are continually evolving. There can be no assurance that our technologies and product candidates will prove superior to technologies and products that may currently be available or may become available in the future or that our technologies or research and development activities will result in any commercially profitable products.

We may not successfully establish and maintain collaborative and licensing arrangements, which could adversely affect our ability to develop and commercialize our product candidates. " ALIGN="right">3,027 34,437

Other comprehensive income (loss)

- 2,501 - 2,501 (56) 2,445

Common shares issued, net of withholding tax

(602) - - (602) - (602)

Common shares in NQ plans

550 - - 550 - 550

Stock-based compensation

5,965 - - 5,965 - 5,965

Purchases and retirement of common shares

(4,680) - (22,902) (27,582) - (27,582)

Cash dividends declared

- - (11,470) (11,470) - (11,470)

Payments to noncontrolling interest

-	-	-	-	(4,901)	(4,901)

Balance at August 31, 2015

$290,311	$(48,203)	$507,776	$749,884	$89,007	$838,891

The components of the changes in other comprehensive loss were as follows:

(in thousands)	Foreign Currency Translation	Pension Liability Adjustment	Cash Flow Hedges	Accumulated Other Comprehensive Loss
Balance as of May 31, 2015	$ (20,717)	$ (15,003)	$ (14,984)	$ (50,704)
Other comprehensive income (loss) before reclassifications	1,879	(8)	(8,092)	(6,221)
Reclassification adjustments to income (a)	-	-	9,330	9,330
Income taxes	-	-	(608)	(608)
Balance as of August 31, 2015	$ (18,838)	$ (15,011)	$ (14,354)	$ (48,203)

(a) The statement of earnings classification of amounts reclassified to income for cash flow hedges is disclosed in NOTE N Derivative Instruments and Hedging Activities.

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NOTE J Stock-Based Compensation

Non-Qualified Stock Options

During the three months ended August 31, 2015, we granted non-qualified stock options covering a total of 153,500 common shares under our stock-based compensation plans. The option price of $30.92 per share was equal to the market price of the underlying common shares at the grant date. The fair value of these stock options, based on the Black-Scholes option-pricing model, calculated at the grant date, was $9.55 per share. The calculated pre-tax stock-based compensation expense for these stock options, after an estimate for forfeitures, is $1,305,000 and will be recognized on a straight-line basis over the three-year vesting period. The following assumptions were used to value these stock options:

Dividend yield	2.33%
Expected volatility	38.40%
Risk-free interest rate	1.98%
Expected term (years)	6.0

Expected volatility is based on the historical volatility of our common shares and the risk-free interest rate is based on the United States Treasury strip rate for the expected term of the stock options. The expected term was developed using historical exercise experience.

Service-Based Restricted Common Shares

During the three months ended August 31, 2015, we granted an aggregate of 148,850 service-based restricted common shares under our stock-based compensation plans. The fair value of these restricted common shares was equal to the closing market price of the underlying common shares on the date of grant, or $30.92 per share. The calculated pre-tax stock-based compensation expense for these restricted common shares, after an estimate for forfeitures, is $4,096,000 and will be recognized on a straight-line basis over the three-year service-based vesting period.

Performance Share Awards

We have awarded performance shares to certain key employees that are earned based on the level of achievement with respect to corporate targets for cumulative corporate economic value added, earnings per share growth and, in the case of business unit executives, business unit operating income targets for the three-year periods ending May 31, 2016, 2017 and 2018. These performance share awards will be paid, to the extent earned, in common shares of the Company in the fiscal quarter following the end of the applicable three-year performance period. The fair values of our performance shares are determined by the closing market prices of the underlying common shares at their respective grant dates and the pre-tax stock-based compensation expense is based on our periodic assessment of the probability of the targets being achieved and our estimate of the number of common shares that will ultimately be issued. During the three months ended August 31, 2015, we granted performance share awards covering an aggregate of 94,700 common shares (at target levels). The calculated pre-tax stock-based compensation expense for these performance shares is $2,852,000 and will be recognized over the three-year performance period.

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NOTE K Income Taxes

Income tax expense for the three months ended August 31, 2015 and August 31, 2014 reflected estimated annual effective income tax rates of 31.8% and 32.8%, respectively. The annual effective income tax rates exclude any impact from the inclusion of net earnings attributable to noncontrolling interests in our consolidated statements of earnings. Net earnings attributable to noncontrolling interests are primarily a result of our Spartan, Worthington Nitin Cylinders, Worthington Aritas, and TWB consolidated joint ventures. The earnings attributable to the noncontrolling interests in Spartan and TWB s U.S. operations do not generate tax expense to Worthington since the investors in Spartan and TWB s U.S. operations are taxed directly based on the earnings attributable to them. The tax expense of Worthington Aritas and Worthington Nitin Cylinders, both foreign corporations, and TWB s wholly-owned foreign corporations, is reported in our consolidated tax expense. Management is required to estimate the annual effective income tax rate based upon its forecast of annual pre-tax income for domestic and foreign operations. Our actual effective income tax rate for fiscal 2016 could be materially different from the forecasted rate as of August 31, 2015.

NOTE L Earnings Per Share

The following table sets forth the computation of basic and diluted earnings per share for the three months ended August 31, 2015 and 2014:

(in thousands, except per share amounts)	Three Months Ended August 31, 2015	2014
Numerator (basic & diluted):		
Net earnings attributable to controlling interest income available to common shareholders	$ 31,410	$ 44,168
Denominator:		
Denominator for basic earnings per share attributable to controlling interest weighted average common shares	63,993	67,567
Effect of dilutive securities	1,736	2,171
Denominator for diluted earnings per share attributable to controlling interest adjusted weighted average common shares	65,729	69,738
Basic earnings per share attributable to controlling interest	$ 0.49	$ 0.65
Diluted earnings per share attributable to controlling interest	$ 0.48	$ 0.63

Stock options covering 318,904 and 87,976 common shares have been excluded from the computation of diluted earnings per share for the three months ended August 31, 2015 and August 31, 2014, respectively, because the effect would have been anti-dilutive as the exercise price of the stock options was greater than the average market price of the common shares during the period.

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NOTE M Segment Operations

Summarized financial information for our reportable segments is shown in the following table:

(in thousands)	Three Months Ended August 31, 2015	2014
Net sales		
Steel Processing	$ 490,800	$ 552,331
Pressure Cylinders	224,394	248,959
Engineered Cabs	38,617	49,554
Other	4,336	11,570
Total net sales	$ 758,147	$ 862,414
Operating income (loss)		
Steel Processing	$ 23,638	$ 35,869
Pressure Cylinders	16,819	19,606
Engineered Cabs	(9,291)	(2,145)
Other	(170)	(1,128)
Total operating income	$ 30,996	$ 52,202
Impairment of long-lived assets		
Steel Processing	$ -	$ 1,950
Pressure Cylinders	-	-
Engineered Cabs	3,000	-
Other	-	-
Total impairment of long-lived assets	$ 3,000	$ 1,950
Restructuring and other expense (income)		
Steel Processing	$ 462	$ (30)
Pressure Cylinders	731	23
Engineered Cabs	1,878	-
Other	(2)	107
Total restructuring and other expense	$ 3,069	$ 100

(in thousands)	August 31, 2015	May 31, 2015
Total assets		
Steel Processing	$ 818,834	$ 829,116
Pressure Cylinders	791,752	804,799
Engineered Cabs	89,018	94,506
Other	346,306	356,721
Total assets	$ 2,045,910	$ 2,085,142

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NOTE N Derivative Instruments and Hedging Activities

We utilize derivative financial instruments to manage exposure to certain risks related to our ongoing operations. The primary risks managed through the use of derivative instruments include interest rate risk, currency exchange risk and commodity price risk. While certain of our derivative instruments are designated as hedging instruments, we also enter into derivative instruments that are designed to hedge a risk, but are not designated as hedging instruments and therefore do not qualify for hedge accounting. These derivative instruments are adjusted to current fair value through earnings at the end of each period.

