

MICROFLUIDICS INTERNATIONAL CORP  
Form 10-Q  
November 15, 2010  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**Form 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2010

OR

- 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: 0-11625

**MICROFLUIDICS INTERNATIONAL CORPORATION**

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(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**04-2793022**

(I.R.S. Employer Identification No.)

**30 Ossipee Road, Newton, Massachusetts**

(Address of principal executive offices)

**02464**

(Zip Code)

**(617) 969-5452**

(Registrant's telephone number, including area code)

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 (the "Act") 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  No

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  No

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

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

As of November 10, 2010, 10,426,647 shares of the registrant's Common Stock, par value \$.01 per share, were outstanding.

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Table of Contents**PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****MICROFLUIDICS INTERNATIONAL CORPORATION****Condensed Consolidated Balance Sheets***(Unaudited - in thousands, except share and per share amounts)*

	September 30, 2010	December 31, 2009
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 1,980	\$ 2,185
Accounts receivable, net of allowance of \$39 and \$44 on September 30, 2010 and December 31, 2009, respectively	2,861	2,571
Inventories	2,675	2,916
Prepaid and other current assets	281	280
Total current assets	7,797	7,952
Property and equipment, net	684	891
Other non-current assets	396	535
Total assets	\$ 8,877	\$ 9,378
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,009	\$ 545
Accrued expenses	1,265	1,727
Customer advances	390	1,137
Total current liabilities	2,664	3,409
Long-term liabilities:		
Convertible debt	4,720	4,679
Total liabilities	7,384	8,088
Stockholders' equity:		
Common stock; \$.01 par value; 30,000,000 and 30,000,000 shares authorized; 10,662,093 and 10,630,228 shares issued; 10,426,647 and 10,394,782 shares outstanding as of September 30, 2010 and December 31, 2009, respectively.	107	106
Additional paid-in capital	18,450	18,254
Accumulated deficit	(16,395)	(16,401)
Treasury stock, 235,446 shares, at cost, as of September 30, 2010 and December 31, 2009	(669)	(669)
Total stockholders' equity	1,493	1,290
Total liabilities and stockholders' equity	\$ 8,877	\$ 9,378

See notes to unaudited condensed consolidated financial statements.



Table of Contents**MICROFLUIDICS INTERNATIONAL CORPORATION****Condensed Consolidated Statements of Operations***(Unaudited - in thousands, except share and per share amounts)*

	For The Three Months Ended September 30,		For The Nine Months Ended September 30,	
	2010	2009	2010	2009
Revenues	\$ 4,077	\$ 4,462	\$ 12,904	\$ 11,490
Cost of sales	1,644	1,533	5,002	4,679
Gross profit	2,433	2,929	7,902	6,811
Operating expenses:				
Research and development	468	433	1,444	1,301
Selling	1,093	1,007	3,224	3,154
General and administrative	939	920	2,688	2,375
Total operating expenses	2,500	2,360	7,356	6,830
Income (loss) from operations	(67)	569	546	(19)
Interest expense	(176)	(144)	(540)	(425)
Interest income				2
Net income (loss)	\$ (243)	\$ 425	\$ 6	\$ (442)
Net income (loss) per common share:				
Basic	\$ (.02)	\$ 0.04	\$	\$ (0.04)
Diluted	\$ (.02)	\$ 0.04	\$	\$ (0.04)
Weighted average number of common and common equivalent shares outstanding:				
Basic	10,422,525	10,387,282	10,412,252	10,376,949
Diluted	10,422,525	10,474,532	10,613,592	10,376,949

See notes to unaudited condensed consolidated financial statements.

Table of Contents**MICROFLUIDICS INTERNATIONAL CORPORATION****Condensed Consolidated Statements of Cash Flows***(Unaudited - in thousands)*

	<b>For The Nine Months Ended September 30,</b>	
	<b>2010</b>	<b>2009</b>
<b>Cash flows from operating activities:</b>		
Net income (loss)	\$ 6	\$ (442)
<b>Adjustments to reconcile net income (loss) to net cash flows:</b>		
Depreciation	92	120
Amortization of leasehold improvements	127	122
Amortization of intangibles	4	4
Amortization of deferred financing fees	135	47
Non-cash interest	41	
Allowance for doubtful accounts	(5)	
Provision for obsolete inventory	144	50
Stock-based compensation	178	144
<b>Changes in assets and liabilities:</b>		
Accounts receivable	(285)	(401)
Inventories	97	(129)
Prepaid expenses and other current assets	(1)	3
Accounts payable	464	(166)
Accrued expenses	(462)	(93)
Customer advances	(747)	603
Net cash flows used in operating activities	(212)	(138)
<b>Cash flows from investing activities:</b>		
Purchase of property, plant and equipment	(12)	(72)
Net cash flows used in investing activities	(12)	(72)
<b>Cash flows from financing activities:</b>		
Net proceeds from issuance of common stock	19	9
Net cash flows provided by financing activities	19	9
Net change in cash and cash equivalents	(205)	(201)
Cash and cash equivalents at beginning of period	2,185	1,895
Cash and cash equivalents at end of period	\$ 1,980	\$ 1,694

See notes to unaudited condensed consolidated financial statements.

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**MICROFLUIDICS INTERNATIONAL CORPORATION**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(Unaudited)**

**1. Basis of Presentation**

The unaudited interim condensed consolidated financial statements of Microfluidics International Corporation along with its wholly-owned subsidiary, Microfluidics Corporation (collectively, the Company, we, us, or our ) were prepared in accordance with generally accepted accounting principles in the United States of America ( U.S. GAAP ) and reflects all adjustments (including normal recurring accruals) which, in the opinion of management, are considered necessary for the fair presentation of the financial position at such dates and of the operating results and cash flows for the period presented. Certain accounts in the condensed consolidated financial statements and related notes have been reclassified to conform to current period presentation. The balance sheet as of December 31, 2009 has been derived from the Company s audited financial statements at that date but does not include all of the information and notes required by U.S. GAAP for complete financial statements. The information contained in this Form 10-Q should be read in conjunction with the Company s audited financial statements and notes thereto included in its Annual Report on Form 10-K for the year ended December 31, 2009 as filed with the U.S. Securities and Exchange Commission ( SEC ) on March 29, 2010.

The significant accounting policies underlying the accompanying unaudited interim condensed consolidated financial statements are set forth in Note 1 to the Company s consolidated financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2009 as filed with the SEC on March 29, 2010. Since December 31, 2009, there have been no material changes in the Company s significant accounting policies.

**2. Recent Accounting Pronouncements**

In April 2010, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update ( ASU ) No. 2010-17, *Revenue Recognition - Milestone Method (Topic 605): Milestone Method of Revenue Recognition* which clarifies that for research and development transactions, consideration that is contingent on the achievement of a milestone in its entirety may be recognized as revenue in the period in which the milestone is achieved, only if the milestone is judged to meet certain criteria. The guidance will be effective for fiscal years beginning on or after June 15, 2010 and may be applied prospectively to milestones achieved after the adoption date or retrospectively for all periods presented, with earlier application permitted. The adoption of this guidance is not expected to have a material impact on the Company s consolidated results of operations or financial position.

In October 2009, the FASB issued ASU No. 2009-13 - *Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements (a consensus of the FASB Emerging Issues Task Force)* that (a) requires the total consideration received at the inception of a multiple deliverable revenue arrangement to be allocated to the separate units of accounting based on their relative selling prices, (b) eliminates the residual method of allocation and (c) significantly enhances disclosures. The guidance in this ASU is effective prospectively for revenue arrangements entered into or materially modified in the fiscal years beginning on or after June 15, 2010. Early application is permitted. The adoption of this guidance is not expected to have a material impact on the Company s consolidated results of operations or financial position.



### 3. Stock-Based Compensation

We recognize compensation expense for all stock-based awards made to employees and directors. For the three and nine month periods ended September 30, 2010 and 2009 stock-based compensation expense was as follows:

(in thousands)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2010	2009	2010	2009	2010	2009	2010	2009
Research and development	\$ 19	\$ 16	\$ 46	\$ 39				
Selling	14	12	37	30				
General and administrative	37	28	95	75				
Total	\$ 70	\$ 56	\$ 178	\$ 144				

Total unrecognized stock-based compensation expense related to unvested stock options expected to be recognized over a service period of 4 years, was approximately \$668,000 and \$714,000 at September 30, 2010 and 2009, respectively. The Company did not capitalize any stock-based compensation. There were no significant tax benefits on the stock-based compensation during the three and nine month periods ended September 30, 2010 and 2009.

