Cardiogenesis Corp /CA
Form 10-Q
November 05, 2010

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2010.

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from __________ to __________

Commission file number 0-28288

CARDIOGENESIS CORPORATION
(Exact name of registrant as specified in its charter)

California	**77-0223740**
(State of incorporation or organization)	(I.R.S. Employer Identification Number)

11 Musick
Irvine, California 92618
(Address of principal executive offices)
(949) 420-1800
(Issuer s telephone number)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act:

Large accelerated filer o	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company þ

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

As of October 31, 2010, there were 46,691,249 shares of the registrant s common stock, no par value, outstanding.

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PART I
FINANCIAL INFORMATION

Item 1. Financial Statements

CARDIOGENESIS CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	September 30, 2010 (unaudited)	December 31, 2009 (audited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,139	$ 2,568
Accounts receivable, net of allowance for doubtful accounts of $10 and $6, respectively	1,137	933
Inventories	768	914
Prepaids and other current assets	462	253
Total current assets	4,506	4,668
Property and equipment, net	248	341
Other assets, net	9	9
Total assets	$ 4,763	$ 5,018
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 382	$ 127
Accrued salaries and related	559	604
Accrued liabilities	362	299
Deferred revenue	704	744
Note payable	177	88
Current portion of capital lease obligations	10	9
Total current liabilities	2,194	1,871
Capital lease obligations, less current portion	5	14
Total liabilities	2,199	1,885
Commitments and contingencies		
Shareholders equity:		
Preferred stock:		
no par value; 5,000 shares authorized; none issued and outstanding		
Common stock:		
no par value; 75,000 shares authorized; 45,888 and 45,549 shares issued and outstanding, respectively	174,387	174,217
Accumulated deficit	(171,823)	(171,084)

Total shareholders equity		2,564		3,133
Total liabilities and shareholders equity	$	4,763	$	5,018

See accompanying notes.

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CARDIOGENESIS CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2010	**2009**	**2010**	**2009**
Net revenues	$ 2,764	$ 2,134	$ 8,426	$ 7,222
Cost of revenues	454	380	1,363	1,307
Gross profit	2,310	1,754	7,063	5,915
Operating expenses:				
Research and development	272	379	830	1,013
Sales and marketing	1,443	1,363	4,728	4,104
General and administrative	740	730	2,211	2,375
Total operating expenses	2,455	2,472	7,769	7,492
Operating loss	(145)	(718)	(706)	(1,577)
Other income (expense):				
Interest expense		(4)	(3)	(35)
Interest income		1	1	3
Other non-operating expense	(2)	(20)	(2)	(20)
Total other expense, net	(2)	(23)	(4)	(52)
Loss before provision for income taxes	(147)	(741)	(710)	(1,629)
Provision for income taxes	7	(2)	14	14
Net loss	$ (154)	$ (739)	$ (724)	$ (1,643)
Net loss per share:				
Basic	$ (0.00)	$ (0.02)	$ (0.02)	$ (0.04)
Diluted	$ (0.00)	$ (0.02)	$ (0.02)	$ (0.04)
Weighted average shares outstanding:				
Basic	45,928	45,549	45,727	45,519
Diluted	45,928	45,549	45,727	45,519

See accompanying notes.

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CARDIOGENESIS CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine months ended September 30, 2010	Nine months ended September 30, 2009
Cash flows from operating activities:		
Net loss	$ (724)	$ (1,643)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	193	233
Provision for doubtful accounts	4	10
Stock-based compensation expense	203	156
Changes in operating assets and liabilities:		
Accounts receivable	(208)	379
Inventories	81	15
Prepaids and other current assets	(10)	197
Accounts payable	255	138
Accrued liabilities	18	(83)
Deferred revenue	(40)	171
Net cash used in operating activities	(228)	(427)
Cash flows from investing activities:		
Acquisition of property and equipment	(35)	(24)
Proceeds from the sale of marketable securities		75
Net cash (used in) provided by investing activities	(35)	51
Cash flows from financing activities:		
Shares withheld to satisfy income tax withholding obligations	(48)	
Payments on note payable	(110)	(18)
Net proceeds from issuance of common stock from exercise of options and from stock purchased under the Employee Stock Purchase Plan		10
Payments on capital lease obligations	(8)	(6)
Net cash (used in) provided by in financing activities	(166)	(14)
Net decrease in cash and cash equivalents	(429)	(390)
Cash and cash equivalents at beginning of period	2,568	2,907
Cash and cash equivalents at end of period	$ 2,139	$ 2,517
Supplemental schedule of cash flow information:		
Interest paid	$ 2	$ 2
Taxes paid	$ 12	$ 6

Supplemental schedule of non-cash investing and financing activities:		
Financing of insurance premiums under note payable	$ 199	$ 158
Financing of property and equipment	$	$ 12
Reclassification of inventories to property and equipment	$ 65	$ 165

See accompanying notes.

