ARIES VENTURES INC Form 10KSB December 22, 2005

# 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 SEPTEMBER 30, 2005

000-14136

(Commission file number)

# **ARIES VENTURES INC.**

(Name of small business issuer in its charter)

Nevada (State of incorporation) 84-0987840 (IRS Employer Identification No.)

**3611 Valley Centre Drive, Suite 525 San Diego, California 92130** (Address of principal executive offices)

(858) 436-1000 (Issuer s telephone number)

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

None

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

#### Common Stock, \$0.01 par value per share

Check whether Aries Ventures Inc. (Aries) is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. O

Check whether Aries (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 Aries was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  $\circ$  Yes o 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 Aries 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.  $\acute{y}$ 

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

Aries revenues for its most recent fiscal year were \$0.

The aggregate market value of Aries common stock held by non-affiliates of Aries as of December 13, 2005 was approximately \$49,867,740 (based on the closing sale price of \$2.10 on December 13, 2005). For this purpose, all of Aries officers and directors and their affiliates were assumed to be affiliates of Aries.

Check whether Aries has filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Exchange Act after the distribution of securities under a plan confirmed by a court.  $\circ$  Yes o No

As of December 21, 2005, 29,249,801 shares of Aries 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 Aries definitive proxy statement for its Annual Meeting of Stockholders to be held in January 2006, to be filed no later than 120 days after the fiscal year end covered by this Form 10-KSB.

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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 will, should, could, historical fact. Words such as may, would, expects, plans, believes, anticipates, intends, estimates, 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 conduct and outcome of regulatory submissions and clinical trials;

the performance of Generx<sup>TM</sup> 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 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 product candidates;

our growth, expansion and acquisition 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 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;

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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-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 SEC.

#### PART I

### ITEM 1. DESCRIPTION OF BUSINESS

#### **Overview and Recent Events**

Aries Ventures Inc. was incorporated in Nevada on April 21, 2000 as a wholly-owned subsidiary of Casmyn Corp., a Colorado corporation, and merged with Casmyn Corp. on April 28, 2000, with Aries as the surviving corporation. As of September 30, 2005, Aries had no business operations and was focused on maintaining its corporate entity and seeking a new business opportunity.

On October 20, 2005, Aries completed a reverse merger (the Merger ) with privately held Cardium Therapeutics, Inc., a Delaware corporation, whereby a newly formed and wholly-owned subsidiary of Aries was merged with and into Cardium. As a result, Cardium became a wholly-owned subsidiary of Aries. At the time of the Merger, Aries had divested itself of all its assets and investments other than \$1.5 million in cash and had no outstanding contractual commitments.

We plan to hold a meeting of our stockholders in January 2006 to seek their approval, among other things, to merge Aries into Cardium, with Cardium as the surviving entity, for the purpose of effectively changing our state of incorporation from Nevada to Delaware, changing our name to Cardium Therapeutics, Inc. and more clearly reflecting our business plans and objectives following the Merger. Our common stock will continue to trade under the Aries Ventures name and ticker symbol until the completion of the merger of Aries into Cardium, provided such merger is approved by our stockholders, at which time our common stock would begin to trade under the Cardium Therapeutics name and with a new ticker symbol.

For financial reporting purposes, Cardium was the acquirer in the Merger. As a result, from and after the Merger, our fiscal year end will be December 31 (Cardium s fiscal year end) and the assets, liabilities and historical operations reflected in the financial statements in our financial reports will be those of Cardium, beginning with our Annual Report on Form 10-KSB for the fiscal year ending December 31, 2005 to be filed with the SEC no later than March 31, 2006. Since the Merger occurred in October 2005 and this report contains financial information for periods through September 30, 2005, the assets, liabilities and historical operations reflected in the financial statements in this report under Item 7 are still those of pre-Merger Aries.

Unless the context requires otherwise, all references in this report to the Company, Aries, we, our, and us refer to Aries Ventures Inc. and, a applicable, its wholly-owned subsidiary Cardium.

#### Cardium s Business

#### Overview

Cardium was incorporated in Delaware in December 2003 and is an interventional cardiology company focused on the late-stage clinical development and commercialization of DNA-based, myocardial-derived, growth factor therapeutics as potential treatments for coronary artery disease and heart attack. Upon the close of the Merger, Cardium acquired a portfolio of cardiovascular growth factor therapeutic assets from Schering AG (Germany) (Schering) and/or its affiliates for a purchase price of approximately \$4,000,000 (Schering Transaction). Since the Merger, Cardium has continued its business under the name Cardium Therapeutics, Inc. as a wholly-owned subsidiary of Aries. In addition to the Schering Transaction, Cardium plans to also seek to broaden and expand its product base and financial resources through other corporate development transactions intended to enhance stockholder value.

Cardium s initial primary focus will be the commercial development of cardiovascular-directed growth factor therapeutics for interventional cardiology applications based on the product portfolio acquired by Cardium from Schering, which products include Generx<sup>TM</sup> and Corgentin<sup>TM</sup>. Generx, based on myocardial-derived fibroblast growth factor 4 (mdFGF-4), is our lead product candidate and has advanced to Phase 2b/3 clinical studies. Generx is a non-surgical angiogenic therapy designed to be a one-time treatment with long-lasting therapeutic benefits for patients with recurrent angina due to coronary disease. Corgentin, a pre-clinical product candidate, is a next-generation therapeutic based on myocardial-derived insulin-like Growth Factor-I (mdIGF-I). Corgentin is being designed to be a one-time cardiomyocyte-directed treatment to promote the repair and restoration of damaged

cardiomyocytes and enhance cardiac function following a heart attack (acute myocardial infarction) through the beneficial cardiac effects of prolonged IGF-I protein expression.

In addition, Cardium has secured the rights to Genvascor<sup>TM</sup>, a pre-clinical, DNA-based, endothelial nitric oxide synthase (eNOS) therapeutic. Genvascor is being designed to induce production of nitric oxide and is directed at mediating the effects of multiple growth factors to enhance neovascularization and increased blood flow for the potential treatment of patients with critical limb ischemia due to advanced peripheral arterial occlusive disease (PAOD). We may elect to develop Genvascor alone or in collaboration with a development partner.

The following chart summarizes certain attributes of the above-described product candidates acquired in connection with the Schering Transaction:

Product	<b>Growth Factor</b>	Indication	Mechanism of Action
Generx	Fibroblast Growth Factor-4 (FGF-4)	Recurrent angina due to coronary disease	Promote and enhance the growth of collateral circulation in ischemic heart disease
Corgentin	Insulin-like Growth Factor-I (IGF-I)	Acute coronary syndrome following myocardial infarction	Improve recovery of injured myocardium and restore function following heart attack
Genvascor	Endothelial Nitric Oxide Synthase (eNOS)	Critical limb ischemia due to advanced peripheral arterial occlusive disease	Promote multiple vasculoprotective effects and mediate growth factors to enhance neovascularization and increased blood flow to the ischemic limb

**Business Strategy** 

The practical integration of pharmaceutical agents and medical devices, exemplified by the advent of drug-eluting stents, represents an important advancement in effective cardiovascular therapeutic innovation. Likewise, we believe that merging biologic therapy and medical device applications represents a new therapeutic product class, targeting the highly innovative and rapidly growing interventional cardiology market. Rather than simply directing drug therapy at alleviating clinical symptoms, DNA-based cardiovascular therapy attempts to leverage the body s own physiologic responsiveness to treat the underlying cardiac disease. Cardium seeks to advance the current standard of care for patients with cardiovascular disease through the development of directed therapy to enhance the body s natural healing process when used in concert with or, as a supplement to, existing vascular-directed or other therapies.

Building upon our core 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 basis. The key elements of our strategy are to:

Initiate a redesigned clinical development program for Generx, which would include a new clinical study (AGENT-5) targeted to patients with recurrent angina and, with positive clinical data, initiate a pivotal Phase 3 clinical study (AGENT-6);

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;

Seek to monetize the economic value of Cardium s product portfolio by establishing strategic collaborations at appropriate valuation inflection points; and

Seek to 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.

We recognize that the practical realities of cardiovascular drug development 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. In the future, we plan to aggressively seek access to other therapeutics and/or medical device opportunities, as well as medical-related technologies, to further strengthen and broaden our portfolio, and will consider the opportunistic acquisition of other companies having financial and development resources that offer the potential to enhance our near and long-term stockholder value.

#### Historical Background

In 1995, Christopher Reinhard, Cardium s Co-Founder, and both Cardium s and Aries Chairman, President and Chief Executive Officer, co-founded Collateral Therapeutics, Inc. (Collateral Therapeutics), a former Nasdaq listed public company, to commercialize medical discoveries and technology licensed from the University of California, San Diego related to the potential therapeutic application of methods of gene therapy to stimulate cardiac angiogenesis. In 1996, Collateral Therapeutics and Schering entered into a strategic research and development collaboration to commercially develop angiogenic gene therapy products based on Collateral Therapeutics technology platform, which included a portfolio of therapeutic genes, vectors and methods of gene therapy to enhance cardiac function. This research and development collaboration yielded two product candidates based on the human Fibroblast Growth Factor-4 gene (FGF-4) that entered clinical trials.

During the collaboration with Schering, Mr. Reinhard and other members of Collateral Therapeutics management team, several of whom have joined Cardium, successfully worked with Schering to promote Collateral Therapeutics lead product candidate through several human clinical trials that were principally funded and conducted by Schering and its United States affiliates, including Berlex Laboratories. In 2002, as a result of the success of the Collateral Therapeutics/Schering collaboration and following positive Phase 1/2 and Phase 2a clinical studies for Generx, Collateral Therapeutics was acquired by Schering for approximately \$160 million. This acquisition included all of Collateral Therapeutics intellectual property and assets, including the rights to the lead product candidate, Generx. After completion of the acquisition by Schering, Mr. Reinhard **continued as Chief Executive Officer of Collateral Therapeutics through December 2004.** 

Following the acquisition, Schering initiated a multi-center Phase 2b/3 clinical program that was designed to evaluate up to 1,000 patients in a U.S. study and a concurrent European study. However, although Phase 1/2 and subsequent Phase 2 clinical data were encouraging, Schering announced in January 2004 that an interim analysis of the Generx Phase 2b/3 (AGENT-3) U.S. clinical study suggested that the Phase 2b/3 (AGENT-3) study as designed appeared to not be sufficient to demonstrate efficacy and it elected to discontinue enrollment pending a review of the study. Schering also reported, however, that the study revealed no evidence of serious safety concerns. On June 15, 2004, Schering announced that it was terminating its cardiovascular research and development activities (including angiogenic DNA-based therapeutics and small molecule drugs) and refocusing on its core business areas. In November 2004, an internal retrospective subgroup analysis of the data from the AGENT-3 clinical study was completed by Schering and has provided positive efficacy insights and reconfirmed the positive safety data. As a result of this retrospective analysis, Cardium was formed to acquire Schering s portfolio of clinical and pre-clinical stage cardiovascular growth factor therapeutic assets, including exclusive rights to Generx.

Generx Clinical Studies

Generx has been evaluated in studies of 663 patients (including 450 Generx-treated patients and 213 controls) in four multi-center, double-blind, placebo-controlled clinical studies. These studies have been conducted at over 70 U.S., Canadian, European and South American medical centers.

Results from two multi-center, randomized, double-blind, placebo-controlled studies (Phase 1/2 and Phase 2), conducted by Schering in collaboration with Collateral Therapeutics, have provided important safety and preliminary efficacy information. Based on intracoronary administration to 450 patients, Generx appears to be safe and well tolerated with no significant adverse side effects. Results from the Phase 1/2 study (AGENT-1) demonstrated that, in patients whose baseline exercise treadmill tests (ETT) were equal to, or less than 10 minutes, Generx showed a significant improvement in ETT time compared to patients that received the placebo control. A Phase 2 study (AGENT-2), designed to assess enhancement of myocardial perfusion (blood flow to the heart) following intracoronary delivery of Generx in patients with documented reversible ischemia measured by stress

adenosine single-photon emission computed tomography (SPECT) imaging, demonstrated that Generx provided improvement in myocardial perfusion in patients with moderate to severe angina.

Positive data from AGENT-1 and AGENT-2 supported the advancement of the Generx development program into two large-scale Phase 2b/3 trials worldwide (AGENT-3 and AGENT-4), which were designed to enroll up to 1,000 patients at more than 100 medical centers in the U.S., Canada, South America and Europe. Based on an interim analysis of 307 patients in the U.S.-based AGENT-3 study, the clinical data further confirmed the product s positive safety profile and suggested improvements to study design in view of the level of placebo response observed among generally healthier patients. However, enrollment in the studies was stopped because, as designed, the studies were not considered sufficient to provide statistical evidence of efficacy. An independent Data Safety Monitoring Board monitored the studies and reported that there was no evidence of safety concerns. A detailed subgroup analysis of the AGENT-3 data confirmed that there were statistically significant improvements in the primary end-point (i.e. exercise treadmill testing or ETT) in the key patient populations. This subgroup analysis is believed to provide support for further clinical trial evaluation to demonstrate the safety and effectiveness of Generx in patients with myocardial ischemia and associated symptomatic recurrent angina.

The following chart summarizes the clinical development of Generx:

Date	Trial	Study Objective	No. of Patients	Clinical Results
1999	AGENT 1	First in Man U.S. Phase 1/2 Clinical Studies	79	Positive Safety & Preliminary Efficacy
2001	AGENT 2	Phase 2a Clinical Study Multi-Center, Randomized, Placebo-Controlled, U.S. Mechanism of Action Study Evaluation of Cardiac Perfusion	52	Positive Safety & Preliminary Efficacy, Positive Information About Mechanism of Action (Cardiac Perfusion)
2004	AGENT 3	Multi-Center, Randomized, Placebo-Controlled, U.S. Phase 2b/3 Clinical Study Evaluate Safety & Efficacy	416	Positive Safety, Efficacy Not Statistically Sufficient Based on Protocol Design
2004	AGENT 3 (Retrospective Subgroup Analysis)	Multi-Center, Randomized, Placebo-Controlled, U.S. Phase 2b/3 Clinical Study Evaluate Safety & Efficacy	416	Positive Safety and Statistically Significant Efficacy in Subgroup Patients (>55 years of age) with Severe Angina or Limited Exercise Capacity
2004	AGENT 4	Multi-Center, Randomized, Placebo-Controlled, Europe, Canada, South America Phase 2b/3 Clinical Study Evaluate Safety & Efficacy	116	Positive Safety, Efficacy Not Statistically Sufficient Based on Protocol Design
2006	Planned AGENT 5	Multi-Center, Randomized, Placebo-Controlled, U.S. Phase 2b/3 Clinical Study	TBD	Further Evaluate Safety, Explore Efficacy Using Modified Patient Population and Re-confirm Angiogenic Mechanism of Action (Cardiac Perfusion) Using Advanced Diagnostic Imaging

Comparative Anti-Anginal Therapeutic Approaches

During the past two decades several drugs have been approved by the United States Food and Drug Administration (FDA) for the management of chronic stable angina pectoris, including beta-blockers, nitrates and calcium channel blockers. These drugs were approved based upon improvement in total ETT time and, in general, have demonstrated placebo-corrected increases of approximately 20 to 50 seconds. However, no new class of medications to treat angina has been approved for over 15 years. Currently, fatty acid oxidation inhibitors such as Ranolazine are

being developed as a potential new alternative to or addition to existing therapies. The clinical trial

experience in AGENT-3 suggests that in patients with more severe angina, Generx, after a one-time administration, can produce sustained increases in total ETT time that are clinically meaningful when considered in the context of these available therapies. Most importantly, the effects of Generx have been demonstrated in patients who are already receiving one or more chronic anti-anginal medications.

Looking comparatively, the Ranolazine<sup>TM</sup> clinical trial data suggest that the magnitude of its effect is similar to the currently available drugs. For example, in the CARISA trial, Ranolazine achieved an approximately 24 second improvement in total ETT time over placebo at trough drug levels (as defined in the trial protocol). In addition to drug therapy, mechanical revascularization procedures such as percutaneous coronary intervention (PCI) and coronary artery bypass surgery graft (CABG) surgery are commonly employed interventional procedures used to manage patients with chronic angina. While there have been few published controlled clinical trials of PCI or CABG surgery that have collected ETT data, two studies that have directly compared PCI and CABG surgery using ETT have shown sustained improvements in total ETT time of approximately 90 to 114 seconds for PCI and 132 to 174 seconds for CABG surgery.

Study	Treatment Group	# Patients	Mean ETT Change in Seconds	p-Value
DNA-Based Angiogenic Therapy	Placebo	27	28.1 (11.5%)	
Generx [mdFGF-4] AGENT-3/4 Age > 55, Baseline	Generx 10e9 v.p. dosage	27	92.0 (38.3%)	0.03
ETT ≤ 300 Seconds @ Six Months	Generx 10e10 v.p. dosage	37	75.3 (31.2%)	0.02
Small Molecule Drug Ranolazine	Placebo	258	91.7 (21.9%)	
*CARISA Study(1) CV Therapeutics	Ranolazine 750 mg Ranolazine 1000 mg	272 261	115.4 (27.7%) 115.8 (27.9%)	0.03 0.03
Mechanical Revascularizations American Heart	Coronary Artery Bypass Surgery	46	132 (29.7%)	5.05
Journal(2)	PCI - Angioplasty	40	114 (23.5%)	
Mechanical Revascularizations ACIP Study(3)	Coronary Artery Bypass Surgery PCI - Angioplasty	78 92	174 (34.9%) 90 (19.4%)	

#### Comparative Clinical Data Based on Total Exercise Treadmill Time: Change from Baseline

\*CARISA data are least square means and other study data are arithmetic means.