Interest Rate Risk Management We are exposed to the impact of interest rate changes. Our objective is to manage the impact of interest rate changes on cash flows and the market value of our borrowings. We utilize a mix of debt maturities along with both fixed-rate and variable-rate debt to manage changes in interest rates. In addition, we enter into interest rate swaps to further manage our exposure to interest rate variations related to our borrowings and to lower our overall borrowing costs.

Currency Exchange Risk Management We conduct business in several major international currencies and are therefore subject to risks associated with changing foreign exchange rates. We enter into various contracts that change in value as foreign exchange rates change to manage this exposure. Such contracts limit exposure to both favorable and unfavorable currency fluctuations. The translation of foreign currencies into United States dollars also subjects us to exposure related to fluctuating exchange rates; however, derivative instruments are not used to manage this risk.

Commodity Price Risk Management We are exposed to changes in the price of certain commodities, including steel, natural gas, zinc and other raw materials, and our utility requirements. Our objective is to reduce earnings and cash flow volatility associated with forecasted purchases and sales of these commodities to allow management to focus its attention on business operations. Accordingly, we enter into derivative contracts to manage the associated price risk.

We are exposed to counterparty credit risk on all of our derivative instruments. Accordingly, we have established and maintain strict counterparty credit guidelines and enter into derivative instruments only with major financial institutions. We have credit support agreements in place with certain counterparties to limit our credit exposure. These agreements require either party to post cash collateral if its cumulative market position exceeds a predefined liability threshold. At August 31, 2015, we had posted total cash collateral of $2,711,000 to our margin accounts. Amounts posted to the margin accounts accrue interest at market rates and are required to be refunded in the period in which the cumulative market position falls below the required threshold. We do not have significant exposure to any one counterparty and management believes the risk of loss is remote and, in any event, would not be material.

Refer to Note O Fair Value for additional information regarding the accounting treatment for our derivative instruments, as well as how fair value is determined.

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The following table summarizes the fair value of our derivative instruments and the respective financial statement caption in which they were recorded in our consolidated balance sheet at August 31, 2015:

	Asset Derivatives		Liability Derivatives	
(in thousands)	**Balance Sheet Location**	**Fair Value**	**Balance Sheet Location**	**Fair Value**
Derivatives designated as hedging instruments:				
Commodity contracts	Receivables	$ -	Accounts payable	$ 16,557
	Other assets	-	Other liabilities	424
		-		16,981
Interest rate contracts	Receivables	-	Accounts payable	81
	Other assets	-	Other liabilities	79
		-		160
Totals		$ -		$ 17,141
Derivatives not designated as hedging instruments:				
Commodity contracts	Receivables	$ -	Accounts payable	$ 4,852
	Other assets	-	Other liabilities	119
		-		4,971
Foreign exchange contracts	Receivables	11	Accounts payable	-
		11		-
Totals		$ 11		$ 4,971
Total Derivative Instruments		$ 11		$ 22,112

The amounts in the table above reflect the fair value of the Company s derivative contracts on a net basis. Had these amounts been recognized on a gross basis, the impact would have been a $310,000 decrease in receivables with a corresponding decrease in accounts payable.

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The following table summarizes the fair value of our derivative instruments and the respective line in which they were recorded in the consolidated balance sheet at May 31, 2015:

	Asset Derivatives		Liability Derivatives	
(in thousands)	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Commodity contracts	Receivables	$ -	Accounts payable	$ 17,241
	Other assets	-	Other liabilities	592
		-		17,833
Interest rate contracts	Receivables	-	Accounts payable	81
	Other assets	-	Other liabilities	113
		-		194
Foreign exchange contracts	Receivables	75	Accounts payable	
Totals		$ 75		$ 18,027
Derivatives not designated as hedging instruments:				
Commodity contracts	Receivables	$ 96	Accounts payable	$ 4,104
	Other assets	-	Other liabilities	-
Totals		$ 96		$ 4,104
Total Derivative Instruments		$ 171		$ 22,131

The amounts in the table above reflect the fair value of the Company s derivative contracts on a net basis. Had these amounts been recognized on a gross basis, the impact would have been a $500,000 increase in receivables with a corresponding increase in accounts payable.

Cash Flow Hedges

We enter into derivative instruments to hedge our exposure to changes in cash flows attributable to interest rates, foreign exchange rates, and commodity price fluctuations associated with certain forecasted transactions. These derivative instruments are designated and qualify as cash flow hedges. Accordingly, the effective portion of the gain or loss on the derivative instrument is reported as a component of other comprehensive income (loss) (OCI) and reclassified into earnings in the same financial statement caption associated with the forecasted transaction and in the same period during which the hedged transaction affects earnings. The ineffective portion of the gain or loss on the derivative instrument is recognized in earnings immediately.

The following table summarizes our cash flow hedges outstanding at August 31, 2015:

(in thousands)	Notional Amount	Maturity Date
Commodity contracts	$ 78,081	September 2015 - December 2016
Interest rate contracts	17,153	September 2019

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The following table summarizes the gain (loss) recognized in OCI and the gain (loss) reclassified from accumulated OCI into earnings for derivative instruments designated as cash flow hedges during the three months ended August 31, 2015 and 2014:

(in thousands)	Gain (Loss) Recognized in OCI (Effective Portion)	Location of Gain (Loss) Reclassified from Accumulated OCI (Effective Portion)	Gain (Loss) Reclassified from Accumulated OCI (Effective Portion)	Location of Gain (Loss) (Ineffective Portion) and Excluded from Effectiveness Testing	Gain (Loss) (Ineffective Portion) and Excluded from Effectiveness Testing
For the three months ended August 31, 2015:					
Commodity contracts	$ (8,126)	Cost of goods sold	$ (9,187)	Cost of goods sold	$ -
Interest rate contracts	34	Interest expense	(139)	Interest expense	-
Foreign currency contracts	-	Miscellaneous income	(4)	Miscellaneous income	-
Totals	$ (8,092)		$ (9,330)		$ -
For the three months ended August 31, 2014:					
Commodity contracts	$ (413)	Cost of goods sold	$ (796)	Cost of goods sold	$ -
Interest rate contracts	-	Interest expense	(1,148)	Interest expense	-
Totals	$ (413)		$ (1,944)		$ -

The estimated net amount of the losses recognized in accumulated OCI at August 31, 2015 expected to be reclassified into net earnings within the succeeding twelve months is $12,131,000 (net of tax of $7,029,000). This amount was computed using the fair value of the cash flow hedges at August 31, 2015, and will change before actual reclassification from OCI to net earnings during the fiscal years ending May 31, 2016 and 2017.

