

Cardium Therapeutics, Inc.
Form 10QSB
November 14, 2006
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-QSB

QUARTERLY REPORT

under Section 13 or 15(d)

of the Securities Exchange Act of 1934

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2006

000-14136

(Commission file number)

CARDIUM THERAPEUTICS, INC.

(Name of small business issuer as specified in its charter)

Delaware
(State of incorporation)

27-0075787
(IRS Employer Identification No.)

3611 Valley Centre Drive, Suite 525

San Diego, California 92130
(Address of principal executive offices)

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

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

Edgar Filing: Cardium Therapeutics, Inc. - Form 10QSB

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

As of November 1, 2006, 31,770,869 shares of Cardium's common stock were outstanding.

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

Table of Contents

TABLE OF CONTENTS

	Page
PART I <u>FINANCIAL INFORMATION</u>	1
Item 1. <u>Financial Statements (unaudited)</u>	1
<u>Condensed Consolidated Balance Sheet</u>	1
<u>Condensed Consolidated Statements of Operations</u>	2
<u>Condensed Consolidated Statements of Cash Flows</u>	3
<u>Notes to Condensed Consolidated Financial Statements</u>	4
Item 2. <u>Management's Discussion and Analysis or Plan of Operation</u>	13
Item 3. <u>Controls and Procedures</u>	32
PART II <u>OTHER INFORMATION</u>	32
Item 1. <u>Legal Proceedings</u>	32
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	33
Item 3. <u>Defaults Upon Senior Securities</u>	33
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	33
Item 5. <u>Other Information</u>	33
Item 6. <u>Exhibits</u>	33
<u>SIGNATURES</u>	38

Table of Contents**PART I FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****Cardium Therapeutics, Inc.**

(a development stage company)

Condensed Consolidated Balance Sheet**September 30, 2006****(Unaudited)**

Assets	
Current assets:	
Cash and cash equivalents	\$ 11,526,335
Accounts receivable	61,581
Inventory	600,037
Prepaid expenses	160,320
Total current assets	12,348,273
Property and equipment, net of accumulated depreciation of \$180,499	754,804
Patented technology, net of accumulated amortization of \$406,510	5,374,203
Intangibles, net of accumulated amortization of \$47,056	401,447
Deposits	72,367
Total assets	\$ 18,951,094
Liabilities and Stockholders' Equity	
Current liabilities:	
Accounts payable	\$ 768,488
Accrued liabilities	945,362
Total liabilities	1,713,850
Stockholders' equity:	
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 31,750,482 shares issued and outstanding	3,175
Additional paid-in capital	34,232,673
Deficit accumulated during development stage	(16,998,604)
Total stockholders' equity	17,237,244
Total liabilities and stockholders' equity	\$ 18,951,094

See accompanying notes, which are an integral part of these financial statements.

Table of Contents**Cardium Therapeutics, Inc.**

(a development stage company)

Condensed Consolidated Statements of Operations**(Unaudited)**

	Three Months Ended		Nine Months Ended		Period from
	September 30,		September 30,		December 22, 2003
					(Inception) to
					September 30,
	2006	2005	2006	2005	2006
Revenues	\$ 134,062	\$	\$ 382,842	\$	\$ 382,842
Cost of goods sold	163,114		444,932		444,932
Gross loss	(29,052)		(62,090)		(62,090)
Operating expenses					
Research and development	3,218,652		3,685,165		7,685,165
Sales and marketing	279,884		636,817		636,817
General and administrative	1,876,865	206,831	7,319,953	525,390	8,912,202
Amortization - intangibles	194,664		453,566		453,566
Total operating expenses	5,570,065	206,831	12,095,501	525,390	17,687,750
Interest income	173,497		604,642		751,236
Net loss	\$ (5,425,620)	\$ (206,831)	\$ (11,552,949)	\$ (525,390)	\$ (16,998,604)
Loss per common share					
Net loss per common share basic and diluted	\$ (0.17)	\$ (0.03)	\$ (0.37)	\$ (0.10)	
Weighted average shares outstanding basic and diluted	31,750,482	7,828,261	31,136,590	5,070,513	

See accompanying notes, which are an integral part of these financial statements.

Table of Contents**Cardium Therapeutics, Inc.**

(a development stage company)

Condensed Consolidated Statements of Cash Flows**(Unaudited)**

	Nine Months Ended		Period from
	September 30,		December 22, 2003
			(Inception)
			To September 30,
	2006	2005	2006
Cash Flows From Operating Activities			
Net loss	\$ (11,552,949)	\$ (525,390)	\$ (16,998,604)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	168,853		180,499
Amortization - intangibles	453,566		453,566
Common stock issued for services and reimbursement of expenses		41,500	41,500
Stock based compensation expense	1,177,078		1,177,078
In-process purchased technology	1,027,529		1,027,529
Changes in operating assets and liabilities, excluding effects of acquisition:			
Accounts receivable	115,012		115,012
Inventory	(503,373)		(503,373)
Prepaid expenses	28,310	(69,358)	(141,772)
Deposits	(24,230)		(45,706)
Accounts payable	557,190	114,740	720,059
Accrued liabilities	(408,928)	350,000	41,711
Net cash used in operating activities	(8,961,942)	(88,508)	(13,932,501)
Cash Flows From Investing Activities			
In-process technology purchased from Tissue Repair Company	(1,000,000)		(1,000,000)
Purchases of property and equipment	(351,391)		(735,234)
Net cash used in investing activities	(1,351,391)	(88,508)	(1,735,234)
Cash Flows From Financing Activities			
Proceeds from officer loan		62,882	62,882
Cash acquired in Aries merger and Innercool acquisition	51,800		1,551,800
Cash issued for fractional shares	(1)		(1)
Proceeds from the sale of common stock		20,000	25,579,389
Net cash provided by financing activities	51,799	82,882	27,194,070
Net (decrease) increase in cash	(10,261,534)	(5,626)	11,526,335
Cash and cash equivalents at beginning of period	21,787,869	13,039	
Cash and cash equivalents at end of period	\$ 11,526,335	\$ 7,413	\$ 11,526,335

Edgar Filing: Cardium Therapeutics, Inc. - Form 10QSB

Non-Cash Activity:

Subscription receivable for common shares	\$	\$	\$	17,000
Common stock issued to retire start-up loans	\$	\$	\$	62,882
Net assets acquired for the issuance of common stock (exclusive of cash)	\$	5,824,000	\$	\$

See accompanying notes, which are an integral part of these financial statements.

Table of Contents

Cardium Therapeutics, Inc.

(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

Note 1. Business and Basis of Presentation

Business

Cardium Therapeutics, Inc. (the Company, Cardium, we, our and us) was organized in Delaware in December 2003. We are a medical technology company primarily focused on the development, manufacture and sale of innovative products for cardiovascular and related indications. We have initially focused on acquiring fallen angel opportunities having potential unrealized value. In October 2005, we acquired a portfolio of biologic growth factors and related delivery techniques from the Schering AG Group, Germany, which we plan to develop as cardiovascular-directed growth factor therapeutics for potential use by interventional cardiologists as a one-time treatment to promote and stimulate the growth of collateral circulation in the hearts of patients with ischemic conditions such as recurrent angina. In March 2006, we acquired the technologies and products of Innercool Therapies, Inc., a medical technology company in the emerging field of therapeutic hypothermia, whose systems and products are designed to rapidly and controllably cool the body to reduce cell death and damage following acute ischemic events such as cardiac arrest and stroke, and to potentially lessen or prevent associated injuries such as adverse neurologic outcomes. In August 2006, we acquired rights to assets and technologies of Tissue Repair Company, a company focused on the development of growth factor therapeutics for the potential treatment of tissue wounds such as severe chronic diabetic wounds, and whose product candidate, Excellerate™ is initially being developed as a single administration for the treatment of non-healing, neuropathic diabetic foot ulcers. Innercool Therapies and Tissue Repair Company are each operated as a wholly-owned subsidiary of Cardium.

