

ARIES VENTURES INC  
Form 10KSB  
December 22, 2005

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**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)

**3611 Valley Centre Drive, Suite 525  
San Diego, California 92130**

(Address of principal executive offices)

**84-0987840**

(IRS Employer Identification No.)

**(858) 436-1000**

(Issuer's telephone number)

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

**None**

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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.

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.  Yes  No

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will be contained, to the best of 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.

Indicate by check mark whether Aries is a shell company (as defined in Rule 12b-2 of the Exchange Act.):  Yes  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.  Yes  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.

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



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**SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS**

Certain statements in this report, including information incorporated by reference, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934, and the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect current views about future events and financial performance based on certain assumptions. They include opinions, forecasts, intentions, plans, goals, projections, guidance, expectations, beliefs or other statements that are not statements of historical fact. Words such as may, will, should, could, would, expects, plans, believes, anticipates, intends, estimates, 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;

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, as 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™ and Corgentin™. 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™, 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:

<b>Product</b>	<b>Growth Factor</b>	<b>Indication</b>	<b>Mechanism of Action</b>
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.

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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

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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:

<b>Date</b>	<b>Trial</b>	<b>Study Objective</b>	<b>No. of Patients</b>	<b>Clinical Results</b>
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™ 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.

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

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

\*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.**



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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.

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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 of specific post-marketing studies to further evaluate safety and effectiveness. Rigorous and extensive FDA regulation of pharmaceutical products continues after approval, particularly with respect to compliance with current 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.

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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.

### *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 efficient, more effective, or safer competitive therapy for treatment of the same or similar diseases we have targeted, or one that offers significantly lower costs of treatment, our business, financial condition and results of operations could be materially adversely affected. In view of the relatively early stage of the industry, we believe that the most significant competitive factor in the field of gene therapy and biologics is the effectiveness and safety of a product candidate, as well as its relative safety, efficacy and cost as compared to other products, product candidates or approaches that may be useful for treating a particular disease condition.

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

We are aware of products currently under development by competitors targeting the same or similar cardiovascular and vascular diseases as our Genex 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 manufacturer 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*

*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

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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 breached agreement could be terminated by NYU.

Yale University License Agreement

In September 2000, Schering entered into an agreement with Yale University pursuant to which Yale University granted to Schering an exclusive worldwide license (with the right to sublicense) to certain technology covering

development, manufacture, use and sale of gene therapy products based on a phosphomimetic mutant of human endothelial nitric oxide synthase (eNOS) for the treatment of all cardiovascular diseases. As part of the Schering Transaction, 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

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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	High	Low	High	Low
First Quarter	\$ 0.26	\$ 0.15	\$ 0.91	\$ 0.25	\$ 0.91	\$ 0.25	\$ 0.91	\$ 0.25
Second Quarter	\$ 0.15	\$ 0.15	\$ 0.55	\$ 0.25	\$ 0.55	\$ 0.25	\$ 0.55	\$ 0.25
Third Quarter	\$ 0.46	\$ 0.15	\$ 0.35	\$ 0.30	\$ 0.35	\$ 0.30	\$ 0.35	\$ 0.30
Fourth Quarter	\$ 1.51	\$ 0.46	\$ 0.30	\$ 0.25	\$ 0.30	\$ 0.25	\$ 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™ and Corgentin™. 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™, 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);

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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.***

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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 difficulty 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.

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Many factors, known and unknown, can adversely affect clinical trials and the ability to evaluate a product's efficacy. 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.

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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 medical 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 Genex 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 manufacture our products 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 acquisitions 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.