1. Chaitman BR, Pepine CJ, Parker JO, Skopal J, Chumakova G, et al. Effects of ranolazine with atenolol, amlodipine, or diltiazem on exercise tolerance and angina frequency in patients with severe chronic angina: a randomized controlled trial. JAMA 2004;291(3):309-316.

2. Mulcahy D, Keegan J, Phadke K, Wright C, Sparrow J, Purcell H, Fox K. Effects of coronary artery bypass surgery and angioplasty on the total ischemic burden: a study of exercise testing and ambulatory ST segment monitoring. Am Heart J 1992;123(3):597-603.

3. Bourassa MG, Knatterud GL, Pepine CJ, Sopko G, Rogers WJ, et al. Asymptomatic Cardiac Ischemia Pilot (ACIP) Study. Improvement of cardiac ischemia at 1 year after PTCA and CABG. Circ 1995;92(9 Suppl):II1-7.

These data confirmed earlier studies and suggested that the treatment could benefit patients with more serious angina that typically occurs as a result of advanced coronary artery disease. This may allow targeting patients who have had previous interventions such as angioplasty or bypass surgery, but have recurrent angina despite drug therapy. Furthermore, based on this substantial human clinical experience with Generx, coupled with unique insights regarding a particularly responsive patient population for what is considered to be the key efficacy end-point, we believe that Generx has the potential to obtain approvable clinical data in a pivotal trial in the foreseeable

future and ahead of potential competition.

We plan to redesign Schering s Phase 2b/3 clinical study protocol and initiate AGENT-5, a new clinical study that would continue to evaluate Generx s safety, assess the appropriateness of our modified clinical protocol design and reconfirm the FGF-4 angiogenic mechanism of action (utilizing advanced diagnostic cardiac imaging techniques). With positive data we hope to obtain from AGENT-5, we plan to further build on Schering s six-year clinical development activities and advance forward with AGENT-6, a newly redesigned, Phase 3 pivotal study that would be structured and powered to serve as the basis for a regulatory submission seeking marketing approval from the FDA.

#### Generx Clinical Development Strategy

Since 1995, members of Cardium s management, during their employment with Collateral Therapeutics and Schering, have had considerable experience in accomplishing regulatory clearance in pre-clinical research, pre-clinical toxicology, manufacturing, distribution and global clinical development of Generx that should allow Cardium to begin its clinical development program in a more favorable position than most of its competitors. As part of the Schering Transaction, Cardium received from Schering an active IND in the United States, Canada and several European and South American countries, and information about manufacturing and analytical processes approved by the FDA and the European Regulatory Agency.

Cardium plans to initiate AGENT-5, a multi-center, randomized, double-blind, placebo-controlled study to prospectively evaluate the efficacy and safety of mdFGF-4 in the patient population identified as responders in the retrospective analysis of AGENT-3. This trial may begin enrollment in the second quarter of 2006, assuming the successful manufacture of clinical supplies and the initiation or reinitiation of clinical sites. Approximately fifteen clinical sites would be expected to participate in this AGENT-5 study.

Corgentin Pre-Clinical Development

Corgentin, a pre-clinical product candidate, is a next-generation DNA-based therapeutic based on myocardial derived insulin-like growth factor-I (mdIGF-I) that is being designed as a one-time cardiomyocyte-derived treatment to promote the repair and restoration of damaged cardiomyocytes and enhance cardiac function following a heart attack (acute myocardial infarction) through the beneficial cardiac effects of prolonged IGF-I protein expression. We believe that myocardial derived IGF-I offers the potential to improve post-infarct cardiac healing through DNA-based, targeted myocardial cell delivery and resulting sustained cardiac-restorative bioactivity. Corgentin would be delivered using our methods of intracoronary cardiac administration. The biological properties of IGF-I, including inhibition of apoptosis, adaptive cardiomyocyte hypertrophy, recruitment of cardiac progenitor cells, as well as the induction of angiogenesis and enhancement of cardiac function, provide the rationale for the development of a therapy directed at myocardial repair and restoration. This biology predicts Corgentin s potential to improve functional recovery and prevent ventricular dysfunction and the associated progression to congestive heart failure following myocardial infarction and reperfusion.

The safety of systemic IGF-I protein therapy has been confirmed in multiple human clinical studies for a number of medical indications. While there is abundant published scientific literature validating the multiple beneficial cardiac effects of IGF-I, systemic IGF-I protein delivery generally lacks the ability to target cardiomyocytes for effective therapy. We believe that by targeting the heart with intracoronary, DNA-coded, myocardial-directed delivery, using the methods pioneered for the Generx development program by Collateral Therapeutics and Schering, mdIGF-I has the potential to induce a positive biologic response. The targeted cardiomyocytes are expected to produce sustained therapeutic protein levels in the myocardium where it is needed. We estimate that over 1,000 patients have been treated with various dose levels of IGF-I protein, and 450 patients have received Generx via intracoronary administration of DNA-based myocardial delivery of the FGF-4 angiogenic growth factor. We believe the safety and preliminary efficacy from these studies provide further support for the clinical potential of Corgentin.

Collateral Therapeutics *in vitro* pre-clinical development studies provided data supporting the myocardial benefits of IGF-I in cell-based assays by protecting cardiomyocytes against apoptosis, inducing adaptive cardiomyocyte hypertrophy and inducing proliferation of human coronary artery endothelial cells. Cardium *s in vivo* proof-of-concept pilot study in pigs, based on its coronary occlusion/reperfusion myocardial infarct model, tested intracoronary mdIGF-I administration to promote myocardial repair following a significant heart attack (myocardial infarction). This double-blind, randomized, placebo-controlled study was designed to simulate the clinical approach

in which Corgentin could be administered after emergency reperfusion therapy to a heart attack patient. Following infarction, echocardiographic analysis documented recovery and restoration of ventricular function and reversal of early left ventricular remodeling in the Corgentin-treated group, compared to placebo. Post-mortem analysis of the hearts provided histological evidence of the potential for post-infarct myocardial protection with this therapy. The initial clinical studies for Corgentin would be designed to seek product registration for use in patients with acute ST-elevation myocardial infarction undergoing percutaneous coronary intervention with or without associated fibrinolysis.

Corgentin Therapeutic Approach for Heart Attack

We will seek to advance the current standard of care for patients with acute coronary syndrome 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 for heart attack patients immediately following percutaneous coronary intervention. The objective of this treatment approach is focused on enhancing myocardial repair and restoration for 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 repair cells that have been injured as a result of a heart attack.

It should be noted that even with the best of care and successful early intervention, about 30% of heart attack patients will eventually go on to develop congestive heart failure with decompensated coronary syndrome and the potential for eventual left ventricular remodeling. This explains in large part why heart failure remains an epidemic health problem despite improved treatments for acute cardiac events. A therapeutic approach such as Corgentin has the potential to change the clinical outcome for heart attack patients by slowing or preventing the development of decompensated coronary syndrome and subsequent heart failure.

To further confirm the utility of the Corgentin approach and establish its commercialization potential, we plan to develop additional pre-clinical information through sponsored studies. If confirmatory, we may then consider initiating clinical studies, on our own or with a corporate development partner.

Genvascor Pre-Clinical Development

As part of the Schering Transaction, Cardium 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 arterial occlusive disease. We may seek to develop additional pre-clinical information through sponsored studies and, if confirmatory, anticipate we would seek to further develop Genvascor either alone or through a corporate collaboration.

Nitric oxide (NO) is believed to play an important role in angiogenesis by mediating some of the effect of vascular endothelial growth factor (VEGF) and other growth factors and by inhibiting local anti-angiogenic mechanisms (*e.g.*, VEGF receptor down-regulation). In the setting of atherosclerotic arterial disease and the presence of multiple concurrent cardiovascular risk factors, activation of vascular endothelial cells leads to reduced production of endothelial nitric oxide and impaired local angiogenesis. We believe that a treatment that re-establishes a sufficient level of bioavailable nitric oxide can potentially lead to enhanced neovascularization and increased blood flow to an ischemic limb. Based on its multiple vasculoprotective mechanisms, as well as the anti-inflammatory activity that nitric oxide exerts while also stimulating angiogenesis and arteriogenesis, treatment with Genvascor could lead to superior clinical efficacy to relieve peripheral limb ischemia over single growth factor treatments that are currently in development.

Critical limb ischemia due to advanced peripheral arterial occlusive disease (PAOD) is characterized by reduced blood flow and oxygen delivery with exercise or even at rest with severe disease, resulting in claudication (muscle pain) and eventual non-healing skin ulcers that can lead to gangrene. The estimated incidence of critical limb ischemia is 500-1000 per million per year in the United States. Progressive microcirculatory dysfunction and impairment of angiogenesis/arteriogenesis are crucial pathophysiologic determinants of critical limb ischemia. As critical limb ischemia progresses, deregulation of the microcirculation occurs, characterized by activation of white blood cells, platelet aggregation, plugging of capillaries, endothelial damage and release of free radicals, all of

which promote further ischemia leading to tissue damage and eventual tissue necrosis. The prognosis of patients with critical limb ischemia is very poor. The survival rate for patients with significant tissue necrosis without major amputation is less than 50% after one year. Many patients presenting with ischemic pain and ulcers are not suitable candidates for surgical revascularization or angioplasty due to diffuse, distal occlusive vascular disease. Current pharmacotherapy has had little impact on limb salvage in patients with advanced critical limb ischemia and, likewise, little symptomatic effect.

Angiogenesis and collateral vessel formation in an extremity are complex processes that require the coordination of multiple factors. Therefore, the potential efficacy of treatments currently under development using a single growth factor may be limited. We believe that the delivery of the gene directed at the production of nitric oxide to mediate the effect of multiple growth factors to induce angiogenesis represents a promising new approach for the treatment of critical limb ischemia. Nitric oxide availability to the tissues can reverse ischemia through multiple mechanisms including stimulating impaired angiogenesis, ameliorating existing microvascular dysfunction, restoring vasomotor (vasodilator) activity of existing vessels and contributing to the remodeling and maturation of existing collateral vessels. This biology-based revascularization of ischemic limb tissues could possibly be efficacious for patients who are not amenable to percutaneous or surgical revascularization.

The proprietary endothelial nitric oxide synthase mutant Cardium acquired in the Schering Transaction has an increased specific activity of the nitric oxide synthase enzyme, which induces the production of high local levels of nitric oxide. This production is not only independent of the level of endogenous growth factors present, but also is not inhibited by common concurrent risk factors such as hypercholesterolemia or increased oxidative stress, which are known to inhibit the activity of endogenous wildtype eNOS. The properties of this eNOS mutant, Genvascor, may predict a beneficial effect in chronic ischemic conditions. Significant improvement in revascularization and limb salvage has been shown with intramuscular delivery of Genvascor in eNOS-knock-out mouse models of chronic limb ischemia. Efficacy of Genvascor has also been demonstrated in mouse chronic limb ischemia models with reported functional deficiencies in eNOS due to diabetes, the most common cause of PAOD. Treatment with Genvascor therefore has the potential to be efficacious in patients with chronic limb ischemia who also exhibit severe endothelial nitric oxide deficiency, either due to genetic causes or due to metabolic or inflammatory factors. These properties may provide Genvascor a competitive advantage over single growth factor therapies in development as a novel therapy for symptomatic, severe PAOD.

#### 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 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 investigational new drug 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 investigational new drug application process can thus result in substantial delay and expense. Human gene therapy products, the 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 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 require additional studies. In addition, the FDA may condition marketing approval on the conduct or 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 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 products.

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. Any product candidate 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 vascular disease. 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 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 have recently initiated 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. recently 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.

#### Manufacturing Strategy

To leverage our experience and available financial resources, we do not plan to develop company-owned and operated manufacturing facilities. We plan to outsource all product manufacturing to a contract manufacture of clinical drug products that operates at a manufacturing facility in compliance with current good manufacturing practices or 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 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

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*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.

#### Marketing and Sales

Our product candidates must undergo testing and development in clinical trials and pre-clinical studies. 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.

#### Intellectual Property

As part of the Schering Transaction, pursuant to a Technology Transfer Agreement entered into between Cardium and Schering, Cardium acquired from Schering a portfolio of methods and compositions directed at the treatment of cardiovascular diseases. Cardium also has exclusive licenses to methods for introducing DNA to the heart and for improving heart muscle function, as well as to various biologics. Cardium s 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. Our intellectual property portfolio currently includes more than five issued U.S. patents and more than 60 U.S. patent applications or foreign counterpart patents or patent applications. 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.

Cardium has entered into certain collaborative and licensing arrangements in connection with the Schering Transaction. We expect to continue evaluations of the safety, efficacy and possible commercialization of our therapeutic genes and methods of gene therapy. 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 herein.

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

Cardium 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 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 Cardium 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, Cardium 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 Cardium at any time on 60 days notice, following which Cardium would continue to be responsible only for obligations and liabilities accrued before termination. Under the agreement, Cardium is 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. Cardium is also obligated to reimburse the Regents for ongoing patent expenses incurred in connection with the licensed technologies. Cardium is obligated to make milestone payments to the Regents of \$100,000 payable on the earlier to occur of the beginning of new Phase II clinical trials in the United States or June 30, 2006, and \$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 Cardium 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, Cardium is required to diligently proceed with the development and commercialization of the products covered by the licensed patents. To demonstrate its diligence, Cardium is required to attain certain developmental milestones on or before deadlines set forth in the licenses. If and after Cardium receives marketing approval of the products, it 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 Cardium in connection with the Schering Transaction and amended in certain respects pursuant to an agreement with NYU. Upon assumption, this agreement as amended provides Cardium 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, Cardium is 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. Cardium is also obligated to reimburse NYU for ongoing patent expenses incurred in 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, Cardium 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 Cardium completes one full year of sales of licensed products and continuing thereafter until the agreement terminates or expires, Cardium 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, Cardium is 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 breach

### 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, Cardium 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 first \$10 million in net sales. If Cardium achieves sales of licensed products, Cardium 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, Cardium is 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.

#### Employees

Cardium currently employs approximately 10 employees on a full time basis and expects to hire approximately six to eight additional employees during the next twelve 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. Cardium also relies on various consultants and advisors to provide services to it.

### **ITEM 2. DESCRIPTION OF PROPERTY**

As of September 30, 2005, Aries occupied offices provided by an affiliate on a month to month basis at 11111 Santa Monica Boulevard, Suite 1250, Los Angeles, California 90025. Effective on November 1, 2005, we entered into a two year lease with Kilroy Realty, L.P., a Delaware limited partnership (Lease), to lease approximately 5,727 square feet at 3611 Valley Centre Drive, Suite 525, San Diego, California 92130, the location of our current principal executive offices. 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. During the first year of the Lease, our monthly installment of base rent will be approximately \$21,500, which amount will increase by approximately four percent in the second year of the Lease. We will also be required to pay our proportionate share of operating and tax expenses for the office park in which our space is located.

#### **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 December 21, 2005, neither Aries nor its subsidiary Cardium were a party to any material pending legal proceeding nor was any of their property the subject of any material pending legal proceeding. It is anticipated, however, that we will be regularly engaged in various patent prosecution matters related to the technology we develop and/or license, including the technologies described in Item 1 above. For example, Collateral Therapeutics has assisted the University of California, as the licensor, in an interference proceeding involving the University of California s technology for cardiovascular gene therapy and a pending patent application filed by Jeffrey Leiden et al. (a U.S. counterpart of international application PCT/US93/11133, which published as WO94/11506). In a related matter, Collateral Therapeutics successfully opposed a European counterpart to the Leiden PCT application (EP-B-668913), which led to a decision to revoke their

patent grant in Europe. However, the patentee, Arch Development Corporation, has appealed from the decision against them. If the interference, opposition or other adverse proceedings were to ultimately be decided adversely, we may be compelled to seek a license to the Leiden technology, which may not be available on terms that we find commercially reasonable. In addition, such proceedings, even if decided in our favor, involve a lengthy process, are subject to appeal, and typically result in substantial costs and diversion of resources. Cardium is obligated to reimburse Schering for the expenses of any interference or other proceedings accrued on or after April 1, 2005 in connection with the technologies licensed.

### 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 September 30, 2005.

### PART II

### ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

#### **Market Information**

Our common stock trades on the over-the-counter market (pink sheets) under the symbol ARVT. Below are the high and low closing prices of our common stock as reported by Nasdaq for each quarter of the fiscal years ended September 30, 2005 and 2004:

	Fiscal 2005				Fiscal 2004		
	High		Low		High		Low
First Quarter	\$ 0.26	\$	0.15	\$	0.91	\$	0.25
Second Quarter	\$ 0.15	\$	0.15	\$	0.55	\$	0.25
Third Quarter	\$ 0.46	\$	0.15	\$	0.35	\$	0.30
Fourth Quarter	\$ 1.51	\$	0.46	\$	0.30	\$	0.25

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.