We are a development stage company in the initial stage of our operations. We have yet to generate positive cash flows from operations, and are essentially dependent on debt and equity funding to finance our operations. Before October 2005, cash requirements were funded by loans from executive officers. In October 2005, we closed a private placement of 19,325,651 shares of our common stock at a purchase price of \$1.50 per share and received net proceeds of \$25,542,389. In connection with the offering, we completed a reverse merger, whereby Cardium merged with Aries Ventures Inc. (Aries), a publicly-traded company (see Note 6). As a result of these transactions, the stockholders of Cardium became the controlling stockholders of Aries. Accordingly, the acquisition of Cardium by Aries was a reverse merger. The historical financial results before the reverse merger on October 20, 2005, are those of Cardium. Aries results of operations are included in Cardium's financial results beginning October 20, 2005.

In January 2006, Aries was merged with and into Cardium, with Cardium as the surviving entity and the successor issuer to Aries. As a result, we are now in our present form a publicly-traded, Delaware corporation named Cardium Therapeutics, Inc.

Basis of Presentation

We expect our principal activities to focus on the commercialization of our licensed and other technologies, and the expansion of our existing products. The accompanying financial statements have been prepared in accordance with Statement of Financial Accounting Standard (SFAS) No. 7, Development Stage Enterprises.

The accompanying interim, unaudited, condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and pursuant to the instructions to Form 10-QSB and applicable rules and regulations. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. In management's opinion, all adjustments necessary for a fair presentation of the

Table of Contents

financial position, results of operations and cash flows have been included and are of a normal, recurring nature. The results of operations for the three and nine month periods ended September 30, 2006, are not necessarily indicative of the operating results for the full fiscal year or any future periods.

You should read the accompanying condensed consolidated financial statements and these notes in conjunction with our audited financial statements included in our Annual Report on Form 10-KSB for the year ended December 31, 2005 (2005 Annual Report).

Principles of Consolidation

The accompanying consolidated financial statements include the financial statements of Cardium and its wholly-owned subsidiaries, Innercool Therapies, Inc. and Tissue Repair Company. All inter-company balances and transactions have been eliminated in consolidation.

Cash and Cash Equivalents

Cash and cash equivalents, including approximately \$ 11,100,000 invested in short-term commercial paper and money market funds, includes all highly-liquid investments with an original maturity of three months or less at the date of purchase. We attempt to reduce our credit risk by investing our cash and cash equivalents with major banks and financial institutions located primarily in the United States. At times, cash balances held at financial institutions may exceed federally-insured limits.

Loss Per Common Share

We compute earnings per share in accordance with SFAS No. 128, Earnings Per Share. SFAS No. 128 requires dual presentation of basic and diluted earnings per share.

Basic 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 common share for the three and nine month periods ended September 30, 2006 and 2005, because we 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. The common stock issued and outstanding with respect to the stockholders of Aries has been included since October 20, 2005, the effective date of the reverse merger.

Potentially dilutive securities consisted of outstanding stock options and warrants to acquire 8,096,819 shares as of September 30, 2006. As of September 30, 2005, there were no outstanding options or warrants.

Stock-Based Compensation

Effective January 1, 2006, the Company adopted the fair value recognition provisions of SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R), using the modified prospective transition method. Under the transition method, stock-based compensation expense is recognized (i) for all stock-based compensation awards granted before, but not yet vested as of, January 1, 2006, based on the grant date fair value estimated in accordance with the original provision of SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123), and (ii) for all stock-based compensation awards granted after January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS 123R.

Before the adoption of SFAS 123R on January 1, 2006, the Company recognized stock-based compensation expense in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and provided pro forma disclosure amounts in accordance with SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure* (SFAS 148), as if the fair value method defined by SFAS 123 had been applied to its stock-based compensation. The pro forma

Table of Contents

table below reflects net loss, and net loss per common share, as if the Company had applied the fair value recognition provisions of SFAS 123 to all outstanding and unvested awards in fiscal 2005:

	Three Months	Nine Months
	Ended September 30, 2005	Ended September 30, 2005
Net loss, as reported	\$ (206,831)	\$ (525,390)
Add: compensation expense included in net loss		
Less: compensation expense pursuant to SFAS No. 123		
Pro forma net loss	\$ (206,831)	\$ (525,390)
Pro forma net loss per common share (basic and diluted)	\$ (0.03)	\$ (0.10)

We recognize stock-based compensation costs on a straight-line basis over the requisite service period of the award, which is generally the vesting term of the award.

Total stock-based compensation expense included in the consolidated statements of operations was \$461,976 for the three months ended September 30, 2006, and \$1,177,078 for the nine months ended September 30, 2006, and was recorded as a component of general and administrative expenses. As of September 30, 2006, the Company had \$5,849,603 of unvested stock-based compensation at fair value remaining to be expensed ratably over the period July 2006 through June 2010.

In the quarter ended September 30, 2006, we reclassified certain components of our stockholders equity section to reflect the elimination of deferred compensation arising from unvested share-based compensation pursuant to the requirements of Staff Accounting Bulletin No. 107, regarding Statement of Financial Accounting Standards No. 123(R), Share-Based Payment. This deferred compensation was previously recorded as an increase to additional paid-in capital with a corresponding reduction to stockholders equity for such deferred compensation. This reclassification has no effect on net income or total stockholders equity as previously reported. The Company will record an increase to additional paid-in capital as the share-based payments vest.

The fair value of the stock options and similar equity instruments (collectively, options) granted during the three and nine months ended September 30, 2006, was estimated on the date of grant using the Black-Scholes option valuation model. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. Option valuation models require the input of highly subjective assumptions, including expected life and stock price volatility. The following weighted-average assumptions were used: risk-free interest rate of 5.02% for the three months ended September 30, 2006, and 4.60% for the nine months ended September 30, 2006; dividend yield of 0%; stock price volatility of 66%; and expected life of 5.25 years. There were no options issued or outstanding during the nine months ended September 30, 2005.

Option Activity

We have an equity incentive plan that was established in 2005 under which 5,665,856 shares of our common stock have been reserved for issuance to employees, non-employee directors and consultants of the Company. In November 2005, options to purchase 2,095,000 shares of our common stock, in the aggregate, were granted under the plan. The options vest over three years, have a ten year term and have an exercise price of \$1.95 per share.

During the nine months ended September 30, 2006, options to purchase 1,555,000 shares were granted under the plan. The options granted in 2006 under the plan have exercise prices ranging from \$1.90 to \$3.00, terms ranging from seven to ten years, and vest over approximately four years. During the nine months ended September 30, 2006, unvested options to purchase 35,000 shares of our common stock were

Table of Contents

cancelled and are available for future issuance under the plan. Warrants to purchase 1,636,500 shares were granted outside the plan during the nine months ended September 30, 2006 to employees and consultants of our wholly-owned subsidiaries. The warrants granted in 2006 outside the plan have exercise prices ranging from \$2.05 to \$2.40, vest over three to four years and have a term of seven to ten years. The fair value of the 2006 grants was \$1.15 to \$1.65 for the grants made under the plan, and \$1.15 to \$1.45 for the warrants granted outside of the plan.

The following is a summary of stock option activity under our equity incentive plan and warrants issued outside of the plan to employees and consultants, during the nine months ended September 30, 2006:

	Number of Options or Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Balance outstanding, December 31, 2005	2,095,000	\$ 1.95	9.1	
Granted	3,191,500	2.47	8.5	
Exercised				
Expired				
Cancelled	(45,000)	2.04		
Balance outstanding, September 30, 2006	5,241,500	\$ 2.26	8.8	\$ 1,257,960
Exercisable, September 30, 2006	254,583	\$ 2.32		

The following is a summary of unvested options and warrants as of September 30, 2006, and changes during nine months ended September 30, 2006:

	Number of Options or Warrants	Weighted Average Grant Date Fair Value
Unvested balance outstanding, December 31, 2005	2,095,000	\$ 1.17
Granted	3,191,500	1.36
Vested	(254,583)	1.41
Expired		
Cancelled	(45,000)	1.17
Unvested balance outstanding, September 30, 2006	4,986,917	\$ 1.35

Note 2. Business Combinations*Innercool Therapies Acquisition*

On March 8, 2006, Cardium, through wholly-owned subsidiary, Innercool Therapies, Inc., a Delaware corporation, acquired substantially all of the assets and the business of Innercool Therapies, Inc., an unaffiliated California corporation, in the development stage, engaged in the business of researching, developing, manufacturing, marketing, selling and distributing products and services related to endovascular temperature control therapy. As partial consideration therefore, Cardium issued to the seller 2,500,000 shares of Cardium's common stock. In addition, as part of the acquisition, Cardium agreed to (i) deliver to the seller \$5,000,000 in cash or shares of Cardium's common stock, at Cardium's election, if net sales revenue from certain of Innercool's products acquired in the acquisition equals or exceeds \$20,000,000 in any one calendar year beginning with 2006 and ending December 31, 2011; (ii) assume

Table of Contents

certain liabilities of Innercool Therapies in the aggregate amount of approximately \$580,000; and (iii) pay certain transaction costs associated with the acquisition and amounts that may be payable to former employees of the seller for accrued and unpaid vacation estimated, in the aggregate, to be approximately \$170,000, as well as certain audit fees and other expenses of approximately \$100,000. The acquisition was recorded based on Cardium's common stock price of \$2.35 per share.