Economic (Non-designated) Hedges

We enter into foreign currency contracts to manage our foreign exchange exposure related to inter-company and financing transactions that do not meet the requirements for hedge accounting treatment. We also enter into certain commodity contracts that do not qualify for hedge accounting treatment. Accordingly, these derivative instruments are adjusted to current market value at the end of each period through earnings.

The following table summarizes our economic (non-designated) derivative instruments outstanding at August 31, 2015:

(in thousands)	Notional Amount	Maturity Date(s)
Commodity contracts	$ 31,275	September 2015 - February 2017
Foreign currency contracts	774	November 2015

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The following table summarizes the gain (loss) recognized in earnings for economic (non-designated) derivative financial instruments during the three months ended August 31, 2015 and 2014:

(in thousands)	Location of Gain (Loss) Recognized in Earnings	Gain (Loss) Recognized in Earnings for the Three Months Ended August 31, 2015	2014
Commodity contracts	Cost of goods sold	$ (2,755)	$ (57)
Foreign exchange contracts	Miscellaneous income (expense)	-	261
Total		$ (2,755)	$ 204

The gain (loss) on the foreign currency derivatives significantly offsets the gain (loss) on the hedged item.

NOTE O Fair Value

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value is an exit price concept that assumes an orderly transaction between willing market participants and is required to be based on assumptions that market participants would use in pricing an asset or a liability. Current accounting guidance establishes a three-tier fair value hierarchy as a basis for considering such assumptions and for classifying the inputs used in the valuation methodologies. This hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair values are as follows:

Level 1	Observable prices in active markets for identical assets and liabilities.
Level 2	Observable inputs other than quoted prices in active markets for identical assets and liabilities.
Level 3	Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets and liabilities.

Recurring Fair Value Measurements

At August 31, 2015, our financial assets and liabilities measured at fair value on a recurring basis were as follows:

(in thousands)	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Totals
Assets				
Derivative contracts (1)	$ -	$ 11	$ -	$ 11
Total assets	$ -	$ 11	$ -	$ 11
Liabilities				
Derivative contracts (1)	$ -	$ 22,112	$ -	$ 22,112
Contingent consideration obligations (2)	-	-	3,979	3,979
Total liabilities	$ -	$ 22,112	$ 3,979	$ 26,091

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At May 31, 2015, our financial assets and liabilities measured at fair value on a recurring basis were as follows:

(in thousands)	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Totals
Assets				
Derivative contracts (1)	$ -	$ 171	$ -	$ 171
Total assets	$ -	$ 171	$ -	$ 171
Liabilities				
Derivative contracts (1)	$ -	$ 22,131	$ -	$ 22,131
Contingent consideration obligation (2)	-	-	3,979	3,979
Total liabilities	$ -	$ 22,131	$ 3,979	$ 26,110

(1) The fair value of our derivative contracts is based on the present value of the expected future cash flows considering the risks involved, including non-performance risk, and using discount rates appropriate for the respective maturities. Market observable, Level 2 inputs are used to determine the present value of the expected future cash flows. Refer to Note N Derivative Instruments and Hedging Activities for additional information regarding our use of derivative instruments.

(2) The fair value of the contingent consideration obligation is determined using a probability weighted cash flow approach based on management s projections of future cash flows of the acquired business. The fair value measurement was based on Level 3 inputs not observable in the market.

Non-Recurring Fair Value Measurements

At August 31, 2015, our financial assets and liabilities measured at fair value on a non-recurring basis were as follows:

(in thousands)	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Totals
Assets				
Long-lived assets held and used (1)	$ -	$ 1,059	$ -	$ 1,059
Total assets	$ -	$ 1,059	$ -	$ 1,059

(1) During the first quarter of fiscal 2016, management reviewed certain long-lived assets of its Engineered Cabs facility in Florence, South Carolina, for impairment. In accordance with the applicable accounting guidance, long-lived assets with a carrying value of $4,059,000 were written down to their estimated fair value of $1,059,000 resulting in an impairment charge of $3,000,000 during the three months ended August 31, 2015. Comparable market transactions were used to measure fair value. Refer to NOTE C Impairment of Long-Lived Assets for additional information.

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At May 31, 2015, our assets measured at fair value on a non-recurring basis were categorized as follows:

(in thousands)	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Totals
Assets				
Long-lived assets held and used (1)	$ -	$ -	$ 12,403	$ 12,403
Total assets	$ -	$ -	$ 12,403	$ 12,403

(1) During the fourth quarter of fiscal 2015, management reviewed certain intangible assets related to our CNG fuel systems joint venture, dHybrid, for impairment. In accordance with the applicable accounting guidance, the intangible assets were written down to their fair value of $600,000, resulting in an impairment charge of $2,344,000. The key assumptions that drove the fair value calculation were projected cash flows and the discount rate.

During the third quarter of fiscal 2015, the Company concluded that an interim impairment test of the goodwill of its Engineered Cabs operating segment was necessary. Prior to conducting the goodwill impairment test, the Company first evaluated the other long-lived assets of the Engineered Cabs operating segment for recoverability. Recoverability was tested using future cash flow projections based on management s long-range estimates of market conditions. The sum of the undiscounted future cash flows for the customer relationship intangible asset and the property, plant and equipment of the Florence, South Carolina facility were less than their respective carrying values. As a result, these assets were written down to their respective fair values of $2,000,000 and $9,803,000. The fair value measurements were based on Level 3 inputs not observable in the market. The key assumptions that drove the fair value calculations were projected cash flows and the discount rate.

The fair value of non-derivative financial instruments included in the carrying amounts of cash and cash equivalents, receivables, notes receivable, income taxes receivable, other assets, accounts payable, short-term borrowings, accrued compensation, contributions to employee benefit plans and related taxes, other accrued items, income taxes payable and other liabilities approximate carrying value due to their short-term nature. The fair value of long-term debt, including current maturities, based upon models utilizing market observable (Level 2) inputs and credit risk, was $596,651,000 and $610,028,000 at August 31, 2015 and May 31, 2015, respectively. The carrying amount of long-term debt, including current maturities, was $581,747,000 and $580,193,000 at August 31, 2015 and May 31, 2015, respectively.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

Selected statements contained in this Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations constitute forward-looking statements as that term is used in the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based, in whole or in part, on management s beliefs, estimates, assumptions and currently available information. For a more detailed discussion of what constitutes a forward-looking statement and of some of the factors that could cause actual results to differ materially from such forward-looking statements, please refer to the Safe Harbor Statement in the beginning of this Quarterly Report on Form 10-Q and Part I - Item 1A. - Risk Factors of our Annual Report on Form 10-K for the fiscal year ended May 31, 2015.

Introduction

The following discussion and analysis of market and industry trends, business developments, and the results of operations and financial position of Worthington Industries, Inc., together with its subsidiaries (collectively, we, our, Worthington, or our Company), should be read conjunction with our consolidated financial statements and notes thereto included in Item 1. Financial Statements of this Quarterly Report on Form 10-Q. Our Annual Report on Form 10-K for the fiscal year ended May 31, 2015 (fiscal 2015) includes additional information about Worthington, our operations and our consolidated financial position and should be read in conjunction with this Quarterly Report on Form 10-Q.

As of August 31, 2015, excluding our joint ventures, we operated 33 manufacturing facilities worldwide, principally in three operating segments, which correspond with our reportable business segments: Steel Processing, Pressure Cylinders and Engineered Cabs. Our remaining operating segments, which do not meet the applicable aggregation criteria or quantitative thresholds for separate disclosure, are combined and reported in the Other category. These include Construction Services and Worthington Energy Innovations (WEI). The Company is in the process of exiting the businesses within Construction Services.