### Holders

As of December 2, 2005, there were approximately 362 stockholders of record of our common stock.

#### Dividends

During the last two fiscal years ended September 30, 2005 and 2004, no dividends were declared or paid on Aries common stock.

#### **Recent Sales of Unregistered Securities**

During the fiscal years ended September 30, 2005, 2004 and 2003, we did not sell any unregistered securities.

#### Repurchases

During the fourth quarter of fiscal 2005, 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 7 and elsewhere in this report, which identify certain important factors that could cause our future financial condition and results of operations to vary.

#### **Plan of Operation**

Aries has not had revenues from operations during the last two fiscal years ended September 30, 2005 and 2004. As of September 30, 2005, Aries had no business operations and was focused on maintaining its corporate entity and seeking a new business opportunity.

On October 20, 2005, Aries completed a reverse merger with privately held Cardium Therapeutics, Inc., a Delaware corporation, whereby a newly formed and wholly-owned subsidiary of Aries was merged with and into Cardium. As

a result, Cardium became a wholly-owned subsidiary of Aries. At the time of the Merger, Aries had divested itself of all its assets and investments other than \$1.5 million in cash and had no outstanding contractual commitments.

At the time of the Merger, we also closed a private placement of 19,325,651 shares of Aries common stock at a purchase price of \$1.50 per share, which represented net proceeds of \$25,552,390. A portion of the proceeds was used to acquire Cardium s portfolio of cardiovascular growth factor therapeutic assets from Schering and/or its affiliates for a purchase price of approximately \$4,000,000.

We plan to hold a meeting of our stockholders in January 2006 to seek their approval, among other things, to merge Aries into Cardium, with Cardium as the surviving entity, for the purpose of effectively changing our state of incorporation from Nevada to Delaware, changing our name to Cardium Therapeutics, Inc. and more clearly reflecting our business plans and objectives following the Merger. Our common stock will continue to trade under the Aries Ventures name and ticker symbol until the completion of the merger of Aries into Cardium, provided such merger is approved by our stockholders, at which time our common stock would begin to trade under the Cardium Therapeutics name and with a new ticker symbol.

Since the Merger, Cardium has continued its business under the name Cardium Therapeutics, Inc. as a wholly-owned subsidiary of Aries. Cardium s initial primary focus will be the commercial development of cardiovascular-directed growth factor therapeutics for interventional cardiology applications based on the product portfolio acquired by Cardium from Schering, which products include Generx<sup>TM</sup> and Corgentin<sup>TM</sup>. Generx, based on myocardial-derived fibroblast growth factor 4 (mdFGF-4), is our lead product candidate and has advanced to Phase 2b/3 clinical studies. Generx is a non-surgical angiogenic therapy designed to be a one-time treatment with long-lasting therapeutic benefits for patients with recurrent angina due to coronary disease. Corgentin, a pre-clinical product candidate, is a next-generation therapeutic based on myocardial-derived insulin-like Growth Factor-I (mdIGF-I). Corgentin is being designed to be a one-time cardiomyocyte-directed treatment to promote the repair and restoration of damaged cardiomyocytes and enhance cardiac function following a heart attack (acute myocardial infarction) through the beneficial cardiac effects of prolonged IGF-I protein expression.

In addition, Cardium has secured the rights to Genvascor<sup>TM</sup>, a pre-clinical, DNA-based, endothelial nitric oxide synthase (eNOS) therapeutic. Genvascor is being designed to induce production of nitric oxide and is directed at mediating the effects of multiple growth factors to enhance neovascularization and increased blood flow for the potential treatment of patients with critical limb ischemia due to advanced peripheral arterial occlusive disease (PAOD). We may elect to develop Genvascor alone or in collaboration with a development partner.

**Business Strategy** 

Building upon our core 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 basis. The key elements of our strategy are to:

Initiate a redesigned clinical development program for Generx, which would include a new clinical study (AGENT-5) targeted to patients with recurrent angina and, with positive clinical data, initiate a pivotal Phase 3 clinical study (AGENT-6);

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;

Seek to monetize the economic value of Cardium s product portfolio by establishing strategic collaborations at appropriate valuation inflection points; and

Seek to 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.

We recognize that the practical realities of cardiovascular drug development 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. In the future, we plan to aggressively seek access to other therapeutics and/or medical device opportunities, as well as medical-related technologies, to further strengthen and broaden our portfolio, and will consider the opportunistic acquisition of other companies having financial and development resources that offer the potential to enhance our near and long-term stockholder value.

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

#### **Off-Balance Sheet Arrangements**

As of September 30, 2005, we did not have any off-balance sheet debt nor did we have any transactions, arrangements, obligations (including contingent obligations) or other relationships with any unconsolidated entities or other persons that may have a material current or future effect on financial condition, changes in financial condition, results of operations, liquidity, capital expenditures, capital resources, or significant components of revenue or expenses.

#### **Critical Accounting Policies and Estimates**

Our financial statements included under Item 7 in this report have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of financial statements in accordance with GAAP requires that we make estimates and assumptions that affect the amounts reported in our financial statements and their accompanying notes. We have identified certain policies that we believe are important to the portrayal of our financial condition and results of operations. These policies require the application of significant judgment by our management. We base our estimates on our historical experience, industry standards, and various other assumptions that we believe are reasonable under the circumstances. Actual results could differ from these estimates under different assumptions or conditions. An adverse effect on our financial condition, changes in financial condition, and results of operations could occur if circumstances change that alter the various assumptions or conditions used in such estimates or assumptions. Our significant accounting policies are described in the notes to our financial statements.

#### **Recent Accounting Pronouncements**

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), Share Based Payment (SFAS 123R), a revision to SFAS No. 123, Accounting for Stock-Based Compensation. SFAS 123R supersedes Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and amends SFAS No. 95, Statement of Cash Flows. SFAS 123R requires that we measure the cost of employee services received in exchange for equity awards based on the grant date fair value of the awards. The cost will be recognized as compensation expense over the vesting period of the awards. We are required to adopt SFAS 123R effective for annual periods beginning after December 15, 2005. Under this method, we will begin recognizing compensation cost for equity-based compensation for all new or modified grants after the date of adoption. In addition, we will recognize the unvested portion of the grant date fair value of awards issued before adoption based on the fair values previously calculated for disclosure purposes over the remaining vesting period of the outstanding options and warrants. We are currently evaluating the potential effect that the adoption of SFAS 123R will have on our financial statements.

The Emerging Issues Tax Force ( EITF ) has adopted EITF Issue 04-8, The Effect of Contingently Convertible Instruments on Diluted Earnings per Share. The EITF reached a consensus that contingently convertible instruments, such as contingently convertible debt, contingently convertible preferred stock, and other such securities should be included in diluted earnings per share (if dilutive) regardless of whether the market price trigger has been met. The consensus became effective for reporting periods ending after December 15, 2004. The adoption of this pronouncement did not have an effect on our financial statements.

In September 2005, the FASB ratified the EITF s Issue No. 05-7, Accounting for Modifications to Conversion Options Embedded in Debt Instruments and Related Issues, which addresses whether a modification to a conversion option that changes its fair value affects the recognition of interest expense for the associated debt instrument after the modification and whether a borrower should recognize a beneficial conversion feature, not a debt extinguishment, if a debt modification increases the intrinsic value of the debt.

In September 2005, the FASB ratified the following consensus reached in EITF Issue No. 05-8, Income Tax Consequences of Issuing Convertible Debt with a Beneficial Conversion Feature: (a) The issuance of convertible debt with a beneficial conversion feature results in a basis difference in applying SFAS No. 109, Accounting for Income Taxes. Recognition of such a feature effectively creates a debt instrument and a separate equity instrument for book purposes, whereas the convertible debt is treated entirely as a debt instrument for income tax purposes; (b) The resulting basis difference should be deemed a temporary difference because it will result in a taxable amount when the recorded amount of the liability is recovered or settled; and (c) Recognition of deferred taxes for the temporary difference should be reported as an adjustment to additional paid-in capital.

Both of the above issues are effective in the first interim or annual reporting period commencing after December 15, 2005, with early application permitted. The effect of applying the consensus should be accounted for retroactively to all debt instruments containing a beneficial conversion feature that are subject to EITF Issue 00-27, Application of Issue No. 98-5 to Certain Convertible Debt Instruments (and thus is applicable to debt instruments converted or extinguished in prior periods but which are still presented in the financial statements). We do not believe this pronouncement will have a material impact on our financial statements.

#### Risks

You should carefully consider the risks described below, as well as the other information in this report, when evaluating our business and future prospects. If any of the following risks actually occur, our business, financial condition and results of operations 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 common stock.

Cardium is 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.

Due to the development stage of Cardium s business, our development and start-up costs, including significant amounts we expect to spend to fund the research and development activities and clinical trials for Generx and other product candidates, and our lack of revenue during our development stage, you should expect that we will sustain operating losses, which may be substantial, in the early years of operation. A large portion of our expenses are fixed, including expenses related to facilities, equipment 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 revenues and become profitable will depend on our ability, alone or with potential collaborators, to timely, efficiently and successfully complete the development of our product candidates, conduct pre-clinical and clinical tests, obtain necessary regulatory approvals, and manufacture and market our product candidates. 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.

Cardium s business prospects are difficult to evaluate because it is a new company.

Because Cardium has a short operating history, it may be difficult for you to assess our growth, partnering and earnings potential. It is likely that we will face many of the difficulties that companies in the early stages of their development often face. These include, among others: limited financial resources; developing and marketing a new product for which a market is not yet established and may never become established; delays in reaching our goals; challenges related to the development, approval and acceptance of a new technology or product; lack of revenues and cash flow; high start-up and development costs; competition from larger, more established companies; and difficultly recruiting qualified employees for management and other positions.

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

## We will need substantial additional funding to develop our products and for our future operations. If we are unable to obtain the funds necessary to do so, we may be required to delay, scale back or eliminate our product development or may be unable to continue our business.

The development of our product candidates will require a commitment of substantial funds in excess of the proceeds of from the private placement to conduct the costly and time-consuming research, pre-clinical and clinical testing necessary to obtain regulatory approvals and bring our products to market. Our future capital requirements will depend on many factors, including: the progress of our research and 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 product candidates; the cost of prosecuting, defending and enforcing patent claims and other intellectual property rights; competing technological and market developments; and our ability to establish and maintain collaborative and other arrangements with third parties to assist in bringing our products to market and the cost of such arrangements.

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, 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. Fluctuating interest rates could also increase the costs of any debt financing we may obtain.

Failure to successfully address ongoing liquidity requirements will have a material adverse effect on our business. If we are unable to obtain additional capital on acceptable terms when needed, we may be required to take actions that harm our business and our ability to achieve cash flow in the future, including possibly the surrender of our rights to some technologies or product opportunities, delaying our clinical trials or curtailing or ceasing operations.

If our right to use any intellectual property we intend to license or license from third parties is terminated or adversely affected, our financial condition, operations or ability to develop and commercialize our product candidates may be harmed.

We expect to substantially rely on licenses to use certain technologies that are material to our operations. For example, we have licensed patents, patent applications and other intellectual property from New York University for the use of the FGF-4 technology in our product candidates for vascular and cardiovascular disease. We also have obtained licenses from the University of California to use certain patents and patent applications relating to gene therapy delivery methods in connection with the use of FGF-4 and other molecules for gene therapy. We do not own the patents, patent applications and other intellectual property rights that underlie these licenses. We rely on our licensors to properly prosecute and enforce the patents, file patent applications and prevent infringement of those patents and patent applications.

While our licenses and associated agreements provide us with exclusive rights in specified fields, the scope of our rights under these and other licenses may be subject to dispute by our licensors or third parties. In addition, the licenses and technology transfer agreements noted above contain certain milestones that we must meet and certain minimum payments that we must make to maintain the licenses. There is no assurance that we will be able to meet such milestones or make such payments. Our licensors may terminate the licenses if we fail to meet the applicable milestones or make the applicable payments.

Cardium is an early stage company and currently has no 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. If our product candidates are delayed or fail, our financial condition will be negatively affected, and

#### we may have to curtail or cease our operations.

We are in the early stage of product development and currently do not sell any products and do not expect to have any products commercially available for several years, if at all. Our product candidates require additional research and development, clinical testing and regulatory clearances before marketing. There are many reasons that our product candidates may fail or not advance beyond clinical testing, including the possibility that: our 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 proposed product; our potential collaborators may withdraw support for or otherwise impair the development and commercialization of our product candidates; other parties may hold or acquire proprietary rights that could prevent us or our potential collaborators from developing or marketing our product candidates; or others may develop equivalent or superior products.

In addition, our product candidates are subject to the risks of failure inherent in the development of gene therapy 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, our financial condition may be negatively affected, and we may have to curtail or cease our operations.

# We may experience delays in our Generx or other clinical trials that could adversely affect our financial results and our commercial prospects.

To obtain regulatory approvals, we must, among other requirements, complete clinical trials showing that Generx is safe and effective for a particular indication. We plan to submit a protocol to the FDA in 2006 and plan to conduct verbal and written communications with the FDA to continue to evaluate our Generx product candidate. We plan on initiating our clinical trials in 2006 but there is no assurance we will be able to do so as the timing of the commencement of the trial may be dependent on, among other things, FDA reviews and other factors outside of our control. Furthermore, there can be no assurance that our clinical trials will in fact demonstrate that Generx is safe or effective.

Additionally, we may not be able to identify or recruit a significant number of acceptable patients or may experience delays in enrolling patients for our clinical trials for Generx. The FDA or we may suspend our clinical trials at any time if either believes that we are exposing the subjects participating in the trials to unacceptable health risks. The FDA or institutional review boards and/or institutional biosafety committees at the medical institutions and healthcare facilities where we sponsor clinical trials may suspend any trial indefinitely if they find deficiencies in the conduct of the trials.

Product development costs to us and our potential collaborators will increase if we have delays in testing or approvals or if we need to perform more or larger clinical trials than planned. We expect to continue to rely on third party clinical investigators at medical institutions and healthcare facilities to conduct our clinical trials, and, as a result, we may face additional delaying factors outside our control. Significant delays may adversely affect our financial results and the commercial prospects for our product candidates and delay our ability to become profitable.

If our product candidates do not successfully complete the clinical trial process, we will not be able to market them. Even successful clinical trials may not result in a marketable product and may not be entirely indicative of a product s safety or efficacy.

Generx is the only product candidate 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 we or a collaborator will successfully complete the clinical trials necessary to receive regulatory product approvals. This process is lengthy and expensive. To obtain regulatory approvals, we or a collaborative partner must demonstrate through pre-clinical studies and clinical trials that our product candidates are safe and effective for use in at least one medical indication.

Many factors, known and unknown, can adversely affect clinical trials and the ability to evaluate a product sefficacy. For example, clinical trials are often conducted with patients who have the most advanced stages of disease. During the course of treatment, these patients can die or suffer other adverse events for reasons that may or may not be related to the proposed product being tested. For instance, as reported in December 1999, the death of a patient enrolled in the Phase 1/2 trial for Generx, which occurred approximately five months after the one-time product administration, was determined to have been unlikely to be causally related to the therapy. However, even if unrelated to our product, such events can nevertheless adversely impact our clinical trials. As a result, our ability to ultimately develop and market the products and obtain revenues would suffer.

Our clinical trials may also be adversely impacted by patient deaths or problems that occur in other trials. For example, the death of a patient in another trial in 1999 who had received an adenoviral gene delivery vector expressing an ornithine transcarbamylase gene triggered several government investigations and reviews of past and ongoing gene therapy trials.

Deaths and other adverse events that occur in the conduct of clinical trials may result in an increase in governmental regulation 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 a halt of our clinical trial, any of which results would negatively affect 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. Many factors or variables could effect 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.

In addition, 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 that they will complete the treatment process. Delays in patient enrollment or treatment in clinical trials may result in increased costs, program delays or both.

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.

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

Possible side effects of gene therapy 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 could delay or prevent approval of our products and our revenues would suffer. For example, possible serious side effects of viral vector-based gene transfer include viral infections resulting from contamination with replication-competent viruses and inflammation or other injury to the heart or other parts of the body. In addition, the development or worsening of cancer in a patient may 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.

Because we cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates, we cannot predict the timing of any future revenue from these product candidates. To our knowledge, the FDA has not yet approved any gene therapy products.

We cannot commercialize any of our product candidates to generate revenue until the appropriate regulatory authorities have reviewed and approved the applications for our product candidates. We cannot assure you that the regulatory agencies will complete their review processes in a timely manner or that we will obtain regulatory approval for any product candidate we or our potential collaborators develop. Satisfaction of regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product and

requires the expenditure of substantial resources. Regulatory approval processes outside the United States include all or many of the risks associated with the FDA approval process and potentially others as well. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review.