The results of operations have been included in the accompanying consolidated financial statements from the date of acquisition. The estimated total cost of the acquisition is as follows:

Issuance of common stock	\$ 5,875,000
Total purchase price	\$ 5,875,000

The allocation of the purchase price for the Innercool Therapies acquisition as of March 8, 2006, the date of the acquisition, is as follows:

Assets acquired:	
Cash	\$ 51,800
Accounts receivable	176,593
Inventory, net	96,664
Property and equipment	110,943
Prepaid expenses	18,548
Deposits	24,381
Intangible assets (amortizable over 3-6 years)	448,503
Acquired technology (amortizable over 8 years)	5,780,713
Total assets acquired	\$ 6,708,145
Liabilities assumed:	
Accounts payable	\$ 387,105
Other accrued expenses	446,040
Total liabilities assumed	\$ 833,145
Total consideration	\$ 5,875,000

Tissue Repair Company Acquisition

On August 11, 2006, Cardium through its newly-formed, wholly-owned subsidiary, Cardium Biologics, Inc., a Delaware corporation, acquired rights to assets and technologies of Tissue Repair Company, a privately-held, San Diego-based Delaware corporation focused on the development of growth factor therapeutics for the potential treatment of tissue wounds such as dermal ulcers. The rights acquired included product rights to a lead product candidate, Excellerate™, a DNA-activated collagen gel for topical treatment formulated with an adenovector delivery carrier encoding human platelet-derived growth factor-B (PDGF-B). Excellerate is initially being developed as a single administration for the treatment of non-healing, neuropathic diabetic foot ulcers. The Excellerate topical gel is designed to stimulate angiogenesis and granulation tissue formation through the recruitment and proliferation of chemotactic cells such as monocytes and fibroblasts, which are necessary for the stimulation of a variety of wound healing processes. The rights acquired also included technologies applicable to the treatment of ischemic heart disease. Following the acquisition, Cardium Biologics, Inc. changed its name to Tissue Repair Company (TRC).

As consideration for the rights acquired, Cardium, through its TRC subsidiary, paid the seller \$1.0 million and assumed approximately \$120,000 in liabilities of the seller. If TRC advances the Excellerate product candidate to a Phase 2 clinical study, TRC would be obligated to pay a product advancement milestone of

Table of Contents

\$1.0 million. TRC has the right to return the assets and product rights at anytime before the milestone payment and would have no further obligation under the terms of the acquisition. If TRC successfully commercializes Excellerate, TRC would pay royalties based on worldwide net sales of such product. The royalty rate to the seller would be 10% minus any applicable third party royalties (including a royalty to the University of Michigan under a license agreement assumed by TRC), and would also be subject to a development cost-recovery offset that could be deducted at the rate of \$5.0 million per year from any applicable royalty obligations. The deduction for third party royalties would apply until worldwide net sales exceeded \$100 million per year. The cost-recovery offset would apply until TRC recovered 50% of its associated product development costs. TRC would also have a right to buy out the ongoing royalty obligation based on a one-time payment of 30% of net sales for the fifth calendar year or the first year in which sales exceeded \$250 million. If pre-specified milestones relating to the commercial development of Excellerate are not satisfied, and TRC did not elect to return the assets to the seller, then Cardium would issue to the seller stock purchase warrants to purchase up to an aggregate of 2.0 million shares of Cardium's common stock (one 500,000 share allotment for each of up to four missed events) at an exercise price of \$4.00 per share. The seller could also require TRC to return certain product rights if TRC failed to meet the Excellerate development milestones by more than six months, excluding delays caused by defined product-related limitations.

The results of operations of TRC have been included in the accompanying condensed consolidated financial statements from the date of acquisition.

Based on the Company's evaluation, the preliminary allocation of the purchase price for the Tissue Repair Company acquisition is as follows as of August 11, 2006, the date of the acquisition:

Assets acquired:	
Property and equipment	\$ 89,126
Deposits	2,280
In-process Purchased Technology	1,027,529
Total assets acquired	\$ 1,118,935
Liabilities assumed:	
Other accrued expenses	\$ 118,935
Total liabilities assumed	\$ 118,935
Cash consideration	\$ 1,000,000

Unaudited pro forma consolidated financial information is presented below as if the Innercool Therapies and Tissue Repair Company acquisitions had occurred prior to the beginning of the periods shown. The results have been adjusted to account for the amortization of acquired technology and intangibles and other pro forma adjustments. The pro forma information presented below does not purport to present what actual results would have been if the acquisition occurred at the beginning of such periods, nor does the information project results for any future period. The unaudited pro forma consolidated financial information should be read in conjunction with the historical financial information of Cardium included in this report, as well as the historical financial information of Cardium and Innercool Therapies included in other reports and documents we file with the SEC. The unaudited pro forma consolidated financial information for the three and nine month periods ended September 30, 2005 and 2006 is as follows:

Table of Contents

	Pro Forma Combined for the			
	Three Months		Nine Months	
	Ended		Ended	
	September 30,		September 30,	
	2006	2005	2006	2005
Revenues				
Net sales	\$ 134,062	\$ 156,714	\$ 530,542	\$ 476,498
Net loss	(4,481,131)	(1,427,518)	(11,373,230)	(4,466,171)
Net loss per common share basic and diluted	\$ (0.14)	\$ (0.14)	\$ (0.36)	\$ (0.59)
Weighted average common shares outstanding basic and diluted	31,750,482	10,328,261	31,750,143	7,561,355

Note 3. Purchase of Technology from Schering AG Group (Germany)

In October 2005, we completed a transaction with Schering AG Group (Germany) and related licensors, including the University of California, New York University and Yale University, for 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 (iii) other technology and know-how, including manufacturing and formulation technology, as well as data relating to the clinical development of Generx™ and corresponding Food and Drug Administration regulatory matters. Under the terms of the transaction, we paid Schering a \$4 million fee, and will pay a \$10 million milestone payment upon the first commercial sale of each resulting product. We also are obligated to pay the following future 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. To date, no royalty payments have been required.

Note 4. Commitments and Contingencies*Operating Leases*

Effective November 1, 2005, we entered into a two year lease for our 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, the monthly installment of base rent is approximately \$21,500, which amount will increase to approximately \$22,335 in the second year of the lease. In addition to base rent, we also are required to pay our proportionate share of operating and tax expenses for the office park in which our space is located.

As part of the acquisition of Innercool Therapies, Cardium, through its wholly-owned Innercool subsidiary, acquired all of the rights and assumed all of the obligations of the seller under the terms of a lease for approximately 24,000 square feet in San Diego, California, and a sublease of approximately 6,602 square feet of such facilities to an unaffiliated third party. The base monthly rent under the lease is \$25,200. The monthly base rent payable to Innercool under the terms of the sublease is approximately \$7,262. The lease and the sublease both expire October 31, 2007.

Table of Contents

As part of the acquisition of Tissue Repair Company, Cardium, through its wholly-owned TRC subsidiary, acquired all of the rights and assumed all of the obligations of the seller under the terms of a month to month lease for approximately 2,700 square feet in San Diego, California. The base monthly rent under the lease is \$2,700.