We also held equity positions in 13 active joint ventures, which operated 51 manufacturing facilities worldwide, as of August 31, 2015. Six of these joint ventures are consolidated with the equity owned by the other joint venture member(s) shown as noncontrolling interests in our consolidated balance sheets, and the other joint venture member(s) portion of net earnings and other comprehensive income shown as net earnings or comprehensive income attributable to noncontrolling interests in our consolidated statements of earnings and consolidated statements of comprehensive income, respectively. The remaining seven of these joint ventures are accounted for using the equity method.

Overview

The Company generated solid earnings during the first quarter of fiscal 2016 despite challenging market conditions resulting from declining steel and oil prices. Inventory holding losses in Steel Processing and lower volume in the oil and gas equipment business in Pressure Cylinders weighed on earnings; however, lower overall manufacturing costs and improved operations in the industrial gas and consumer product end markets in Pressure Cylinders helped to offset the impact. Demand remained steady in most of our key end markets, with the exception of the oil and gas equipment, construction and agriculture end markets. The Company continues to take action to reduce the cost structure of certain facilities serving these markets in order to remain cash flow positive. During the current quarter, the Company announced an additional workforce reduction at three of its five oil and gas equipment facilities. The previously announced closure of the Company s Engineered Cabs facility in Florence, South Carolina, remains on track, as the Company ceased production at the facility on September 30, 2015, and is in the process of transferring certain business to the Engineered Cabs facility in Greeneville, Tennessee.

Equity in net income of unconsolidated affiliates (equity income) was down 5% from the prior year quarter driven by $1.7 million of product development expenses related to the alternative fuels business and lower earnings at Serviacero, which was negatively impacted by lower steel prices. Record earnings at WAVE and higher contributions from ClarkDietrich, Samuel and ArtiFlex partially offset the overall decrease in equity income. We received cash distributions of $21.1 million from our unconsolidated affiliates during the first quarter of fiscal 2016.

Recent Business Developments

During the quarter, the Company repurchased a total of 1,000,000 common shares for $27.6 million at an average price of $27.58.

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On September 23, 2015, the board of directors declared a quarterly dividend of $0.19 per share payable on December 29, 2015 to shareholders of record on December 15, 2015.

Market & Industry Overview

We sell our products and services to a diverse customer base and a broad range of end markets. The breakdown of our net sales by end market for the first three months of each of fiscal 2016 and fiscal 2015 is illustrated in the following chart:

The automotive industry is one of the largest consumers of flat-rolled steel, and thus the largest end market for our Steel Processing operating segment. Approximately 60% of the net sales of our Steel Processing operating segment are to the automotive market. North American vehicle production, primarily by Chrysler, Ford and General Motors (the Detroit Three automakers), has a considerable impact on the activity within this operating segment. The majority of the net sales of four of our unconsolidated joint ventures are also to the automotive end market.

Approximately 10% of the net sales of our Steel Processing operating segment, 60% of the net sales of our Engineered Cabs operating segment and substantially all of the net sales of our Construction Services operating segment are to the construction market. The construction market is also the predominant end market for two of our unconsolidated joint ventures: WAVE and ClarkDietrich. While the market price of steel significantly impacts these businesses, there are other key indicators that are meaningful in analyzing construction market demand, including U.S. gross domestic product (GDP), the Dodge Index of construction contracts and, in the case of ClarkDietrich, trends in the relative price of framing lumber and steel.

Substantially all of the net sales of our Pressure Cylinders operating segment, and approximately 30% and 40% of the net sales of our Steel Processing and Engineered Cabs operating segments, respectively, are to other markets such as consumer products, industrial, lawn and garden, agriculture, oil and gas equipment, heavy truck, mining, forestry and appliance. Given the many different products that make up these net sales and the wide variety of end markets, it is very difficult to detail the key market indicators that drive this portion of our business. However, we believe that the trend in U.S. GDP growth is a good economic indicator for analyzing these operating segments.

We use the following information to monitor our costs and demand in our major end markets:

	Three Months Ended August 31,		
	2015	**2014**	**Inc / (Dec)**
U.S. GDP (% growth year-over-year) [1]	1.4%	2.8%	-1.4%
Hot-Rolled Steel ($ per ton) [2]	$ 461	$ 671	($ 210)
Detroit Three Auto Build (000 s vehicles)[3]	2,355	2,238	117
No. America Auto Build (000 s vehicles)[3]	4,446	4,172	274
Zinc ($ per pound) [4]	$ 0.88	$ 0.99	($ 0.11)
Natural Gas ($ per mcf) [5]	$ 2.78	$ 4.61	($ 1.83)
On-Highway Diesel Fuel Prices ($ per gallon) [6]	$ 2.75	$ 3.88	($ 1.13)

[1] 2014 figures based on revised actuals [2] CRU Hot-Rolled Index; period average [3] IHS Global [4] LME Zinc; period average [5] NYMEX Henry Hub Natural Gas; period average [6] Energy Information Administration; period average

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U.S. GDP growth rate trends are generally indicative of the strength in demand and, in many cases, pricing for our products. A year-over-year increase in U.S. GDP growth rates is indicative of a stronger economy, which generally increases demand and pricing for our products. Conversely, decreasing U.S. GDP growth rates generally indicate a weaker economy. Changes in U.S. GDP growth rates can also signal changes in conversion costs related to production and in selling, general and administrative (SG&A) expense.

The market price of hot-rolled steel is one of the most significant factors impacting our selling prices and operating results. When steel prices fall we typically have higher-priced material flowing through cost of goods sold, while selling prices compress to what the market will bear, negatively impacting our results. On the other hand, in a rising price environment, our results are generally favorably impacted, as lower-priced material purchased in previous periods flows through cost of goods sold, while our selling prices increase at a faster pace to cover current replacement costs.

The following table presents the average quarterly market price per ton of hot-rolled steel during fiscal 2016, fiscal 2015 and fiscal 2014:

(Dollars per ton [1])

	Fiscal Year		
	2016	**2015**	**2014**
1st Quarter	$ 461	$ 671	$ 627
2nd Quarter	N/A	$ 651	$ 651
3rd Quarter	N/A	$ 578	$ 669
4th Quarter	N/A	$ 464	$ 655
Annual Avg.	N/A	$ 591	$ 651

[1] CRU Hot-Rolled Index, period average

No single customer contributed more than 10% of our consolidated net sales during the first quarter of fiscal 2016. While our automotive business is largely driven by the production schedules of the Detroit Three automakers, our customer base is much broader and includes other domestic manufacturers and many of their suppliers. During the first quarter of fiscal 2016, overall vehicle production for the Detroit Three automakers was up 5% and North American vehicle production as a whole increased 7%.

Certain other commodities, such as zinc, natural gas and diesel fuel, represent a significant portion of our cost of goods sold, both directly through our plant operations and indirectly through transportation and freight expense.

