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Cardium Therapeutics (ASE/CXM)

BUY **Excellagen receives FDA nod;**
Reiterate Buy rating

Cardium Therapeutics is developing wound care and cardiovascular products

Investment Highlights

1) Cardium Therapeutics received FDA 510(k) clearance earlier this month for their Excellagen formulated collagen topical gel for the management of diabetic foot ulcers, pressure ulcers and other dermal wounds. The product will be packaged in an innovative kit containing four single-use syringes, (see right), and will be initially marketed by the Company through a direct-to-consumer web-based consumer awareness program as well as to key wound care centers (about 100) and physicians. Further down the road, the Company is seeking collaborative partners to support a broader market penetration plan expanding the use of Excellagen to additional therapeutic areas beyond diabetic foot ulcers via post marketing (phase IV) studies. Excellagen uses the Company's proprietary flowable, fibrillar collagen-based matrix technology and newly-established manufacturing process. Cardium recently published a more detailed presentation on specifics of Excellagen, the Company's near-term marketing plan, and potential commercial market for the product on their website. Our estimates for product launch and potential partnerships are late 2011 and early 2012, respectively.



2) In addition to the recent 510(k) approval for Excellagen, the Company has been busy in other developmental areas. First, in August Cardium launched the fourth product this year in their MedPodium over-the-counter dietary supplement line, and now offers Cerex for improved cognitive performance, Alena and Linee for weight management, and D-Sorb, a Vitamin D3 supplement, to combat Vitamin D deficiency. Next up for MedPodium (medpodium.com) are two entries in a new Nutra-Apps product line. Nutra-Apps are compact capsules packaged in a 2- or 4-capsule unit to be sold in a near-register

Current Price **\$0.39**

Price Target **\$1.50**

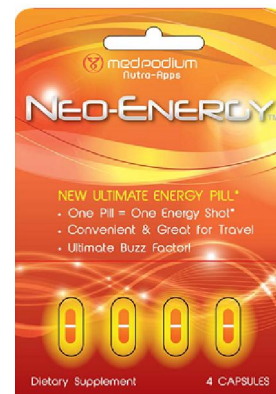
Estimates	F2009A	F2010E	F2011E
Revenues(\$000s)	\$445	\$244	\$400
EPS	(\$0.24)	(\$0.06)	(\$0.08)

Stock Data	
52-Week Range	\$0.13-\$0.60
Shares Outstanding (mil)	83.1
Market Capitalization (mil.)	\$32.4
Enterprise Value (mil.)	\$27.9
Debt to Capital (6/11)	0.0%
Book Value/Share (6/11)	\$0.05
Price/Book	8.0 x
Average Trading Volume (3-Month)	860,000
Insider Ownership	9.7%
Institutional Ownership	1.6%
Short interest	680,000
Dividend / Yield	\$0.00/0.0%



Price target and ratings changes over the past 3 yrs:
 Initiated - April 20, 2010 - Buy -Price Target \$1.50

display in convenience stores and retail outlets, similar to 5-hour Energy products, and targeted to the 60 million “Millennials” audience of 20-35 year olds in the US. The first two Nutra-App products scheduled for release in the US early next year are Neo-Energy (see diagram to the right) for extra energy and Neo-Carb Bloc for weight management support. Cardium is also moving forward with its Generx DNA therapy-based therapeutic for advanced cardiovascular disease, now named Cardionovo for the Russian market. On tap for Generx is the planned initiation early next year for the 100-person, Phase III/registration ASPIRE study for Cardionovo using SPECT imaging for an efficacy endpoint. The trial will enroll Russian patients with advanced coronary artery disease who have limited access to bypass surgery and angioplasty/stent procedures more common in the US and Europe. Cardium has hired bioRASI to help conduct this study and the Company is also exploring additional developing markets, specifically India and Brazil, for potential registration of Generx following Russia.



3) Through the first six months of 2011, Cardium has reported a net loss of \$3.45 million or (\$0.04) per share, on no revenues, including \$1.3 million in research and development expenditures and \$2.5 million in general and administrative costs, offset by non-cash gains on fair value of derivative liabilities. At the end of the first six months of the year (June 30th, 2011), Cardium held approximately \$3.2 million in cash and equivalents, down from \$6.4 million at the start of the year. In addition, Cardium received over \$1.1 million in July from Philips Electronics (NYSE/PHG/Not Rated) related to Philips’ 2009 acquisition of InnerCool therapies from Cardium, which previously had been part of the Company’s \$1.2 million in restricted cash on their balance sheets. At the current rate of approximately \$1.5-\$2.0 million in cash burn per quarter, we estimate that Cardium would need to raise additional operating capital sometime early next year, unless one or more of the following occurs in the short term:

- Cardium signs a marketing/development partnership for the US for Excellagen, with upfront licensing fees and sales royalties as part of this agreement;
- Cardium is able to exercise part or all of its 20 million in warrants and options exercisable below \$1 per share; or
- Cardium is able to draw down all or part of its current \$4.5 million at-the-market (ATM) equity market line.