Future annual minimum rental payments along with sub-lease income under the leases are as follows:

Year Ending December 31,	Facilities (Operating Lease)	Sub-Lease (Income)	Net
2006	\$ 141,000	\$ (21,500)	\$ 119,500
2007	475,000	(73,000)	402,000
Total	\$ 616,000	\$ (94,000)	\$ 521,500

Rent expense was \$113,688 for the three months ended September 30, 2006, and \$293,872 for the nine months ended September 30, 2006. We did not incur rent expense during the three and nine months ended September 30, 2005.

Note 5. Stockholders Equity*Common Stock*

Cardium was incorporated in Delaware on December 22, 2003. On December 31, 2003, we sold 1,700,000 shares of our common stock to our founders and executives for \$17,000. On April 1, 2005, we issued an additional 3,800,000 shares of our common stock (of which 3,650,000 shares were issued to our co-founders and the remainder was issued to another employee of Cardium), in exchange for services and reimbursement of expenses valued at \$38,000.

On May 19, 2005, our Board of Directors and stockholders approved an increase in our authorized shares of common stock from 5,500,000 shares to 100,000,000 shares and a change in the par value of our shares of common stock from \$0.001 to \$0.0001.

On May 20, 2005, we issued 350,000 shares of our common stock to our co-founders in exchange for services and reimbursement of expenses valued at \$3,500. On July 1, 2005, we sold 2,000,000 shares of our common stock for \$20,000 to one of our founders.

On October 20, 2005, we completed a reverse merger with Aries Ventures Inc., a publicly-traded shell company, whereby a newly formed and wholly-owned subsidiary of Aries was merged with and into Cardium. At the time of the reverse merger, Cardium had 7,850,000 shares of its common stock outstanding and Aries had 2,032,226 shares of its common stock outstanding. In connection with the reverse merger, a three year warrant to purchase 400,000 shares of our 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 before the reverse merger, as consideration for such stockholder's agreement not to sell any of such stockholder's shares for a specified period of time.

Concurrently with the reverse merger, we closed a private placement of 19,325,651 shares of common stock at a purchase price of \$1.50 per share and received net proceeds of \$25,542,389. 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. Warrants to purchase 424,263 shares of common stock, in the aggregate, were issued to such investors.

In October 2005, one of our executive officers was issued 41,924 shares of our common stock as repayment for advances totaling \$62,882 that had been made to fund our early start-up costs.

Table of Contents

On March 8, 2006, we acquired substantially all of the assets of Innercool Therapies, Inc. As partial consideration, we issued to the seller 2,500,000 shares of our common stock. In addition, as part of the acquisition, we agreed to deliver to the seller \$5,000,000 in cash or shares of our common stock, at our election, if net sales revenue from certain of Innercool's existing line of business products acquired in the acquisition equals or exceeds \$20,000,000 in any one calendar year beginning with 2006 and ending December 31, 2011.

On May 16, 2006, 681 shares of common stock were issued when a warrant to purchase 1,499 shares of common stock was exercised in a cashless transaction, whereby a portion of the warrant representing the right to purchase 818 shares of common stock was cancelled as the method of payment for the exercise of the warrant. The warrant had an exercise price of \$1.50 per share.

In October 2006, 20,387 shares of common stock were issued when warrants to purchase 41,030 shares of common stock were exercised in a cashless transaction, whereby a portion of the respective warrants representing the right to purchase 20,643 shares of common stock was cancelled as the method of payment for the exercise of the warrants. The warrants had an exercise price of \$1.50 per share.

Warrant Activity

The following table summarizes warrant activity for the year ended December 31, 2005 and the nine months ended September 30, 2006:

	Number of Warrants	Exercise Price \$	Weighted Average Remaining Contractual Life (in years)
Balance outstanding, December 31, 2004			
Warrants issued	2,856,818	\$ 1.50 - \$1.75	3 - 5
Warrants exercised			
Warrants expired			
Warrants cancelled			
Balance outstanding, December 31, 2005	2,856,818	\$ 1.50 - \$1.75	3 - 5
Warrants issued			
Warrants exercised	(1,499)	1.50	5
Warrants expired			
Warrants cancelled			
Balance outstanding, September 30, 2006	2,855,319	\$ 1.50 - \$1.75	3 - 5
Warrants exercisable at September 30, 2006	2,855,319	\$ 1.50 - \$1.75	3 - 5

The table above summarizes investor warrant activity and warrants issued in connection with the reverse merger transaction. It does not include warrants issued to employees and consultants described and included under "Option Activity" above.

Note 6. Reverse Merger Transaction

On October 20, 2005, we completed a reverse merger with Aries Ventures Inc., a publicly-traded shell company, whereby a newly formed and wholly-owned subsidiary of Aries was merged with and into Cardium. For financial reporting purposes, Cardium was the acquirer in the merger and the merger was accounted for as a reverse merger. At the time of the reverse merger, Cardium had 7,850,000 shares of its common stock outstanding and Aries had 2,032,226 shares of its common stock outstanding.

Table of Contents

Concurrently with the reverse merger, we closed a private placement of 19,325,651 shares of common stock at a purchase price of \$1.50 per share and received net proceeds of \$25,542,389. 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. Warrants to purchase 424,263 shares of common stock, in the aggregate, were issued to such investors.

In connection with the private placement, we incurred selling commissions, marketing allowances and management fees payable to the placement agent totaling approximately \$3,049,000, and legal, accounting and other fees and expenses totaling approximately \$397,000. In addition, five-year warrants to purchase 2,032,555 shares of our common stock were issued to the placement agent at an exercise price of \$1.50 per share.

Note 7. Stockholder Rights Plan

On July 10, 2006, Cardium's Board of Directors approved the adoption of a Stockholder Rights Plan (Rights Plan) with the intention to protect against potential takeover tactics that are not in the best interest of Cardium and its stockholders, such as acquisitions of control without paying all stockholders a fair premium, coercive tender offers and inadequate offers. The Rights Plan was not adopted in response to any specific effort to acquire control of Cardium and it is not intended to prevent an offer that the Board of Directors concludes is in the best interests of Cardium and its stockholders.

Pursuant to the Rights Plan, Cardium issued a dividend of one right for each share of its common stock held by stockholders of record as of the close of business on July 21, 2006. The rights are not immediately exercisable and will become exercisable only upon the occurrence of certain events. In general, if a person or group acquires, or announces a tender or exchange offer that would result in the acquisition of, 15% or more of Cardium's common stock while the Rights Plan remains in place, then, unless the rights are redeemed by Cardium for \$0.001 per right, the rights will become exercisable by all rights holders except the acquiring person or group for one one-thousandth of a share of newly created Series A Preferred Stock of the Company at an exercise price of \$40.00. Until the rights become exercisable, the rights will be represented by, and will automatically trade with, the Company's common stock certificates.

The Rights Plan will be reviewed and evaluated every three years by a committee of independent directors of Cardium's Board of Directors to consider whether the plan continues to be in the best interests of Cardium and its stockholders. The Rights Plan may be amended or revoked by Cardium at any time and unless earlier terminated or amended, the rights will expire on July 10, 2016.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

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;

Table of Contents

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

the performance of Innercool's Celsius Control SystemTM, GenerxTM, ExcellerateTM and other product candidates and their potential to attract development partners and/or generate revenues;

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

the development or commercialization of competitive products or medical procedures;

our development of new products and product candidates;

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

the outcome of litigation matters;

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

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

our personnel, consultants and collaborators;

operations outside the United States;

current and future economic and political conditions;

overall industry and market performance;

the impact of accounting pronouncements;

management's goals and plans for future operations; and

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

Edgar Filing: Cardium Therapeutics, Inc. - Form 10QSB

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 our 2005 Annual Report, as well as in other reports and documents we file with the United States Securities and Exchange Commission(SEC).