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Results of Operations

First Quarter - Fiscal 2016 Compared to Fiscal 2015

Consolidated Operations

The following table presents consolidated operating results for the periods indicated:

	Three Months Ended August 31,				
(Dollars in millions)	**2015**	**% of Net sales**	**2014**	**% of Net sales**	**Increase/ (Decrease)**
Net sales	$ 758.1	100.0%	$ 862.4	100.0%	$ (104.3)
Cost of goods sold	645.1	85.1%	732.9	85.0%	(87.8)
Gross margin	113.0	14.9%	129.5	15.0%	(16.5)
Selling, general and administrative expense	75.9	10.0%	75.3	8.7%	0.6
Impairment of long-lived assets	3.0	0.4%	1.9	0.2%	1.1
Restructuring and other expense	3.1	0.4%	0.1	0.0%	3.0
Operating income	31.0	4.1%	52.2	6.1%	(21.2)
Miscellaneous income (expense)	(0.6)	-0.1%	0.3	0.0%	(0.9)
Interest expense	(7.9)	-1.0%	(9.5)	-1.1%	1.6
Equity in net income of unconsolidated affiliates	26.6	3.5%	27.9	3.2%	(1.3)
Income tax expense	(14.7)	-1.9%	(22.1)	-2.6%	7.4
Net earnings	34.4	4.5%	48.8	5.7%	(14.4)
Net earnings attributable to noncontrolling interests	3.0	0.4%	4.6	0.5%	1.6
Net earnings attributable to controlling interest	$ 31.4	4.1%	$ 44.2	5.1%	$ (12.8)

Net earnings attributable to controlling interest for the three months ended August 31, 2015 decreased $12.8 million from the comparable period in the prior year. Net sales and operating highlights were as follows:

Net sales decreased $104.3 million from the comparable period in the prior year. The decrease was driven by lower volume in all business segments, which reduced net sales by $79.4 million, combined with lower average selling prices in Steel Processing driven by the decline in the market price of steel.

Gross margin decreased $16.5 million from the comparable period in the prior year on lower volume and the unfavorable impact of inventory holding losses in Steel Processing in the current period compared to gains in the prior year period. Lower manufacturing expenses partially offset the overall decrease in gross margin.

SG&A expense increased slightly over the comparable prior year period to $75.9 million as the impact of acquisitions was partially offset by lower profit sharing and bonus expense.

Impairment charges of $3.0 million in the current period related to the pending closure of the Engineered Cabs facility in Florence, South Carolina. Impairment charges in the comparable prior year period related to the Company s stainless steel business, Precision Specialty Metals, Inc. (PSM). For additional information, refer to Item 1. Financial Statements Notes to Consolidated Financial

Statements NOTE C Impairment of Long-Lived Assets of this Quarterly Report on Form 10-Q.

Restructuring and other expense of $3.1 million in the current period consisted primarily of accruals for employee severance costs related to the pending closure of the Florence facility in Engineered Cabs ($1.9 million) and the recently announced workforce reductions in our oil and gas equipment businesses ($690,000).

Interest expense of $7.9 million was $1.6 million lower than the comparable period in the prior year. The decrease was driven by lower average debt levels.

Equity income decreased $1.3 million from the comparable period in the prior year. The decrease was driven by $1.7 million of product development expenses related to the alternative fuels business and lower earnings at Serviacero,

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which was negatively impacted by lower steel prices. Record earnings at WAVE and higher contributions from ClarkDietrich, Samuel and ArtiFlex partially offset the overall decrease in equity income. For additional financial information regarding our unconsolidated affiliates, refer to Item 1. Financial Statements Notes to Consolidated Financial Statements NOTE B Investments in Unconsolidated Affiliates of this Quarterly Report on Form 10-Q.

Income tax expense decreased $7.4 million from the comparable period in the prior year due primarily to lower earnings. The current quarter expense of $14.7 million was calculated using an estimated annual effective income tax rate of 31.8% versus 32.8% in the prior year quarter. Refer to Item 1. Financial Statements Notes to Consolidated Financial Statements NOTE K Income Taxes of this Quarterly Report on Form 10-Q for more information on our tax rates.

Segment Operations

Steel Processing

The following table presents a summary of operating results for our Steel Processing operating segment for the periods indicated:

	Three Months Ended August 31,				
(Dollars in millions)	**2015**	**% of Net sales**	**2014**	**% of Net sales**	**Increase/ (Decrease)**
Net sales	$ 490.8	100.0%	$ 552.3	100.0%	$ (61.5)
Cost of goods sold	433.8	88.4%	482.6	87.4%	(48.8)
Gross margin	57.0	11.6%	69.7	12.6%	(12.7)
Selling, general and administrative expense	32.9	6.7%	31.9	5.8%	1.0
Impairment of long-lived assets	-	0.0%	1.9	0.3%	(1.9)
Restructuring and other expense	0.5	0.1%	-	0.0%	0.5
Operating income	$ 23.6	4.8%	$ 35.9	6.5%	$ (12.3)
Material cost	$ 348.2		$ 394.9		$ (46.7)
Tons shipped (in thousands)	866		905		(39)

Net sales and operating highlights were as follows:

Net sales decreased $61.5 million from the comparable period in the prior year. Declining steel prices led to lower average selling prices, which reduced net sales by $41.8 million. Volume also declined in the current period reducing net sales by an additional $19.7 million as lower tolling volume more than offset contributions from the recent acquisition of Rome Strip Steel. The mix of direct versus toll tons processed was 63% to 37% compared to 60% to 40% in the first quarter of fiscal 2015.

Operating income decreased $12.3 million from the comparable period in the prior year. The decrease was driven primarily by the unfavorable impact of inventory holding losses in the current period compared to inventory holding gains in the prior year period. Restructuring and other expense in the current period consisted of severance accruals related primarily to the closure of PSM.

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Pressure Cylinders

The following table presents a summary of operating results for our Pressure Cylinders operating segment for the periods indicated:

	Three Months Ended August 31,				
(Dollars in millions)	**2015**	**% of Net sales**	**2014**	**% of Net sales**	**Increase/ (Decrease)**
Net sales	$ 224.4	100.0%	$ 249.0	100.0%	$ (24.6)
Cost of goods sold	170.0	75.8%	194.4	78.1%	(24.4)
Gross margin	54.4	24.2%	54.6	21.9%	(0.2)
Selling, general and administrative expense	36.9	16.4%	35.0	14.1%	1.9
Restructuring and other expense	0.7	0.3%	-	0.0%	0.7
Operating income	$ 16.8	7.5%	$ 19.6	7.9%	$ (2.8)
Material cost	$ 99.1		$ 118.4		$ (19.3)
Net sales by principal class of products:					
Consumer Products	$ 55.0		$ 55.6		$ (0.6)
Industrial Products	105.1		109.1		(4.0)
Alternative Fuels	24.8		21.8		3.0
Oil and Gas Equipment	32.9		57.3		(24.4)
Cryogenics	6.6		5.2		1.4
Total Pressure Cylinders	$ 224.4		$ 249.0		$ (24.6)
Units shipped by principal class of products:					
Consumer Products	11,977,945		12,346,630		(368,685)
Industrial Products	7,147,952		7,916,492		(768,540)
Alternative Fuels	91,956		104,089		(12,133)
Oil and Gas Equipment	1,320		2,987		(1,667)
Cryogenics	237		187		50
Total Pressure Cylinders	19,219,410		20,370,385		(1,150,975)

Net sales and operating highlights were as follows:

Net sales decreased $24.6 million from the comparable period in the prior year on lower volume, particularly in the oil and gas equipment businesses.