#### Our technologies and product candidates are unproven and they may fail to gain market acceptance.

Our future depends on the success of our technologies and product candidates. Gene-based therapy is a new and rapidly evolving medial approach that has not been shown to be effective on a widespread basis. Biotechnology and pharmaceutical companies have successfully developed and commercialized only a limited number of gene-based products to date. In addition, no gene therapy product has received regulatory approval in the United States or internationally. 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. Our success will depend in part on our ability to demonstrate the clinical benefits, reliability, safety and cost effectiveness of our product candidates and technology, 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 product candidates, when and if we are able to commercialize them, and the technology underlying them, 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 is 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.

Our strategy for the development, testing, manufacturing and commercialization of our product candidates generally relies on establishing and maintaining collaborations with corporate partners, licensors and other third parties. For example, we have licenses from New York University and the University of California relating to the use and delivery of our Generx product candidates for the treatment of vascular disease, as well as a relationship with Schering regarding the transfer of information about certain manufacturing and regulatory matters concerning our product candidates. We may not be able to maintain or expand these licenses and collaborations or establish additional licensing and collaboration arrangements necessary to develop and commercialize our product candidates. Even if we are able to maintain or establish licensing or collaboration arrangements, these arrangements may not be on favorable terms and may contain provisions that will restrict our ability to develop, test and market our product candidates. Any failure to maintain or establish licensing or collaboration arrangements on favorable terms could adversely affect our business prospects, financial condition or ability to develop and commercialize our product candidates.

We expect to rely at least in part on third party collaborators to perform a number of activities relating to the development and commercialization of our product candidates, including the manufacturing of product materials, the design and conduct of clinical trials, and potentially the obtaining of regulatory approvals and marketing and distribution of any successfully developed products. Our collaborative partners may also have or acquire rights to control aspects of our product development and clinical programs. As a result, we may not be able to conduct these programs in the manner or on the time schedule we currently contemplate. In addition, if any of these collaborative partners withdraw support for our programs or product candidates or otherwise impair their development, our business could be negatively affected. To the extent we undertake any of these activities internally, our expenses may increase.

In addition, our success depends on the performance of our collaborators of their responsibilities under these arrangements. Some potential collaborators may not perform their obligations in a timely fashion or in a manner satisfactory to us.

We will rely on third parties to manufacture our product candidates. There can be no guarantee that we can obtain sufficient and acceptable quantities of our product candidates on acceptable terms, which may delay or impair our ability to develop, test and market such products.

Our business strategy relies on third parties to manufacture and produce our product candidates and the catheters used to deliver the products in accordance with good manufacturing practices established by the FDA. These third party manufacturers are subject to extensive government regulation and must receive FDA approval before they can produce clinical material or commercial product.

Our product candidates may be in competition with other products for access to these facilities and may be subject to delays in manufacture if third parties give other products greater priority than our product candidates. These third parties also may not deliver sufficient quantities of our product candidates, manufacture our product candidates in accordance with specifications, or comply with applicable government regulations. Successful large-scale manufacturing of gene-based therapy products has been shown by very few companies, and it is anticipated that significant process development changes will be necessary for the commercial process.

Additionally, if the manufactured products fail to perform as specified, our business and reputation could be severely impacted. Our product materials will be produced by a third party collaborator, and we expect to enter into a manufacturing agreement for the production of additional product materials for anticipated clinical trials and initial commercial use. If any manufacturing agreement is terminated or any third party collaborator experiences a significant problem that could result in a delay or interruption in the supply of product materials to us, there are very few contract manufacturers who currently have the capability to produce our product candidates on acceptable terms, or on a timely and cost-effective basis. There can be no assurance that manufacturers on whom we will depend will be able to successfully produce our product candidates on acceptable terms, or on a timely or cost-effective basis. There can also be no assurance that manufacturers will be able to manufacturers will be able to manufacture our product in accordance with our product specifications. We must have sufficient and acceptable quantities of our product materials to conduct our clinical trials and to market our product candidates, if and when such products have been approved by the FDA for marketing. If we are unable to obtain sufficient and acceptable quantities of our product material, we may be required to delay the clinical testing and marketing of our products.

# If we do not comply with applicable regulatory requirements in the manufacture and distribution of our product candidates, we may incur penalties that may inhibit our ability to commercialize our products and adversely affect our revenue.

Our failure or the failure of our potential collaborators or third party manufacturers to comply with applicable FDA or other regulatory requirements including manufacturing, quality control, labeling, safety surveillance, promoting and reporting may result in criminal prosecution, civil penalties, recall or seizure of our products, total or partial suspension of production or an injunction, as well as other regulatory action against our product candidates or us. Discovery of previously unknown problems with a product, supplier, manufacturer or facility may result in restrictions on the sale of our products, including a withdrawal of such products from the market. The occurrence of any of these events would negatively impact our business and results of operations.

If we are unable to create and maintain sales, marketing and distribution capabilities or enter into agreements with third parties to perform those functions, we will not be able to commercialize our product candidates.

We currently have no sales, marketing or distribution capabilities. Therefore, to commercialize our product candidates, if and when such products have been approved and are ready for marketing, we expect to collaborate with third parties to perform these functions.

We have no experience in developing, training or managing a sales force and will incur substantial additional expenses if we are forced to market our future products directly. Developing a marketing and sales force is also time consuming and could delay launch of our future products. In addition, we will compete with many companies that currently have extensive and well-funded marketing and sales operations. Our marketing and sales efforts may be unable to compete successfully against these companies.

If we are unable to attract and retain key personnel and advisors, it may adversely affect our ability to obtain financing, pursue collaborations or develop our product candidates.

Our future success depends on our ability to attract, retain and motivate highly qualified management and scientific and regulatory personnel and advisors. To pursue our business strategy, we will need to hire or otherwise engage qualified scientific personnel and managers, including personnel with expertise in clinical trials, government regulation and manufacturing. Competition for qualified personnel is intense among companies, academic

institutions and other organizations. If we are unable to attract and retain key personnel and advisors, it may negatively affect our ability to successfully develop, test and commercialize our product candidates.

## We will use hazardous and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our products and processes will involve the controlled storage, use and disposal of certain hazardous and biological materials and waste products. We and our suppliers and other collaborators are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Even if we and these suppliers and collaborators comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of any insurance we may obtain and exceed our financial resources. We may not be able to maintain insurance on acceptable terms, or at all. We may incur significant costs to comply with current or future environmental laws and regulations.

#### Future acquisitions could disrupt our business and harm our financial condition.

To remain competitive, we may decide to acquire additional businesses, products and technologies. As we have limited experience in evaluating and completing acquisitions, our ability as an organization to make such acquisitions is unproven. Acquisitions could require significant capital infusions and could involve many risks, including, but not limited to, the following: we may have to issue convertible debt or equity securities to complete an acquisition, which would dilute our stockholders and could adversely affect the market price of our common stock; an acquisition may negatively impact our results of operations because it 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 it may cause adverse tax consequences, substantial depreciation or deferred compensation charges; we may encounter difficulties in assimilating and integrating the business, technologies, products, personnel or operations of companies that we acquire; certain acquisition may disrupt our relationship with existing collaborators who are competitive to the acquired business; acquisitions may require significant capital infusions and the acquired businesses, products or technologies may not generate sufficient revenue to offset acquisition costs; an acquisition may disrupt our ongoing business, divert resources, increase our expenses and distract our management; acquisitions may involve the entry into a geographic or business market in which we have little or no prior experience; and key personnel of an acquired company may decide not to work for us.

## To the extent we enter markets outside the United States, our business will be subject to political, economic, legal and social risks in those markets, which could adversely affect our business.

There are significant regulatory and legal barriers in markets outside the United States that we must overcome to the extent we enter or attempt to enter markets in countries other than the United States. We will be subject to the burden of complying with a wide variety of national and local laws, including multiple and possibly overlapping and conflicting laws. We also may experience difficulties adapting to new cultures, business customs and legal systems. Any sales and operations outside the United States would be subject to political, economic and social uncertainties including, among others: changes and limits in import and export controls; increases in custom duties and tariffs; changes in currency exchange rates; economic and political instability; changes in government regulations and laws; absence in some jurisdictions of effective laws to protect our intellectual property rights; and currency transfer and other restrictions and regulations that may limit our ability to sell certain products or repatriate profits to the United States.

Any changes related to these and other factors could adversely affect our business to the extent we enter markets outside the United States.

Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.

Ethical, social and legal concerns about gene therapy and genetic research could 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.

We are subject to significant government regulation with respect to our product candidates. Compliance with government regulation can be a costly and time-consuming process, with no assurance of ultimate regulatory approval. If these approvals are not obtained, we will not be able to sell our product candidates. To our knowledge, the FDA has not yet approved any gene therapy products.

We and our collaborators are subject to extensive and rigorous government regulation in the United States and abroad. The FDA, the National Institute of Health and comparable agencies in foreign countries impose many requirements on the introduction of new pharmaceutical products through lengthy and detailed clinical testing procedures and other costly and time consuming compliance procedures. These requirements vary widely from country to country and make it difficult to estimate when our product candidates will be commercially available, if at all. 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. If we are delayed or fail to obtain required approvals for our product candidates, our operations and financial condition would be damaged. Neither we nor our potential commercialization partners may sell our products without applicable regulatory approvals. Numerous regulations in the United States and abroad also govern the manufacturing, safety, labeling, storage, record keeping, reporting and marketing of our product candidates. Compliance with these regulatory requirements is 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.

We cannot assure you that our product candidates will prove safe and effective in clinical trials and will meet all of the applicable regulatory requirements needed to receive regulatory approval. We or a partner will need to conduct significant research, pre-clinical testing and clinical trials before we can file product approval applications with the FDA and similar regulatory authorities in other countries. Preclinical testing and clinical trials are long, expensive and uncertain processes. We may spend several years completing our testing for any particular product candidate, and failure can occur at any stage.

Even if we achieve positive results in early clinical trials, these results do not necessarily predict final results. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after achieving positive results in earlier trials. Negative or inconclusive results or adverse medical events during a clinical trial could cause the FDA or us to terminate a clinical trial or require that we repeat a clinical trial.

# We face intense competition and must cope with rapid technological change, which may adversely affect our financial condition and/or our ability to successfully commercialize our product candidates.

Our competitors and potential competitors include large pharmaceutical and medical device companies and more established biotechnology companies. These companies have significantly greater financial and other resources and greater expertise than us in research and development, manufacturing, pre-clinical and clinical testing, obtaining regulatory approvals and marketing. This may make it easier for them to respond more quickly to new or changing opportunities, technologies or market needs. Small companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical companies or through acquisition or development of intellectual property rights. Our larger competitors may be able to devote greater resources to research and development, marketing, distribution and other activities that could provide them with a competitive advantage. Many of these competitors have significant products approved or in development and operate large, well-funded research and development programs. Our potential competitors also include academic institutions, governmental agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for product and clinical development and marketing.

We are engaged in DNA-based therapy. Our industry is characterized by extensive research and development, rapid technological change, frequent innovations and new product introductions, and evolving industry standards. Existing products and therapies to treat vascular and cardiovascular disease, including drugs and surgical procedures, will compete directly with the products that we are seeking to develop and market. In addition, our competitors may develop more effective or more affordable products, or achieve earlier patent protection or product commercialization and market penetration than us. As these competitors develop their technologies, they may

develop proprietary positions that prevent us from successfully commercializing our future products. To be successful, we must be able to adapt to rapidly changing technologies by continually enhancing our products and introducing new products. If we are unable to adapt, products and technologies developed by our competitors may render our product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors. We may never be able to capture and maintain the market share necessary for growth and profitability and there is no guarantee we will be able to compete successfully against current or future competitors.

# Changes and reforms in the health care system or reimbursement policies may adversely affect the sale of our future products or our ability to obtain an adequate level of reimbursement or acceptable prices for our future products.

We currently have no products approved for marketing. Our ability to earn sufficient returns on our future products, if and when such products are approved and ready for marketing, will depend in part on the extent to which reimbursement for our products and related treatments will be available from government health administration authorities, private health coverage insurers, managed care organizations and other third-party payers. If we fail to obtain appropriate reimbursement, it could prevent us from successfully commercializing our future products.

There have been and continue to be efforts by governmental and third-party payers to contain or reduce the costs of health care through various means, including limiting coverage and the level of reimbursement. We expect that there will continue to be a number of legislative proposals to implement government controls and other reforms to limit coverage and reimbursement. The announcement of these proposals or reforms could impair our ability to raise capital. The adoption of these proposals or reforms could impair our operations and financial condition.

Additionally, third-party payers, including Medicare, are increasingly challenging the price of medical products and services and are limiting the reimbursement levels offered to consumers for these medical products and services. If purchasers or users of our future products are not able to obtain adequate reimbursement from third-party payers for the cost of using these products, they may forego or reduce their use. Significant uncertainty exists as to the reimbursement status of newly approved health care products, including gene therapy treatments, and whether adequate third-party coverage will be available.

# If our product candidates are not effectively protected by valid, issued patents or if we are not otherwise able to protect our proprietary information, it could harm our business.

The success of our operations will depend in part on our ability and that of our licensors to: obtain patent protection for our methods of gene therapy, therapeutic genes and/or gene-delivery methods both in the United States and in other countries with substantial markets; defend patents once obtained; maintain trade secrets and operate without infringing upon the patents and proprietary rights of others; and obtain appropriate licenses upon reasonable terms to patents or proprietary rights held by others that are necessary or useful to us in commercializing our technology, both in the United States and in other countries with substantial markets.

# If we are not able to maintain adequate patent protection for our product candidates, we may be unable to prevent our competitors from using our technology or technology that we license.

The patent positions of gene therapy technologies such as those being developed by us and our collaborators involve complex legal and factual uncertainties. As a result, we cannot be certain that we or our collaborators will be able to obtain adequate patent protection for our product

candidates. There can be no assurance that (i) any patents will be issued from any pending or future patent applications of ours or our collaborators; (ii) the scope of any patent protection will be sufficient to provide us with competitive advantages; (iii) any patents obtained by us or our collaborators will be held valid if subsequently challenged; or (iv) others will not claim rights in or ownership of the patents and other proprietary rights we or our collaborators may hold. Unauthorized parties may try to copy aspects of our products and technologies or obtain and use information we consider proprietary. Policing the unauthorized use of our proprietary rights is difficult. We cannot guarantee that no harm or threat will be made to our or our collaborators intellectual property. In addition, changes in, or different interpretations of, patent laws in the United States and other countries may also adversely affect the scope of our patent protection and our competitive situation.

Due to the significant time lag between the filing of patent applications and the publication of such patents, we cannot be certain that our anticipated licensors were the first to file the patent applications we intend to license or,

even if they were the first to file, also were the first to invent, particularly with regards to patent rights in the United States. In addition, a number of pharmaceutical and biotechnology companies and research and academic institutions have developed technologies, filed patent applications or received patents on various technologies that may be related to our operations. Some of these technologies, applications or patents may conflict with our or our licensors technologies or patent applications. A conflict could limit the scope of the patents, if any, that we or our licensors may be able to obtain or result in denial of our or our licensors patent applications. If patents that cover our activities are issued to other companies, we may not be able to develop or obtain alternative technology.

Patents issued and patent applications filed internationally relating to gene therapy are numerous, and we cannot assure you that current and potential competitors or other third parties have not filed or received, or will not file or receive applications in the future for patents or obtain additional proprietary rights relating to products or processes used or proposed to be used by us.

Additionally, there is certain subject matter which is patentable in the United States but not generally patentable outside of the United States. Differences in what constitutes patentable subject matter in various countries may limit the protection we can obtain outside of the United States. For example, methods of treating humans are not patentable in many countries outside of the United States. These and other issues may prevent us from obtaining patent protection outside of the United States, which would have a material adverse effect on our business, financial condition and results of operations.

# We may be subject to costly claims, and, if we are unsuccessful in resolving conflicts regarding patent rights, we may be prevented from developing or commercializing our product candidates.

There has been, and will likely continue to be, substantial litigation regarding patent and other intellectual property rights in the biotechnology industry. As the biotechnology industry expands and more patents are issued, the risk increases that our processes and product candidates may give rise to claims that they infringe on the patents of others. Others could bring legal actions against us claiming damages and seeking to stop clinical testing, manufacturing and marketing of the affected product or use of the affected process. Litigation may be necessary to enforce our or our licensors proprietary rights or to determine the enforceability, scope and validity of proprietary rights of others. If we become involved in litigation, it could be costly and divert our efforts and resources. In addition, if any of our competitors file patent applications in the United States claiming technology also invented by us or our licensors, we may need to participate in interference proceedings held by the U.S. Patent and Trademark Office to determine priority of invention and the right to a patent for the technology. Like litigation, interference proceedings can be lengthy and often result in substantial costs and diversion of resources.

Collateral Therapeutics has assisted the University of California, as the licensor, in one such interference proceeding involving the University of California s technology for cardiovascular gene therapy and a pending patent application filed by Jeffrey Leiden et al. (a U.S. counterpart of international application PCT/US93/11133, which published as WO94/11506). In a related matter, Collateral Therapeutics successfully opposed a European counterpart to the Leiden PCT application (EP-B-668913), which led to a decision to revoke their patent grant in Europe. However, the patentee, Arch Development Corporation, has appealed from the decision against them. If the interference, opposition or other adverse proceedings were to ultimately be decided adversely, we may be compelled to seek a license to the Leiden technology, which may not be available on terms that we find commercially reasonable. In addition, such proceedings, even if decided in our favor, involve a lengthy process, are subject to appeal, and typically result in substantial costs and diversion of resources.