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CARDIOGENESIS CORPORATION
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Operations:

Cardiogenesis Corporation (Cardiogenesis or the Company) was founded in 1989 to design, develop, and distribute surgical lasers and single-use fiber optic laser delivery systems (handpieces) for the treatment of cardiovascular disease.

Cardiogenesis markets its products for sale primarily in the United States and operates in a single segment.

2. Summary of Significant Accounting Policies:

Interim Financial Information:

The accompanying unaudited condensed consolidated financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States of America (GAAP) for interim financial information, and pursuant to the instructions to Form 10-Q and Article 8 of Regulation S-X promulgated by the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statement presentation. In the opinion of management, all adjustments (consisting primarily of normal recurring accruals) considered necessary for a fair presentation have been included. The Company has evaluated subsequent events through the filing date of this Form 10-Q, and determined that no subsequent events have occurred that would require recognition in the condensed consolidated financial statements or disclosure in the notes thereto other than as disclosed in the accompanying notes. These unaudited condensed consolidated financial statements should be read in conjunction with the Company s audited consolidated financial statements and notes thereto for the year ended December 31, 2009, contained in the Company s Annual Report on Form 10-K, as filed with the SEC.

These unaudited condensed consolidated financial statements contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. Cardiogenesis has incurred significant losses and as of September 30, 2010 it had an accumulated deficit of $171.8 million. Management believes its cash balance as of September 30, 2010 and expected results of operations are sufficient to meet the Company s capital and operating requirements for the next 12 months.

However, the Company may require additional financing in the future if revenues are not as expected or the Company s costs exceed its estimates. In particular, the Company expects to incur significant costs in connection with its planned clinical trials for the PHOENIX handpiece and if the Company is not able to significantly increase its revenues, it will have to obtain additional financing to fund the clinical trials or abandon the clinical trials. There can be no assurance that the Company will be able to obtain additional debt or equity financing if and when needed or on terms acceptable to the Company. Any additional debt or equity financing may involve substantial dilution to the Company s shareholders, restrictive covenants or high interest costs. The failure to raise needed funds on sufficiently favorable terms could have a material adverse effect on the Company s business, operating results and financial condition. The Company s long term liquidity also depends upon its ability to increase revenues from the sale of its products and achieve consistent profitability. The failure to achieve these goals could have a material adverse effect on the business, operating results and financial condition.

Net Earnings (Loss) Per Share:

Basic earnings (loss) per share (BEPS) is computed by dividing the net income (loss) by the weighted average number of common shares outstanding for the period. Diluted earnings (loss) per share (DEPS) is computed giving effect to all dilutive potential common shares that were outstanding during the period. Dilutive potential common shares consist of incremental shares issuable upon the exercise of stock options and warrants using the treasury stock method. The computation of DEPS does not assume conversion, exercise or contingent exercise of securities that would have an anti-dilutive effect on earnings.

For the three and nine months ended September 30, 2010, there were approximately 673,000 and 704,000 potentially dilutive shares, respectively, that were excluded from diluted loss per share as their effect would have been anti-dilutive for the periods then ended. For the three and nine months ended September 30, 2009, there were approximately 716,000 and 418,000 potentially dilutive shares, respectively.

Use of Estimates:

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates. Significant estimates made in preparing the consolidated financial statements include (but are not limited to) the determination of the allowance for bad debt, inventory reserves, valuation allowance relating to deferred tax assets, warranty reserve, the assessment of future cash flows in evaluating long-lived assets for impairment and assumptions used in fair value determination of stock-based compensation.

Risks and Concentrations:

Cardiogenesis sells its products to hospitals and other healthcare providers primarily in the United States. Cardiogenesis performs ongoing credit evaluations of its customers and generally does not require collateral. Although Cardiogenesis maintains allowances for potential credit losses that it believes to be adequate, a payment default on a significant sale could materially and adversely affect its operating results and financial condition. At September 30, 2010 and December 31, 2009, no customer individually accounted for more than 10% of gross accounts receivable. For the three and nine month periods ended September 30, 2010 and September 30, 2009, no customer individually accounted for more than 10% of net revenues.