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Inventories consist of the following:

(in thousands)	September 30, 2010	December 31, 2009
Raw materials	\$ 1,903	\$ 2,037
Work in progress	53	174
Finished goods	1,059	901
	3,015	3,112
Less: provision for excess inventory	(340)	(196)
Total inventories	\$ 2,675	\$ 2,916

**5. Property and Equipment**

Property, plant and equipment consist of the following:

(in thousands)	September 30, 2010	December 31, 2009
Furniture, fixtures and office equipment	\$ 931	\$ 923
Machinery, equipment and tooling	530	530
Leasehold improvements	910	906
	2,371	2,359
Less: accumulated depreciation and amortization	(1,687)	(1,468)
	\$ 684	\$ 891

**6. Accrued Expenses**

Accrued expenses consist of the following:

(in thousands)	September 30, 2010	December 31, 2009
Accrued expenses	\$ 232	\$ 319
Accrued wages, bonus and vacation pay	276	644
Accrued commissions	346	367
Accrued interest	371	338
Accrued warranty	40	59
	\$ 1,265	\$ 1,727

**7. Earnings Per Share**

Basic net income (loss) per common share was determined by dividing net income (loss) applicable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock, unless the effects of dilution would be anti-dilutive.

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Shares for computation of basic net income (loss) per share	10,423	10,387	10,412	10,377
Shares for computation of diluted net income (loss) per share	10,423	10,475	10,614	10,377

**8. Industry Segment, Geographic and Enterprise-Wide Information**

The Company has determined that it conducts its operations in one business segment: producing and marketing a broad line of proprietary high shear fluid processing systems used primarily in the pharmaceutical, biotechnology, chemical, nutraceutical/food, academic and cosmetics industries. The Company has less than 3% of total assets in foreign countries. As a result, the financial information disclosed herein represents all of the material financial information related to the Company's principal operating segment.

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Approximate sales to customers by geographic markets, and percentage of total sales by geographic market, are as follows:

(in thousands)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2010		2009		2010		2009	
North America	\$ 2,754	67.6%	\$ 3,208	71.9%	\$ 7,867	61.0%	\$ 7,193	62.6%
Asia	466	11.4%	300	6.7%	1,823	14.1%	1,541	13.4%
Europe	857	21.0%	954	21.4%	3,214	24.9%	2,756	24.0%
	\$ 4,077	100.0%	\$ 4,462	100.0%	\$ 12,904	100.0%	\$ 11,490	100.0%

No customer accounted for more than 10% of the Company's revenues for the three months ended September 30, 2010. Two customers together accounted for 42.0% of the Company's revenues for the three months ended September 30, 2009. For the nine month period ended September 30, 2010 no customer accounted for more than 10% of the Company's revenues. For the nine months ended September 30, 2009, one customer accounted for 19.7% of the Company's revenues.

No customer accounted for greater than 10% of the Company's trade accounts receivables as of September 30, 2010 or 2009.

## 9. Stockholders Equity

During the three months ended September 30, 2010, the Company issued no shares of common stock from the exercise of options by employees or directors. During the nine months ended September 30, 2010, the Company issued 9,500 shares of common stock from the exercise of options by a former director and an employee which generated cash of approximately \$4,000. During the three and nine months ended September 30, 2009, the Company issued 3,500 shares of common stock from the exercise of options by a former employee, generating cash proceeds of \$1,750.

During the three months ended September 30, 2010 and 2009, the Company issued 12,365 and 12,000 shares of common stock, respectively, from the purchase of shares under the Company's Employee Stock Purchase Plan. During the nine months ended September 30, 2010 and 2009, the Company issued 22,365 and 27,000 shares, respectively, of common stock from the purchase of shares under the Employee Stock Purchase Plan, generating cash proceeds of approximately \$15,000 and \$8,000, respectively.

## 10. Credit Facility

On October 23, 2009, the Company and its subsidiary entered into a senior secured \$1 million revolving line of credit pursuant to a loan agreement (the "Revolving Line of Credit") with Webster Bank, National Association, as lender ("Webster Bank"). The initial term of the Revolving Line of Credit was for a period of one year. On October 22, 2010, the Company entered into an amendment to extend the maturity of the Revolving Line of Credit until October 22, 2011. See, Note 12, Subsequent Events, below. The Company may not extend the Revolving Line of Credit beyond this period without the consent of Global Strategic Partners LLC ("GSP"), the holder of the Company's Convertible Debenture. See Note 11, Long Term Debt, below. The actual amount of credit that is available from time to time under the Revolving Line of

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Credit is limited to a borrowing base amount that is determined according to, among other things, a percentage of the value of eligible accounts receivables. The Revolving Line of Credit contains customary representations and warranties and restrictive covenants relating to matters, such as indebtedness, liens, investments, acquisitions, mergers, dispositions and dividends. The Revolving Line of Credit also has two financial covenants that require the Company to maintain a senior debt to twelve month trailing EBITDA (Earnings Before Interest, Taxation, Depreciation and Amortization) of 2:1, and requires the Company to maintain \$500,000 of available cash or excess availability under the Revolving Line of Credit. The proceeds of any borrowings under the Revolving Line of Credit are available for working capital and other general corporate purposes.

The Company's borrowings under the Revolving Line of Credit will generally accrue interest at a margin of 5.50% over the London Interbank Offered Rate ( LIBOR ) (LIBOR at September 30, 2010 was 0.29%) and are secured by a lien on substantially all of its personal property. The Revolving Line of Credit generally contains customary events of default for credit facilities of this type. Upon an event of default that is not cured or waived within any applicable cure periods, in addition to other remedies that may be available to Webster Bank, the obligations under the Revolving Line of Credit may be accelerated and remedies may be exercised against the collateral.

In connection with the closing of the Revolving Line of Credit, the Company also amended the Convertible Debenture and Warrant Purchase Agreement with GSP and related agreements to permit the Revolving Line of Credit as senior indebtedness and provide for certain other covenants, including a cross default provision with the Revolving Line of Credit, and GSP agreed to subordinate the indebtedness under the Convertible Debenture to the Company's indebtedness to Webster Bank. As of September 30,

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2010, the Company had not drawn down on the Revolving Line of Credit.

**11. Long-Term Debt**

Long-term debt as of the following dates consisted of:

(in thousands)	September 30, 2010	December 31, 2009
Convertible debt, (net of discount of \$280 and \$321 in 2010 and 2009, respectively)	\$ 4,720	\$ 4,679
Less: current portion		
Long-term debt, net of current portion	\$ 4,720	\$ 4,679

On November 14, 2008, we entered into the Convertible Debenture and Warrant Purchase Agreement (the Agreement) with GSP. The total amount of the Convertible Debenture is \$5,000,000 and bears interest at nine percent (9.0%) per annum payable quarterly in arrears. The Convertible Debenture is due and payable on the earlier to occur of: (i) November 14, 2015 or (ii) the acceleration of the maturity of the Convertible Debenture upon the occurrence of an event of default. We may, at our option and upon 30 days notice to GSP, on an interest payment date prepay all of the principal balance of the Convertible Debenture, without penalty, together with any accrued and unpaid interest through the date of prepayment. Our right to prepay is subject to GSP's right to convert the Convertible Debenture as contemplated in the Convertible Debenture. GSP may, at its option, on any of the maturity date, the date that any interest payment is due, or the date on which a change of control occurs, convert all or any portion of the outstanding principal amount of the Convertible Debenture into shares of the Company's common stock at a \$1.25 per share. In May 2009, after an initial quarterly interest payment of approximately \$113,000, GSP agreed to defer the interest payments due and payable under the Convertible Debenture on each of July 1, 2009, October 1, 2009 and January 4, 2010. The deferred payments accrue interest at nine percent per annum and are payable in eight equal quarterly installments on the first day of such quarter beginning on April 1, 2010. The Convertible Debenture is secured by all assets, property rights and interests of the Company, and is subordinate to the Company's Revolving Line of Credit with Webster Bank. As of September 30, 2010, a total of approximately \$371,000 of accrued interest expense is included as part of the Accrued Expenses. See Note 6, above. The Convertible Debenture is presented net of the discount of approximately \$280,000 and \$321,000 as of September 30, 2010 and December 31, 2009, respectively. The discount represents the value of the Warrant granted as part of the financing which was approximately \$382,000 at the date of grant, which is being accreted over the seven year life of the loan as interest expense.