As more potentially competing patent applications are filed, and as more patents are actually issued, in the field of gene therapy and with respect to component methods or compositions that we may employ, the risk increases that we or our licensors may be subjected to litigation or other proceedings that claim damages or seek to stop our product development or commercialization efforts. Even if such patent applications or patents are ultimately proven to be invalid, unenforceable or non-infringed, such proceedings are generally expensive and time consuming and could consume a significant portion of our resources and substantially impair our product development efforts.

If there were an adverse outcome of any litigation or interference proceeding, we could have a potential liability for significant damages. In addition, we could be required to obtain a license to continue to make or market the affected product or use the affected process. Costs of a license may be substantial and could include ongoing royalties. We may not be able to obtain such a license on acceptable terms, or at all.

#### We may not have adequate protection for our unpatented proprietary information, which could adversely affect our competitive position.

We will substantially rely on trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. However, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. To protect our trade secrets, we may enter into confidentiality agreements with employees, consultants and potential collaborators. However, these agreements may not provide meaningful protection of our trade secrets or adequate remedies in the event of unauthorized use or disclosure of such information. Likewise, our trade secrets or know-how may become known through other means or be independently discovered by our competitors. Any of these events could prevent us from developing or commercializing our product candidates.

#### We face the risk of product liability claims, which could adversely affect our business and financial condition.

Our operations will expose us to product liability risks that are inherent in the testing, manufacturing and marketing of gene therapy products. Failure to obtain sufficient product liability insurance or otherwise protect against product liability claims could prevent or delay the commercialization of our product candidates or negatively affect our financial condition. Regardless of the merit or eventual outcome, product liability claims may result in withdrawal of product candidates from clinical trials, costs of litigation, damage to our reputation, substantial monetary awards to plaintiffs and decreased demand for products.

Product liability may result from harm to patients using our products, a complication that was either not communicated as a potential side-effect or was more extreme than communicated. We will require all patients enrolled in our clinical trials to sign consents, which explain the risks involved with participating in the trial. The consents, however, provide only a limited level of protection, and product liability insurance will be required. Additionally, we will indemnify the clinical centers and related parties in connection with losses they may incur through their involvement in the clinical trials. We may not be able to obtain or maintain product liability insurance on acceptable terms or with adequate coverage against potential liabilities.

#### The price of our common stock is expected to be volatile and an investment in our common stock could decline in value.

The market price of our common stock, and the market prices for securities of pharmaceutical and biotechnology companies in general, are expected to be highly volatile. The following factors, in addition to other risk factors described in this report, and the potentially low volume of trades in our common stock, may have a significant impact on the market price of our common stock, some of which are beyond our control: actual or anticipated variations in operating results; announcements of technological innovations; developments concerning any research and development, clinical trials, manufacturing, and marketing collaborations; new products or services that we or our competitors offer; the initiation, conduct and/or outcome of intellectual property and/or litigation matters; changes in financial estimates by securities analysts; conditions or trends in bio-pharmaceutical or other healthcare industries; global unrest, terrorist activities, and economic and other external factors; regulatory developments in the United States and other countries; changes in the economic performance and/or market valuations of other biotechnology and medical device companies; our announcement of significant acquisitions, strategic partnerships, joint ventures or capital commitments; additions or departures of key personnel; and sales or other transactions involving our common stock.

The stock market in general has recently experienced relatively large price and volume fluctuations. In particular, market prices of securities of biotechnology and medical device companies have experienced fluctuations that often have been unrelated or disproportionate to the operating results of these companies. Continued market fluctuations could result in extreme volatility in the price of the common stock, which could cause a decline in the value of the common stock. Prospective investors should also be aware that price volatility may be worse if the trading volume

of the common stock is low.

#### ITEM 7. FINANCIAL STATEMENTS

#### **Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Shareholders of Aries Ventures Inc.

We have audited the accompanying balance sheet of Aries Ventures Inc. (the Company ) as of September 30, 2005, and the related statements of operations, shareholders equity and cash flows for the year then ended. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Aries Ventures Inc. as of September 30, 2005, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ Marcum & Kliegman LLP New York, New York December 16, 2005

#### **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders of Aries Ventures Inc.

We have audited the accompanying balance sheet of Aries Ventures Inc., a Nevada corporation (the Company ) as of September 30, 2004, and the related statements of operations, shareholders equity and cash flows for the year then ended. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Aries Ventures Inc. as of September 30, 2004, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States.

/s/ Weinberg & Company, P.A. Boca Raton, Florida December 17, 2004

#### Aries Ventures Inc.

#### **Balance Sheets**

		Septem	ber 30	),						
		2005		2004						
ASSETS										
CURRENT										
Cash and cash equivalents	\$	2,513,262	\$	2,686,241						
Marketable securities		30,000								
Prepaid expenses and other current assets				18,147						
Total current assets		2,543,262		2,704,388						
PROPERTY AND EQUIPMENT		27,363		27,363						
Less: accumulated depreciation and amortization		(27,363)		(26,642)						
				721						
DEPOSITS				2,309						
	Ma	rch 31,								
	201	5		221		\$ 22.81		\$23.4	6	\$ 5,1
March 31, 2014		130		\$ 19	9.92	\$	19.98	\$	2,605	
Note 13. Commitments and Loss Conti	ngen	cy								

# Commitments

During the three months ended March 31, 2015, the Company entered into several leases in the ordinary course of business. The following is a schedule of future minimum rental payments required under operating leases that have noncancelable lease terms as of March 31, 2015 (in thousands):

	Amount
2015 (remaining nine months)	\$ 171
2016	452
2017	452
2018	452
2019	452
2020	1,962
2021 and thereafter	12,869
Total minimum payments required	\$ 16,810

During the three months ended March 31, 2015, the Company entered into agreements with third-party vendors in the ordinary course of business whereby the Company committed to purchase goods and services used in its normal operations. These agreements, which are not cancelable, generally range from one to five year periods and contain fixed or minimum annual commitments. Certain of these agreements allow for renegotiation of the minimum annual commitments based on certain conditions. The following is a schedule of the future minimum purchases remaining under the agreements as of March 31, 2015 (in thousands):

	A	mount
2015 (remaining nine months)	\$	1,656
2016		787
2017		633
2018		
2019		
2020		
2021 and thereafter		
Total minimum payments required	\$	3,076

Except as outlined above, there have not been any material changes to the outstanding contractual obligations from the disclosure in our Annual Report on Form 10-K for the year ended December 31, 2014.

# Loss Contingency

The Company from time to time is involved in legal actions arising in the ordinary course of business. With respect to these matters, management believes that the Company has adequate legal defenses and/or when possible and appropriate, provided adequate accruals related to those matters such that the ultimate outcome will not have a material adverse effect on the Company s financial position or results of operations.

## Note 14. Defined Benefit Pension Plan and Postretirement Benefits

#### **Defined Benefit Pension Plans**

The following table provides information about the net periodic benefit cost for the Company s pension plans (in thousands):

	Thre	Three Months Ended March 31,				
	201	5		2014		
Service cost	\$	115	\$		100	
Interest cost		36			30	
Recognized actuarial (gains)		(11)			(12)	
Net periodic benefit cost	\$	140	\$		118	

## **Employee Retirement Savings Plans**

The Company maintains a 401(k) plan covering defined employees who meet established eligibility requirements. Under the plan provisions, the Company matches 50% of participant contributions to a maximum matching amount of 2% of participant compensation. The Company s contributions included in the accompanying Condensed Consolidated Statements of Operations were as follows (in thousands):

	Thr	ee Months E	nded M	Iarch 31,
	20	15		2014
401(k) plan contributions	\$	283	\$	260

#### **Split-Dollar Life Insurance Arrangement**

In 1996, the Company entered into a split-dollar life insurance arrangement to benefit the former Chairman and Chief Executive Officer of the Company. Under the terms of the arrangement, the Company retained a collateral interest in the policy to the extent of the premiums paid by the Company. The postretirement benefit obligation included in Other long-term liabilities and the unrealized gains (losses) included in Accumulated other comprehensive income in the accompanying Condensed Consolidated Balance Sheets were as follows (in thousands):

	March 3	31, 2015	Decen	nber 31, 2014
Postretirement benefit obligation	\$	44	\$	46
Unrealized gains (losses) in AOCI (1)	\$	327	\$	342

<sup>(1)</sup> Unrealized gains (losses) are impacted by changes in discount rates related to the postretirement obligation.

## Note 15. Stock-Based Compensation

The Company s stock-based compensation plans include the 2011 Equity Incentive Plan, the 2004 Non-Employee Director Fee Plan and the Deferred Compensation Plan. The following table summarizes the stock-based compensation expense (primarily in the Americas), income tax benefits related to the stock-based compensation and excess tax benefits (deficiencies) (in thousands):

	Thr	Three Months Ended March 31			
		2015	2	2014	
Stock-based compensation (expense) <sup>(1)</sup>	\$	(1,996)	\$	(754)	
Income tax benefit <sup>(2)</sup>		729		264	
Excess tax benefit (deficiency) from stock-based compensation <sup>(3)</sup>		169		54	

<sup>(1)</sup> Included in General and administrative costs in the accompanying Condensed Consolidated Statements of Operations.

- <sup>(2)</sup> Included in Income taxes in the accompanying Condensed Consolidated Statements of Operations.
- <sup>(3)</sup> Included in Additional paid-in capital in the accompanying Condensed Consolidated Statements of Changes in Shareholders Equity.

There were no capitalized stock-based compensation costs as of March 31, 2015 and December 31, 2014.

**2011 Equity Incentive Plan** The Company s Board adopted the Sykes Enterprises, Incorporated 2011 Equity Incentive Plan (the 2011 Plan ) on March 23, 2011, as amended on May 11, 2011 to reduce the number of shares of common stock available to 4.0 million shares. The 2011 Plan was approved by the shareholders at the May 2011 annual shareholders meeting. The 2011 Plan replaced and superseded the Company s 2001 Equity Incentive Plan (the

2001 Plan ), which expired on March 14, 2011. The outstanding awards granted under the 2001 Plan will remain in effect until their exercise, expiration or termination. The 2011 Plan permits the grant of restricted stock, stock appreciation rights, stock options and other stock-based awards to certain employees of the Company, members of the Company s Board of Directors and certain non-employees who provide services to the Company in order to encourage them to remain in the employment of, or to faithfully provide services to, the Company and to increase their interest in the Company s success.

<u>Stock Appreciation Rights</u> The Board, at the recommendation of the Compensation and Human Resources Development Committee (the Compensation Committee ), has approved in the past, and may approve in the future, awards of stock-settled stock appreciation rights (SARs) for eligible participants. SARs represent the right to receive, without payment to the Company, a certain number of shares of common stock, as determined by the Compensation Committee, equal to the amount by which the fair market value of a share of common stock at the time of exercise exceeds the grant price. The SARs are granted at the fair market value of the Company s common stock on the date of the grant and vest one-third on each of the first three anniversaries of the date of grant, provided the participant is employed by the Company on such date. The SARs have a term of 10 years from the date of grant. The fair value of each SAR is estimated on the date of grant using the Black-Scholes valuation model that uses various assumptions.

The following table summarizes the assumptions used to estimate the fair value of SARs granted (none in 2015):

	Three Months	Ended March 31,
	2015	2014
Expected volatility		38.9%
Weighted-average volatility		38.9%
Expected dividend rate		0.0%
Expected term (in years)		5.0
Risk-free rate		1.7%

The following table summarizes SARs activity as of March 31, 2015 and for the three months then ended:

Stock Appreciation Rights	Shares (000s)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (000s)
Outstanding at January 1, 2015	959	\$		
Granted		\$		
Exercised	(44)	\$		
Forfeited or expired		\$		
Outstanding at March 31, 2015	915	\$	6.7	\$ 6,026
Vested or expected to vest at March 31, 2015	915	\$	6.7	\$ 6,026
Exercisable at March 31, 2015	708	\$	6.1	\$ 4,638

The following table summarizes information regarding SARs granted and exercised (in thousands, except per SAR amounts):

	Three M	Three Months Ended March 31,			
	201	5	2014		
Number of SARs granted			246		
Weighted average grant-date fair value per SAR	\$		\$ 7.20		
Intrinsic value of SARs exercised	\$	402	\$ 208		
Fair value of SARs vested	<b>\$</b> 1	,302	\$ 1,553		
Charles Caller and CAD and CAD and Caller and Calle	21 2015	41	41 41		

The following table summarizes nonvested SARs activity as of March 31, 2015 and for the three months then ended:

Nonvested Stock Appreciation Rights	Shares (000s)	Weight Average G Date Fair	Frant-
Nonvested at January 1, 2015	411	\$	6.61
Granted		\$	
Vested	(204)	\$	6.41
Forfeited or expired		\$	
Nonvested at March 31, 2015	207	\$	6.80

As of March 31, 2015, there was \$1.4 million of total unrecognized compensation cost, net of estimated forfeitures, related to nonvested SARs granted under the 2011 Plan. This cost is expected to be recognized over a weighted average period of 1.3 years.

**<u>Restricted Shares</u>** The Board, at the recommendation of the Compensation Committee, has approved in the past, and may approve in the future, awards of performance and employment-based restricted shares (restricted shares) for eligible participants. In some instances, where the issuance of restricted shares has adverse tax consequences to the recipient, the Board may instead issue restricted stock units (RSUs). The restricted shares are shares of the Company s common stock (or in the case of RSUs, represent an equivalent number of shares of the Company s common stock) which are issued to the participant subject to (a) restrictions on transfer for a period of time and (b) forfeiture under certain conditions. The performance goals, including revenue growth and income from operations targets, provide a range of vesting possibilities from 0% to 100% and will be measured at the end of the performance period. If the performance conditions are met for the performance period, the shares will vest and all restrictions on the transfer of the restricted shares will lapse (or in the case of RSUs, an equivalent number of shares of the Company s common stock will be issued to the recipient). The Company recognizes compensation cost, net of estimated forfeitures, based on the fair value (which approximates the current market price) of the restricted shares (and RSUs) on the date of grant ratably over the requisite service period based on the probability of achieving the performance goals.

Changes in the probability of achieving the performance goals from period to period will result in corresponding changes in compensation expense. The employment-based restricted shares currently outstanding vest one-third on each of the first three anniversaries of the date of grant, provided the participant is employed by the Company on such date.

The following table summarizes nonvested restricted shares/RSUs activity as of March 31, 2015 and for the three months then ended:

Nonvested Restricted Shares and RSUs	Shares (000s)	Avera	'eighted age Grant- Fair Value
Nonvested at January 1, 2015	1,194	\$	16.80
Granted		\$	
Vested	(125)	\$	16.10
Forfeited or expired	(224)	\$	15.21
Nonvested at March 31, 2015	845	\$	17.33

The following table summarizes information regarding restricted shares/RSUs granted and vested (in thousands, except per restricted share/RSU amounts):

	Three Months Ended March 31,			
	2015 2014			
Number of restricted shares/RSUs granted			500	
Weighted average grant-date fair value per restricted share/RSU	\$	\$	19.77	
Fair value of restricted shares/RSUs vested	\$ 2,019	\$	895	

As of March 31, 2015, based on the probability of achieving the performance goals, there was \$9.1 million of total unrecognized compensation cost, net of estimated forfeitures, related to nonvested restricted shares/RSUs granted under the 2011 Plan. This cost is expected to be recognized over a weighted average period of 1.5 years.

**2004** Non-Employee Director Fee Plan The Company s 2004 Non-Employee Director Fee Plan (the 2004 Fee Plan ), as last amended on May 17, 2012, provided that all new non-employee directors joining the Board would receive an initial grant of shares of common stock on the date the new director is elected or appointed, the number of which will be determined by dividing \$60,000 by the closing price of the Company s common stock on the trading day immediately preceding the date a new director is elected or appointed, rounded to the nearest whole number of shares. The initial grant of shares vested in twelve equal quarterly installments, one-twelfth on the date of grant and an additional one-twelfth on each successive third monthly anniversary of the date of grant. The award lapses with respect to all unvested shares in the event the non-employee director ceases to be a director of the Company, and any unvested shares are forfeited.

The 2004 Fee Plan also provided that each non-employee director would receive, on the day after the annual shareholders meeting, an annual retainer for service as a non-employee director (the Annual Retainer ). Prior to May 17, 2012, the Annual Retainer was \$95,000, of which \$50,000 was payable in cash, and the remainder was paid in stock. The annual grant of cash vested in four equal quarterly installments, one-fourth on the day following the annual meeting of shareholders, and an additional one-fourth on each successive third monthly anniversary of the date of grant. The annual grant of shares paid to non-employee directors prior to May 17, 2012 vests in eight equal quarterly installments, one-eighth on the day following the annual meeting of shareholders, and an additional one-eighth on each successive third monthly anniversary of the date of grant. On May 17, 2012, upon the

recommendation of the Compensation Committee, the Board adopted the Fifth Amended and Restated Non-Employee Director Fee Plan (the Amendment ), which increased the common stock component of the Annual Retainer by \$30,000, resulting in a total Annual Retainer of \$125,000, of which \$50,000 was payable in cash and the remainder paid in stock. In addition, the Amendment also changed the vesting period for the annual equity award, from a two-year vesting period, to a one-year vesting period (consisting of four equal quarterly installments, one-fourth on the date of grant and an additional one-fourth on each successive third monthly anniversary of the date of grant). The award lapses with respect to all unpaid cash and unvested shares in the event the non-employee director ceases to be a director of the Company, and any unvested shares and unpaid cash are forfeited.