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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

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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

	2005	September 30,	2004
<b>ASSETS</b>			
<b>CURRENT</b>			
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
<b>PROPERTY AND EQUIPMENT</b>			
Less: accumulated depreciation and amortization	(27,363)		(26,642)
			721
<b>DEPOSITS</b>			
			2,309
			2,309
	\$ 2,543,262	\$	2,707,418
<b>LIABILITIES</b>			
<b>CURRENT</b>			
Accounts payable	\$ 576	\$	50,045
Accrued liabilities	95,000		10,135
Total current liabilities	95,576		60,180
<b>COMMITMENTS AND CONTINGENCIES</b>			
<b>SHAREHOLDERS EQUITY</b>			
Preferred stock, \$0.01 par value; Authorized 10,000,000 shares; Issued and outstanding			
None			
Common stock, \$0.01 par value; Authorized 50,000,000 shares; Issued and outstanding			
2,032,226 and 3,311,981 shares at September 30, 2005 and 2004 respectively	20,322		33,120
Additional paid-in capital	469,914		1,800,859
Retained earnings	1,957,450		2,157,002
Less: shares held in treasury at September 30, 2004 1,279,755 shares of common stock at cost			(1,343,743)
	2,447,686		2,647,238
	\$ 2,543,262	\$	2,707,418

*See accompanying notes to financial statements.*

## Aries Ventures Inc.

## Statements Of Operations

	Years Ended September 30,	
	2005	2004
REVENUES	\$	\$
COSTS AND EXPENSES		
General and administrative	249,408	349,525
Depreciation and amortization	721	506
Interest expense	725	768
Appreciation of marketable securities	(30,000)	
Interest income	(21,302)	(5,202)
NET LOSS	\$ (199,552)	\$ (345,597)
NET LOSS PER COMMON SHARE BASIC AND DILUTED	\$ (0.10)	\$ (0.16)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING BASIC AND DILUTED	2,032,226	2,200,063

*See accompanying notes to financial statements.*

**Aries Ventures Inc.**  
**Statements of Shareholders Equity**  
**Years Ended September 30, 2005 and 2004**

	Common Stock		Preferred Stock		Securities Held in Treasury	Additional Paid-in Capital	Retained Earnings	Total
	Shares	Par Value	Shares	Par Value				
Balance, September 30, 2003	3,311,981	\$ 33,120		\$	\$	\$ 1,800,859	\$ 2,502,599	\$ 4,336,578
Common stock repurchased					(1,343,743)			(1,343,743)
Net loss							(345,597)	(345,597)
Balance, September 30, 2004	3,311,981	33,120			(1,343,743)	1,800,859	2,157,002	2,647,238
Retired treasury shares	(1,279,755)	(12,798)			1,343,743	(1,330,945)		
Net loss							(199,552)	(199,552)
Balance, September 30, 2005	2,032,226	\$ 20,322		\$	\$	\$ 469,914	\$ 1,957,450	\$ 2,447,686

*See accompanying notes to financial statements.*



## Aries Ventures Inc.

## Statements Of Cash Flows

	Years Ended September 30,	
	2005	2004
<b>OPERATING ACTIVITIES</b>		
Net loss	\$ (199,552)	\$ (345,597)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	721	506
Appreciation of marketable securities	(30,000)	
Changes in operating assets and liabilities:		
(Increase) decrease in:		
Prepaid expenses and other assets	20,456	25,597
(Increase) decrease in:		
Accounts payable	(49,469)	(2,657)
Accrued liabilities	84,865	(20,153)
Net cash used in operating activities	(172,979)	(342,304)
<b>INVESTING ACTIVITIES</b>		
Payments from related entity		65,250
Increase in amounts due from related entity		(38,356)
Purchase of property and equipment		(119)
Net cash provided by investing activities		26,775
<b>FINANCING ACTIVITIES</b>		
Repurchase of securities		(1,343,743)
Net cash used in financing activities		(1,343,743)
<b>CASH AND CASH EQUIVALENTS</b>		
Net decrease in cash and cash equivalents	(172,979)	(1,659,272)
Balance at beginning of year	2,686,241	4,345,513
Balance at end of year	\$ 2,513,262	\$ 2,686,241
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION</b>		
Cash paid for interest	\$ 725	\$ 768
Cash paid for taxes	\$	\$

*See accompanying notes to financial statements.*

**ARIES VENTURES INC.**

**NOTES TO FINANCIAL STATEMENTS**

**YEARS ENDED SEPTEMBER 30, 2005 AND 2004**

**1. Organization and Business**

Aries Ventures Inc. ( Aries or the Company ) was incorporated in Nevada on April 21, 2000. As of September 30, 2005, Aries had no business operations. On October 20, 2005, Aries completed a reverse merger with Cardium Therapeutics, Inc. (See Note 8.)