**12. Subsequent Events**

On October 22, 2010, the Company entered into an amendment to its Revolving Line of Credit with Webster Bank, extending the maturity of the Company's Revolving Line of Credit from October 22, 2010 until October 22, 2011. There were no other changes to the Revolving Line of Credit. Also, see Note 10, Credit Facility, above. Subsequent events have been evaluated through the time of filing this Quarterly Report on Form 10-Q with the SEC.

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

**Future Operating Results**

This report may contain forward-looking statements that are subject to certain risks and uncertainties including statements relating to the Company's plan to achieve, maintain, and/or increase revenue growth, and/or operating profitability, and to achieve, maintain, and/or increase net operating profitability. Such statements are based on the Company's current expectations and are subject to a number of factors and uncertainties that could cause actual results achieved by us to differ materially from those described in the forward-looking statements. We caution investors that there can be no assurance that the actual results or business conditions will not differ materially from those projected or suggested in such forward-looking statements as a result of various factors, including but not limited to, the following risks and uncertainties: (i) whether the performance advantages of the Company's Microfluidizer® materials processing equipment will be realized commercially or that a commercial market for the equipment will continue to develop, (ii) whether the timing of orders will significantly affect quarter to quarter revenues and resulting net income results for a particular quarter, which may cause increased volatility in the Company's stock price, (iii) whether we will have access to sufficient working capital through continued and improving cash flow from sales and ongoing borrowing availability, the latter being subject to the Company's ability to maintain compliance with the covenants and terms of the Company's financing agreements, (iv) whether the Company's technology will be adopted by customers as a means of producing Microfluidics Reaction Technology or MRT innovative materials in large quantities, (v) whether we will be able to deploy further prototype MRT systems for nanoparticle production and then manufacture and introduce commercial production MRT equipment, (vi) whether we will achieve a greater proportion of the Company's sales in the future through the sale of advanced processor production systems, and (vii) those risks set forth in Part II, Item 1A, Risk Factors of this quarterly report on Form 10-Q and the Company's other periodic reports filed with the SEC. We assume no responsibility to update any forward-looking statements as a result of new information, future events, or otherwise.

**Overview**

For over 25 years we have specialized in manufacturing and marketing a broad line of materials processing systems, more specifically known as high shear fluid processors, which are used in numerous applications in the pharmaceutical, biotechnology, chemical, nutraceutical/food, energy, academics and cosmetics industries.

The Company's line of lab and production equipment, marketed under the Company's Microfluidizer® trademark and trade name, process premixed formulations to produce small, uniform structures, usually of the submicron and nanoscale size (commonly defined as particles having dimensions less than 100 nanometers) including nanoemulsions and nanosuspensions.

Additionally, the Company's equipment is used for cell disruption to harvest the cultivated contents of cells such as e.coli, bacterial yeast, mammalian and/or plant cells and for liposomal encapsulation of materials primarily for the pharmaceutical, biotechnology, nutraceutical/food and cosmetic industries.

The technology embodied within the Company's Microfluidizer high shear fluid processors is used in formulating products that are normally very difficult to mix and stabilize. We believe that the Company's Microfluidizer processors, through process intensification, allow manufacturers to produce higher quality products with better characteristics, on a more consistent basis, than with other blending, mixing or

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homogenizing techniques. Further, the Company's processor equipment is able to scale up formulations and results from flow rates as low as 100 to 200 milliliters per minute on the Company's laboratory and bench top models to more than 15 gallons per minute on the Company's production models, which is a competitive advantage for the Company's customers.

We have begun to sell beta versions and associated process technology consulting services to the Company's commercial customers incorporating the Company's MRT technology in the proprietary equipment. In 2009 we launched the MRT processor, the CR5. The combination of the process development and processor was used successfully to produce drug suspensions of the desired particle size via crystallization. The Company's management believes that once commercialized, the manufacturing capability of the Company's processing equipment and the Company's MRT technology may enable the Company's pharmaceutical and other customers to implement further their nanotechnology based products.

In August 1997, we filed a patent application for the MRT processor device and its processes with the United States Patent and Trademark Office (USPTO). We filed a Patent Cooperation Treaty (PCT) application on May 5, 1998 and we have filed for protection in selected countries during the third quarter of 2010. In April 2010, the Company applied for a Japanese patent on MRT entitled Apparatus and



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Methods for Nanoparticle Generation and Process Intensification of Transport and Reaction Systems .

In July and November 2000, we were issued by the USPTO notices of allowances of utility patent claims regarding the Microfluidizer Mixer/Reactor ( MMR ) and the use thereof. On September 18, 2002, the European Patent Office advised us it would grant its MMR patent substantially as applied for, including its device and process claims. We have gained national entry of the patent in France, Germany, Italy, The Netherlands, and the United Kingdom.

During the third quarter of 2010, we continue to see and adjust to changes in the pharmaceutical landscape, which may have an impact on the timing and amount of capital spending. Some of our initiatives to address these changes include increasing our presence at universities, contract research organizations and smaller pharmaceutical and biotechnology companies and improving our sales coverage. We have also seen improvement in adjacent markets, including the chemical and cosmetics industries, which may help to offset the changes in big pharmaceutical companies. In the third quarter of 2010, we have continued to see an increase in the sale of laboratory machines, including our LVI Low Volume Microfluidizer which was introduced in March 2010, as compared to large production machines. We believe that the increase in the sale of laboratory machines may create additional opportunities in the future as customers move from laboratory machines to production machines. Our revenue declined 8.6% in the third quarter of 2010 as compared to the third quarter of 2009, primarily related to a decline in spare parts. In addition, the third quarter of 2009 was a strong quarter with sales of production machines and spare parts related to the H1N1 vaccine, which did not repeat itself in the third quarter of 2010.

We were incorporated in Delaware in 1983 under the name Biotechnology Development Corporation. The Company's principal executive offices are located at 30 Ossipee Road, in Newton, Massachusetts 02464 and the Company's telephone number is (617) 969-5452.

**Critical Accounting Policies**

The preparation of financial statements and related disclosures in conformity with generally accepted accounting principles in U. S. GAAP requires management to make judgments, assumptions and estimates that affect the amounts in the consolidated financial statements and accompanying notes. The Company's critical accounting policies that are impacted by judgments, assumptions and estimates are set forth in Management's Discussion and Analysis of Financial Condition and Results of Operations in the Company's Annual Report on Form 10-K for the year ended December 31, 2009 as filed with the SEC on March 29, 2010. Since December 31, 2009, there have been no material changes in the Company's critical accounting policies.

**Results of Operations**

Three Months Ended September 30, 2010 vs. September 30, 2009

*Revenues*

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Total revenues for the three months ended September 30, 2010 were approximately \$4,077,000, as compared to revenues of approximately \$4,462,000 for the three months ended September 30, 2009, a decrease of \$385,000, or 8.6%.

North American revenues for the three months ended September 30, 2010 decreased to approximately \$2,754,000, or by 14.2% as compared to revenues of approximately \$3,208,000 for the three months ended September 30, 2009. This decrease in North American revenues was principally due to a reduction in the sale of production machines of \$584,000 and spare parts of approximately \$276,000 partially offset by an increase in the sale of lab machines of approximately \$181,000.

Foreign revenues for the three months ended September 30, 2010 increased to approximately \$1,323,000 or by 5.5% as compared to revenues of approximately \$1,254,000 for the three months ended September 30, 2009. The increase in foreign revenues was principally due to an increase in the sale of production machines of approximately \$434,000 offset by a decrease in the sale of spare parts of \$335,000.

Due to the nature of the sale of capital equipment, one specific quarter can be impacted by the timing of the sale of one or more production machines. In addition, the percentage of North American revenues and foreign revenues to total revenues can vary from quarter to quarter depending on the nature of the capital equipment sold in that geographical region.

Our sales order backlog on September 30, 2010 was approximately \$1,320,000 as compared to approximately \$4,754,000 on September 30, 2009. This decrease was primarily due to a reduction in spare parts orders. Backlog represents orders in hand that typically take between one and six months to deliver.

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*Cost of Sales*

Cost of sales for the three months ended September 30, 2010 was approximately \$1,644,000, or 40.3% of revenue, compared to approximately \$1,533,000, or 34.4% of revenue, for the three months ended September 30, 2009.

The increase in cost of sales as a percentage of revenues is primarily attributable to the sales of a production machines in the third quarter of 2009 with a higher margin attributable to an expedite fee. The Company's major product lines have different margins, as well as varied profit margins within each product line. As a result, the makeup of revenues in the quarter can cause a swing in margins.