Conclusion/Stock Valuation

Cardium’s management has a long track record of successful product line development and exit, and currently has a short-term catalyst in Excellagen and MedPodium product approvals and launch; and longer-term development potential in Excellerate and Generx, as well as potential new areas not yet announced. Thus, we are maintaining our BUY rating on CXM shares and 18-24 month price target of \$1.50, based on a sum-of-the-parts valuation analysis, as outlined below:

1) **Excellagen** – According to statistics from the American Diabetes Association and the US Department of Health and Human Services, there are approximately 1.3 million patients in the US with diabetic foot ulcers who make 14 visits per year to a physician on average. Assuming roughly one-half of these annual visits require surgical debridement and a \$95 price for Excellagen treatment, this equates to a potential \$800 million revenue opportunity for Excellagen treatment. However, assuming just a 10% market penetration level, a 20% royalty/manufacturing contribution percentage, and 5X revenue valuation equates to an \$80 million value for Excellagen to Cardium, or approximately \$1.00 per share;

2) **Generx** – Although Cardium and its predecessor companies and former partners have spent a great deal of money to develop this novel therapeutic, (over \$250 million) for our valuation purposes we will limit analysis to the market potential in Russia. Assuming the very lowest end of the matrix of potential revenues for

Cardionovo (Generx), a Level 1 treatment of \$2,000/dose and 50,000 doses per year, and using a 20% profit/contribution margin to Cardium, equates to \$20 million valuation for Generx, or \$0.25 per share; and

3) MedPodium/Nutra-Apps – Applying even a very small penetration rate for these products (1%) to the successful multi-billion (\$5 billion) dietary supplement/energy drink market and a 40% profit margin would equate to \$20 million in value for Cardium, or \$0.25 per share, for a total of \$1.50 per share.

Potential Catalysts/Investor Timeline

- 1) Excellagen FDA approval – October 2011
- 2) Excellagen Launch – Q1/2012
- 3) Partnership(s)/Additional Indications for Excellagen – H1/2011-2012
- 4) Begin Phase III trials for Cardionovo (Generx) in Russia – Q1/2012
- 5) Additional International development agreements/clinical studies for Generx – 2011/2012
- 6) Launch of MedPodium product line – 2011
- 7) Launch of new Nutra-Apps product lines – Q1/2011
- 8) Additional portfolio R&D programs or new venture-based subsidiaries – 2011/2012

Risk Factors

In addition to normal economic and market risk factors that impact most equities and the common risks shared by Cardium with other companies in the industry, we believe an investment in Cardium Therapeutics involves the following risks:

- **FDA and regulatory risks** – Cardium is subject to regulatory review for its ongoing research and development activities, principally the US Food and Drug Administration but also potentially with other regulatory agencies as well, including in Eastern Europe, Latin America and Asia. In addition, the manufacture and handling of the Company's tissue repair products and cardiac therapeutics are subject to oversight and regulation by the FDA if approved and marketed.
- **Reliance on joint venture partners and/or additional capital** — Currently, Cardium has enough cash on hand to fund ongoing research and marketing development programs into calendar 2012, approximately. The Company may need to raise additional equity capital to fund operations in the near future. Alternatively, the Company could obtain partnership agreements or government funding to offset planned R&D spending or to accelerate development of an existing or new R&D program in the pipeline. While other companies in the cardiology and wound care market areas have obtained such partnerships or grants in the past, there can be no assurance that Cardium will do so in the present environment.
- **Need to defend patents and other intellectual property** – Cardium may need to defend its patents in the US and overseas in the future, particularly if one or more products receive approval and are successfully marketed.
- **Risk of losing stock listing on American Stock Exchange (NYSE Amex)** – In November 2010, Cardium received a notice from the staff of the NYSE Amex (the Exchange) noting that based on their review the stock did not meet certain of the Exchange's continued listing requirements related to the maintenance of a minimum level of stockholders' equity and losses from ongoing operations. Since that date, Company management has responded to the notice and in September 2011, the Company was notified that its compliance plan was accepted by the NYSE Amex. Under this compliance plan, Cardium has an extension until December 31, 2011 to regain compliance with the continued listing standards, in particular the \$6 million stockholders equity requirement. As of June 30th, 2011, Cardium had \$4.1 million in stockholders'

equity. There can be no assurance that the Company will be successful in increasing this amount by December 31st, and therefore could be in danger of losing its listing on the NYSE Amex.