In addition to the Annual Retainer award, the 2004 Fee Plan also provided for any non-employee Chairman of the Board to receive an additional annual cash award of \$100,000, and each non-employee director serving on a committee of the Board to receive an additional annual cash award. The additional annual cash award for the Chairperson of the Audit Committee is \$20,000 and Audit Committee members are entitled to an annual cash

award of \$10,000. Prior to May 20, 2011, the annual cash awards for the Chairpersons of the Compensation Committee, Finance Committee and Nominating and Corporate Governance Committee were \$12,500 and the members of such committees were entitled to an annual cash award of \$7,500. On May 20, 2011, the Board increased the additional annual cash award to the Chairperson of the Compensation Committee to \$15,000. All other additional cash awards remained unchanged.

The 2004 Fee Plan expired in May 2014, prior to the 2014 Annual Shareholder Meeting. In March 2014, upon the recommendation of the Compensation Committee, the Board determined that, following the expiration of the 2004 Fee Plan, the compensation of non-employee Directors should continue on the same terms as provided in the Fifth Amended and Restated Non-Employee Director Fee Plan, and that the stock portion of such compensation would be issued under the 2011 Plan.

At the Board s regularly scheduled meeting on December 9, 2014, upon the recommendation of the Compensation Committee, the Board determined that the amount of the cash and equity compensation payable to non-employee directors beginning on the date of the 2015 annual shareholder meeting would be increased as follows: cash compensation would be increased by \$5,000 per year to a total of \$55,000 and equity compensation would be increased by \$25,000 per year to a total of \$55,000 and equity compensation would be increased by \$25,000 per year to a total of \$100,000. No change would be made in the additional amounts payable to the Chairman of the Board or the Chairs or members of the various Board committees for their service on such committees, and no changes would be made in the payment terms described above for such cash and equity compensation.

The Board may pay additional cash compensation to any non-employee director for services on behalf of the Board over and above those typically expected of directors, including but not limited to service on a special committee of the Board.

The following table summarizes nonvested common stock share award activity as of March 31, 2015 and for the three months then ended:

Nonvested Common Stock Share Awards	Shares (000s)	Weig Average Date Fai	Grant-
Nonvested at January 1, 2015	12	\$	20.24
Granted		\$	
Vested	(8)	\$	20.10
Forfeited or expired		\$	
Nonvested at March 31, 2015	4	\$	20.53

The following table summarizes information regarding common stock share awards granted and vested (in thousands, except per share award amounts):

Three Months Ended March 31, 2015 2014

Number of share awards granted			
Weighted average grant-date fair value per share award	\$	\$	
Fair value of share awards vested	<b>\$</b> 1	160 \$	150

As of March 31, 2015, there was \$0.1 million of total unrecognized compensation cost, net of estimated forfeitures, related to nonvested common stock share awards granted under the 2004 Fee Plan. This cost is expected to be recognized over a weighted average period of 1.1 years.

**Deferred Compensation Plan** The Company s non-qualified Deferred Compensation Plan (the Deferred Compensation Plan ), which is not shareholder-approved, was adopted by the Board effective December 17, 1998, It was amended and restated on August 20, 2014, effective as of January 1, 2014. It provides certain eligible employees the ability to defer any portion of their compensation until the participant s retirement, termination, disability or death, or a change in control of the Company. Using the Company s common stock, the Company matches 50% of the amounts deferred by certain senior management participants on a quarterly basis up to a total of \$12,000 per year for the president, chief executive officer and executive vice presidents and \$7,500 per year for senior vice presidents, global vice presidents and vice presidents (participants below the level of vice president are

not eligible to receive matching contributions from the Company). Matching contributions and the associated earnings vest over a seven year service period. Deferred compensation amounts used to pay benefits, which are held in a rabbi trust, include investments in various mutual funds and shares of the Company s common stock (see Note 6, Investments Held in Rabbi Trust). As of March 31, 2015 and December 31, 2014, liabilities of \$7.6 million and \$7.0 million, respectively, of the Deferred Compensation Plan were recorded in Accrued employee compensation and benefits in the accompanying Condensed Consolidated Balance Sheets.

Additionally, the Company s common stock match associated with the Deferred Compensation Plan, with a carrying value of approximately \$1.6 million and \$1.5 million at March 31, 2015 and December 31, 2014, respectively, is included in Treasury stock in the accompanying Condensed Consolidated Balance Sheets.

The following table summarizes nonvested common stock activity as of March 31, 2015 and for the three months then ended:

Nonvested Common Stock	Shares (000s)	Avera	eighted age Grant- Fair Value
Nonvested at January 1, 2015	5	\$	17.88
Granted	5	\$	24.85
Vested	(6)	\$	23.35
Forfeited or expired		\$	
Nonvested at March 31, 2015	4	\$	18.62

The following table summarizes information regarding shares of common stock granted and vested (in thousands, except per common stock amounts):

	Three	Three Months Ended March 3			
	2015		2014		
Number of shares of common stock granted		5		5	
Weighted average grant-date fair value per common stock	\$	24.85	\$	19.87	
Fair value of common stock vested	\$	129	\$	101	
Cash used to settle the obligation	\$	65	\$	21	

As of March 31, 2015, there was less than \$0.1 million of total unrecognized compensation cost, net of estimated forfeitures, related to nonvested common stock granted under the Deferred Compensation Plan. This cost is expected to be recognized over a weighted average period of 2.1 years.

#### Note 16. Segments and Geographic Information

The Company operates within two regions, the Americas and EMEA. Each region represents a reportable segment comprised of aggregated regional operating segments, which portray similar economic characteristics. The Company aligns its business into two segments to effectively manage the business and support the customer care needs of every client and to respond to the demands of the Company s global customers.

The reportable segments consist of (1) the Americas, which includes the United States, Canada, Latin America, Australia and the Asia Pacific Rim, and provides outsourced customer contact management solutions (with an emphasis on technical support and customer service) and technical staffing and (2) EMEA, which includes Europe, the Middle East and Africa, and provides outsourced customer contact management solutions (with an emphasis on technical support and customer service) and fulfillment services. The sites within Latin America, Australia and the Asia Pacific Rim are included in the Americas segment given the nature of the business and client profile, which is primarily made up of U.S.-based companies that are using the Company services in these locations to support their customer contact management needs.

Information about the Company s reportable segments is as follows (in thousands):

	A	mericas	I	EMEA	Other <sup>(1)</sup>		Co	nsolidated
Three Months Ended March 31, 2015:								
Revenues	\$	264,173	\$	59,495	\$	17	\$	323,685
Percentage of revenues		81.6%		18.4%		0.0%		100.0%
Depreciation, net	\$	9,580	\$	1,143	\$	336	\$	11,059
Amortization of intangibles	\$	3,431	\$		\$		\$	3,431
Income (loss) from operations	\$	32,541	\$	3,788	\$	(13,788)	\$	22,541
Other (expense), net						(1,102)		(1,102)
Income taxes						(5,800)		(5,800)
Net income							\$	15,639
Total assets as of March 31, 2015	<b>\$</b> 1	1,069,686	\$1	,370,912	<b>\$ (</b>	1,521,514)	\$	919,084
Three Months Ended March 31, 2014:								
Revenues	\$	261,246	\$	63,183	\$		\$	324,429
Percentage of revenues		80.5%		19.5%		0.0%		100.0%
Depreciation, net	\$	10,140	\$	1,158	\$		\$	11,298
Amortization of intangibles	\$	3,651	\$		\$		\$	3,651
Income (loss) from operations	\$	22,647	\$	2,884	\$	(11,053)	\$	14,478
Other (expense), net						395		395
Income taxes						(4,560)		(4,560)
Net income							\$	10,313

Total assets as of March 31, 2014	\$ 1,084,443	\$1,446,686	\$(1,594,458)	\$	936,671
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(1) Other items (including corporate and other costs, impairment costs, other income and expense, and income taxes) are shown for purposes of reconciling to the Company s consolidated totals as shown in the tables above for the three months ended March 31, 2015 and 2014. Inter-segment revenues are not material to the Americas and EMEA segment results. The Company evaluates the performance of its geographic segments based on revenues and income (loss) from operations, and does not include segment assets or other income and expense items for management reporting purposes.

### Note 17. Other Income (Expense)

Other income (expense) consists of the following (in thousands):

	Three Months Ended March 2015 2014			,
Foreign currency transaction gains (losses)	\$	(935)	\$	(128)
Gains (losses) on foreign currency derivative instruments not designated as				
hedges		(164)		723
Other miscellaneous income (expense)		270		68
-				
	\$	(829)	\$	663

#### Note 18. Related Party Transactions

In January 2008, the Company entered into a lease for a customer contact management center located in Kingstree, South Carolina. The landlord, Kingstree Office One, LLC, is an entity controlled by John H. Sykes, the founder, former Chairman and Chief Executive Officer of the Company and the father of Charles Sykes, President and Chief Executive Officer of the Company. The lease payments on the 20-year lease were negotiated at or below market rates, and the lease is cancellable at the option of the Company. There are significant penalties for early cancellation which decrease over time. The Company paid \$0.1 million to the landlord during both the three months ended March 31, 2015 and 2014 under the terms of the lease.

# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of

Sykes Enterprises, Incorporated

400 North Ashley Drive

Tampa, Florida

We have reviewed the accompanying condensed consolidated balance sheet of Sykes Enterprises, Incorporated and subsidiaries (the Company ) as of March 31, 2015, and the related condensed consolidated statements of operations and comprehensive income for the three-month periods ended March 31, 2015 and 2014, of changes in shareholders equity for the three-month period ended March 31, 2015, and of cash flows for the three-month periods ended March 31, 2015 and 2014. These interim financial statements are the responsibility of the Company s management.

We conducted our reviews in accordance with the standards of the Public Company Accounting Oversight Board (United States). A review of interim financial information consists principally of applying analytical procedures and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with the standards of the Public Company Accounting Oversight Board (United States), the objective of which is the expression of an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

Based on our reviews, we are not aware of any material modifications that should be made to such condensed consolidated interim financial statements for them to be in conformity with accounting principles generally accepted in the United States of America.

We have previously audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of Sykes Enterprises, Incorporated and subsidiaries as of December 31, 2014, and the related consolidated statements of operations, comprehensive income, shareholders equity, and cash flows for the year then ended (not presented herein); and in our report dated February 19, 2015, we expressed an unqualified opinion on those consolidated financial statements. In our opinion, the information set forth in the accompanying condensed consolidated balance sheet as of December 31, 2014 is fairly stated, in all material respects, in relation to the consolidated balance sheet from which it has been derived.

/s/ Deloitte & Touche LLP Certified Public Accountants Tampa, Florida

May 5, 2015

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

This discussion should be read in conjunction with the condensed consolidated financial statements and notes included elsewhere in this report and the consolidated financial statements and notes in the Sykes Enterprises, Incorporated (SYKES, our, we or us) Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the Securities and Exchange Commission (SEC).

Our discussion and analysis may contain forward-looking statements (within the meaning of the Private Securities Litigation Reform Act of 1995) that are based on current expectations, estimates, forecasts, and projections about SYKES, our beliefs, and assumptions made by us. In addition, we may make other written or oral statements, which constitute forward-looking statements, from time to time. Words such as believe, estimate, project, expect, intend, may, anticipate, plan, seek, variations of such words, and similar expressions are intended to identify such forward-looking statements. Similarly, statements that describe our future plans, objectives, or goals also are forward-looking statements. These statements are not guarantees of future performance and are subject to a number of risks and uncertainties, including those discussed below and elsewhere in this report. Our actual results may differ materially from what is expressed or forecasted in such forward-looking statements, and undue reliance should not be placed on such statements. All forward-looking statements are made as of the date hereof, and we undertake no obligation to update any such forward-looking statements, whether as a result of new information, future events or otherwise.

Factors that could cause actual results to differ materially from what is expressed or forecasted in such forward-looking statements include, but are not limited to: (i) the impact of economic recessions in the U.S. and other parts of the world, (ii) fluctuations in global business conditions and the global economy, (iii) currency fluctuations, (iv) the timing of significant orders for our products and services, (v) variations in the terms and the elements of services offered under our standardized contract including those for future bundled service offerings, (vi) changes in applicable accounting principles or interpretations of such principles, (vii) difficulties or delays in implementing our bundled service offerings, (viii) failure to achieve sales, marketing and other objectives, (ix) construction delays of new or expansion of existing customer contact management centers, (x) delays in our ability to develop new products and services and market acceptance of new products and services, (xi) rapid technological change, (xii) loss or addition of significant clients, (xiii) political and country-specific risks inherent in conducting business abroad, (xiv) our ability to attract and retain key management personnel, (xv) our ability to continue the growth of our support service revenues through additional technical and customer contact management centers, (xvi) our ability to further penetrate into vertically integrated markets, (xvii) our ability to expand our global presence through strategic alliances and selective acquisitions, (xviii) our ability to continue to establish a competitive advantage through sophisticated technological capabilities, (xix) the ultimate outcome of any lawsuits, (xx) our ability to recognize deferred revenue through delivery of products or satisfactory performance of services, (xxi) our dependence on trend toward outsourcing, (xxii) risk of interruption of technical and customer contact management center operations due to such factors as fire, earthquakes, inclement weather and other disasters, power failures, telecommunication failures, unauthorized intrusions, computer viruses and other emergencies, (xxiii) the existence of substantial competition, (xxiv) the early termination of contracts by clients, (xxv) the ability to obtain and maintain grants and other incentives (tax or otherwise), (xxvi) the potential of cost savings/synergies associated with acquisitions not being realized, or not being realized within the anticipated time period, (xxvii) risks related to the integration of the acquisitions and the impairment of any related goodwill, and (xxviii) other risk factors which are identified in our most recent Annual Report on Form 10-K, including factors identified under the headings Business, Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations.

#### **Executive Summary**

We provide comprehensive customer contact management solutions and services to a wide range of clients including Fortune 1000 companies, medium-sized businesses and public institutions around the world, primarily in the communications, financial services, technology/consumer, transportation and leisure and healthcare industries. We serve our clients through two geographic operating regions: the Americas (United States, Canada, Latin America, Australia and the Asia Pacific Rim) and EMEA (Europe, the Middle East and Africa). Our Americas and EMEA groups primarily provide customer contact management services (with an emphasis on inbound technical support and customer service), which include customer assistance, healthcare and roadside assistance, technical support and product sales to our clients customers. These services, which represented 98.6% and 98.2% of consolidated revenues during the three months ended March 31, 2015 and 2014, respectively, are delivered through multiple communication channels encompassing phone, e-mail, social media, text messaging and chat. We also provide

various enterprise support services in the United States (U.S.) that include services for our client s internal support operations, from technical staffing services to outsourced corporate help desk services. In Europe, we also provide fulfillment services including order processing, payment processing, inventory control, product delivery, and product returns handling. Our complete service offering helps our clients acquire, retain and increase the lifetime value of their customer relationships. We have developed an extensive global reach with customer contact management centers throughout the United States, Canada, Europe, Latin America, Australia, the Asia Pacific Rim and Africa.

# **Results of Operations**

The following table sets forth, for the periods indicated, the amounts presented in the accompanying Condensed Consolidated Statements of Operations as well as the changes between the respective periods:

	Three Months Ended March 31, 2015			
(in thousands)	2015	2014	\$ Change	
Revenues	\$ 323,685	\$324,429	\$ (744)	
Operating expenses:				
Direct salaries and related costs	213,927	221,625	(7,698)	
General and administrative	72,727	73,377	(650)	
Depreciation, net	11,059	11,298	(239)	
Amortization of intangibles	3,431	3,651	(220)	
Total operating expenses	301,144	309,951	(8,807)	
Income from operations	22,541	14,478	8,063	
Other income (expense):				
Interest income	166	231	(65)	
Interest (expense)	(439)	(499)	60	
Other income (expense)	(829)	663	(1,492)	
Total other income (expense)	(1,102)	395	(1,497)	
Income before income taxes	21,439	14,873	6,566	
Income taxes	<b>5,800</b>	4,560	1,240	
	5,000	4,500	1,240	
Net income	\$ 15,639	\$ 10,313	\$ 5,326	
	\$ 15,039	φ 10,515	φ <i>3,32</i> 0	

# Three Months Ended March 31, 2015 Compared to Three Months Ended March 31, 2014

#### Revenues

	Three Months Ended March 31,				
	20	15	2014		
		% of		% of	
(in thousands)	Amount	Revenues	Amount	Revenues	\$ Change
Americas	\$ 264,173	81.6%	\$261,246	80.5%	\$ 2,927
EMEA	59,495	18.4%	63,183	19.5%	(3,688)
Other	17	0.0%		0.0%	17
Consolidated	\$ 323,685	100.0%	\$324,429	100.0%	\$ (744)

Consolidated revenues decreased \$0.7 million, or (0.2)%, for the three months ended March 31, 2015 from the comparable period in 2014.