*Research and Development Expenses*

Research and development expenses for the three months ended September 30, 2010 were approximately \$468,000, as compared to approximately \$433,000 for the three months ended September 30, 2009, an increase of \$35,000, or 8.1%. The increase in research and development expenses was primarily due to an increase in expenses related to MRT.

*Selling Expenses*

Selling expenses for the three months ended September 30, 2010 were approximately \$1,093,000, as compared to approximately \$1,007,000 for the three months ended September 30, 2009, an increase of \$86,000, or 8.5%. This increase was primarily due to higher commission expenses of approximately \$108,000, as a result of the sales mix for in house account sales which have a lower commission rate.

*General and Administrative Expenses*

General and administrative expenses for the three months ended September 30, 2010, were approximately \$939,000, as compared to approximately \$920,000 for the three months ended September 30, 2009, an increase of \$19,000, or 2.1%. This increase was primarily attributable to an increase in professional fees of approximately \$136,000 and an adverse impact from the currency exchange rate of approximately \$33,000, offset by reductions of \$145,000 in travel, insurance and bonus expenses.

*Interest Expense*

Interest expense for the three months ended September 30, 2010 was approximately \$176,000 as compared to approximately \$144,000 for the three months ended September 30, 2009, an increase of \$32,000, or 22.2%. This increase was primarily due to the amortization of expenses

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related to the Webster Bank Revolving Line of Credit of approximately \$29,000.

### *Income Tax Provision*

As described in Note 9 to our consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2009 as filed with the SEC on March 29, 2010, we have recorded a full valuation allowance for the amount of the net deferred tax assets.

### *Nine Months Ended September 30, 2010 vs. September 30, 2009*

### *Revenues*

Total revenues for the nine months ended September 30, 2010 were approximately \$12,904,000, as compared to revenues of \$11,490,000 for the nine months ended September 30, 2009, an increase of approximately \$1,414,000, or 12.3%.

North American revenues for the nine months ended September 30, 2010 increased to approximately \$7,867,000, or by 9.4%, as compared to revenues of approximately \$7,193,000 for the nine months ended September 30, 2009. This increase in North American revenues was principally due to an increase in the sale of spare parts and services of approximately \$1,334,000 and an increase in lab machines sales of \$551,000, partially offset by a reduction in the sale of production machines of \$1,229,000.

Foreign revenues for the nine months ended September 30, 2010 increased to approximately \$5,037,000, or by 17.2%, as compared to approximately \$4,297,000 for the nine months ended September 30, 2009. The increase in foreign revenues was primarily due to the increase in the sales of production machines of approximately \$1,069,000, partially offset by the reduction in parts and services of approximately \$280,000.

Due to the nature of the sale of capital equipment, one specific period can be impacted by the timing of the sale of one or more

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production machines. In addition, the percentage of North American revenues and foreign revenues to total revenues can vary from period to period depending on the nature of the capital equipment sold in that geographical region.

*Cost of Sales*

Cost of sales for the nine months ended September 30, 2010 was approximately \$5,002,000, or 38.8% of revenue, as compared to approximately \$4,679,000, or 40.7% of revenue, for the nine months ended September 30, 2009.

The increase in cost of sales in absolute dollars reflects an overall increase in sales over the same period last year. The improvement in margins reflects a more efficient manufacturing process and better margins on our second generation lab machines. The Company's major product lines have different profit margins, as well as varied profit margins within each product line.

*Research and Development Expenses*

Research and development expenses for the nine months ended September 30, 2010 were approximately \$1,444,000, as compared to \$1,301,000 for the nine months ended September 30, 2009, an increase of \$143,000, or 11.0%. This increase was primarily due to higher payroll expenses and related costs of approximately \$75,000, travel costs of approximately \$26,000 and consulting costs of approximately \$28,000.

*Selling Expenses*

Selling expenses for the nine months ended September 30, 2010 were approximately \$3,224,000 as compared to approximately \$3,154,000 for the nine months ended September 30, 2009, an increase of \$70,000, or 2.2%. This increase was primarily due to higher commissions resulting from higher revenues as compared to the same period last year.

*General and Administrative Expenses*

General and administrative expenses for the nine months ended September 30, 2010 were approximately \$2,688,000, as compared to \$2,375,000 for the nine months ended September 30, 2009, an increase of \$313,000, or 13.2%. The increase was primarily attributable to an increase in professional fees of approximately \$407,000 and an adverse impact from the foreign currency exchange rate losses of approximately \$120,000, partially offset by reductions of \$194,000 in travel, insurance and bonus expenses.

*Interest Income/Expense*

Interest expense for the nine months ended September 30, 2010 was approximately \$540,000, as compared to \$425,000 for the nine months ended September 30, 2009, an increase of \$115,000, or 27.1%. This increase was primarily due to the amortization of expenses related to the Webster Bank Revolving Line of Credit of approximately \$88,000.

There was no interest income for the nine months ended September 30, 2010, as compared to approximately \$2,000 for the nine months ended September 30, 2009.

*Income Tax Provision*

As described in Note 9 to our consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2009 as filed with the SEC on March 29, 2010, we have recorded a full valuation allowance for the amount of the deferred tax assets.

As of December 31, 2009, the Company has available federal net operating loss carry forwards for income tax purposes of approximately \$12,757,000 and state net operating loss carry forwards of approximately \$2,784,000, which expire at various dates through 2029, and federal research and development credit carry forwards of approximately \$356,000 expiring in varying amounts during the period through 2024. Ownership changes, as defined in the Internal Revenue Code, may limit the amount of operating loss carry forwards that can be utilized annually to offset future taxable income. Subsequent ownership changes could further affect the limitation in future years.

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**Liquidity and Capital Resources**

*Liquidity*

The Company has funded its working capital requirements primarily through the proceeds from a Convertible Debenture, funds generated from operations and customer advances. The Company expects to fund its liquidity requirements, including interest on a Convertible Debenture and capital expenditures, primarily through revenue and bookings for which the Company receives customer advances in advance of shipments and as needed, through unused borrowings available under the Company's Revolving Line of Credit with Webster Bank, which has been extended through October 22, 2011. The Company anticipates that with expected revenues and customer advances, together with the existing cash balance at September 30, 2010 and the Revolving Line of Credit, that it will have sufficient cash to meet its working capital requirements for the next twelve months. However, if the Company does not achieve the revenues and customer advances as and when planned, and/or if the Company is unable to access its Revolving Line of Credit, the Company may face substantial liquidity pressures that it may not be able to sustain if it is unable to access additional sources of liquidity.

*Long Term Debt*

On November 14, 2008, the Company entered into a Convertible Debenture and Warrant Purchase Agreement (the Agreement) with GSP, as described above in Note 11 of the Company's Notes to Condensed Consolidated Financial Statements (unaudited) for the three and nine months ended September 30, 2010. The Convertible Debenture issued pursuant to the terms of the Agreement (the Convertible Debenture) bears interest at nine percent (9.0%) per annum payable quarterly in arrears. The Convertible Debenture is due and payable on the earlier to occur of (i) November 14, 2015 or (ii) the acceleration of the maturity of the Convertible Debenture upon the occurrence of an Event of Default (as defined in the Convertible Debenture). The Company may, at its option and upon 30 days notice to GSP, prepay on an interest payment date all of the principal balance of the Convertible Debenture, without penalty, together with any accrued and unpaid interest through the date of prepayment. The Company's right to prepay is subject to Global Strategic Partners (GSP), the holder of the Convertible Debenture, right to convert the Convertible Debenture as contemplated in the Convertible Debenture. GSP may, at its option, on any of the maturity dates, the date that any interest payment is due, or the date on which a change of control occurs, convert all or any portion of the outstanding principal amount of the Convertible Debenture into shares of our common stock at \$1.25 per share. In May 2009, GSP agreed to defer the interest payments due and payable under the Convertible Debenture on each of July 1, 2009, October 1, 2009 and January 4, 2010. The deferred payments accrue interest at nine percent (9.0%) per annum and are payable in eight equal quarterly installments on the first day of each quarter beginning on April 1, 2010. The Convertible Debenture is secured by all assets, property rights and interests of the Company, and is subordinate to the Revolving Line of Credit.