Operating income decreased $2.8 million from the comparable period in the prior year as declines in oil and gas equipment more than offset improvements in the industrial gas and consumer products businesses resulting from lower manufacturing costs and an improved product mix. Restructuring expense in the current period consisted of an accrual for employee severance costs related to the recently announced workforce reductions in our oil and gas equipment businesses.

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Engineered Cabs

The following table presents a summary of operating results for our Engineered Cabs operating segment for the periods indicated:

	Three Months Ended August 31,				
(Dollars in millions)	**2015**	**% of Net sales**	**2014**	**% of Net sales**	**Increase/ (Decrease)**
Net sales	$ 38.6	100.0%	$ 49.6	100.0%	$ (11.0)
Cost of goods sold	37.6	97.4%	44.9	90.5%	(7.3)
Gross margin	1.0	2.6%	4.7	9.5%	(3.7)
Selling, general and administrative expense	5.4	14.0%	6.8	13.7%	(1.4)
Impairment of long-lived assets	3.0	7.8%	-	0.0%	3.0
Restructuring and other expense	1.9	4.9%	-	0.0%	1.9
Operating loss	$ (9.3)	-24.1%	$ (2.1)	-4.2%	$ (7.2)
Material cost	$ 18.0		$ 22.0		$ (4.0)

Net sales and operating highlights were as follows:

Net sales decreased $11.0 million from the comparable period in the prior year due to the January 2015 sale of the assets of Advanced Component Technologies, Inc. and lower volume in the construction and agriculture end markets.

Operating loss increased $7.2 million due to higher impairment and restructuring charges and the unfavorable impact of lower volume. Impairment and restructuring charges totaled $4.9 million in the current period and related to the previously announced closure of the Engineered Cabs facility in Florence, South Carolina.

Other

The Other category includes the Construction Services and WEI operating segments, which do not meet the quantitative thresholds for separate disclosure. Certain expense items not allocated to our operating segments are also included in the Other category. The following table presents a summary of operating results for the Other category for the periods indicated:

	Three Months Ended August 31,				
(Dollars in millions)	**2015**	**% of Net sales**	**2014**	**% of Net sales**	**Increase/ (Decrease)**
Net sales	$ 4.3	100.0%	$ 11.6	100.0%	$ (7.3)
Cost of goods sold	3.7	86.0%	11.1	95.7%	(7.4)
Gross margin	0.6	14.0%	0.5	4.3%	0.1
Selling, general and administrative expense	0.8	18.6%	1.5	12.9%	(0.7)
Restructuring and other expense	-	0.0%	0.1	0.9%	(0.1)
Operating loss	$ (0.2)	-4.7%	$ (1.1)	-9.5%	$ 0.9

Net sales and operating highlights were as follows:

Net sales decreased $7.3 million from the comparable period in the prior year on lower volume in Construction Services, which the Company is exiting.

Operating loss of $0.2 million in the current period was driven primarily by losses within Construction Services.

Liquidity and Capital Resources

During the three months ended August 31, 2015, we generated $137.8 million of cash from operating activities, invested $38.5 million in property, plant and equipment and paid dividends of $11.6 million on our common shares.

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Additionally, we paid $27.6 million to repurchase 1,000,000 of our common shares. The following table summarizes our consolidated cash flows for the three months ended August 31, 2015 and 2014:

	Three Months Ended August 31,	
(in millions)	**2015**	**2014**
Net cash provided by operating activities	$ 137.8	$ 54.5
Net cash used by investing activities	(40.1)	(69.0)
Net cash used by financing activities	(110.0)	(28.7)
Decrease in cash and cash equivalents	(12.3)	(43.2)
Cash and cash equivalents at beginning of period	31.1	190.1
Cash and cash equivalents at end of period	$ 18.8	$ 146.9

We believe we have access to adequate resources to meet our needs for normal operating costs, mandatory capital expenditures and debt redemptions, dividend payments and working capital for our existing businesses. These resources include cash and cash equivalents, cash provided by operating activities and unused lines of credit. We also believe that we have adequate access to the financial markets to allow us to be in a position to sell long-term debt or equity securities. However, uncertainty and volatility in the financial markets may impact our ability to access capital and the terms under which we can do so.

The cash and cash equivalents balance at August 31, 2015 included $4.4 million of cash held by subsidiaries outside of the United States that the Company intends to indefinitely reinvest. Although the majority of this cash is available for repatriation, bringing the money into the United States could trigger federal, state and local income tax obligations. We do not have any intentions to repatriate this cash.

Operating Activities

Our business is cyclical and cash flows from operating activities may fluctuate during the year and from year to year due to economic conditions. We rely on cash and short-term borrowings to meet cyclical increases in working capital needs. These needs generally rise during periods of increased economic activity or increasing raw material prices due to higher levels of inventory and accounts receivable. During economic slowdowns, or periods of decreasing raw material costs, working capital needs generally decrease as a result of the reduction of inventories and accounts receivable.

Net cash provided by operating activities was $137.8 million during the three months ended August 31, 2015 compared to $54.5 million in the comparable period of fiscal 2015. The increase was driven primarily by declining working capital levels as a result of lower steel prices.

Investing Activities

Net cash used by investing activities was $40.1 million during the three months ended August 31, 2015 compared to $69.0 million in the prior year period. The decrease from the prior year period was driven primarily by the absence of acquisitions partially offset by higher capital expenditures. There were no acquisitions completed in the first quarter of fiscal 2016; however, in the comparable period in the prior year, the Company spent a combined $36.6 million, net of cash acquired, for the net assets of Midstream Equipment Fabrication LLC and James Russell Engineering Works, Inc.

Investment activities are largely discretionary, and future investment activities could be reduced significantly, or eliminated, as economic conditions warrant. We assess acquisition opportunities as they arise, and such opportunities may require additional financing. There can be no assurance, however, that any such opportunities will arise, that any such acquisitions will be consummated, or that any needed additional financing will be available on satisfactory terms when required.

Financing Activities

Net cash used by financing activities was $110.0 million during the three months ended August 31, 2015 compared to $28.7 million in the prior year period. Short-term borrowings declined $68.5 million during the first quarter of fiscal 2016 as the $60.0 million outstanding under our

revolving trade accounts receivable securitization facility (the AR Facility) at May 31, 2015, was paid in full. Additionally, we paid $27.6 million to repurchase 1,000,000 of our common shares and paid dividends of $11.6 million on our common shares.

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As of August 31, 2015, we were in compliance with our short-term and long-term debt covenants. These debt agreements do not include credit rating triggers or material adverse change provisions. Our credit ratings at August 31, 2015 were unchanged from those reported as of May 31, 2015.

Common shares - The Board declared a quarterly dividend of $0.19 per common share for the first quarter of fiscal 2016 compared to $0.18 per common share for the first quarter of fiscal 2015. Dividends paid on our common shares totaled $11.6 million during the three months ended August 31, 2015, compared to $10.1 million in the prior year period. On September 23, 2015, the Board declared a quarterly dividend of $0.19 per common share payable on December 29, 2015 to shareholders of record on December 15, 2015.

On June 25, 2014, the Board authorized the repurchase of up to 10,000,000 of our outstanding common shares. A total of 3,453,855 common shares have been repurchased under this authorization, including 1,000,000 during the first quarter of fiscal 2016, leaving 6,546,145 common shares available for repurchase.