The increase in Americas revenues was due to higher volumes from existing clients of \$27.8 million and new clients of \$3.2 million, partially offset by end-of-life client programs of \$24.5 million and a negative foreign currency impact of \$3.6 million. Revenues from our offshore operations represented 42.2% of Americas revenues, compared to 36.8% for the comparable period in 2014.

The decrease in EMEA s revenues was due to a negative foreign currency impact of \$12.5 million and end-of-life client programs of \$0.6 million, partially offset by higher volumes from existing clients of \$7.6 million and new clients of \$1.9 million.

On a consolidated basis, we had 39,900 brick-and-mortar seats as of March 31, 2015, a decrease of 1,300 seats from the comparable period in 2014. This decrease in seats was primarily due to on-going capacity rationalization. The capacity utilization rate on a combined basis was 80% compared to 76% in the comparable period in 2014. This increase was primarily due to capacity rationalization and higher demand.

On a geographic segment basis, 33,200 seats were located in the Americas, a decrease of 1,800 seats from the comparable period in 2014, and 6,700 seats were located in EMEA, an increase of 500 seats from the comparable period in 2014. Capacity utilization rates as of March 31, 2015 were 78% for the Americas and 88% for EMEA, compared to 74% and 85%, respectively, in the comparable period in 2014, primarily due to capacity rationalization and higher demand. We strive to attain an 85% capacity utilization metric at each of our locations.

We plan to add approximately 1,700 seats on a gross basis in 2015 to support certain client program expansions. Approximately 400 seats were added during the three months ended March 31, 2015, with more than three-quarters of the gross seat additions to be added in or around the first half of 2015. Total seat count on a net basis for the full year, however, is expected to remain unchanged as we continue to rationalize excess capacity.

### **Direct Salaries and Related Costs**

Three Months Ended March 31,							
	201	15	2014				
		% of		% of	C	hange in % of	
(in thousands)	Amount	Revenues	Amount	Revenues	\$ Change	Revenues	
Americas	\$ 171,099	64.8%	\$175,534	67.2%	\$ (4,435)	-2.4%	
EMEA	42,828	72.0%	46,091	72.9%	(3,263)	-0.9%	
Consolidated	\$ 213,927	66.1%	\$221,625	68.3%	\$ (7,698)	-2.2%	

The decrease of \$7.7 million in direct salaries and related costs included a positive foreign currency impact of \$5.6 million in the Americas and a positive foreign currency impact of \$9.0 million in EMEA.

The decrease in Americas direct salaries and related costs, as a percentage of revenues, was primarily attributable to lower compensation costs of 2.2% driven by the increase in new client program ramp up costs in the prior period in the communications vertical, and lower communication costs of 0.2%.

The decrease in EMEA s direct salaries and related costs, as a percentage of revenues, was primarily attributable to lower compensation costs of 1.3% driven by the increase in new and existing client program ramp up costs in the prior period in the communications vertical, and lower billable supply costs of 1.0%, partially offset by higher fulfillment materials costs of 0.6%, higher communication costs of 0.6% and higher other costs of 0.2%.

# General and Administrative

Three Months Ended March 31,						
	20	)15	20	014		
		% of		% of	C	hange in % of
(in thousands)	Amount	Revenues	Amount	Revenues	\$ Change	Revenues
Americas	\$47,522	18.0%	\$49,274	18.9%	\$ (1,752)	-0.9%
EMEA	11,736	19.7%	13,050	20.7%	(1,314)	-1.0%
Other	13,469		11,053		2,416	
Consolidated	\$72,727	22.5%	\$73,377	22.6%	\$ (650)	-0.1%

The decrease of \$0.7 million in general and administrative expenses included a positive foreign currency impact of \$1.1 million in the Americas and a positive foreign currency impact of \$2.4 million in EMEA.

The decrease in Americas general and administrative expenses, as a percentage of revenues, was primarily attributable to lower facility-related costs of 0.4%, lower other taxes of 0.3% and lower compensation costs of 0.2%.

The decrease in EMEA s general and administrative expenses, as a percentage of revenues, was primarily attributable to lower compensation costs of 0.6%, lower communication costs of 0.3% and lower other costs of 0.1%.

The increase of \$2.4 million in Other general and administrative expenses, which includes corporate and other costs, was primarily attributable to higher compensation costs of \$1.7 million, higher legal and professional fees of \$0.4 million and higher consulting costs of \$0.3 million.

## Depreciation and Amortization

Three Months Ended March 31,							
	20	15	20	14			
		% of		% of	C	Change in % of	
(in thousands)	Amount	Revenues	Amount	Revenues	\$ Change	Revenues	
Depreciation, net:							
Americas	\$ 9,580	3.6%	\$10,140	3.9%	\$ (560)	-0.3%	
EMEA	1,143	1.9%	1,158	1.8%	(15)	0.1%	
Other	336				336		
Consolidated	\$ 11,059	3.4%	\$11,298	3.5%	\$ (239)	-0.1%	
Amortization of intangibles:							
Americas	\$ 3,431	1.3%	\$ 3,651	1.4%	\$ (220)	-0.1%	
EMEA		0.0%		0.0%		0.0%	
Other							
Consolidated	\$ 3,431	1.1%	\$ 3,651	1.1%	\$ (220)	0.0%	

The decrease in depreciation was primarily due to fully depreciated net fixed assets.

The decrease in amortization was primarily due to certain fully amortized intangible assets.

#### **Other Income (Expense)**

	Three Months Ended March 31,					
(in thousands)		2015		2014	<b>\$ (</b>	Change
Interest income	\$	166		231	\$	(65)
Interest (expense)	\$	(439)	\$	(499)	\$	60
Other income (expense):						
Foreign currency transaction gains (losses)	\$	(935)	\$	(128)	\$	(807)
Gains (losses) on foreign currency derivative instruments not						
designated as hedges		(164)		723		(887)
Other miscellaneous income (expense)		270		68		202
Total other income (expense)	\$	(829)	\$	663	\$	(1,492)

Interest income and interest (expense) remained consistent with the comparable period in 2014.

Other income (expense) excludes the cumulative translation effects and unrealized gains (losses) on financial derivatives that are included in Accumulated other comprehensive income (loss) in shareholders equity in the

accompanying Condensed Consolidated Balance Sheets.

# Income Taxes

	Thr	Three Months Ended March 31,					
(in thousands)		2015 2014					
Income before income taxes	\$	21,439	\$	14,873	\$	6,566	
Income taxes	\$	\$ 5,800		4,560	\$	1,240	
					01.	Change	
					-70	Change	
Effective tax rate		27.1%		30.7%		-3.6%	

The increase in income taxes in 2015 compared to 2014 is due to several factors, including fluctuations in earnings among the various jurisdictions in which we operate, none of which are individually material.

## **Client Concentration**

Our top ten clients accounted for approximately 49.8% and 46.6% of our consolidated revenues in the three months ended March 31, 2015 and 2014, respectively.

Total revenues by segment from AT&T Corporation ( AT&T ), a major provider of communication services for which we provide various customer support services over several distinct lines of AT&T businesses, were as follows (in thousands):

	Thr	Three Months Ended March 31,				
	20	2015		)14		
		% of		% of		
	Amount	Revenues	Amount	Revenues		
Americas	\$ 60,023	22.7%	\$47,899	18.3%		
EMEA	750	1.3%	897	1.4%		
	\$ 60,773	18.8%	\$48,796	15.0%		

We have multiple distinct contracts with AT&T spread across multiple lines of businesses, which expire at varying dates between 2015 and 2017. We have historically renewed most of these contracts. However, there is no assurance that these contracts will be renewed, or if renewed, will be on terms as favorable as the existing contracts. Each line of business is governed by separate business terms, conditions and metrics. Each line of business also has a separate decision maker such that a loss of one line of business would not necessarily impact our relationship with the client and decision makers on other lines of business. The loss of (or the failure to retain a significant amount of business with) any of our key clients, including AT&T, could have a material adverse effect on our performance. Many of our contracts contain penalty provisions for failure to meet minimum service levels and are cancelable by the client at any time or on short notice. Also, clients may unilaterally reduce their use of our services under our contracts without penalty.

Total revenues by segment from our next largest client, which was in the financial services vertical in each of the periods, were as follows (in thousands):

		Three Months Ended M 2015		
		% of	_~	)14 % of
	Amount	Revenues	Amount	Revenues
Americas	\$ 14,794	5.6%	\$18,975	7.3%
EMEA		0.0%		0.0%
	\$ 14,794	4.6%	\$18,975	5.8%

Other than AT&T, total revenues by segment of our clients that each individually represents 10% or greater of that segment s revenues in each of the periods were as follows (in thousands):

	Thr	Three Months Ended March 31,				
	20	015	2014			
		% of		% of		
	Amount	Revenues	Amount	Revenues		
Americas	\$	0.0%	\$	0.0%		
EMEA	23,890	40.2%	17,437	27.6%		
	\$ 23,890	7.4%	\$17,437	5.4%		

#### **Business Outlook**

For the three months ended June 30, 2015, we anticipate the following financial results:

Revenues in the range of \$300.0 million to \$305.0 million;

Effective tax rate of approximately 27.0%;

Fully diluted share count of approximately 42.4 million;

Diluted earnings per share in the range of \$0.18 to \$0.21; and

Capital expenditures in the range of \$17.0 million to \$20.0 million For the twelve months ended December 31, 2015, we anticipate the following financial results:

Revenues in the range of \$1,270.0 million to \$1,285.0 million;

Effective tax rate of approximately 26.0%;

Fully diluted share count of approximately 42.8 million;

Diluted earnings per share in the range of \$1.32 to \$1.40; and

#### Capital expenditures in the range of \$50.0 million to \$55.0 million

We are fine tuning our full-year 2015 diluted earnings per share and revenues outlook due to on-going foreign exchange volatility and somewhat lower demand forecasted from a handful of existing clients within the communications vertical. Since the initial full-year 2015 business outlook, which was disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014, the functional currencies of our various international operations have weakened further relative to the U.S. Dollar. This further weakening is expected to impact 2015 revenues by an incremental \$17.0 million, above the initial \$50.0 million in foreign exchange impact forecasted in our initial full-year 2015 business outlook. In addition to the foreign exchange impact, a handful of clients have forecasted lower volumes for the remainder of the year due in large part to more muted competitive dynamics expected in the industry, which is also impacting revenues by approximately \$20.0 million.

Our revenues and earnings per share assumptions for the second quarter and full-year 2015 are based on foreign exchange rates as of April 2015. Therefore, the continued volatility in foreign exchange rates between the U.S. dollar

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and the functional currencies of the markets we serve could have a further impact, positive or negative, on revenues and earnings per share relative to the business outlook for the second quarter and full-year as disclosed above.

We anticipate a slightly lower effective tax rate for full-year 2015 relative to initial expectations, driven chiefly by a shift in the geographic mix of earnings to lower tax rate jurisdictions.

Not included in this guidance is the impact of any future acquisitions, share repurchase activities or a potential sale of previously exited customer contact management centers.

# Liquidity and Capital Resources

Our primary sources of liquidity are generally cash flows generated by operating activities and from available borrowings under our revolving credit facility. We utilize these capital resources to make capital expenditures associated primarily with our customer contact management services, invest in technology applications and tools to further develop our service offerings and for working capital and other general corporate purposes, including repurchase of our common stock in the open market and to fund acquisitions. In future periods, we intend similar uses of these funds.

On August 18, 2011, the Board authorized us to purchase up to 5.0 million shares of our outstanding common stock (the 2011 Share Repurchase Program ). A total of 4.2 million shares have been repurchased under the 2011 Share Repurchase Program since inception. The shares are purchased, from time to time, through open market purchases or in negotiated private transactions, and the purchases are based on factors, including but not limited to, the stock price, management discretion and general market conditions. The 2011 Share Repurchase Program has no expiration date.

The shares repurchased under our share repurchase program were as follows (in thousands, except per share amounts):

		Range of Prices Paid Per Share				e Tot	<b>Total Cost</b>		
	Total Number of Shares					S	of Shares		
	Repurchased		Low	]	High		irchased		
Three Months Ended:									
March 31, 2015	221	\$	22.81	\$	23.46	\$	5,136		
March 31, 2014	130	\$	19.92	\$	19.98	\$	2,605		

During the three months ended March 31, 2015, cash increased \$28.6 million from operating activities and \$0.2 million from excess tax benefits from stock-based compensation. The increase in cash was offset by \$10.9 million used for capital expenditures, \$1.0 million to repay long-term debt, \$5.1 million to repurchase common stock and \$1.1 million to repurchase common stock for minimum tax withholding on equity awards, resulting in a \$1.1 million decrease in available cash (including the unfavorable effects of foreign currency exchange rates on cash and cash equivalents of \$11.8 million).

Net cash flows provided by operating activities for the three months ended March 31, 2015 were \$28.6 million, compared to \$16.2 million for the comparable period in 2014. The \$12.4 million increase in net cash flows from operating activities was due to a \$5.3 million increase in net income and a net increase of \$8.1 million in cash flows from assets and liabilities, partially offset by a \$1.0 million decrease in non-cash reconciling items such as

depreciation, amortization, unrealized foreign currency transaction (gains) losses and deferred income taxes. The \$8.1 million increase in 2015 from 2014 in cash flows from assets and liabilities was principally a result of a \$15.8 million decrease in accounts receivable, a \$1.6 million increase in taxes payable and a \$7.3 million increase in other liabilities, partially offset by a \$12.1 million increase in other assets and a \$4.5 million decrease in deferred revenue. The \$15.8 million decrease in the change in accounts receivable was primarily due to lower volumes within certain clients as well as the timing of billings and collections in the three months ended March 31, 2015 over the comparable period in 2014. The \$12.1 million increase in other assets was primarily due to a change in the net investment hedge of \$6.3 million and a change in deferred tax assets of \$6.8 million in the three months ended March 31, 2015 over the comparable period in 2014.

Capital expenditures, which are generally funded by cash generated from operating activities, available cash balances and borrowings available under our credit facilities, were \$10.9 million for the three months ended March 31, 2015, compared to \$11.7 million for the comparable period in 2014, a decrease of \$0.8 million. In 2015, we anticipate capital expenditures in the range of \$50.0 million to \$55.0 million, primarily for new seat additions, Enterprise Resource Planning upgrades, facility upgrades, maintenance and systems infrastructure.

On May 3, 2012, we entered into a \$245 million revolving credit facility (the 2012 Credit Agreement ) with a group of lenders and KeyBank National Association, as Lead Arranger, Sole Book Runner and Administrative Agent (KeyBank). The 2012 Credit Agreement replaced our previous \$75 million revolving credit facility dated February 2, 2010, as amended, which agreement was terminated simultaneous with entering into the 2012 Credit Agreement. The 2012 Credit Agreement is subject to certain borrowing limitations and includes certain customary financial and restrictive covenants. At March 31, 2015, we were in compliance with all loan requirements of the 2012 Credit Agreement and had \$74.0 million and \$75.0 million of outstanding borrowings under this facility as of March 31, 2015 and December 31, 2014, respectively, with an average daily utilization of \$74.3 million and \$96.3 million for the three months ended March 31, 2015 and 2014, respectively. During the three months ended March 31, 2015 and 2014, respectively. During the three months ended March 31, 2015 and 2014, respectively. During the three months ended March 31, 2015 and 2014, respectively. During the three months ended March 31, 2015 and 2014, respectively. During the three months ended March 31, 2015 and 2014, respectively. During the three months ended March 31, 2015 and 2014, respectively. During the three months ended March 31, 2015 and 2014, respectively. During the three months ended March 31, 2015 and 2014, respectively. During the three months ended March 31, 2015 and 2014, respectively. During the three months ended March 31, 2015 and 2014, respectively. During the three months ended March 31, 2015 and 2014, respectively. During the three months ended March 31, 2015 and 2014, respectively. During the three months ended March 31, 2015 and 2014, respectively. During the three months ended March 31, 300.2 million and \$0.3 million, respectively, which represented weighted average interest rates of 1.3% and 1.3%, respectively.

The 2012 Credit Agreement includes a \$184 million alternate-currency sub-facility, a \$10 million swingline sub-facility and a \$35 million letter of credit sub-facility, and may be used for general corporate purposes including acquisitions, share repurchases, working capital support and letters of credit, subject to certain limitations. We are not currently aware of any inability of our lenders to provide access to the full commitment of funds that exist under the 2012 Credit Agreement, if necessary. However, there can be no assurance that such facility will be available to us, even though it is a binding commitment of the financial institutions. The 2012 Credit Agreement will mature on May 2, 2017.

Borrowings under the 2012 Credit Agreement will bear interest at the rates set forth in the Credit Agreement. In addition, we are required to pay certain customary fees, including a commitment fee of 0.175%, which is due quarterly in arrears and calculated on the average unused amount of the 2012 Credit Agreement.

The 2012 Credit Agreement is guaranteed by all of our existing and future direct and indirect material U.S. subsidiaries and secured by a pledge of 100% of the non-voting and 65% of the voting capital stock of all of our direct foreign subsidiaries and those of the guarantors.