**2. Summary of Significant Accounting Policies**

**a. Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

**b. Cash and Cash Equivalents**

Cash and cash equivalents include all highly-liquid investments with an original maturity of three months or less at the date of purchase. The Company minimizes its credit risk by investing its cash and cash equivalents with major banks and financial institutions located primarily in the United States. However, cash balances exceeded federally-insured levels by approximately \$2,500,000 at September 30, 2005 and \$2,700,000 at September 30, 2004.

**c. Marketable Securities**

Marketable securities held by are recorded at fair market value and are classified as trading securities. Unrealized gains and losses for trading securities are included in income on a current basis.

**d. Property and Equipment**

Depreciation of furniture, fixtures and office equipment is provided on the straight-line method over the estimated useful lives of the respective assets.

**e. Loss Per Common Share**

Loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding, plus the issuance of common shares, if dilutive, resulting from the exercise of outstanding stock options and warrants. These potentially dilutive securities were not included in the calculation of loss per share for the years ended September 30, 2005 and 2004 because the Company incurred a loss during such periods and thus their inclusion would have been anti-dilutive. Accordingly, basic and diluted loss per common share are the same for all periods presented.

As of September 30, 2005 and 2004, potentially dilutive securities consisted of outstanding Series A common stock purchase warrants and stock options to acquire 2,056,226 shares and 353,318 shares, respectively.

**f. Stock-Based Compensation**

The Company adopted the disclosure requirements of SFAS No. 123, Accounting for Stock-Based Compensation ( SFAS No. 123 ), for stock options and similar equity instruments (collectively, Options ) issued to employees, and continues to apply the intrinsic value based method of accounting for options issued to employees prescribed by Accounting Principles Board ( APB ) Opinion No. 25, Accounting for Stock Issues to Employees, rather than the fair value based method of accounting prescribed by SFAS No. 123. SFAS No. 123 also applies to transactions in

which an entity issues its equity instruments to acquire goods or services from non-employees. Those transactions must be accounted for based on the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured.

On December 31, 2002, the FASB issued SFAS No. 148 ( SFAS No. 148 ), Accounting for Stock-Based Compensation-Transition and Disclosure. SFAS No. 148 amends SFAS No. 123, to provide an alternative method of transition to SFAS No. 123's fair value method of accounting for stock based employee compensation. SFAS No. 148 also amends the disclosure provisions of SFAS No. 123 and APB Opinion No. 28, Interim Financial Reporting, to require disclosure in the summary of significant accounting policies of the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements.

The Black-Scholes option valuation model was used to estimate the fair value of the options granted during the year ended September 30, 2004. The model includes subjective input assumptions that can materially affect the fair value estimates. The model was developed for use in estimating the fair market value of options that have no vesting restrictions and are fully transferable. The expected volatility is estimated based on the most recent historical period of time equal to the weighted average life of the options granted. There were no stock options granted during fiscal 2005.

Had compensation cost for stock option grants made under the Employee Stock Option Plan and the Management Incentive Stock Option Plan been determined under SFAS No. 123, the Company's net loss and net loss per common share for the years ended September 30, 2005 and 2004 would have been as follows:

	2005	2004
Net loss, as reported	\$ (199,552)	\$ (345,597)
Less: additional compensation pursuant to SFAS No. 123		(1,662)
Net loss, as adjusted	\$ (199,552)	\$ (347,259)
Net loss per common share (basic and diluted), as adjusted	\$ (0.10)	\$ (0.16)

The fair value of the stock options granted for 2004 were estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions: risk-free interest rate 5%; dividend yield of 0%; stock price volatility of 100%; and expected life of five years.