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

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

We are a medical technology company primarily focused on the development, manufacture and sale of innovative products for cardiovascular and related indications. Building upon our core products and

Table of Contents

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

initiate a late-stage clinical study for Generx;

initiate a Phase 2 clinical study for Excellerate;

seek to accelerate the development and sales of Innercool's Celsius Control System™ and, at the same time, broaden and expand our therapeutic hypothermia technology into other medical indications and applications;

leverage our financial resources and focused corporate infrastructure through the use of contract manufacturers to produce clinical supplies and a contract research organization to manage or assist planned clinical studies;

advance the pre-clinical development of Corgentin and potentially seek partnering opportunities for the Corgentin and Genvascor product candidates;

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; and

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

We have initially focused on acquiring fallen angel opportunities that we believe have unrealized value but with the potential for significant future growth or partnering prospects. 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.

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

In October 2005, we completed a private placement of our common stock that resulted in net proceeds to the Company of more than \$25 million, and we believe that we could fund operations for the next 12 months from remaining cash, cash equivalents and short-term investments. However, the amount and timing of cash requirements will depend on the amount and rate at which resources are applied to clinical trials and other activities associated with researching, developing, manufacturing, commercializing and supporting our products and product candidates, which could lead to our cash resources being consumed sooner than currently expected. If we do not have sufficient cash to maintain operations and fund planned programs, we would either need to reduce or slow our expenditures, which could cause a delay in the implementation or accomplishment of one or more components of our operation described above, or seek additional financing through the sale of equity securities, debt financing, and/or strategic licensing agreements. Any additional capital may not be available on terms that are desirable or acceptable to us, or at all.

More detailed information about our products, product candidates and our intended efforts to develop our products is included in our 2005 Annual Report.

Table of Contents

Risk Factors

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

Risks Related to Our Business and Industry

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

We have sustained operating losses to date and will likely continue to sustain losses as we seek to accelerate our product development efforts. We expect these losses to be substantial in the early years of our operations because our product development and other costs, including significant amounts we expect to spend on development activities and clinical trials for Generx , Excellerate and other product candidates, cannot be offset by our limited revenues during our development stage. As of September 30, 2006, our accumulated deficit was approximately \$17 million, and our cash equivalents were approximately \$11.5 million. To date, we have generated limited revenues, consisting of revenues from sales of our Innercool Celsius Control System and associated disposables, as well as interest income. A large portion of our expenses are fixed, including expenses related to facilities, equipment, contractual commitments and personnel. As a result, we expect our net losses from operations to continue for at least the next five years. Our ability to generate additional revenues and potential to become profitable will depend largely on our ability, alone or with potential collaborators, to efficiently and successfully complete the development of our product candidates, successfully complete pre-clinical and clinical tests, obtain necessary regulatory approvals, and manufacture and market our products. There can be no assurance that any such events will occur or that we will ever become profitable. Even if we do achieve profitability, we cannot predict the level of such profitability. If we sustain losses over an extended period of time, we may be unable to continue our business.

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

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

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

Conducting the costly and time consuming research, pre-clinical and clinical testing necessary to obtain regulatory approvals and bring our products to market will require a commitment of substantial funds in excess of our current capital. Our future capital requirements will depend on many factors, including, among others: the progress of our current and new product development programs; the progress, scope and results of our pre-clinical and clinical testing; the time and cost involved in obtaining regulatory approvals;

Table of Contents

the cost of manufacturing our products and product candidates; the cost of prosecuting, enforcing and defending against patent claims and other intellectual property rights; competing technological and market developments; and our ability and costs to establish and maintain collaborative and other arrangements with third parties to assist in potentially bringing our products to market.

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

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

potential loss of key employees of the acquired company; and

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

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

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

We are in the early stage of product development and, other than Innercool's Celsius Control System and related disposables that are approved only for limited uses, we currently do not sell any other products and may not have any other products commercially available for several years, if at all. Our product candidates, and the potential expansion of our therapeutic hypothermia products into other medical indications and applications, require additional research and development, clinical testing and regulatory clearances before we can market them. To our knowledge, the U.S. Food and Drug Administration, or FDA, has not yet approved any gene therapy or similar product and there can be no assurance that it will. There are many reasons that our products and product candidates may fail or not advance beyond clinical testing, including the possibility that:

our products and product candidates may be ineffective, unsafe or associated with unacceptable side effects;

our product candidates may fail to receive necessary regulatory approvals or otherwise fail to meet applicable regulatory standards;

our product candidates may be too expensive to develop, manufacture or market;

Table of Contents

physicians, patients, third-party payers or the medical community in general may not accept or use our products;

our potential collaborators may withdraw support for or otherwise impair the development and commercialization of our products or product candidates;

other parties may hold or acquire proprietary rights that could prevent us or our potential collaborators from developing or marketing our products or product candidates; or

others may develop equivalent, superior or less expensive products.

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

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

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

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

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

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

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

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

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

Edgar Filing: Cardium Therapeutics, Inc. - Form 10QSB

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

Table of Contents

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

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

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

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

changes in governmental regulations or administrative actions affect the conduct of the clinical trial or the interpretation of its results. Significant delays may adversely affect our financial results and the commercial prospects for our product candidates and delay our ability to become profitable.

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

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

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

Clinical trials for products such as ours are often conducted with patients who have more advanced forms of a particular disease. For example, in clinical trials for our lead product candidate Generx, we expect to study patients who are not only suffering from severe forms of heart disease but are also older and much more likely to develop cancers and other serious adverse conditions. During the course of treatment, these patients could die or suffer other adverse events for reasons that may or may not be related to the proposed product being tested. Our clinical trials may also be adversely impacted by patient deaths or problems that occur in other trials. However, even if unrelated to our product, such events can nevertheless adversely impact our clinical trials. As a result, our business and ability to ultimately develop and market the products and obtain revenues would suffer.

Deaths and other adverse events that occur in the conduct of clinical trials may also result in an increase in governmental regulations or litigation, and could result in delays or halts being imposed upon clinical trials, including our own. In addition, patients involved in clinical trials such as ours often have unknown as well as known health risks and pre-existing conditions. An adverse event may therefore appear to have been caused or exacerbated by the administration of study product, even if it was not actually related. Such consequences can also increase the risk that any potential adverse event in our trial could give rise to claims

Table of Contents

for damages against us, or could cause further delays or halt our clinical trial, any of which results would negatively impact us. In addition, fears regarding the potential consequences of gene therapy trials or the conduct of such trials could dissuade investigators or patients from participating in our trials, which could substantially delay or prevent our product development efforts.

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

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

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

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

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

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

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

Table of Contents

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

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

We may not successfully establish and maintain collaborative and licensing arrangements, which could adversely affect our ability to develop and commercialize our product candidates.

Our strategy for the development, testing, manufacturing and commercialization of our product candidates generally relies on establishing and maintaining collaborations with corporate partners, licensors and other third parties. For example, we have licenses from New York University and the University of California relating to the use and delivery of our Generx product candidates for the treatment of vascular disease, as well as a relationship with Schering AG Group (Germany) 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 service providers and collaborators to perform a number of activities relating to the development and commercialization of our product candidates, including the manufacture of product materials, the design and conduct of clinical trials, and potentially the obtaining of regulatory approvals and the marketing and distribution of any successfully developed products. Our collaborative partners also may 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.

Our success hinges on the proper and effective performance of our service providers and collaborators of their responsibilities under their arrangements with us. Our existing or potential collaborators may not perform their obligations in a timely fashion or in a manner satisfactory to us. We and our present and future collaborators may fail to develop or effectively commercialize products covered by our present and future collaborations if, among other things:

we do not achieve our objectives under our collaboration agreements;

Table of Contents

we or our collaborators are unable to obtain patent protection for the products or proprietary technologies we develop in our collaborations;

we are unable to manage multiple simultaneous product discovery and development collaborations;

our collaborators become competitors of ours or enter into agreements with our competitors;

we or our collaborators encounter regulatory hurdles that prevent commercialization of our products; or

we develop products and processes or enter into additional collaborations that conflict with the business objectives of our other collaborators.

In addition, conflicts may arise with our collaborators, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. If any conflicts arise with our existing or future collaborators, they may act in their self-interest, which may be adverse to our best interest. If we or our collaborators are unable to develop or commercialize products, or if conflicts arise with our collaborators, we will be delayed or prevented from developing and commercializing products which will harm our business and financial results.