On November 14, 2008, the Company also issued a Warrant to GSP pursuant to the terms of the Agreement, giving it the right to purchase up to fifty percent (50%) of our outstanding common stock, on a fully diluted basis, less the number of shares of common stock into which the Convertible Debenture is convertible. The Warrant can be exercised by GSP in two (2) tranches at any time prior to the earlier to occur of: (i) the seventh anniversary of the date of the Agreement, (ii) the third anniversary of the date of the Agreement in the event that we retire the Convertible Debenture on or before such date (the Third Anniversary) or (iii) such time as GSP has acquired fifty percent (50%) of the total number of shares of our common stock then outstanding on a fully diluted basis. The first tranche is exercisable at \$2.00 per share up to forty percent (40%) of our common stock then outstanding on a fully diluted basis and the second tranche is exercisable at \$3.00 per share up to fifty percent (50%) of our common stock then outstanding on a fully diluted basis.

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The aggregate number of shares of Common Stock (the **Tranche One Maximum** ) that may be purchased pursuant to one or more tranche one exercises of the Warrant (the **Tranche One Exercises** ) is forty percent (40%) of the Common Stock then outstanding on a fully diluted basis, minus that number of shares of Common Stock that GSP is or was entitled to acquire (or has theretofore acquired) upon exercise of the conversion feature of the Convertible Debenture. Notwithstanding the preceding sentence, if all or any portion of the principal amount of the Convertible Debenture has been prepaid by the Company prior to the Third Anniversary, then the **Tranche One Maximum** will also include a number of shares of common stock equal to the quotient of: (i) the amount of the Convertible Debenture's principal amount that was so repaid by the Third Anniversary, divided by (ii) \$1.25 (the **Prepayment Shares** ).

The aggregate number of shares of Common Stock that may be purchased pursuant to one or more tranche two exercises of the Warrant (the **Tranche Two Exercises** ) is equal to (a) fifty percent (50%) of the common stock then outstanding on a fully diluted basis, minus (b) that number of shares of common stock that GSP is or was entitled to acquire (or has theretofore acquired) upon



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(i) exercise of the conversion feature of the Convertible Debenture, and (ii) the Tranche One Exercise, plus (c) the Prepayment Shares. A Tranche Two Exercise may only be made after the full number of shares exercisable pursuant to Tranche One Exercises has been purchased.

*Revolving Line of Credit*

On October 23, 2009, the Company entered into a one year senior secured \$1 million Revolving Line of Credit with Webster Bank described above in Note 10 of the Company's Notes to Condensed Consolidated Financial Statements (unaudited) for the three and nine months ended September 30, 2010. On October 22, 2010 the Company entered into an amendment extending the maturity date of the Revolving Line of Credit until October 22, 2011. The Revolving Line of Credit is senior to the Company's Convertible Debenture and the Company may not extend the Revolving Line of Credit beyond this period without the consent of GSP, the holder of the Convertible Debenture. As noted above, the actual amount of credit that is available from time to time under the Revolving Line of Credit is limited to a borrowing base amount that is determined according to, among other things, a percentage of the value of eligible accounts receivables. The Revolving Line of Credit contains customary representations and warranties and restrictive covenants relating to matters, such as indebtedness, liens, investments, acquisitions, mergers, dispositions and dividends. The Revolving Line of Credit also has two financial covenants that require the Company to maintain a senior debt to twelve month trailing EBITDA of 2:1, and to maintain \$500,000 of available cash or excess availability under the Revolving Line of Credit. The proceeds of any borrowings under the Revolving Line of Credit are available for working capital and other general corporate purposes.

The Company's borrowings under the Revolving Line of Credit will generally accrue interest at a margin of 5.50% over LIBOR and are secured by a lien on substantially all of its personal property, which is senior in rights to its Convertible Debenture. The Revolving Line of Credit generally contains customary events of default for credit facilities of this type. Upon an event of default that is not cured or waived within any applicable cure periods, in addition to other remedies that may be available to Webster Bank, the obligations under the Loan Agreement may be accelerated and remedies may be exercised against the collateral.

In connection with the closing of the Revolving Line of Credit, the Company also amended the Agreement and Convertible Debenture with GSP to permit the Revolving Line of Credit as senior indebtedness and provide for certain other covenants, including a cross default provision with the Revolving Line of Credit.

As of September 30, 2010, we had not drawn upon the Revolving Line of Credit.

*Operating, Investing and Financing Activities*

As of September 30, 2010, the Company had approximately \$1,980,000 in cash and cash equivalents, as compared to approximately \$2,185,000 on December 31, 2009. The decrease of \$205,000 in cash resulted primarily from changes in working capital, particularly lower customer advances.

The Company's operating activities used cash of approximately \$212,000 for the nine months ended September 30, 2010 compared to cash used of approximately \$138,000 for the nine months ended September 30, 2009. The increase in cash flows used from operating activities was

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primarily due to overall changes in working capital from year to year, particularly lower customer advances.

The Company used cash of \$12,000 and \$72,000 for investing activities for the nine months ended September 30, 2010 and 2009, respectively, for the purchase of capital equipment.

The Company generated cash of \$19,000 and \$9,000 from financing activities for the nine months ended September 30, 2010 and 2009, respectively, as a result of option exercises and issuances of shares under the Company's Employee Stock Purchase Plan.

### *Contractual Obligations*

Information related to the Company's contractual obligations can be found in the Consolidated Financial Statements of the Company's annual report on Form 10-K for the year ended December 31, 2009 as filed with the SEC on March 29, 2010. During the nine months ended September 30, 2010, there have been no changes outside the ordinary course of business in contractual obligations.

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*Off-Balance Sheet Arrangements*

We are not a party to any off-balance sheet arrangements.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

During the nine months ended September 30, 2010, there were no material changes to the Company's market risk policies or market risk sensitive instruments and positions as described in the Company's annual report on Form 10-K for the year ended December 31, 2009, as filed with the SEC on March 29, 2010.

**Item 4. Controls and Procedures**

The certificates of the Company's principal executive officer and principal financial officer attached as Exhibits 31.1 and 31.2 to this Quarterly Report on Form 10-Q include, in paragraph 4 of such certifications, information concerning the Company's disclosure controls and procedures, and internal control over financial reporting. Such certifications should be read in conjunction with the information contained in this Item 4 for a more complete understanding of the matters covered by such certifications.

**Disclosure Controls and Procedures**

The Company's management, with the participation of the Company's chief executive officer and principal financial and accounting officer, evaluated the effectiveness of the Company's disclosure controls and procedures as of September 30, 2010. The term "disclosure controls and procedures", as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its chief executive officer and principal financial and accounting officer, as appropriate, to allow timely decisions to be made regarding required disclosure. It should be noted that any system of controls and procedures, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system are met and that management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of the Company's disclosure controls and procedures as of September 30, 2010, the Company's chief executive officer and principal financial and accounting officer concluded that, as of such date, the Company's disclosure controls and procedures were effective at the reasonable assurance level.

**Changes in Internal Control Over Financial Reporting**

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There were no changes to the Company's internal control over financial reporting during the quarter ended September 30, 2010 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

### **PART II. OTHER INFORMATION**

#### **Item 1. Legal Proceedings.**

The Company is not a party to any material legal proceedings.

#### **Item 1A. Risk Factors.**

You should carefully consider the risks and uncertainties described below and the other information in this filing before deciding to invest in our common stock. If any of these risks or uncertainties occurs, our business, financial condition or operating results could be materially harmed. In that case the trading price of our common stock could decline and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we may face. We believe that this filing contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. Such forward-looking

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statements are subject to risks and uncertainties described herein or that are unknown to us or that we currently deem immaterial, are based on management's current expectations and are subject to facts that could cause results to differ materially from the forward-looking statements.

***We have experienced net losses in four of our last five fiscal years, including the fiscal year ended December 31, 2009, and we may not be able to achieve consistent profitability in the future.***

For four of the past five fiscal years, including for fiscal 2009, and for the most recent fiscal quarter, we have experienced net losses. For the year ended December 31, 2009 and the year ended December 31, 2008, we had a net loss of \$362,000 and \$4,011,000, respectively. Although we have significantly improved our operating results during fiscal 2009 and 2010, which included recording a positive net income in the third and fourth quarters of 2009 and the first and second quarters of 2010, we experienced a net loss in the third quarter of 2010. In the future the Company may not be able to achieve consistent profitability on a quarter by quarter and year over year basis.