#### **g. 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 the Company 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. The Company is required to adopt SFAS 123R effective for annual periods beginning after December 15, 2005. Under this method, the Company will begin recognizing compensation cost for equity-based compensation for all new or modified grants after the date of adoption. In addition, the Company 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. The Company is currently evaluating the potential effect that the adoption of SFAS 123R will have on its 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). Management does not believe this pronouncement will have a material impact on the Company's financial statements.

### 3. Due from Related Party

During the years ended September 30, 2005 and 2004, the Company allocated certain common corporate services (consisting of rent, utilities, common area services, insurance and other office services) to Resource Ventures, Inc. (Resource), a related entity with certain common officers and directors. The allocation of common corporate services between the Company and Resource ceased effective December 31, 2004. Activity with respect to the allocation of such services is summarized as follows:

Balance, October 1, 2003	\$ 26,894
Amounts allocated to Resource	38,356
Payments by Resource to Company	(65,250)
Balance, September 30, 2004	
Amounts allocated to Resource	16,459
Payments by Resource to Company	(16,459)
Balance, September 30, 2005	\$

### 4. Commitments and Contingencies

#### a. Operating Leases

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During the year ended September 30, 2004, the Company leased its executive and administrative offices under an operating lease that expired on September 30, 2004. Subsequent to September 30, 2004, such facilities were occupied on a month-to-month basis. Effective January 1, 2005, the Company moved to new offices on a month-to-month basis.

Rent expense for the years ended September 30, 2005 and 2004 was \$9,655 and \$22,441, respectively.

**b. Employment Agreements**

At September 30, 2004, the Company had employment agreements with its Chairman of the Board of Directors and its President and Chief Financial Officer, providing for compensation of \$60,000 to each officer per year for the period from October 1, 2002 through September 30, 2005. The employment agreements also provide that in the event of a change in majority ownership of the Company, each such person has the option to terminate his employment with the Company and receive a payment equal to three times his base annual compensation.

Effective October 1, 2004, the Chairman and the President each agreed to reduce their compensation to \$18,000 per year for the remainder of the term of the respective employment agreements.

Effective December 31, 2004, the Chairman resigned from the Board of Directors, and his employment agreement was terminated. No further compensation was required to be paid to the Chairman as a result of his termination.

The President received a bonus of \$50,000 (paid in October 2005), which was recorded as a liability as of September 30, 2005.

**5. Income Taxes**

As of September 30, 2005, the Company had Federal net operating loss carryforwards of approximately \$71,500,000 expiring in various years through 2024, portions of which may be used to offset future taxable income, if any. The Company has a deferred tax asset arising from such operating losses for which a full valuation allowance has been established due to the uncertainty as to their realizability in future periods.

Due to the restrictions imposed by the Internal Revenue Code of 1986, as amended, regarding substantial changes in ownership of companies with loss carryforwards, the utilization of the Company's federal net operating loss carryforwards will likely be limited as a result of cumulative changes in stock ownership.

The Company's net deferred tax assets (using a Federal corporate income rate of approximately 34%) consisted of the following at September 30, 2005 and 2004:

	September 30,	
	2005	2004
Deferred tax assets:		
Operating loss carryforwards	\$ 26,497,000	\$ 26,412,000
Valuation allowances	170,000	180,000
Depreciation	1,000	1,000
	26,668,000	26,593,000
Less: Valuation allowance	(26,668,000)	(26,593,000)



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Net deferred tax assets	\$	\$
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As a result of the Company's significant operating loss carryforwards and the corresponding valuation allowance, no income tax benefit has been recorded at September 30, 2005 and 2004. The provision for income taxes using the statutory federal tax rate as compared to the Company's effective tax rate is summarized as follows:

	September 30,	
	2005	2004
Tax benefit at statutory rate	(34.0)%	(34.0)%
State income taxes		
Adjustments to change in valuation allowance	34.0	34.0

**6. Related Party Transactions**

In addition to the related party transactions described at Notes 3 and 4, the Company had the following related party transactions for the years ended September 30, 2005 and 2004:

During the years ended September 30, 2005 and 2004, the Company paid annual board committee fees of approximately \$21,800 and \$19,000, respectively, to non-employee directors.