We are currently under audit in several tax jurisdictions. We received assessments for the Canadian 2003-2009 audit. Requests for Competent Authority Assistance were filed with both the Canadian Revenue Agency and the U.S. Internal Revenue Service and we paid mandatory security deposits to Canada as part of this process. The total amount

of deposits, net of fluctuations in the foreign exchange rate, are \$14.7 million and \$15.9 million as of March 31, 2015 and December 31, 2014, respectively, and are included in Deferred charges and other assets in the accompanying Condensed Consolidated Balance Sheets. Although the outcome of examinations by taxing authorities is always uncertain, we believe we are adequately reserved for these audits and resolution is not expected to have a material impact on our financial condition and results of operations.

As of March 31, 2015, we had \$214.1 million in cash and cash equivalents, of which approximately 90.9%, or \$194.5 million, was held in international operations and is deemed to be indefinitely reinvested offshore. These funds may be subject to additional taxes if repatriated to the United States, including withholding tax applied by the country of origin and an incremental U.S. income tax, net of allowable foreign tax credits. There are circumstances where we may be unable to repatriate some of the cash and cash equivalents held by our international operations due

to country restrictions. We do not intend nor currently foresee a need to repatriate these funds. We expect our current domestic cash levels and cash flows from operations to be adequate to meet our domestic anticipated working capital needs, including investment activities such as capital expenditures and debt repayment for the next twelve months and the foreseeable future. However, from time to time, we may borrow funds under our 2012 Credit Agreement as a result of the timing of our working capital needs, including capital expenditures. Additionally, we expect our current foreign cash levels and cash flows from foreign operations to be adequate to meet our foreign anticipated working capital needs, including investment activities such as capital expenditures for the next twelve months and the foreseeable future.

If we should require more cash in the U.S. than is provided by our domestic operations for significant discretionary unforeseen activities such as acquisitions of businesses and share repurchases, we could elect to repatriate future foreign earnings and/or raise capital in the U.S through additional borrowings or debt/equity issuances. These alternatives could result in higher effective tax rates, interest expense and/or dilution of earnings. We have borrowed funds domestically and continue to have the ability to borrow additional funds domestically at reasonable interest rates.

Our cash resources could also be affected by various risks and uncertainties, including but not limited to, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2014.

#### **Off-Balance Sheet Arrangements and Other**

As of March 31, 2015, we did not have any material commercial commitments, including guarantees or standby repurchase obligations, or any relationships with unconsolidated entities or financial partnerships, including entities often referred to as structured finance or special purpose entities or variable interest entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

From time to time, during the normal course of business, we may make certain indemnities, commitments and guarantees under which we may be required to make payments in relation to certain transactions. These include, but are not limited to: (i) indemnities to clients, vendors and service providers pertaining to claims based on negligence or willful misconduct and (ii) indemnities involving breach of contract, the accuracy of representations and warranties, or other liabilities assumed by us in certain contracts. In addition, we have agreements whereby we will indemnify certain officers and directors for certain events or occurrences while the officer or director is, or was, serving at our request in such capacity. The indemnification period covers all pertinent events and occurrences during the officer s or director s lifetime. The maximum potential amount of future payments we could be required to make under these indemnification agreements is unlimited; however, we have director and officer insurance coverage that limits our exposure and enables us to recover a portion of any future amounts paid. We believe the applicable insurance coverage is generally adequate to cover any estimated potential liability under these indemnification agreements. The majority of these indemnities, commitments and guarantees do not provide for any limitation of the maximum potential for future payments we could be obligated to make. We have not recorded any liability for these indemnities, commitments and other guarantees in the accompanying Condensed Consolidated Balance Sheets. In addition, we have some client contracts that do not contain contractual provisions for the limitation of liability, and other client contracts that contain agreed upon exceptions to limitation of liability. We have not recorded any liability in the accompanying Condensed Consolidated Balance Sheets with respect to any client contracts under which we have or may have unlimited liability.

## **Contractual Obligations**

The following table summarizes the material changes to our contractual cash obligations as of March 31, 2015, and the effect these obligations are expected to have on liquidity and cash flow in future periods (in thousands):

Payments Due By Period											
Less Than				After 5							
	Total	1	Year	1 -	3 Years	3 - 5	5 Years		Years		Other
\$	16,810	\$	171	\$	904	\$	904	\$	14,831	\$	
	3,076		1,656		1,420						
\$	19,886	\$	1,827	\$	2,324	\$	904	\$	14,831	\$	
		\$ 16,810 3,076	Total 1   \$ 16,810 \$   3,076 \$	Total 1 Year   \$ 16,810 \$ 171   3,076 1,656	Less Than   Total 1 Year 1 -   \$ 16,810 \$ 171 \$   3,076 1,656	Less Than 1 - 3 Years   Total 1 Year 1 - 3 Years   \$ 16,810 \$ 171 \$ 904   3,076 1,656 1,420	Less Than   Total 1 Year 1 - 3 Years 3 - 3   \$ 16,810 \$ 171 \$ 904 \$   3,076 1,656 1,420 \$	Less Than 1 - 3 Years 3 - 5 Years   \$ 16,810 \$ 171 904 \$ 904   3,076 1,656 1,420 \$ 1,420	Less Than   Total 1 Year 1 - 3 Years 3 - 5 Years   \$ 16,810 \$ 171 \$ 904 \$ 904 \$   3,076 1,656 1,420 \$ \$	Less Than After 5   Total 1 Year 1 - 3 Years 3 - 5 Years Years   \$ 16,810 \$ 171 \$ 904 \$ 904 \$ 14,831   3,076 1,656 1,420 \$ 14,831	Less Than After 5   Total 1 Year 1 - 3 Years 3 - 5 Years Years   \$ 16,810 \$ 171 \$ 904 \$ 904 \$ 14,831 \$   3,076 1,656 1,420 \$ \$ \$

<sup>(1)</sup> Amounts represent the expected cash payments under our operating leases.

(2) Amounts represent the expected cash payments under our purchase obligations, which include agreements to purchase goods or services that are enforceable and legally binding on us and that specify all significant terms, including: fixed or minimum quantities to be purchased; fixed, minimum or variable price provisions; and the approximate timing of the transaction. Purchase obligations exclude agreements that are cancelable without penalty.

Except for the contractual obligations mentioned above, there have not been any material changes to the outstanding contractual obligations from the disclosure in our Annual Report on Form 10-K as of and for the year ended December 31, 2014 filed on February 19, 2015.

## **Critical Accounting Estimates**

See Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report and Form 10-K for the year ended December 31, 2013 filed on February 19, 2015 for a discussion of our critical accounting estimates.

There have been no material changes to our critical accounting estimates in 2015.

## New Accounting Standards Not Yet Adopted

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09 *Revenue from Contracts with Customers (Topic 606)* (ASU 2014-09). The amendments in ASU 2014-09 outline a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and indicate that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this, an entity should identify the contract(s) with a customer, identify the performance obligations in the contract, determine the transaction price, allocate the transaction price to the performance obligations in the contract and recognize revenue when (or as) the entity satisfies a performance obligation. The amendments are effective for annual reporting periods beginning after December 15, 2016, including interim periods

within that reporting period. We are currently evaluating the impact that the adoption of ASU 2014-09 may have on our financial condition, results of operations and cash flows.

In June 2014, the FASB issued ASU 2014-12 Compensation Stock Compensation (Topic 718) Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period (ASU 2014-12). The amendments in ASU 2014-12 require that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. A reporting entity should apply existing guidance in Accounting Standards Codification Topic 718, Compensation Stock Compensation (ASC 718), as it relates to awards with performance conditions that affect vesting to account for such awards. The amendments are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. We do not expect the adoption of ASU 2014-12 to materially impact our financial condition, results of operations and cash flows.

In January 2015, the FASB issued ASU 2015-01 *Income Statement Extraordinary and Unusual Items (Subtopic 225-20) Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items* (ASU 2015-01). These amendments eliminate from U.S. GAAP the concept of extraordinary items as part of the FASB s initiative to reduce complexity in accounting standards. These amendments are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. We do not expect the adoption of ASU 2015-01 to materially impact our financial condition, results of operations and cash flows.

In February 2015, the FASB issued ASU 2015-02 Consolidation (Topic 810) Amendments to the Consolidation Analysis) (ASU 2015-02). These amendments are intended to improve targeted areas of the consolidation guidance for legal entities such as limited partnerships, limited liability corporations and securitization structures. These amendments affect the consolidation evaluation for reporting organizations. In addition, the amendments in this guidance simplify and improve current U.S. GAAP by reducing the number of consolidation models. These amendments are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. We do not expect the adoption of ASU 2015-02 to materially impact our financial condition, results of operations and cash flows.

In April 2015, the FASB issued ASU 2015-03 *Interest Imputation of Interest (Subtopic 835-30) Simplifying the Presentation of Debt Issuance Costs* (ASU 2015-03). These amendments require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. These amendments are effective for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. We do not expect the adoption of ASU 2015-03 to materially impact our financial condition, results of operations and cash flows.

In April 2015, the FASB issued ASU 2015-05 Intangibles Goodwill and Other Internal-Use Software (Subtopic 350-40) Customer s Accounting for Fees Paid in a Cloud Computing Arrangement (ASU 2015-05). These amendments provide guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement as a service contract. The new guidance does not change the accounting for a customer s accounting for service contracts. These amendments are effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2015. We do not expect the adoption of ASU 2015-05 to materially impact our financial condition, results of operations and cash flows.

## Item 3. Quantitative and Qualitative Disclosures About Market Risk Foreign Currency Risk

Our earnings and cash flows are subject to fluctuations due to changes in currency exchange rates. We are exposed to foreign currency exchange rate fluctuations when subsidiaries with functional currencies other than the U.S. Dollar (USD) are translated into our USD consolidated financial statements. As exchange rates vary, those results, when translated, may vary from expectations and adversely impact profitability. The cumulative translation effects for subsidiaries using functional currencies other than USD are included in Accumulated other comprehensive income (loss) in shareholders equity. Movements in non-USD currency exchange rates may negatively or positively affect our competitive position, as exchange rate changes may affect business practices and/or pricing strategies of non-U.S. based competitors.

We employ a foreign currency risk management program that periodically utilizes derivative instruments to protect against unanticipated fluctuations in certain earnings and cash flows caused by volatility in foreign currency exchange (FX) rates. We also utilize derivative contracts to hedge intercompany receivables and payables that are denominated in a foreign currency and to hedge net investments in foreign operations.

We serve a number of U.S.-based clients using customer contact management center capacity in The Philippines and Costa Rica, which are within our Americas segment. Although the contracts with these clients are priced in USDs, a

substantial portion of the costs incurred to render services under these contracts are denominated in Philippine Pesos (PHP) and Costa Rican Colones (CRC), which represent FX exposures. Additionally, our EMEA segment services clients in Hungary and Romania where the contracts are priced in Euros (EUR), with a substantial portion of the costs incurred to render services under these contracts denominated in Hungarian Forints (HUF) and Romanian Leis (RON).

In order to hedge a portion of our anticipated cash flow requirements denominated in PHP, CRC, HUF and RON, we had outstanding forward contracts and options as of March 31, 2015 with counterparties through February 2016 with notional amounts totaling \$152.8 million. As of March 31, 2015, we had net total derivative assets associated with these contracts with a fair value of \$2.2 million, which will settle within the next 11 months. If the USD was to weaken against the PHP and CRC and the EUR was to weaken against the HUF and RON by 10% from current period-end levels, we would incur a loss of approximately \$12.8 million on the underlying exposures of the derivative instruments. However, this loss would be mitigated by corresponding gains on the underlying exposures.

We entered into forward exchange contracts with notional amounts totaling \$63.5 million to hedge net investments in our foreign operations. The purpose of these derivative instruments is to protect against the risk that the net assets of certain foreign subsidiaries will be adversely affected by changes in exchange rates and economic exposures related to our foreign currency-based investments in these subsidiaries. As of March 31, 2015, the fair value of these derivatives was a net asset of \$10.4 million. The potential loss in fair value at March 31, 2015, for these contracts resulting from a hypothetical 10% adverse change in the foreign currency exchange rates is approximately \$5.3 million. However, this loss would be mitigated by corresponding gains on the underlying exposures.

We also entered into forward exchange contracts with notional amounts totaling \$55.0 million that are not designated as hedges. The purpose of these derivative instruments is to protect against FX volatility pertaining to intercompany receivables and payables, and other assets and liabilities that are denominated in currencies other than our subsidiaries functional currencies. As of March 31, 2015, the fair value of these derivatives was a net liability of \$0.2 million. The potential loss in fair value at March 31, 2015, for these contracts resulting from a hypothetical 10% adverse change in the foreign currency exchange rates is approximately \$4.4 million. However, this loss would be mitigated by corresponding gains on the underlying exposures.

We evaluate the credit quality of potential counterparties to derivative transactions and only enter into contracts with those considered to have minimal credit risk. We periodically monitor changes to counterparty credit quality as well as our concentration of credit exposure to individual counterparties.

We do not use derivative financial instruments for speculative trading purposes, nor do we hedge our foreign currency exposure in a manner that entirely offsets the effects of changes in foreign exchange rates.

As a general rule, we do not use financial instruments to hedge local currency denominated operating expenses in countries where a natural hedge exists. For example, in many countries, revenue from the local currency services substantially offsets the local currency denominated operating expenses.

## **Interest Rate Risk**

Our exposure to interest rate risk results from variable debt outstanding under our revolving credit facility. We pay interest on outstanding borrowings at interest rates that fluctuate based upon changes in various base rates. As of March 31, 2015, we had \$74.0 million in borrowings outstanding under the revolving credit facility. Based on our level of variable rate debt outstanding during the three months ended March 31, 2015, a 1.0% increase in the weighted average interest rate, which generally equals the LIBOR rate plus an applicable margin, would have had an impact of \$0.2 million on our results of operations.

We have not historically used derivative instruments to manage exposure to changes in interest rates.

## **Fluctuations in Quarterly Results**

For the year ended December 31, 2014, quarterly revenues as a percentage of total consolidated annual revenues were approximately 24%, 24%, 25% and 27%, respectively, for each of the respective quarters of the year. We have experienced and anticipate that in the future we will experience variations in quarterly revenues. The variations are due to the timing of new contracts and renewal of existing contracts, the timing and frequency of client spending for customer contact management services, non-U.S. currency fluctuations, and the seasonal pattern of customer contact management support and fulfillment services.

#### Item 4. Controls and Procedures

As of March 31, 2015, under the direction of our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a 15(e) under the Securities Exchange Act of 1934, as amended. Our disclosure controls and procedures are designed to provide reasonable assurance that the information required to be disclosed in our SEC reports is recorded, processed, summarized and reported within the time period specified by the SEC s rules and forms, and is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. We concluded that, as of March 31, 2015, our disclosure controls and procedures were effective at the reasonable assurance level.

There were no changes in our internal controls over financial reporting during the quarter ended March 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

## Part II. OTHER INFORMATION

#### Item 1. Legal Proceedings

From time to time, we are involved in legal actions arising in the ordinary course of business. With respect to these matters, we believe that we have adequate legal defenses and/or provided adequate accruals for related costs such that the ultimate outcome will not have a material adverse effect on our future financial position or results of operations.

#### Item 1A. Risk Factors

For risk factors, see Item 1A, Risk Factors, of our Annual Report on Form 10-K for the year ended December 31, 2014 filed on February 19, 2015.

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

Below is a summary of stock repurchases for the three months ended March 31, 2015 (in thousands, except average price per share). See Note 12, Earnings Per Share, of Notes to Condensed Consolidated Financial Statements for information regarding our stock repurchase program.

Period	Total Number Average of Price Shares Paid Per		Total Number of Maximum NumShares Purchased of Shares That Nas Part of PubliclyYet BeAnnouncedPurchasedPlansUnder Plansoror			
January 1, 2015 - January 31, 2015	Purchased <sup>(1)</sup>	Share \$	Programs	Programs 999		
February 1, 2015 - February 28,		Ψ		777		
2015	74	\$ 22.95	74	925		
March 1, 2015 - March 31, 2015	147	\$ 23.29	147	778		
Total	221		221	778		

<sup>(1)</sup> All shares purchased as part of the repurchase plan publicly announced on August 18, 2011. Total number of shares approved for repurchase under the 2011 Repurchase Plan was 5.0 million with no expiration date.

#### Item 3. Defaults Upon Senior Securities

None.

# Item 4. Mine Safety Disclosures Not Applicable.

## Item 5. Other Information None.

## Item 6. Exhibits

The following documents are filed as an exhibit to this Report:

15	Awareness letter.
31.1	Certification of Chief Executive Officer, pursuant to Rule 13a-14(a).
31.2	Certification of Chief Financial Officer, pursuant to Rule 13a-14(a).
32.1	Certification of Chief Executive Officer, pursuant to 18 U.S.C. §1350.
32.2	Certification of Chief Financial Officer, pursuant to 18 U.S.C. §1350.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

#### SIGNATURE

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

SYKES ENTERPRISES, INCORPORATED (Registrant)

By: /s/ John Chapman John Chapman Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)

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Date: May 5, 2015

## EXHIBIT INDEX

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