***The Company must remain cash-flow positive.***

We believe that our expected revenues and customer advances, together with our existing cash balance at September 30, 2010 and the availability under our working capital line should be sufficient to meet our working capital requirements for the next twelve months. In the first quarter of 2009, we initiated an aggressive cost reduction program that included headcount reductions as well as the elimination of all non-essential discretionary spending such as travel, consulting and marketing programs. As a result of these initiatives and the cost reduction program, the Company was cash-flow positive for the year ended December 31, 2009. However, if we sustain a revenue shortfall that we cannot compensate with additional cost cuts or borrowings under our current existing Revolving Line of Credit are unavailable or withdrawn; it is possible that we could face unsustainable liquidity pressures. This concern is accentuated by the fact that current credit markets, coupled with our history of losses, have made it possible that we would not be able to obtain alternative or additional financing. Under these circumstances, it is possible that we could default under our financing agreements, which default could force us to seek protection under the bankruptcy laws and cause our investors to sustain a loss of their investment in our shares.

***Continued or Increased concerns about the financial markets, economic conditions, and corporate profits may exacerbate certain risks affecting our business.***

We cannot predict the extent of the impact of the economic environment specific to our industry. Continued or increased concerns about credit markets, consumer confidence, economic conditions, volatile corporate profits and reduced capital spending could negatively impact demand for our products. In the future, we may experience reduced demand for our products because of the uncertainties in the general economic environment in which our customers and we operate. If our customers and suppliers are unable to obtain financing, or experience increased cost in their financing arrangements in this market, we could experience a decrease in, or deferrals of, or cancellations of, the sale of our products. Although there have been signs of an improving economy, if global economic and market conditions, or economic conditions in the United States, remain uncertain, deteriorate or enter into a period with no or flat growth, we may experience a material adverse effect on our business, operating results and financial condition. Unstable economic, political and social conditions make it difficult for our customers, our suppliers and us to accurately forecast and plan future business activities. If such conditions persist, our business, financial condition and results of operations could suffer.

*The occurrence of an event of default under our financing arrangements could result in substantial losses to our stockholders.*

Both our Revolving Line of Credit and our Convertible Debenture contain events of defaults, which are more fully described in our Form 8-Ks filed with the Securities and Exchange Commission on October 26, 2009 with respect to the Revolving Line of Credit and November 20, 2008 with respect to the Convertible Debenture. In addition, the Revolving Line of Credit and Convertible Debenture contain cross default provisions, which provides that an event of default under our Revolving Line of Credit or Convertible Debenture may also trigger an event of default under the other financing agreement. If we were to experience an event of default under our Revolving Line of Credit or our Convertible Debenture, that is not cured or waived within any applicable cure periods, in addition to other remedies that may be available to Webster Bank, our lender, and GSP, the holder of the Convertible Debenture, the parties may accelerate the obligations under these financing arrangements and they may exercise their remedies against the secured collateral, which is substantially all of our assets. If an event of default occurs, there can be no assurance that we would be able to repay the obligations under these financing arrangements or be able to raise additional funds to make such payments. Failure to repay these financing arrangements could force us to reorganize our debts, possibly in bankruptcy, in which event our common stock could likely become worthless.

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***Our ownership structure includes several investors who own large blocks of common stock or convertible securities whose interests and rights in our Company may differ in important respects from those of our other common stock investors.***

Several investors in the Company own large concentrations of our common stock or securities convertible into our common stock, making our shares more illiquid than if our ownership structure were more widely distributed. The concentration in the ownership of our common stock and the rights of the holder of our Convertible Debenture and Warrant impact the trading liquidity of our common shares, our corporate governance, and the relative economic stake that our common stock and Convertible Debenture and Warrant have in the enterprise value of our business. Although a more active trading market may develop in the future, the limited market liquidity for our common stock may affect your ability to sell at a price that is satisfactory to you. Additionally, if the holder of our Convertible Debenture and Warrant were to convert and/or sell such shares or a large stockholder were to sell their shares our stock price may be adversely affected.

***We face intense competition in many of our markets.***

Our Microfluidizer product line of high-shear fluid processors has direct competition in its major markets, including its most important markets in the pharmaceutical, biotechnology and coatings/chemical industries. The intensity of the competition that we confront requires that we continuously invest in research and development in order to keep our product line competitive. Despite such expenditures, however, there can be no assurance that we will be able to meet the enhancement challenges posed by our competitors, or that we will be able to create or exploit the kinds of innovations, such as our MRT technology, needed to drive future sales.

In addition, we face, and will continue to face, competition from other companies who manufacture and sell fluid processing systems used in particle size reduction, mixing, milling, dispersing, homogenizing, cell disruption and liposomal encapsulation applications. We expect greater competition in the fluid processing systems field as technical advances are made and become more widely known, and such increased competition may have a material adverse effect upon our business.

Our future success will depend in large part on our ability to maintain a technologically superior product line. Rapid technological development by us or others may result in our products or technologies becoming obsolete before we recover the expenses we incur in connection with their development. Products offered by us could be made obsolete by less expensive or more effective technologies, or may never achieve market acceptance. There can be no assurance that we will be able to make the enhancements to our technology successful in the enhancement, introduction, manufacturing and marketing of any new technologies, products or product innovations, or develop and introduce, in a timely manner, innovations to our existing technologies or products that satisfy our customers' needs or achieve market acceptance to compete successfully with newly emerging technologies and products of our competitors.

***If we fail to retain key personnel and hire, train and retain qualified employees, we may not be able to compete effectively, which could result in reduced revenue or increased costs.***

Our success is highly dependent on the continued services of key management, technical and scientific personnel. Our management and other employees may voluntarily terminate their employment at any time upon short notice. The loss of the services of any member of the senior management team, including the Chief Executive Officer, Michael Ferrara, Peter Byczko, Vice President of Finance and the Chief Accounting Officer, William Conroy, the Senior Vice President of Operations and Engineering, Thomai Panagiotou, Chief Technology Officer, William

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Kober, Vice President of Sales The Americas and Western Asia, Xavier Leroy, Vice President of Sales EMEA and South East Asia or any of the managerial, technical or scientific staff may significantly delay or prevent the achievement of product development and other business objectives.

Our future success will also depend on our ability to identify, recruit and retain additional qualified scientific, technical and managerial personnel. Competition for qualified personnel is intense in the marketplace we operate in, particularly in the areas of general management, finance, information technology, engineering and science, and the process of hiring suitably qualified personnel is often lengthy and expensive, and may become more expensive in the future. If we are unable to hire and retain a sufficient number of qualified employees, our ability to conduct and expand our business could be seriously reduced.

*We may be unsuccessful in launching new products or expanding product offerings.*

We announced the launch of our new LV1 Microfluidizer High Shear Fluid Processor on March 17, 2010. We also



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announced that we intend to develop a series of service offerings to address what we believe is a long-term growth opportunity within our customer base. Although we believe the new product and service offerings will present long-term opportunities for the Company, we may be unsuccessful in identifying and pursuing such opportunities. We may be unsuccessful in introducing the new product and service offerings, expanding current product offerings and commercializing new technologies. In addition, there may be a lack of demand in the present or in the future for the products that we introduce.

***Our future growth is dependent upon the development of new products, which require significant research and development, and customer testing, all of which are very expensive and time consuming.***

In order to develop new products and improve current product offerings, we focus our research and development programs largely on the development of next generation and novel technology offerings. The research, development, testing and commercialization of our MRT Processor and other novel technologies are expensive and time consuming. We are in the early stages of commercialization of our MRT Processor, with certain potential customers testing beta products and receiving consulting services. We may experience significant delays in the testing process. Additionally, there are no assurances that our MRT Processor or any of our other next generation or novel technology offerings will gain market acceptance. The failure to gain or a prolonged delay in market acceptance or an extended testing period for our next generation products may have a material adverse effect on our results of operations and financial conditions.

***We are dependent on a relatively small number of customers for a significant portion of our net sales.***

A significant portion of our net sales is derived from a relatively small number of customers. Although no customer accounted for more than 10% of the Company's revenues for the three months ended September 30, 2010, four customers accounted for 25% of our revenues. For the three months ended September 30, 2009, sales to two customers represented 42% of our revenues. We expect to continue to depend upon our principal customers for a significant portion of our sales, although our principal customers may not continue to purchase products and services from us at current levels, if at all. The loss of one or more major customers or a change in their buying patterns could have a material adverse effect on our business, financial condition, and results of operations.