**7. Shareholders Equity**

**a. Common Stock**

Effective November 17, 2003, the Company repurchased from an institutional shareholder 1,279,755 shares of common stock in a private transaction for an aggregate cash purchase price of \$1,343,743. These securities have been classified as treasury securities in the Company's balance sheet at September 30, 2004. On September 16, 2005, the Company retired the treasury shares and recorded them as a reduction in common stock and additional paid in capital. In connection with the purchase of such shares, the Company cancelled 1,194,755 associated warrants.

**b. Stock Option Plans**

Under the Company's Employee Stock Option Plan, the Company may issue stock options to purchase a maximum of 353,318 shares of common stock of the Company. Under the Company's Management Incentive Stock Option Plan, the Company may issue stock options to purchase a maximum of 247,323 shares of common stock of the Company. Both stock option plans were adopted by the Board of Directors on April 12, 2000, and are administered by the Board of Directors. At September 30, 2005, options to purchase 105,995 shares had been issued under the Employee Stock Option Plan and options to purchase 247,323 shares had been issued under the Management Incentive Stock Option Plan.

The purchase price for the shares subject to any incentive stock option granted under the Employee Stock Option Plan or the Management Incentive Stock Option Plan shall not be less than 100% of the fair market value of the shares of common stock of the Company on the date the option is granted (110% for stockholders who own in excess of 10% of the outstanding common stock). No option shall be exercisable after the expiration of 10 years after the date the option is granted. In addition, subject to certain exceptions, no option shall be exercisable after the expiration of three months after the date the optionee's employment with the Company terminates if termination is for any reason other than permanent disability or death, or one year after the date the optionee's employment terminates if termination is a result of death or permanent disability. Unless sooner terminated by the Board of Directors, both option plans expire on April 11, 2010.

Such options granted are exercisable for a period of five years. The exercise price of such options was the fair market value on the date of grant (\$0.23 per share), except for the Chairman, a more than 10% stockholder of the Company; the exercise price of the Chairman's option was 110%

of the fair market value on the date of grant (\$0.25 per share). The stock options vested in equal annual increments over three years.

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Option activity under these stock option plans for the years ended September 30, 2004 and 2005 is summarized as follows:

	Number of Options	Exercise Price	Remaining Contractual Life (in years)
Balance outstanding, October 1, 2003	353,318	\$ 0.23-0.25	
Options issued			
Options exercised			
Options expired			
Balance outstanding, September 30, 2004	353,318	\$ 0.23-0.25	1.1
Options issued			
Options exercised			
Options expired			
Balance outstanding, September 30, 2005	353,318	\$ 0.23-0.25	0.1
Options exercisable at September 30, 2005	353,318	\$ 0.23-0.25	0.1

### c. Warrants

Warrant activity for the fiscal years ended September 30, 2005 and 2004 is summarized below. The Series A warrants entitle the holders to purchase one share of common stock at \$6.00 per share.

	Number of Warrants	Exercise Price	Remaining Contractual Life (in years)
Balance outstanding, October 1, 2003	3,250,981	\$ 6.00	
Warrants issued			
Warrants exercised			
Warrants expired			
Warrants cancelled	(1,194,755)	\$ 6.00	
Balance outstanding, September 30, 2004	2,056,226	\$ 6.00	
Warrants issued			
Warrants exercised			
Warrants expired			
Warrants cancelled			
Balance outstanding, September 30, 2005	2,056,226	\$ 6.00	0.1
Warrants exercisable at September 30, 2005	2,056,226	\$ 6.00	0.1

The warrants expired on November 11, 2005.