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 products and product candidates and the catheters used to deliver the products in accordance with good manufacturing practices established by the FDA and other regulators. For example, we recently entered into a Production Service Agreement with Molecular Medicine Bioservices, Inc. pursuant to which Molecular Medicine will manufacture our lead product candidate, Generx, for late-stage clinical development. 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 products and 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 products. These third parties also may not deliver sufficient quantities of our products, manufacture our products in accordance with specifications, or comply with applicable government regulations. Successful large-scale manufacturing of gene-based therapy products has been accomplished by very few companies, and it is anticipated that significant process development changes will be necessary before commercializing and manufacturing any of our biologic product candidates. Additionally, if the manufactured products fail to perform as specified, our business and reputation could be severely impacted.

If any manufacturing agreement is terminated or any third party service provider or 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. There can be no assurance that manufacturers on whom we depend will be able to successfully produce our products or product candidates on acceptable terms, or on a timely or cost-effective basis, or in accordance with our product specifications and applicable FDA or other governmental regulations. 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, which would negatively impact our business.

Table of Contents

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

Our failure or the failure of our potential collaborators or third party manufacturers to comply with applicable FDA or other product-related 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 products, 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 or market our products.

We currently have limited sales, marketing and distribution capabilities in connection with our Innercool products and none with respect to our other product candidates, which are not yet approved for marketing. To commercialize our other product candidates, if and when such products have been approved and are ready for marketing, we expect either to collaborate with third parties to perform these functions or develop them internally.

We have little experience in developing, training or managing a sales force and will incur substantial additional expenses for any products that we market directly. Developing a marketing and sales force is also time consuming and could delay the launch of new products or expansion of existing product sales. We expect that we will need to develop additional marketing and sales personnel, and/or work with outside providers, to achieve increased sales of our Innercool 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, in which event our business prospects may suffer.

We face intense and increasing competition and must cope with rapid technological change, which may adversely affect our financial condition and/or our ability to successfully commercialize and/or market our products and 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 than us 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 operate large, well-funded research and development programs and have significant products approved or in development. Our potential competitors also include academic institutions, governmental agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for product and clinical development and marketing.

We are engaged in DNA-based therapies and temperature control 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, as well as competitive approaches to temperature control therapy such as those being developed by Alsius Corporation, Radiant Medical, Medivance, Gaymar Industries and Cincinnati Sub-Zero, will compete directly or indirectly with the

Table of Contents

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 products and product candidates uneconomical or obsolete, and we may not be successful in marketing our products and 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 products and future products or our ability to obtain an adequate level of reimbursement or acceptable prices for our products or future products.

Other than Innercool's Celsius Control System and associated disposables, we currently have no products approved for marketing. Our ability to earn sufficient returns on our products and 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 and marketing our products and future products.

There have been and will 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. 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 products or future products are not able to obtain adequate reimbursement from third-party payers for the cost of using the 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 and therapeutic hypothermia treatments, and whether adequate third-party coverage will be available. The announcement or considerations of these proposals or reforms could impair our ability to raise capital and negatively affect our business.

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 or market our products or product candidates.

Our future success depends on our ability to attract, retain and motivate highly qualified management and scientific and regulatory personnel and advisors, as well as production, marketing and sales personnel in connection with our Innercool products. The loss of any of our senior management team, in particular Christopher J. Reinhard, our Chairman of the Board, Chief Executive Officer, President and Treasurer, Tyler M. Dylan, our director, Chief Business Officer, General Counsel, Executive Vice President and Secretary, and Dennis M. Mulroy, our Chief Financial Officer, or our vice presidents, or the operating officers of our subsidiaries, could harm our business.

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, manufacturing, marketing and other areas. 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, commercialize and market our products and product candidates.

Table of Contents

Our facilities are located in or near seismic zones, and an earthquake or other natural disaster or resource shortage could delay our research and development efforts and adversely affect our business.

Our headquarters and research and development facilities in San Diego, California, and our third party manufacturing facilities in Carlsbad, California, are both located in or near seismic zones, and there is a constant possibility that an earthquake or other natural disaster or resource shortage could be disruptive to our operations and result in delays in our research and development efforts. In the event of a natural or other disaster such as earthquake, fire, flood or terrorist attack, if our facilities or the equipment in our facilities, or our clinical supplies, are significantly damaged or destroyed, we may not be able to rebuild or relocate our facility or replace any damaged equipment, records or clinical supplies in a timely manner and our business, financial condition and results of operations could be materially and adversely affected.

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.

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, including those associated with our Innercool products, 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.

Risks Related to Our Intellectual Property and Potential Litigation

If our products and product candidates are not effectively protected by valid, issued patents or if we are not otherwise able to protect our proprietary information, or if our right to use intellectual property that we 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.

Table of Contents

The success of our operations will depend in part on our ability and that of our licensors to: obtain patent protection for our gene therapy, therapeutic genes and/or gene-delivery methods, temperature control devices and procedures, and other methods or components on which we rely 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.

Our business substantially relies on our own or in-licensed intellectual property related to various technologies that are material to our products and processes. We depend on our and our licensors' abilities to successfully prosecute and enforce the patents, file patent applications and prevent infringement of those patents and patent applications. The licenses and other intellectual property rights we acquire may or may not provide us with exclusive rights. To the extent we do not have exclusive rights, others may license the same technology and may develop the technology more successfully or may develop products similar to ours and that compete with our products. Even if we are provided with exclusive rights, the scope of our rights under our licenses may be subject to dispute and termination or reduction by our licensors or third parties. Our licenses also contain milestones that we must meet and/or minimum royalty or other payments that we must make to maintain the licenses. There is no assurance that we will be able to meet such milestones and/or make such payments. Our licenses may be terminated if we fail to meet applicable milestones or make applicable payments.

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

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

Due to the significant time lag between the filing of patent applications and the publication of such patents, we cannot be certain that our licensors were the first to file the patent applications we 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, temperature control therapy, and other of our technologies 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 that is patentable in the United States but not generally patentable outside of the United States. Differences in what constitutes patentable subject matter in various

Table of Contents

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, commercializing or marketing our products and/ or 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, technology, products 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 the 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.

For example, in connection with our exclusive license to the University of California's technology for cardiovascular gene therapy (filed by Hammond et al., an international application of which was published as WO96/26742), we and our predecessor in interest Collateral Therapeutics have assisted the University of California in an interference proceeding against a patent application filed by Jeffrey Leiden et al. (a U.S. counterpart of international application PCT/US93/11133, which published as WO94/11506). In the interference, which is essentially a contest to determine priority of invention, a panel of Administrative Patent Judges of the U.S. Board of Patent Appeals and Interferences or BPAI issued judgment against the Leiden applicants, ordering that the interference count, which represents the disputed subject matter, be awarded to Hammond, and that Leiden et al. be held not entitled to any patent containing claims corresponding to those in the interference. However, the patent applicant, Arch Development Corporation, which had licensed the technology to Boston Scientific Corporation, subsequently appealed the decision against them. In May 2006, the U.S. Court of Appeals for the Federal Circuit, which hears appeals in U.S. patent cases, refused requests by Arch and Boston Scientific to reverse the prior decision of the BPAI regarding priority of invention. The Federal Circuit also refused requests to remand the case for reconsideration of previously-contested matters such as the novelty, nonobviousness or validity of the Hammond patents, and it summarily issued final judgment against the Leiden applicants. Appeals from decisions of the Federal Circuit to the U.S. Supreme Court are rarely granted under such circumstances and were not sought. In a related matter, Collateral Therapeutics, with our assistance, successfully opposed a European counterpart to the Leiden PCT application (EP-B-668913), which led to a decision to revoke the patent grant in Europe. Although the patentee, Arch Development Corporation, subsequently appealed the adverse decision, a ruling following appeal to the European Patent Office's Technical Board of Appeal has now been rendered and the European patent grant to Arch (which had been licensed to Boston Scientific) has now been revoked. If we do not continue to be successful in defending against these and any other adverse claims, we could be compelled to seek licenses from one or more third parties who could be direct or indirect competitors and who might not make licenses available on terms that we find commercially reasonable or at all. In addition, such proceedings, even if decided in our favor, involve lengthy processes, are subject to appeals, and typically result in substantial costs and diversion of resources.