The common shares available for repurchase under this authorization may be purchased from time to time, with consideration given to the market price of the common shares, the nature of other investment opportunities, cash flows from operations, general economic conditions and other relevant considerations. Repurchases may be made on the open market or through privately negotiated transactions.

Dividend Policy

We currently have no material contractual or regulatory restrictions on the payment of dividends. Dividends are declared at the discretion of the Board. The Board reviews the dividend quarterly and establishes the dividend rate based upon our consolidated financial condition, results of operations, capital requirements, current and projected cash flows, business prospects and other relevant factors. While we have paid a dividend every quarter since becoming a public company in 1968, there is no guarantee that payments will continue in the future.

Contractual Cash Obligations and Other Commercial Commitments

Our contractual cash obligations and other commercial commitments have not changed significantly from those disclosed in Part II Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Contractual Cash Obligations and Other Commercial Commitments of our 2015 Form 10-K, other than the changes in borrowings, as described in Part I Item 1. Financial Statements - NOTE G Debt and Receivables Securitization of this Quarterly Report on Form 10-Q.

Off-Balance Sheet Arrangements

We do not have guarantees or other off-balance sheet financing arrangements that we believe are reasonably likely to have a material current or future effect on our consolidated financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources. However, as of August 31, 2015, we were party to an operating lease for an aircraft in which we have guaranteed a residual value at the termination of the lease. The maximum obligation under the terms of this guarantee was approximately $11.4 million at August 31, 2015. We have also guaranteed the repayment of a term loan entered into by our unconsolidated affiliate, ArtiFlex, which had $1.3 million outstanding at August 31, 2015. In addition, we had in place approximately $16.2 million of outstanding letters of credit at August 31, 2015. These letters of credit were issued to third-party service providers and had no amounts drawn against them at August 31, 2015. Based on current facts and circumstances, we have estimated the likelihood of payment pursuant to these guarantees and determined that the fair value of our obligation under each guarantee based on those likely outcomes is not material.

Recently Issued Accounting Standards

In May 2014, amended accounting guidance was issued that replaces most existing revenue recognition guidance under U.S. GAAP. The amended guidance requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The amended guidance is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Early application is not permitted. We are in the process of evaluating the effect this guidance will have on our consolidated financial position and results of operations. The amended guidance permits the use of either the retrospective or cumulative effect transition method. We have not selected a transition method nor have we determined the effect of the amended guidance on our ongoing financial reporting.

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In July 2015, amended accounting guidance was issued regarding the measurement of inventory. The amended guidance requires that inventory accounted for under the first-in, first-out (FIFO) or average cost methods be measured at the lower of cost and net realizable value, where net realizable value represents the estimated selling price of inventory in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The amended guidance has no impact on inventory accounted for under the last-in, first-out (LIFO) or retail inventory methods. For public business entities, the amended guidance is effective prospectively for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early application is permitted as of the beginning of an interim or annual reporting period. We are in the process of evaluating the effect this guidance will have on our consolidated financial position and results of operations, and we have not determined the effect of the amended guidance on our ongoing financial reporting.

Critical Accounting Policies

The discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting periods. We continually evaluate our estimates, including those related to our valuation of receivables, intangible assets, accrued liabilities, income and other tax accruals, and contingencies and litigation. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. These results form the basis for making judgments about the carrying values of assets and liabilities that are not readily obtained from other sources. Critical accounting policies are defined as those that require our significant judgments and involve uncertainties that could potentially result in materially different results under different assumptions and conditions. Although actual results historically have not deviated significantly from those determined using our estimates, our financial position or results of operations could be materially different if we were to report under different conditions or to use different assumptions in the application of such policies. Our critical accounting policies have not significantly changed from those discussed in Part II Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies of our 2015 Form 10-K.

We review our receivables on an ongoing basis to ensure they are properly valued. Based on this review, we believe our reserve for doubtful accounts is adequate. However, if the economic environment and market conditions deteriorate, particularly in the automotive and construction markets where our exposure is greatest, additional reserves may be required. We recognize revenue upon transfer of title and risk of loss provided evidence of an arrangement exists, pricing is fixed and determinable, and the ability to collect is probable. In circumstances where the collection of payment is not probable at the time of shipment, we defer recognition of revenue until payment is collected.

We review the carrying value of our long-lived assets, including intangible assets with finite useful lives, for impairment whenever events or changes in circumstances indicate that the carrying value of an asset or asset group may not be recoverable.

Impairment testing involves a comparison of the sum of the undiscounted future cash flows of the asset or asset group to its respective carrying amount. If the sum of the undiscounted future cash flows exceeds the carrying amount, then no impairment exists. If the carrying amount exceeds the sum of the undiscounted future cash flows, then a second step is performed to determine the amount of impairment, which would be recorded as an impairment charge in our consolidated statements of earnings.

On March 24, 2015, the Company announced its decision to close its Engineered Cabs facility in Florence, South Carolina. During the first quarter of fiscal 2016, management finalized its plan to close the facility and transfer the majority of the business to its Engineered Cabs facility in Greeneville, Tennessee. Certain machinery and equipment will be transferred to the Greeneville facility to support higher volume and the remaining long-lived assets will be liquidated. For the assets to be liquidated, this represents a change in intended use. As a result, management evaluated the recoverability of these assets and determined that long-lived assets with a carrying value of $4.1 million were no longer recoverable and were in fact impaired. As a result, these long-lived assets were written down to their estimated fair value of $1.1 million resulting in an impairment charge of $3.0 million during the three months ended August 31, 2015. The Company ceased production at the Florence facility on September 30, 2015.

As a result of the substantial fall in oil prices, management determined that the long-lived assets related to its oil and gas equipment business in Pressure Cylinders might be impaired. However, the Company s estimate of the undiscounted future cash flows for each of its five oil and gas equipment facilities indicated that the carrying amounts were expected to be recovered.

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The estimated undiscounted future cash flows for each plant were significantly higher than their respective carrying values except for the Garden City, Kansas, location, which had total long-lived assets of $36.7 million at August 31, 2015. The estimated undiscounted future cash flows for this location exceeded book value by less than 5%. It is possible that in the future the estimate of undiscounted cash flows may change resulting in the need to write down these assets to fair value.

Goodwill and intangible assets with indefinite lives are not amortized, but instead are tested for impairment annually, during the fourth quarter, or more frequently if events or changes in circumstances indicate that impairment may be present. Application of goodwill impairment testing involves judgment, including but not limited to, the identification of reporting units and the estimation of the fair value of each reporting unit. A reporting unit is defined as an operating segment or one level below an operating segment. We test goodwill at the operating segment level as we have determined that the characteristics of the reporting units within each operating segment are similar and allow for their aggregation in accordance with the applicable accounting guidance.

The goodwill impairment test consists of comparing the fair value of each operating segment, determined using discounted cash flows, to each operating segment s respective carrying value. If the estimated fair value of an operating segment exceeds its carrying value, there is no impairment. If the carrying amount of the operating segment exceeds its estimated fair value, a goodwill impairment is indicated. The amount of the impairment is determined by comparing the fair value of the net assets of the operating segment, excluding goodwill, to its estimated fair value, with the difference representing the implied fair value of the goodwill. If the implied fair value of the goodwill is lower than its carrying value, the difference is recorded as an impairment charge in the applicable consolidated statement of earnings. We performed our annual impairment evaluation of goodwill and other indefinite-lived intangible assets during the fourth quarter of fiscal 2015 and concluded that the fair value of each reporting unit exceeded its carrying value; therefore, no impairment charges were recognized. Additionally, no impairment indicators were present with regard to our goodwill or intangible assets with indefinite useful lives during the three months ended August 31, 2015.