### 8. Subsequent Events

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On October 20, 2005, Aries completed a reverse merger (the Merger ) with privately held Cardium Therapeutics, Inc., 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, Cardium had 7,850,000 shares of common stock outstanding, which, by virtue of the Merger, were converted into the right to receive one share of common stock of Aries for each share of common stock of Cardium, and Aries had 2,032,226 shares of its common stock outstanding. In addition, a three year warrant to purchase 400,000 shares of Aries common stock at an exercise price of \$1.75 per share was issued to an Aries stockholder who held of record or beneficially more than 45% of the outstanding common stock of Aries prior to the Merger as consideration for such stockholder s agreement not to sell any of such stockholder s shares of Aries common stock for a period of approximately five

months from the effective time of the Merger, subject to certain exceptions based on the market value of such common stock. Aries also agreed to terminate all of its equity incentive plans and adopt Cardium's 2005 Equity Incentive Plan.

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. To accomplish this, Aries formed Vestige Holdings, LLC, a Nevada limited liability company ( Vestige ), and prior to the effective time of the Merger transferred to Vestige \$5,000 in cash and all of Aries' non-cash assets. Before the Merger, Aries transferred all of its right, title and interest in and to Vestige to the holders of all of the then outstanding options, in consideration for the surrender and cancellation by the optionees of all of their options to acquire shares of Aries common stock under Aries' Employee Stock Option Plan and/or Management Incentive Stock Option Plan, as such plans existed prior to the Merger. Immediately before the Merger, Aries declared a cash distribution to its stockholders of approximately \$880,000 or \$0.43 per share.

Concurrently with the Merger, Aries also closed a private placement of 19,325,651 shares of its common stock at a purchase price of \$1.50 per share and received net proceeds of \$25,552,390. In connection therewith, the placement agent received a five-year warrant to purchase 2,032,555 shares of the Aries' common stock at an exercise price of \$1.50 per share and selling commissions, marketing allowances and management fees totaling approximately \$3,048,832. Investors who invested at least \$1,000,000 in shares of common stock received a three-year warrant to buy 10% of the number of shares of common stock purchased in the private placement, at an exercise price of \$1.75 per share. Shares underlying such warrants total 424,263. The warrants are fully exercisable.

In connection with the private placement, the Company incurred legal, accounting and other fees and expenses totaling approximately \$387,000.

An officer of Cardium was repaid advances of \$62,882 made to fund early start-up costs with the issuance of 41,922 shares of Aries common stock during October 2005.

Upon the close of the Merger and the private placement, Cardium acquired a portfolio of cardiovascular growth factor therapeutic assets from Schering AG (Germany) and/or its affiliates for a purchase price of approximately \$4,000,000.

#### **ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

#### **ITEM 8A. CONTROLS AND PROCEDURES**

We maintain certain disclosure controls and procedures. They are designed to help ensure that material information is: (1) gathered and communicated to our management, including our principal executive and financial officers, on a timely basis; and (2) recorded, processed, summarized, reported and filed with the SEC as required under the Securities Exchange Act of 1934.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2005. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective for their intended purpose described above. There were no changes to our internal controls during the fourth quarter ended September 30, 2005 that have materially affected, or that are reasonably likely to materially affect, our internal controls.

**ITEM 8B. OTHER INFORMATION**

None.

**PART III**

**ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(A) OF THE EXCHANGE ACT**

The information for this item is incorporated by reference to the sections Our Board of Directors, Our Executive Officers, Section 16(a) Beneficial Ownership Reporting Compliance, and Code of Ethics in our definitive proxy statement for our Annual Meeting of Stockholders to be held in January 2006.

**ITEM 10. EXECUTIVE COMPENSATION**

The information for this item is incorporated by reference to the sections Director Compensation and Executive Officer Compensation in our definitive proxy statement for our Annual Meeting of Stockholders to be held in January 2006.

**ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information for this item is incorporated by reference to the sections Stock Holdings of Certain Owners and Management and Securities Authorized for Issuance Under Equity Compensation Plans in our definitive proxy statement for our Annual Meeting of Stockholders to be held in January 2006.

**ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

The information for this item is incorporated by reference to the section Certain Relationships and Related Transactions in our definitive proxy statement for our Annual Meeting of Stockholders to be held in January 2006.