As more potentially competing patent applications are filed, and as more patents are actually issued, in the fields of gene therapy, wound healing, adenoviral vectors or therapeutic hypothermia or in other fields in which we may become involved 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 manufacturing, marketing, product development or commercialization efforts. Even if such patent applications or patents are ultimately proven to be invalid, unenforceable or

Table of Contents

non-infringed, such proceedings are generally expensive and time consuming and could consume a significant portion of our resources and substantially impair our marketing and 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, or face an injunction to block our sale or marketing of affected products or use of the affected process. Costs of a license may be substantial and could include up-front payments as well as ongoing royalties. We may not be able to obtain such a license on acceptable terms, or at all, which could substantially impact our business.

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

We also 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 marketing and sale of therapeutic hypothermia products as well as our other operations will expose us to product liability risks that are inherent in the testing, manufacturing and marketing of biotechnology and medical device products. Failure to obtain or maintain sufficient product liability insurance or otherwise protect against product liability claims could prevent or delay the commercialization or marketing of our products or product candidates or expose us to substantial liabilities and diversions of resources, all of which can negatively impact our business. 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, such as 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 various risks involved with participating in the trial. However, patient consents provide only a limited level of protection, and it may be alleged that the consent did not address or did not adequately address a risk that the patient suffered from. Additionally, we will generally be required to indemnify the clinical product manufacturers, clinical trial centers, medical professionals and other parties conducting related activities 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.

Risks Related to Our Common Stock

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

In light of our small size and limited resources, as well as the uncertainties and risks that can affect our business and industry, our stock price is expected to be highly volatile and can be subject to substantial drops, with or even in the absence of news affecting our business. The following factors, in addition to other risk factors described in this prospectus, 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:

anticipated or unanticipated changes in financial conditions, operating results or the perceived value of our business;

Table of Contents

developments concerning any research and development, clinical trials, manufacturing, and marketing efforts or collaborations;

our announcement of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

announcements of technological innovations;

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 or other estimates by securities analysts or other reviewers or evaluators of our business;

conditions or trends in bio-pharmaceutical or other healthcare industries;

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;

additions or departures of key personnel;

sales or other transactions involving our common stock; and

global unrest, terrorist activities, and economic and other external factors.

The stock market in general has recently experienced relatively large price and volume fluctuations. In particular, the market prices of securities of smaller biotechnology and medical device companies have experienced dramatic 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 remains limited or declines.

We could be difficult to acquire due to anti-takeover provisions in our charter, our stockholder rights plan and Delaware law.

Our board of directors has adopted a stockholder rights plan in which preferred stock purchase rights were distributed as a dividend. These provisions may make it more difficult for stockholders to take corporate actions and may have the effect of delaying or preventing a change in control. These provisions also could deter or prevent transactions that stockholders deem to be in their interests. In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law. Subject to specified exceptions, this section provides that a corporation may not engage in any business combination with any interested stockholder during the three year period following the time that such stockholder becomes an interested stockholder. This provision could have the effect of delaying or preventing a change of control of our company. The foregoing factors could reduce the price that investors or an acquirer might be willing to pay in the future for shares of our common stock.

We have never paid cash dividends on our capital stock and we do not anticipate paying dividends in the foreseeable future.

Edgar Filing: Cardium Therapeutics, Inc. - Form 10QSB

We have paid no cash dividends on any of our classes of capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the

Table of Contents

terms of any future debt or credit facility may preclude or limit our ability to pay any dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of potential gain for the foreseeable future.

Off-Balance Sheet Arrangements

As of September 30, 2006, 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

The preparation of our financial statements 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 under Item 7 of our 2005 Annual Report and in the notes to the financial statements included in this report. Our critical accounting policies also include purchase price allocation and amortization of intangibles, stock based compensation, and income taxes.

Purchase Price Allocation and Amortization of Intangibles

The allocation of the purchase price for acquisitions requires extensive use of accounting estimates and judgments to allocate the purchase price to identifiable tangible and intangible assets acquired and liabilities assumed based on their respective fair values. We reach our conclusions regarding the fair values assigned to identifiable tangible and intangible assets based on a number of factors, including valuations from an independent firm. We, however, are ultimately responsible for these valuations. The tangible and intangible assets are depreciated and amortized over the estimated useful life of the assets.

Stock-Based Compensation

Effective January 1, 2006, the Company adopted the fair value recognition provisions of SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R), using the modified prospective transition method. Under the transition method, stock-based compensation expense is recognized (i) for all stock-based compensation awards granted before, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provision of SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123), and (ii) for all stock-based compensation awards granted after January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS 123R.

Before the adoption of SFAS 123R on January 1, 2006, the Company recognized stock-based compensation expense in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and provided pro forma disclosure amounts in accordance with SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure* (SFAS 148), as if the fair value method defined by SFAS 123 had been applied to its stock-based compensation.

Table of Contents

Income Taxes

The Company accounts for income taxes under SFAS No. 109, Accounting for Income Taxes. SFAS No. 109 requires the recognition of deferred tax assets and liabilities for both the expected impact of differences between the financial statements and tax basis of assets and liabilities, and for the expected future tax benefit to be derived primarily from tax loss carryforwards. The Company has established a valuation allowance related to the benefits of net operating losses for which utilization in future periods is uncertain. The Company believes it is more likely than not that it will not realize the benefits of these deductible differences in the near future and, therefore, a valuation allowance has been recorded to offset future tax benefits.

The Company has federal net operating losses available to offset future taxable income, which, if not utilized, will expire in 2025. No provision for income taxes has been recorded in the financial statements as a result of such operating losses.

ITEM 3. 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 Securities and Exchange Commission as required under the Securities Exchange Act of 1934, as amended.

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, 2006. 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 quarterly period ended September 30, 2006 that have materially affected, or that are reasonably likely to materially affect, our internal controls.

PART II OTHER INFORMATION

ITEM 1. 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 November 10, 2006, neither Cardium nor its subsidiaries were a party to any material pending legal proceeding nor was any of their property the subject of any material pending legal proceeding other than patent proceedings and related matters. We anticipate, however, that we will be regularly engaged in various patent prosecution and related matters in connection with the technology we develop and/or license.

For example, in connection with our exclusive license to the University of California's technology for cardiovascular gene therapy (filed by Hammond et al., an international application of which was published as WO96/26742), we and our predecessor in interest, Collateral Therapeutics, have assisted the University of California in an interference proceeding against a patent application filed by Jeffrey Leiden et al. (a U.S. counterpart of international application PCT/US93/11133, which published as WO94/11506). In the interference, which is essentially a contest to determine priority of invention, a panel of Administrative Patent Judges of the U.S. Board of Patent Appeals and Interferences or BPAI issued judgment against the Leiden applicants, ordering that the interference count, which represents the disputed subject matter, be awarded to Hammond, and that Leiden et al. be held not entitled to any patent containing claims corresponding to those in the interference. However, the patent applicant, Arch Development Corporation, which had licensed the technology to Boston Scientific Corporation, subsequently appealed the decision against them. In May 2006, the U.S. Court of Appeals for the Federal Circuit, which hears appeals in U.S. patent cases, refused requests by Arch and Boston Scientific to reverse the prior decision of the BPAI regarding priority of invention. The Federal Circuit also refused requests to remand the case for reconsideration of previously-contested matters such as the novelty, nonobviousness or validity of the

Table of Contents

Hammond patents, and it summarily issued final judgment against the Leiden applicants. Appeals from decisions of the Federal Circuit to the U.S. Supreme Court are rarely granted under such circumstances and were not sought.

In a related matter, Collateral Therapeutics, with our assistance, successfully opposed a European counterpart to the Leiden PCT application (EP-B-668913), which led to a decision to revoke the patent grant in Europe. Although the patentee, Arch Development Corporation, subsequently appealed the adverse decision, a ruling following appeal to the European Patent Office's Technical Board of Appeal has now been rendered and the European patent grant to Arch (which had been licensed to Boston Scientific) has now been revoked.