***We rely on suppliers, vendors and subcontractors.***

We do not manufacture most of the components contained in our Microfluidizer materials processor equipment, but rather subcontract the manufacture of most components. Based on quality, price, and performance, we have selected certain suppliers, vendors, and subcontractors that provide parts, subassemblies, machining and finishing of components that are assembled by our production staff. It is possible that, as a result of the recent economic slowdown or other reasons, one or more of our suppliers, vendors or subcontractors could go out of business, or not ship on open account, or otherwise be unable to supply our needs. Although we have identified alternate sources for parts, components, machining and finishing integral to the manufacture of our products, there can be no assurance that a transition to an alternative source would not entail quality assurance or quality control difficulties, on-time delivery problems, or other transition problems, any or all of which could have an impact on our production of equipment and could have a material adverse effect on our business, financial condition, or results of operations.

***Many of our current and potential customers are from the pharmaceutical and biotechnology industries and are subject to risks faced by those industries.***

We derive a substantial portion of our revenues from pharmaceutical and biotechnology companies. We expect that pharmaceutical and biotechnology companies will continue to be our major sources of revenues for the foreseeable future. As a result, we are subject to risks and uncertainties that affect the pharmaceutical and biotechnology industries, such as pricing pressures as third-party payers continue challenging the pricing of medical products and services, government regulation, ongoing consolidation and uncertainty of technological change, and to reductions and delays in research and development expenditures by companies in these industries.

In particular, the biotechnology industry is dependent on raising capital to fund operations. If biotechnology companies are unable to obtain the financing necessary to purchase our products, our business and results of operations could be materially adversely affected. As it relates to both the biotechnology and pharmaceutical industries, many companies have significant patents that have expired or are about to expire, which could result in reduced revenues for those companies. If pharmaceutical or biotechnology

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companies suffer reduced revenues as a result of these patent expirations, they may be unable to purchase our products, and our business and results of operations could be materially adversely affected.

Mergers and acquisitions are prevalent in the pharmaceutical and biotechnology industries as there has been a recent trend toward increased consolidation in these industries, including the recent acquisition of the parent company of GSP, the holder of the Convertible Debenture. If one or more of our major customers is acquired, there is no guarantee that the acquirer will continue to purchase our products or continue to develop the drugs that use our products. If one or more of our customers is acquired our business could be harmed.

In addition, we are dependent, both directly and indirectly, upon general health care spending patterns, particularly in the research and development budgets of the pharmaceutical and biotechnology industries, as well as upon the financial condition and purchasing patterns of various governments and government agencies. Many of our customers, including universities, government research laboratories, private foundations and other institutions, obtain funding for the purchase of products from grants by governments or government agencies. There exists the risk of potential decrease in the level of governmental spending allocated to scientific and medical research, which could substantially reduce or even eliminate these grants. If government funding necessary to purchase our products were to decrease, our business and results of operations could be materially adversely affected. Spending patterns may also be affected by federal regulation, including the recent health care bills, which may affect research budgets.

Lastly, because our Convertible Debenture was provided by an affiliate of a pharmaceutical company that competes with other pharmaceutical companies, it is possible that the other companies might decide against doing business with us in the future for competitive reasons. If a significant number of pharmaceutical companies were to reduce their purchases of our products for this or any other reason, our business and results of operations could be materially adversely affected.

***We have only one manufacturing facility.***

We have a single manufacturing facility located in Newton, Massachusetts. Our success depends on the efficient and uninterrupted operation of that facility. Whether as a result of a fire, natural disaster, or other cause, any disruption to our manufacturing operations would significantly impair our ability to operate our business on a day-to-day basis. Although we maintain business interruption insurance, our business would be injured by any extended interruption of the operations of our manufacturing facility. Further our insurance coverage may not be adequate to compensate us for all losses that may occur, or may not continue to be available to us.

Finally, if we seek to replicate our manufacturing operations at another location, we will face a number of technical as well as financial challenges, which we may not be able to address successfully.

***We rely on our trade secrets to protect our technology.***

To protect our proprietary rights, we rely on a combination of patent and trademark laws, trade secrets, confidentiality agreements, contractual provisions and technical means. In the event of a breach of these protections, there can be no assurance that these measures will prove to have

been adequate to protect our interests, or that we will have sufficient resources to prosecute or prevail in an action against a third party.

Our Microfluidizer processor equipment method patent expired on March 13, 2007 and our device patent expired on August 6, 2002. In addition, we have neither sought patent protection for our Microfluidizer processor or our interaction chamber nor trademark protection of our Microfluidizer trade name in any country other than the United States. As such, our proprietary rights for key aspects of our Microfluidizer processor equipment are not subject to the protection of patent law or trademark laws of foreign countries where our equipment is sold. Although we have made many alterations, improvements and advances to our Microfluidizer processor equipment over the years and continue to make such advancements with such modifications and innovations having been and being treated by us as trade secrets, the lack of our patent protections will expose us to potential competition that would likely have a material adverse effect on us.

*We have recently filed patent applications for our MRT Technology. If we are unable to obtain or maintain patent protection or if our patents do not provide protection against competitive products of our MRT Technology, our results of operations may be adversely affected.*

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Our future success is dependent in part on our ability to obtain and maintain patent protection for our MRT Technology. In 1997 we completed development of a novel adaptation of our Microfluidizer processor equipment - a Multiple Stream High Pressure Mixer/Reactor, commercially designated as the Microfluidizer Mixer/Reactor (MMR). In August 1997, we filed a patent application for the device and its processes with the United States Patent and Trademark Office (USPTO), and filed a Patent Cooperation Treaty (PCT) application on May 5, 1998. In July and November, 2000, the USPTO issued us notices of allowances of utility patent claims regarding the MMR and the use thereof. On September 18, 2002, the European Patent Office advised us it would grant our MMR patent substantially as applied for, including our device and process claims. We are in the process of pursuing national entry in France, Germany, Italy, The Netherlands, and the United Kingdom.

We are pursuing patent protection in the United States and select foreign jurisdictions with respect to proprietary aspects of our MRT Processor. We filed a U.S Patent application for this technology in March 2008 and a Patent Cooperation Treaty (PCT) in March 2009 and in April 2010, the Company applied for a Japanese patent on MRT entitled Apparatus and Methods for Nanoparticle Generation and Process Intensification of Transport and Reaction Systems. We are awaiting responses to these filings.

There can be no assurance that (i) any patents issued to us will provide us with any competitive advantages or adequate protection for our inventions; (ii) any patents issued to us will not be challenged, invalidated or circumvented by others; or (iii) issued patents, or patents that may be issued, will provide protection against competitive products or otherwise be commercially valuable. Furthermore, patent law relating to the scope of claims in the fields of healthcare and biosciences is still evolving, and our patent rights are subject to this uncertainty. European and United States patent authorities have not adopted a consistent policy regarding the breadth of claims allowed for health and bioscience patents. Our patent rights on our products therefore might conflict with the patent rights of others, whether existing now or in the future.

In order to protect or enforce our patent rights, we may initiate patent litigation against third parties. We may also become subject to interference proceedings conducted in the patent and trademark offices of various countries to determine the priority of inventions. The defense and prosecution, if necessary, of intellectual property suits, interference proceedings and related legal and administrative proceedings would be costly and divert our technical and management personnel from their normal responsibilities. We may not prevail in any of these suits should they occur. An adverse determination of any litigation or defense proceedings could put our patent applications at risk of not issuing.

***The failure of any banking institution in which we deposit our funds or the failure of such banking institution to provide services in the current economic environment could have a material adverse effect on our results of operations, financial condition or access to borrowings.***

The capital and credit markets have been experiencing extreme volatility and disruption. In some cases, the markets have exerted downward pressure on stock prices and credit capacity for certain issuers, as well as pressured the solvency of some financial institutions. Some of these financial institutions, including banks, have had difficulty performing regular services and in some cases have failed or otherwise been largely taken over by governments. If we are unable to access some or all of our cash on deposit, either temporarily or permanently, or are unable to access our Revolving Line of Credit with Webster Bank, it could have a negative impact on our operations, including our reported net income, or our financial position, or both.

***We may be subjected to increased government regulation that could affect our ability to sell our products outside of the United States.***

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Although United States governmental restrictions on technology transfer, import, export and customs regulations and other similar local, state or federal regulations, have not had a significant effect on us historically, any future legislation or administrative action restricting our ability to sell our products to certain countries outside the United States could significantly affect our ability to make certain foreign sales. The extent of adverse governmental regulation, which might result from future legislation or administrative action, cannot be accurately predicted. In particular, the USA Patriot Act and other governmental regulations may impose export restrictions on sale of equipment or transfer of technology to certain countries or groups. There can be no assurance that sale of our equipment will not be impacted by any such legislation or designation. Depending upon which countries and sales may be designated for trade restriction; such actions could have a material adverse effect on our business, financial condition, or results of operations. Also, certain agreements that may be entered into by us involving exclusive license rights may also be subject to national or supranational antitrust regulatory control, the effect of which cannot be predicted.