As of September 30, 2010, approximately $969,000 of the Company s cash and cash equivalents were maintained in money market mutual funds, and approximately $1,170,000 of the Company s cash and cash equivalents were maintained at a major financial institution in the United States. At times, deposits held with the financial institution may exceed the amount of insurance provided by the Federal Deposit Insurance Corporation (the FDIC), which provides deposit coverage with limits up to $250,000 per owner through December 31, 2013. Generally, these deposits may be redeemed upon demand and, therefore, are believed to bear low risk.

After giving effect to the increased FDIC insurance, at September 30, 2010, the Company s uninsured cash totaled approximately $1,985,000.

The Company outsources the manufacturing and assembly of its handpieces to a single contract manufacturer. The Company also outsources the manufacturing of its laser consoles to a different single contract manufacturer.

Certain components of laser consoles and fiber-optic handpieces are generally acquired from multiple sources. Other laser and fiber-optic components and subassemblies are purchased from single sources. Although the Company has identified alternative vendors, the qualification of additional or replacement vendors for certain components or services is a lengthy process. Any significant supply interruption would have a material adverse effect on the Company s ability to manufacture its products and, therefore, would harm its business. The Company intends to continue to qualify multiple sources for components that are presently single sourced.

Revenue Recognition:

Cardiogenesis recognizes revenue on product sales upon shipment of the products when the price is fixed or determinable and when collection of sales proceeds is reasonably assured. Where purchase orders allow customers an acceptance period or other contingencies, revenue is recognized upon the earlier of acceptance or removal of the contingency.

Revenues from sales to distributors and agents are recognized upon shipment when there is evidence of an arrangement, delivery has occurred, the sales price is fixed or determinable and collection of the sales proceeds is reasonably assured. The contracts regarding these sales do not include any rights of return or price protection clauses.

The Company, at times, will loan laser consoles to hospitals and charge an additional amount (the Premium) over the stated list price on its handpieces in exchange for the use of the laser console. In accordance with the accounting standards for leases, these arrangements are recorded as leases as they convey the right to use the laser console over the period of time the customers are purchasing handpieces. The loaned laser consoles are classified as operating leases and are transferred from inventory to property and equipment upon commencement of the loan. In addition, the Premium is considered contingent rent, and therefore, such amounts allocated to the lease of the laser console are recognized as revenue when the contingency is resolved. In these instances, the contingency is resolved upon the sale of the handpiece.

Cardiogenesis enters into contracts to sell its products and services and, while the majority of its sales agreements contain standard terms and conditions, there are agreements that contain multiple elements or non-standard terms and conditions. As a result, significant contract interpretation is sometimes required to determine the appropriate accounting, including whether the deliverables specified in a multiple element arrangement should be treated as separate units of accounting for revenue recognition purposes and, if so, how the contract value should be allocated among the deliverable elements and when to recognize revenue for each element. The Company recognizes revenue for multiple element arrangements, such as sales of laser consoles and handpieces, by allocating revenue for each respective element based on its selling price and when revenue recognition criteria for each element have been met.

In addition to the standard product warranty, the Company periodically offers extended warranties to its customers in the form of product maintenance services. Service agreements on its equipment are typically sold separately from the sale of the equipment. In accordance with the accounting standards for warranties, revenues on these service agreements are recognized ratably over the life of the agreement, typically one to three years.

Segment Disclosures:

The Company operates in one segment. The principal market for the Company s products is in the United States. International sales occur primarily in Europe, Mexico and Asia and amounted to approximately $7,000 and $47,000 for the three and nine months ended September 30, 2010, respectively. For the three and nine months ended September 30, 2009, the Company s international sales were $4,000 and $96,000, respectively. International sales represented less than 1% of total net revenues for both the three and nine months ended September 30, 2010 and less than 1% and approximately 1% of total net revenues for the three and nine months ended September 30, 2009, respectively. The majority of international sales are denominated in U.S. Dollars. All of the Company s long-lived assets are located in the United States.

Recent Accounting Pronouncements:

In September 2009, the Financial Accounting Standards Board (FASB) issued an update to its accounting guidance regarding multiple-deliverable revenue arrangements. The guidance addresses how to measure and allocate consideration to one or more units of accounting. Specifically, the guidance requires that consideration be allocated among multiple deliverables based on relative selling prices. The guidance establishes a selling price hierarchy of (1) vendor-specific objective evidence, (2) third-party evidence and (3) estimated selling price. This guidance is effective for annual periods beginning on or after June 15, 2010 but may be early adopted as of the beginning of an annual period. The Company adopted this guidance on January 1, 2010 and it did not have a material impact on its consolidated financial statements.