- **Need to achieve government reimbursement** – Recently, Cardium received US FDA clearance to market its Excellagen wound care product, and the Company has announced plans to market this product itself to a limited extent and also seek a marketing/development partner. Key to the marketing of many types of medical devices and related products in the US is the receipt of reimbursement codes under the Federal Medicare program. There can be no assurance that the Company and/or its potential partners will receive this listing in the near-term.

Cardium Therapeutics, Inc.
Consolidated Statements of Income
(in \$000s, except EPS)

Robert M. Wasserman

FYE December	<u>2007</u>	<u>2008</u>	<u>2009</u>	<u>2010</u>	<u>2011E</u>	<u>2012E</u>
Revenues						
Grant revenues	\$446	\$417	\$445	\$244	\$200	\$200
Product sales and royalties	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>200</u>	<u>2,000</u>
Total revenues	446	417	445	244	400	2,200
Expenses						
Research and development	10,644	11,042	4,302	2,314	2,600	3,000
General and administrative	7,243	6,529	4,856	4,700	4,900	5,500
One-time and other	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>
Total operating expenses	<u>17,887</u>	<u>17,571</u>	<u>9,158</u>	<u>7,014</u>	<u>7,500</u>	<u>8,500</u>
Loss from operations	(17,441)	(17,154)	(8,713)	(6,770)	(7,100)	(6,300)
Interest income	556	102	12	34	20	20
Interest expense	0	(550)	(6,340)	(3)	(10)	(10)
Other expense, net	(8,436)	(6,996)	3,360	2,003	500	550
Net income (loss)	(25,322)	(24,598)	(11,680)	(4,736)	(6,590)	(5,740)
Basic and diluted income (loss) per share	<u>(\$0.64)</u>	<u>(\$0.55)</u>	<u>(\$0.24)</u>	<u>(\$0.06)</u>	<u>(\$0.08)</u>	<u>(\$0.07)</u>
Basic and diluted shares outstanding	39,311	44,978	48,977	73,852	83,100	86,000
Key ratios:						
Cash Flow/share	(\$0.55)	(\$0.44)	(\$0.20)	(\$0.08)	(\$0.07)	(\$0.06)

Balance Sheets
Investor Catalyst Timeline

	(\$000s)	
	<u>12/31/10</u>	<u>6/30/11</u>
<i>Assets:</i>		
Cash and equivalents	\$6,644	\$3,183
Prepaid expenses & other assets	134	146
Restricted cash & other	<u>1,225</u>	<u>1,225</u>
Total current	8,003	4,554
Restricted cash	200	100
Property & equip., net	235	184
Other assets and patent pending, net	<u>1,074</u>	<u>1,029</u>
TOTAL ASSETS	\$9,512	\$5,867
<i>Liabilities:</i>		
Accounts payable	\$598	\$632
Accrued liabilities & other	748	760
Derivative & other current liabilities	573	273
Current portion of notes & obligations	<u>0</u>	<u>0</u>
Total current	1,919	1,665
Deferred rent	165	144
Stockholders' equity (deficiency)	<u>7,428</u>	<u>4,058</u>
TOTAL LIAB & EQ	\$9,512	\$5,867

	<u>2010</u>	<u>2011E</u>	<u>2012E</u>
ExcellagenXL & FX			
FDA 510(k) approval		Q4	
Product launch			Q1
Partnership			H1
MedPodium			
Initial 4-product launch		H2	
Nutra-apps (2 products) launch			H1
Excellerate			
Reformulation			Early-Mid
Partnership			Mid-Late
Osteorate			X
Other medical areas - Periodontics			X
Other medical areas - Heart attack			X
Genex			
Begin Aspire Phase 3 trial in Russia			H1
Preliminary Aspire results			H2
Additional country trials (Brazil, India)			H2

Source: Dawson James Securities, Inc. estimates; Company documents

Important Disclosures:

Price Chart:



Price target and ratings changes over the past 3 years:

Initiated – April 20, 2010 – Buy – Price Target \$1.50

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Ratings definitions: 1) **Buy:** the stock is expected to appreciate and produce a total return of at least 20% over the next 12-18 months; 2) **Neutral:** the stock is fairly valued for the next 12-18 months; and 3) **Sell:** the stock is expected to decline at least 20% over the next 12-18 months and should be sold.

Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Buy	27	84%	8	30%
Neutral	4	13%	4	75%
Sell	1	3%	0	0%
Total	32	100%	11	34%

Information about valuation methods and risks can be found in the “STOCK VALUATION” and “RISKS” sections of this report.

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