Item 3. - Quantitative and Qualitative Disclosures About Market Risk

Market risks have not changed significantly from those disclosed in Part II - Item 7A. Quantitative and Qualitative Disclosures About Market Risk of our 2015 Form 10-K.

Item 4. - Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures [as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)] that are designed to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Management, with the participation of our principal executive officer and our principal financial officer, performed an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q (the fiscal quarter ended August 31, 2015). Based on that evaluation, our principal executive officer and our principal financial officer have concluded that such disclosure controls and procedures were effective at a reasonable assurance level as of the end of the period covered by this Quarterly Report on Form 10-Q.

Changes in Internal Control Over Financial Reporting

During the fiscal quarter ended August 31, 2015, the Company implemented a new enterprise performance management system. This system was implemented to increase the overall efficiency of the consolidation and financial reporting processes and not in response to any deficiency or material weakness in internal control over financial reporting. While the Company has not completed the testing of the operating effectiveness of all key controls in the new system, we believe that effective internal control over financial reporting was maintained during and after the conversion. There were no other changes that occurred during the period covered by this Quarterly Report on Form 10-Q (the fiscal quarter ended August 31, 2015) in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. - Legal Proceedings

Various legal actions, which generally have arisen in the ordinary course of business, are pending against the Company. None of this pending litigation, individually or collectively, is expected to have a material adverse effect on our consolidated financial position, results of operations or cash flows.

Item 1A. Risk Factors

There are certain risks and uncertainties in our business that could cause our actual results to differ materially from those anticipated. In PART I Item 1A. Risk Factors of the Annual Report on Form 10-K of Worthington Industries, Inc. for the fiscal year ended May 31, 2015 (the 2015 Form 10-K), as filed with the Securities and Exchange Commission on July 30, 2015, and available at www.sec.gov or at www.worthingtonindustries.com, we included a detailed discussion of our risk factors. Our risk factors have not changed significantly from those disclosed in our 2015 Form 10-K. These risk factors should be read carefully in connection with evaluating our business and in connection with the forward-looking statements and other information contained in this Quarterly Report on Form 10-Q. Any of the risks described in our 2015 Form 10-K could materially affect our business, consolidated financial condition or future results and the actual outcome of matters as to which forward-looking statements are made. The risk factors described in our 2015 Form 10-K are not the only risks we face. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial, also may materially adversely affect our business, financial condition and/or future results.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

The following table provides information about purchases made by, or on behalf of, Worthington Industries, Inc. or any affiliated purchaser (as defined in Rule 10b-18(a) (3) under the Securities Exchange Act of 1934, as amended) of common shares of Worthington Industries, Inc. during each month of the fiscal quarter ended August 31, 2015:

Period	Total Number of Common Shares Purchased	Average Price Paid per Common Share	Total Number of Common Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Common Shares that May Yet Be Purchased Under the Plans or Programs (1)
June 1-30, 2015 (2)	70,408	$ 29.32	-	7,546,145
July 1-31, 2015	280,000	$ 27.97	280,000	7,266,145
August 1-31, 2015 (2)	726,212	$ 27.43	720,000	6,546,145
Total	1,076,620	$ 27.69	1,000,000	

(1) The number shown represents, as of the end of each period, the maximum number of common shares that could be purchased under the publicly announced repurchase authorization then in effect. On June 25, 2014, Worthington Industries, Inc. announced that the Board authorized the repurchase of up to 10,000,000 of Worthington Industries outstanding common shares. A total of 6,546,145 common shares were available under this repurchase authorization at August 31, 2015.

The common shares available for repurchase under this authorization may be purchased from time to time, with consideration given to the market price of the common shares, the nature of other investment opportunities, cash flows from operations, general economic conditions and other appropriate factors. Repurchases may be made on the open market or through privately negotiated transactions.

(2) Includes an aggregate of 70,408 and 6,212 common shares surrendered by employees in June 2015 and August 2015, respectively, to satisfy tax withholding obligations upon exercise of stock options and vesting of restricted common shares. These common shares were not counted against the share repurchase authorization in effect throughout the first quarter of fiscal 2016 and discussed in footnote (1) above.

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Item 3. Defaults Upon Senior Securities

Not applicable

Item 4. Mine Safety Disclosures

Not applicable

Item 5. Other Information

Not applicable

Item 6. Exhibits

4.1	Amendment No. 1 to Note Agreement, dated June 10, 2015, among Worthington Industries, Inc., on the one hand, and The Prudential Insurance Company of America, Pruco Life Insurance Company of New Jersey, Pruco Life Insurance Company, Prudential Arizona Reinsurance Universal Company, Prudential Annuities Life Assurance Corporation, The Prudential Life Assurance Company, Ltd. and The Gibraltar Life Insurance Co., Ltd., on the other hand (incorporated herein by reference to Exhibit 4.9 to the Annual Report on Form 10-K of Worthington Industries, Inc. for the fiscal year ended May 31, 2015 (SEC File No. 1-8399))
10.1	Summary of Annual Base Salaries Approved for Named Executive Officers of Worthington Industries, Inc. (effective September 2015) (incorporated herein by reference to Exhibit 10.69 to the Annual Report on Form 10-K of Worthington Industries, Inc. for the fiscal year ended May 31, 2015 (SEC File No. 1-8399))
10.2	Summary of Annual Cash Incentive Bonus Awards, Long-Term Performance Awards, Stock Options and Restricted Common Shares Granted in Fiscal 2016 for Named Executive Officers (incorporated herein by reference to Exhibit 10.74 to the Annual Report on Form 10-K of Worthington Industries, Inc. for the fiscal year ended May 31, 2015 (SEC File No. 1-8399))
31.1	Rule 13a - 14(a) / 15d - 14(a) Certifications (Principal Executive Officer) *
31.2	Rule 13a - 14(a) / 15d - 14(a) Certifications (Principal Financial Officer) *
32.1	Certifications of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
32.2	Certifications of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
101.INS	XBRL Instance Document #
101.SCH	XBRL Taxonomy Extension Schema Document #
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document #
101.LAB	XBRL Taxonomy Extension Label Linkbase Document #
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document #
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document #

* Filed herewith.

** Furnished herewith.

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Attached as Exhibit 101 to this Quarterly Report on Form 10-Q of Worthington Industries, Inc. are the following documents formatted in XBRL (Extensible Business Reporting Language):

(i) Consolidated Balance Sheets at August 31, 2015 and May 31, 2015;
(ii) Consolidated Statements of Earnings for the three months ended August 31, 2015 and August 31, 2014;
(iii) Consolidated Statements of Comprehensive Income for the three months ended August 31, 2015 and August 31, 2014;
(iv) Consolidated Statements of Cash Flows for the three months ended August 31, 2015 and August 31, 2014; and
(v) Notes to Consolidated Financial Statements.

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SIGNATURES

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

WORTHINGTON INDUSTRIES, INC.

Date: October 13, 2015

By: /s/ B. Andrew Rose
B. Andrew Rose,

Executive Vice President and Chief Financial Officer

(On behalf of the Registrant and as Principal

Financial Officer)

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