**ITEM 13. EXHIBITS**

The following exhibit index shows those exhibits filed with this report and those incorporated by reference:

**EXHIBIT INDEX**



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<b>Exhibit Number</b>	<b>Description</b>	<b>Incorporated By Reference To</b>
1.1	Placement Agency Agreement dated July 1, 2005 by and between Cardium Therapeutics, Inc. and National Securities Corporation	Exhibit 1.1 of Aries Current Report on Form 8-K dated October 20, 2005, filed with the commission on October 26, 2005
2.1	Debtor s Second Amended Chapter 11 Plan of Reorganization	Exhibit 2.1 of Aries Current Report on Form 8-K dated March 31, 2000, filed with the commission on April 13, 2000
2.2	Order Confirming Debtor s Second Amended Chapter 11 Plan or Reorganization	Exhibit 2.2 of Aries Current Report on Form 8-K dated March 31, 2000, filed with the commission on April 13, 2000
2.3	Order Authorizing Non-Material Modification of Debtor s Second Amended Chapter 11 Plan of Reorganization	Exhibit 2.1 of Aries Current Report on Form 8-K dated June 1, 2000, filed with the commission on June 19, 2000
2.4	Articles and Plan of Merger of Casmyn Corp. and Aries Ventures Inc.	Exhibit 3.2 of Aries Current Report on Form 8-K dated April 28, 2000, filed with the commission on May 23, 2000
2.5	Agreement and Plan of Merger dated as of October 19, 2005 and effective as of October 20, 2005, by and among Aries Ventures Inc., Aries Acquisition Corporation and Cardium Therapeutics, Inc.	Exhibit 2.1 of Aries Current Report on Form 8-K dated October 20, 2005, filed with the commission on October 26, 2005

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2.6	Certificate of Merger of Domestic Corporation as filed with the Delaware Secretary of State on October 20, 2005	Exhibit 2.1 of Aries Current Report on Form 8-K dated October 20, 2005, filed with the commission on October 26, 2005
3(i)	Articles of Incorporation of Aries Ventures Inc. filed with the Nevada Secretary of State on April 21, 2000	Exhibit 3.1 of Aries Current Report on Form 8-K dated April 28, 2000, filed with the commission on May 23, 2000
3(ii)	By-laws of Aries Ventures Inc. as adopted on April 28, 2000	Exhibit 3.3 of Aries Current Report on Form 8-K dated April 28, 2000, filed with the commission on May 23, 2000
4.1	Form of Warrant issued to National Securities Corporation as Placement Agent	Exhibit 4.1 of Aries Current Report on Form 8-K dated October 20, 2005, filed with the commission on October 26, 2005
4.2	Form of Warrant issued to Lead Investors and Mark Zucker	Exhibit 4.2 of Aries Current Report on Form 8-K dated October 20, 2005, filed with the commission on October 26, 2005
4.3	Form of Lock-Up Agreement executed by officers, directors and employees of Cardium Therapeutics, Inc.	Exhibit 4.3 of Aries Current Report on Form 8-K dated October 20, 2005, filed with the commission on October 26, 2005
10.1	Transfer, Consent to Transfer, Amendment and Assignment of License Agreement effective as of August 31, 2005, by and among New York University, Collateral Therapeutics, Inc. and Cardium Therapeutics, Inc.	Exhibit 10.1 of Aries Current Report on Form 8-K dated October 20, 2005, filed with the commission on October 26, 2005
10.2	Transfer, Consent to Transfer, Amendment and Assignment of License Agreement effective as of August 31, 2005, by and among Yale University, Schering Aktiengesellschaft and Cardium Therapeutics, Inc.	Exhibit 10.2 of Aries Current Report on Form 8-K dated October 20, 2005, filed with the commission on October 26, 2005
10.3	Transfer, Consent to Transfer, Amendment and Assignment of License Agreement effective as of July 31, 2005, by and among the Regents of the University of California, Collateral Therapeutics, Inc. and Cardium Therapeutics, Inc.	Exhibit 10.3 of Aries Current Report on Form 8-K dated October 20, 2005, filed with the commission on October 26, 2005
10.4	Transfer, Consent to Transfer, Amendment and Assignment of License Agreement effective as of July 31, 2005, by and among the Regents of the University of California, Collateral Therapeutics, Inc. and Cardium Therapeutics, Inc.	Exhibit 10.4 of Aries Current Report on Form 8-K dated October 20, 2005, filed with the commission on October 26, 2005
10.5	Technology Transfer Agreement effective as of October 13, 2005, by and among Schering AG, Berlex, Inc., Collateral Therapeutics, Inc. and Cardium Therapeutics, Inc.	Exhibit 10.5 of Aries Current Report on Form 8-K dated October 20, 2005, filed with the commission on October 26, 2005
10.6	Amendment to the Exclusive License Agreement for Angiogenesis Gene Therapy effective as of October 20, 2005, between the Regents of the University of California and Cardium	Exhibit 10.6 of Aries Current Report on Form 8-K dated October 20, 2005, filed with the commission on October 26, 2005
10.7	Amendment to License Agreement effective as of	Exhibit 10.7 of Aries Current Report on