In January 2010, the FASB issued an update to its accounting guidance regarding fair value measurement and disclosure. The guidance affects the disclosures made about recurring and non-recurring fair value measurements. This guidance is effective for annual reporting periods beginning after December 15, 2009, except for the disclosures about purchases, sales, issuances and settlements in the roll forward of activity in Level 3 fair value measurements. Those disclosures are effective for fiscal years beginning after December 15, 2010. Early adoption is permitted. The Company is currently evaluating the impact that this guidance will have on its consolidated financial statements.

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Other recent accounting pronouncements issued by the FASB (including the Emerging Issues Task Force (EITF)) and the American Institute of Certified Public Accountants did not, or are not believed by management to, have a material impact on the Company s present or future consolidated financial statements.

3. Inventories:

Inventories are stated at the lower of cost (first-in, first-out) or market and consist of the following (in thousands):

	September 30, 2010 (unaudited)	December 31, 2009 (audited)
Raw materials	$ 115	$ 141
Work-in-process	174	192
Finished goods	479	581
Total	$ 768	$ 914

4. Stock-Based Compensation:

In accordance with the accounting standards for stock-based compensation, the Company recognizes all share-based payments to employees, including grants of employee stock options and restricted stock grants, based upon their fair values. The Company uses the Black-Scholes option pricing model to estimate the grant-date fair value of share-based awards with the fair value determined at the date of grant. The financial statement effect of forfeitures is estimated at the time of grant and revised, if necessary, if the actual effect differs from those estimates.

Description of Plans

The Company s stock option plans provide for grants of options to employees and directors of the Company to purchase the Company s shares at the fair value of such shares on the grant date (based on the closing price of the Company s common stock). The options vest immediately or up to four years beginning on the grant date and have a 10-year term. The terms of the option grants are determined by the Company s Board of Directors. As of September 30, 2010, the Company is authorized to issue up to an aggregate of 12,125,000 shares under these plans.

The Company s 1996 Employee Stock Purchase Plan (the ESPP) was adopted in April 1996 and amended in July 2005. A total of 1,500,000 common shares are reserved for issuance under the ESPP, as amended. The ESPP permits employees to purchase common shares at a price equal to the lower of 85% of the fair market value of the common stock at the beginning of each offering period or the end of each offering period. The ESPP has two offering periods, the first one from May 16 through November 15 and the second one from November 16 through May 15. Employee purchases are nonetheless limited to 15% of eligible cash compensation, and other restrictions regarding the amount of annual purchases also apply. The Company suspended the ESPP effective at the end of the November 16, 2008 offering period.

The Company has treated the ESPP as a compensatory plan.

Summary of Assumptions and Activity

The fair value of stock-based awards to employees and directors is calculated using the Black-Scholes option pricing model, even though the model was developed to estimate the fair value of freely tradable, fully transferable options without vesting restrictions, which differ significantly from the Company s stock options. The Black-Scholes model also requires subjective assumptions, including future stock price volatility and expected time to exercise, which greatly affect the calculated values. The expected term of options granted is derived from historical data on employee exercises and post-vesting employment termination behavior. The risk-free rate selected to value any particular grant is based on the U.S. Treasury rate that corresponds to the term of the grant effective as of the date of the grant. The expected volatility is based on the historical volatility of the Company s stock price. These factors could change in the future, affecting the determination of stock-based compensation expense in future periods.

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The weighted-average fair value of stock-based compensation is based on the single option valuation approach. Forfeitures are estimated and it is assumed no dividends will be declared. The estimated fair value of stock-based compensation awards to employees is amortized using the straight-line method over the vesting period of the options.

The Company s fair value calculations for stock-based compensation awards to employees under its stock option plans for the nine months ended September 30, 2010 and 2009 were based on the following assumptions:

	Nine Months Ended	
	September 30, 2010	September 30, 2009
Expected term	5.36 5.56 years	6.27 6.35 years
Expected volatility	96.05 97.59%	97.6 105.51%
Risk-free interest rate	1.80 2.53%	1.63 2.84%
Expected dividend yield		

A summary of option activity as of September 30, 2010 and changes during the nine months then ended, is presented below (in thousands except per share data):

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Options outstanding at January 1, 2010	3,223	$0.49		
Options granted	420	$0.37		
Options exercised		$		
Options forfeited/canceled	(425)	$0.80		
Options outstanding and expected to vest at September 30, 2010	3,218	$0.43	5.95	$ 42
Options exercisable at September 30, 2010	2,299	$0.50	5.10	$ 26

The aggregate intrinsic value is calculated as the difference between the exercise price of the stock options and the quoted price of the Company s common stock at period end. There were no stock options exercised during the nine months ended September 30, 2010. There were 1,165,000 options outstanding and 742,846 exercisable options as of September 30, 2010, that were in-the-money. At September 30, 2009, there were no exercisable stock options that were in-the-money.