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***Our stock is listed on the OTC Bulletin Board and may experience a high level of volatility due to the market in general and certain other factors including the liquidity in the trading in our shares.***

Our common stock is quoted on the OTC Bulletin Board, which provides significantly less liquidity than a securities exchange (such as the NYSE Amex, New York Stock Exchanges or The NASDAQ Stock Market). In general, over the past two years, on average, approximately 8,300 shares of our common stock have traded on a daily basis. Although a more active trading market may develop in the future, the limited market liquidity for our stock may affect your ability to sell at a price that is satisfactory to you. The market price of our common stock may have increased volatile and could decline in the future in response to various factors including:

- volatility of the financial markets
- uncertainty regarding domestic and foreign economies
- technological innovations by competitors or competing technologies
- quarterly revenues and operating results fluctuating or failing to meet the expectations of management
- conditions or trends in the pharmaceutical and biotechnology industries
- announcement of significant changes in financing or strategic partnerships

Because we may experience a high level of volatility in our common stock, you should not invest in our stock unless you are prepared to absorb a significant loss of your capital. At any given time, you may not be able to sell your shares at a price that you think is acceptable.

***Our quarterly revenues and stock performance are variable.***

The timing of orders including completion of our factory acceptance testing can impact the actual shipment date, which will significantly affect quarterly revenues and net income results for particular quarters which may cause increased volatility in both our revenues and stock price.

***We allow our customers to lease some of our products and those leases may not turn into sales.***

We sometimes rent our products to our customers prior to or instead of selling a product to a customer. Our products are expensive, and customers frequently want to test out a product's capabilities prior to purchase. We have had reasonable success in converting rentals into subsequent sales of the same or a newer product; however, there is no guarantee that we will continue to be able to convert any of our leases into sales.

*We may be subject to product liability claims from our customers or by persons harmed by our customers' products.*

We maintain what we deem to be reasonable levels of product liability coverage through insurance policies with a reasonably small deductible. Nonetheless, inasmuch as we sell our equipment to a number of customers who make pharmaceutical preparations and consumer cosmetics, there can be no assurance that if a consumer of end products is injured or dies from such product that a suit by an injured party (or a class of similar situated plaintiffs) will not include us as well as the maker of the drug or cosmetic. Although we may have no control over the manufacture of end-products made on our equipment, we may not be able to bar a plaintiff's claims against all parties whose products and equipment were involved in the manufacturing process under a variety of legal theories of liability. We may be required to present a vigorous and costly defense if we cannot be dismissed from such an action. The cost of such legal defense may significantly impact our cash flow.

*Our international business operations expose us to a variety of risks.*

For the three months ending September 30, 2010 and 2009, shipments outside of North America accounted for approximately 32.4% and 28.1%, respectively, of our net revenues in those periods. In particular, approximately 2.5% and 2.7% of our net revenues in the three months ended September 30, 2010 and 2009, respectively, resulted from sales to Japan and approximately 4.3% and 2.7% of our net revenues in the three months ended September 30, 2010 and 2009, respectively resulted from sales to Korea. Approximately 21.0% and 21.4% of our net revenues resulted from sales to Europe in the three months ended September 30, 2010 and 2009, respectively. We expect that shipments outside of North America will continue to account for a significant portion of our total net revenues.



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We attempt to reduce some of our risk related to sales and shipments outside of the United States by requiring that our contracts generally be paid in United States dollars. Nevertheless, a downturn in the economies of Japan, China or Europe might reduce investment in new technology or products while a weakening of foreign currency against the United States dollar would make our products more expensive, each of which could have a substantial impact on our operating results. Additionally, the Company has had and continues to have exposure to fluctuations in foreign currency exchange rates as it maintains a cash balance in a German bank and has certain sales contracts in local currency.

In addition, a significant portion of our total net revenue is subject to the risks associated with shipping to foreign markets in general, including unexpected changes in legal and regulatory requirements; inability to collect receivables, seasonality of our revenue in Europe; changes in tariffs; political and economic instability; risk of terrorism; difficulties in managing distributors and representatives; difficulties in protecting our intellectual property overseas; and natural disasters, any of which could have a negative impact on our operating results.

***We may have unanticipated foreign tax liabilities that could adversely impact our results of operations and financial condition.***

We are subject to taxes in various foreign jurisdictions. The determination of our foreign taxes and tax accruals involves significant estimates and various judgments, based on historical experience and management's knowledge of current events and actions. Although we believe our tax estimates are reasonable, the final determination of any foreign tax audits and any related litigation is subject to uncertainty and could ultimately be materially different than that which is currently reflected in our tax expense and accruals. There can be no assurance that the outcomes from any examinations by foreign tax authorities will not have an adverse effect on our overall income taxes and tax liability. In addition, changes in tax laws, regulations, or rules may adversely affect our future reported financial results, may impact the way in which we conduct our business, or may increase the risk of an audit by a foreign tax authority.

***We may experience difficulties in the future in complying with Sarbanes-Oxley Section 404 ( Section 404 ); and continued implementation and maintenance of internal controls necessary for continued compliance with Section 404 may result in our incurring of additional costs.***

We are required to evaluate our internal controls under Section 404 of the Sarbanes-Oxley Act of 2002. We were also required to furnish a report by our management on our internal controls over financial reporting beginning with our annual report on Form 10-K for the fiscal year ended December 31, 2008. Such report contains, among other matters, an assessment of the effectiveness of our internal control over financial reporting as of the end of our fiscal year, including a statement as to whether or not our internal control over financial reporting is effective. While we have completed our self-assessment as to the effectiveness of internal control over financial reporting for the year ended December 31, 2009, which did not identify material weaknesses in our internal control systems, there can be no assurance that future material weaknesses in our internal control systems will not be identified as a result of changing financial or operating conditions. If we fail to maintain proper and effective internal controls in future periods, it could adversely affect our operating results, financial condition and our ability to run our business effectively and could cause investors to lose confidence in our financial reporting. As a smaller reporting company, we are not required to subject our internal controls to audit by our independent registered public accounting firm. If we were to become subject to an audit, there can be no assurance that such an audit of our internal controls would not result in the identification of a material weakness. In the event that it is determined that our internal control over financial reporting is not effective, as defined under Section 404, investor confidence in us may be adversely affected and could cause a decline in the market price of our stock.

***Future changes in financial accounting standards may adversely affect our reported results of operations.***

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A change in accounting standards can have a significant effect on our reported financial results. New accounting pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. These new accounting pronouncements may adversely affect our reported financial results.

*If our accounting estimates are not correct, our financial results could be adversely affected.*

Management judgment and estimates are necessarily required in the application of our Critical Accounting Policies. If our estimates are incorrect, our future financial operating results and financial condition could be adversely affected. The Company's critical accounting policies that are impacted by management's judgments, assumptions and estimates are set forth in the

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Management's Discussion and Analysis of Financial Condition and Results of Operations of the Company's Annual Report on Form 10-K for the year ended December 31, 2009 as filed with the SEC on March 29, 2010. Since December 31, 2009, there have been no material changes in the Company's critical accounting policies.

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

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. (Removed and Reserved).**

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

**Exhibits**

- 10.1\* Employee Agreement by and between Microfluidics International Corporation and Peter F. Byczko dated September 1, 2010 (Incorporated by reference from the Registrant's Current Report on Form 8-K filed with the Commission on September 8, 2010)
- 10.2\* Employee Agreement by and between Microfluidics International Corporation and William J. Conroy dated September 3, 2010 (Incorporated by reference from the Registrant's Current Report on Form 8-K filed with the Commission on September 8, 2010)
- 31.1 Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

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- 32.1 Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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\* Represents a management contract or compensatory plan or arrangement

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**SIGNATURES**

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

**MICROFLUIDICS INTERNATIONAL  
CORPORATION**

By: /s/ Michael C. Ferrara  
Michael C. Ferrara  
President and Chief Executive Officer  
(Principal Executive Officer)

By: /s/ Peter F. Byczko  
Peter F. Byczko  
Vice President of Finance & Chief Accounting Officer  
(Principal Financial and Accounting Officer)

Dated: November 15, 2010