If we do not continue to be successful in defending against these and any other adverse claims, we could be compelled to seek licenses from one or more third parties who could be direct or indirect competitors and who might not make licenses available on terms that we find commercially reasonable or at all. In addition, such proceedings, even if decided in our favor, involve lengthy processes, are subject to appeals, and typically result in substantial costs and diversion of resources.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Other than as previously reported on our Current Report on Form 8-K filed with the SEC on August 15, 2006, during the quarterly period ended September 30, 2006, we did not sell any unregistered securities.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

None

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

EXHIBIT INDEX

Exhibit Number	Description	Incorporated By Reference To
2.1	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 our Current Report on Form 8-K dated October 20, 2005, filed with the commission on October 26, 2005
2.2	Certificate of Merger of Domestic Corporation as filed with the Delaware Secretary of State on October 20, 2005	Exhibit 2.1 of our Current Report on Form 8-K dated October 20, 2005, filed with the commission on October 26, 2005
2.3	Agreement and Plan of Merger dated January 17, 2006, between Aries Ventures Inc. and Cardium Therapeutics, Inc.	Exhibit 2.4 of our Registration Statement on Form SB-2 (File No. 333-131104), filed with the commission on January 18, 2006

Table of Contents

2.4	Certificate of Merger, as filed with the Delaware Secretary of State on January 17, 2006	Exhibit 2.5 of our Registration Statement on Form SB-2 (File No. 333-131104), filed with the commission on January 18, 2006
3(i)	Second Amended and Restated Certificate of Incorporation of Cardium Therapeutics, Inc. as filed with the Delaware Secretary of State on January 13, 2006	Exhibit 3(i) of our Registration Statement on Form SB-2 (File No. 333-131104), filed with the commission on January 18, 2006
3(ii)	Amended and Restated Bylaws of Cardium Therapeutics, Inc. as adopted on January 12, 2006	Exhibit 3(ii) of our Registration Statement on Form SB-2 (File No. 333-131104), filed with the commission on January 18, 2006
3(iii)	Certificate of Designation of Series A Junior Participating Preferred Stock	Exhibit 3.2 of our Registration Statement on Form 8-A, filed with the commission on July 11, 2006
4.1	Form of Warrant issued to National Securities Corporation as Placement Agent	Exhibit 4.1 of our 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 our 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 our Current Report on Form 8-K dated October 20, 2005, filed with the commission on October 26, 2005
4.4	Form of Warrant issued to employees and consultants of Innercool Therapies, Inc.	Exhibit 4.1 of our Current Report on Form 8-K dated March 8, 2006, filed with the commission on March 14, 2006
4.5	Form of Common Stock Certificate for Cardium Therapeutics, Inc.	Exhibit 4.5 of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2005, filed with the commission on March 31, 2006
4.6	Form of Rights Agreement dated as of July 10, 2006, between Cardium Therapeutics, Inc. and Computershare Trust Company, Inc., as Rights Agent	Exhibit 4.1 of our Registration Statement on Form 8-A, filed with the commission on July 11, 2006
4.7	Form of Rights Certificate	Exhibit 4.2 of our Registration Statement on Form 8-A, filed with the commission on July 11, 2006
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 our Current Report on Form 8-K dated October 20, 2005, filed with the commission on October 26, 2005

Table of Contents

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 our 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 our 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 our 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 Therapeutics, Inc.	Exhibit 10.6 of our 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 October 20, 2005, by and between New York University and Cardium Therapeutics, Inc.	Exhibit 10.7 of our Current Report on 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 our 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 our 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 our 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 our 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	Exhibit 10.12 of our Annual Report on Form 10-KSB for the fiscal year ended September 30, 2005, filed with the commission on December 22, 2005
10.13	Yale Exclusive License Agreement between Yale University and Schering Aktiengesellschaft dated September 8, 2000	Exhibit 10.13 of our Annual Report on Form 10-KSB for the fiscal year ended September 30, 2005, filed with the commission on December 22, 2005

Table of Contents

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)	Exhibit 10.14 of our Annual Report on Form 10-KSB for the fiscal year ended September 30, 2005, filed with the commission on December 22, 2005
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)	Exhibit 10.15 of our Annual Report on Form 10-KSB for the fiscal year ended September 30, 2005, filed with the commission on December 22, 2005
10.16	Placement Agency Agreement dated July 1, 2005 by and between Cardium Therapeutics, Inc. and National Securities Corporation	Exhibit 1.1 of our Current Report on Form 8-K dated October 20, 2005, filed with the commission on October 26, 2005
10.17	Asset Purchase Agreement dated as of March 8, 2006, by and among Cardium Therapeutics, Inc., Innercool Therapies, Inc. (a Delaware corporation), and Innercool Therapies, Inc. (a California corporation) (without schedules)	Exhibit 10.1 of our Current Report on Form 8-K dated March 8, 2006, filed with the commission on March 14, 2006
10.18	Production Service Agreement effective as of January 24, 2006, by and between Molecular Medicine Bioservices, Inc. and Cardium Therapeutics, Inc.	Exhibit 10.18 of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2005, filed with the commission on March 31, 2006
10.19	Executive Employment Agreement dated March 8, 2006 by and between Innercool Therapies, Inc. and Michael Magers*	Exhibit 10.19 of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2005, filed with the commission on March 31, 2006
10.20	Master License Agreement effective as of December 1, 1999, by and between SurModics, Inc. and Innercool Therapies, Inc.	Exhibit 10.20 of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2005, filed with the commission on March 31, 2006
10.21	Lease dated August 12, 1997, by and between R.G. Harris Co., and Elizabeth G. Harris, Henry K. Workman and Don C. Sherwood, Trustees of the Harris Family Revocable Trust (as landlord) and Copper Mountain Networks, Inc. (as tenant)	Exhibit 10.21 of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2005, filed with the commission on March 31, 2006

Table of Contents

10.22	Lease Amendment No. 1 effective as of August 1, 1999, by and among R.G. Harris Co., and Elizabeth G. Harris, Henry K. Workman and Don C. Sherwood, Trustees of the Harris Family Revocable Trust (as landlord), Copper Mountain Networks, Inc. (as tenant), and Neurothermia, Inc. (as assignee)	Exhibit 10.22 of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2005, filed with the commission on March 31, 2006
10.23	Assignment, Assumption and Consent effective as of October 2, 1999, by and among Copper Mountain Networks, Inc., Neurothermia, Inc., and R.G. Harris Co., and Elizabeth G. Harris, Henry K. Workman and Don C. Sherwood, Trustees of the Harris Family Revocable Trust	Exhibit 10.23 of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2005, filed with the commission on March 31, 2006
10.24	Lease Amendment No. 2 effective as of October 16, 2002, by and between E.G. Sirrah, LLC, as successor-in-interest to R.G. Harris Co., and Elizabeth G. Harris, Henry K. Workman and Don C. Sherwood, Trustees of the Harris Family Revocable Trust, and Innercool Therapies, Inc. (formerly known as Neurothermia, Inc.)	Exhibit 10.24 of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2005, filed with the commission on March 31, 2006
10.25	Sublease dated August 30, 2005, by and between Innercool Therapies, Inc., and Acadia Pharmaceuticals Inc.	Exhibit 10.25 of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2005, filed with the commission on March 31, 2006
10.26	Asset Purchase Agreement dated as of August 11, 2006, by and among Cardium Therapeutics, Inc., Cardium Biologics, Inc. (a Delaware corporation), and Tissue Repair Company (a Delaware corporation)	Exhibit 10.26 of our Current Report on Form 8-K dated August 11, 2006, filed with the commission on August 15, 2006
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

* Indicates management contract or compensatory plan or arrangement.

Table of Contents

SIGNATURES

In accordance with the requirements of the Securities Exchange Act of 1934, as amended, Cardium Therapeutics, Inc., the registrant, caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: November 14, 2006

CARDIUM THERAPEUTICS, INC.

By: /s/ Dennis M. Mulroy

Dennis M. Mulroy, Chief Financial Officer

Mr. Mulroy is the principal financial officer of Cardium Therapeutics, Inc. and has been duly authorized to sign on its behalf.