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	October 20, 2005, by and between New York University and Cardium Therapeutics, Inc.	Form 8-K dated October 20, 2005, filed with the commission on October 26, 2005
10.8	Second Amendment to Exclusive License Agreement effective as of October 20, 2005, by and between Yale University and Cardium Therapeutics, Inc.	Exhibit 10.8 of Aries Current Report on Form 8-K dated October 20, 2005, filed with the commission on October 26, 2005
10.9	2005 Equity Incentive Plan as adopted effective as of October 20, 2005*	Exhibit 10.9 of Aries Current Report on Form 8-K dated October 20, 2005, filed with the commission on October 26, 2005
10.10	Employment Agreement dated as of October 20, 2005 by and between Aries Ventures Inc. and Christopher Reinhard*	Exhibit 10.10 of Aries Current Report on Form 8-K dated October 20, 2005, filed with the commission on October 26, 2005
10.11	Employment Agreement dated as of October 20, 2005 by and between Aries Ventures Inc. and Tyler Dylan*	Exhibit 10.11 of Aries Current Report on Form 8-K dated October 20, 2005, filed with the commission on October 26, 2005
10.12	Office Lease between Cardium and Kilroy Realty, L.P. dated as of September 30, 2005 and commencing on November 1, 2005	Filed herewith
10.13	Yale Exclusive License Agreement between Yale University and Schering Aktiengesellschaft dated September 8, 2000	Filed herewith
10.14	Research and License Agreement between New York University and Collateral Therapeutics, Inc. dated March 24, 1997 (with amendments dated April 28, 1998 and March 24, 2000)	Filed herewith
10.15	Exclusive License Agreement for Angiogenesis Gene Therapy between the Regents of the University of California and Collateral Therapeutics, Inc. dated as of September 27, 1995 (with amendments dated September 19, 1996, June 30, 1997, March 11, 1999 and February 8, 2000)	Filed herewith
31.1	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer	Filed herewith
31.2	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer	Filed herewith
32	Section 1350 Certification	Filed herewith

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\* Indicates management contract or compensatory plan or arrangement.

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information for this item is incorporated by reference to the sections Audit Fees, Audit-Related Fees, Tax Fees, All Other Fees and Pre-Approval Policies and Procedures in our definitive proxy statement for our Annual Meeting of Stockholders to be held in January 2006.



**SIGNATURES**

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, Aries Ventures Inc., the registrant, caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: December 21, 2005

ARIES VENTURES INC.

By: /s/ Christopher J. Reinhard  
Christopher J. Reinhard, Chief Executive Officer

In accordance with the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of Aries Ventures Inc., in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Christopher J. Reinhard (Christopher J. Reinhard)	Chief Executive Officer and Chairman of the Board of Directors (principal executive officer)	December 21, 2005
/s/ Dennis M. Mulroy (Dennis M. Mulroy)	Chief Financial Officer (principal financial officer and principal accounting officer)	December 21, 2005
/s/ Robert N. Weingarten (Robert N. Weingarten)	Director	December 21, 2005