The weighted average grant date fair value of options was $0.26 and $0.28 for the three and nine months ended September 30, 2010, respectively. The weighted average grant date fair value of options granted during the three and nine months ended September 30, 2009 was $0.18 and 0.14 per option, respectively.

As of September 30, 2010, there was approximately $132,000, net of forfeitures, of total unrecognized compensation cost related to employee and director stock option compensation arrangements. That cost is expected to be recognized over the weighted average remaining vesting period of approximately 1.1 years. For the three and nine months ended September 30, 2010, the amount of stock-based compensation expense related to stock options was approximately $41,000 and $114,000, respectively as compared to $31,000 and $95,000, respectively recognized in the prior year comparative periods. There was no stock-based compensation expense related to ESPP contributions during the three and nine months ended September 30, 2010. For the three and nine months ended September 30, 2009, the amount of stock-based compensation expense related to ESPP contributions was approximately $0 and $12,000, respectively.

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On March 31, 2009, the Company granted awards of restricted stock to each of its employees totaling approximately 1,208,000 shares with a grant date fair value of approximately $302,000. The shares vest as to 33% of the shares on the first anniversary of the grant date, 33% of the shares on the second anniversary of the grant date and 34% of the shares on the third anniversary of the grant date. In addition, in connection with Paul McCormick s appointment to Executive Chairman on July 1, 2009, Mr. McCormick was granted 300,000 shares of restricted stock, with a grant date fair value of $57,000, under the Company s Stock Option Plan. The restrictions on Mr. McCormick s shares of restricted stock will lapse in equal installments upon the first and second anniversaries of the date of grant. On May 17, 2010, in connection with his amended employment agreement, Mr. McCormick was granted an additional 100,000 shares of restricted stock under the Company s Stock Option Plan. The restrictions of these shares of restricted stock will lapse on the one year anniversary of the grant date. The grant date fair value of these shares of restricted stock was $38,000.

During the nine month period ended September 30, 2010, the Company withheld 125,983 shares of its common stock upon the vesting of 315,324 shares of restricted stock to satisfy its income tax withholding obligations. The value of the shares withheld was approximately $48,000, based on the closing market price on the measurement date. Accordingly, the Company recorded the aggregate original issue price of approximately $33,000 to equity and the difference of the fair value at vesting and the original issue price of approximately $15,000 to accumulated deficit.

For the three and nine months ended September 30, 2010, the stock based compensation related to the amortization of the related compensation cost of the restricted stock was approximately $33,000 and $89,000, respectively. For the three and nine months ended September 30, 2009, the stock compensation related to the amortization of the related compensation cost of the restricted stock was approximately $25,000 and $49,000, respectively. Since shares of restricted stock are subject to vesting, the unvested shares as of September 30, 2010 have been excluded from the issued and outstanding shares and basic loss per share computations. As of September 30, 2010, there was approximately $150,000 of total unrecognized compensation cost related to restricted stock that is expected to be recognized over the weighted average remaining vesting period of approximately 1.2 years.

The following table summarizes the restricted stock activity for the nine months ended September 30, 2010 (in thousands):

	September 30, 2010
Unvested Restricted Stock Outstanding at January 1, 2010	1,256
Granted	100
Forfeited	(88)
Vested	(465)
Unvested Restricted Stock Outstanding at September 30, 2010	803

The following table summarizes stock-based compensation expense related to stock options, restricted stock and ESPP purchases for the three and nine months ended September 30, 2010 and 2009 which was allocated as follows (in thousands):

	Three Months Ended		**Nine Months Ended**	
	September 30, 2010	**September 30, 2009**	**September 30, 2010**	**September 30, 2009**
Stock-based compensation expense included in:				
Research and development	$ 6	$ 4	$ 14	$ 10
Sales and marketing	20	24	76	72
General and administrative	48	28	113	74

	$ 74	$ 56	$ 203	$ 156

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