BIODELIVERY SCIENCES INTERNATIONAL INC
Form 10KSB
April 03, 2006
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-KSB

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x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2005

¨ 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 0-28931

BioDelivery Sciences International, Inc.

(Name of small business issuer in its charter)

Delaware	**35-2089858**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2501 Aerial Center Parkway, Suite 205 Morrisville, NC	**27560**

(Address of principal executive offices) **(Zip Code)**

Issuer s telephone number: (919) 653-5160

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, $.001 par value;

Class A common stock purchase warrants

(Title of class)

Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act ¨

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the past 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 x No ¨

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B is not contained in this form, and no disclosure will be contained, to the best of issuer s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. ¨

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

Issuer s revenues for fiscal year 2005 were $849,562.

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of March 27, 2006 was approximately $17,259,990 based on the closing sale price of the company s common stock on such date of U.S. $2.51 per share, as reported by the Nasdaq Capital Market (formerly known as the Nasdaq SmallCap Market).

As of March 27, 2006, there were 11,908,146 shares of the company s common stock outstanding.

Transitional Small Business Disclosure Format: Yes ¨ No x

EXPLANATORY NOTE

Readers of this Annual Report on Form 10-KSB should be aware that, included in the audited financial statements included herein, is a restatement of certain aspects of our unaudited financial statements for the quarters ended March 31, 2005, June 30, 2005 and September 30, 2005. Readers are therefore cautioned that our previously released financial statements for such periods as filed with the Securities and Exchange Commission should not be relied upon.

These quarterly financial statements were restated solely as a result of revised accounting treatment related to our issuance of financial instruments in February and May 2005 to Laurus Master Fund, Ltd. and to properly record the gain or loss resulting from the fair value adjustment of such financial instruments.

Our determination to make such restatements was made by our board of directors, as well as the audit committee of the board, on March 29, 2006, and was discussed with our independent registered public accounting firm.

In February 2005, we issued a $2.5 million convertible note and a warrant to purchase 350,000 shares of our common stock to Laurus as part of a financing transaction. In May 2005, we issued another $2.5 million convertible note and a warrant to purchase 483,871 shares of our common

stock to Laurus as part of a second financing transaction. Using the guidance in EITF 00-27, Application of EITF Issue No. 98-5, Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios, we had previously accounted for the freestanding warrants and embedded beneficial conversion option associated with the convertible notes as equity.

As a result of our determination, the value of the warrants are now reflected as a financial instrument in the current liabilities section of the our balance sheet as a result of the application of EITF 00-19, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock . We are also required to revalue the liability at each reporting period to reflect the current fair value of the financial instruments. The gain or loss associated with this revaluation is recorded as a component of income (loss) from continuing operations. The accounting changes had no cash flow impact on our company.

This change requires restatement of our unaudited quarterly financial information for the periods ending March 31, 2005, June 30, 2005 and September 30, 2005. No amendments have been made to our Quarterly Reports on Form 10-QSB for the quarters ended March 31, 2005, June 30, 2005 and September 30, 2005 as all relevant changes have been reflected in Footnote 14 to the audited financial statements included with this Report.

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NOTE ON FORWARD-LOOKING STATEMENTS

This Report, including the documents incorporated by reference in this Report, includes forward-looking statements. We have based these forward-looking statements on our current expectations and projections about future events. Our actual results may differ materially from those discussed herein, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as believe, expect, anticipate, intend, estimate, plan, project and other similar expressions. In addition, any statements that refer to expectations or other characterizations of future events or circumstances are forward-looking statements. Forward-looking statements included in this Report or our other filings with the SEC include, but are not necessarily limited to, those relating to:

- our plans regarding the timing and outcome of research, development, commercialization, manufacturing, marketing and distribution efforts relating to the Bioral® and BEMA technology platforms and any proposed formulations or products relating thereto;
- the domestic and international regulatory process relating to our technologies and proposed products and formulations, including the timing, status and results of our filings with the U.S. Food and Drug Administration, which we refer to herein as the FDA, and the timing, status and results of pre-clinical work and clinical studies;
- our ability to generate commercial viability and acceptance of our Bioral® and BEMA technology platforms and our proposed formulations and products, including Emezine®;
- our ability to finance our operations on acceptable terms, either through the raising of capital, the incurrence of convertible or other indebtedness or through strategic financing partnerships;
- the protection and control afforded by our interest in licensed patents, or our ability to enforce our rights under such licenses;
- our ability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed products and formulations;
- the ability of our sublicense partners to commercially exploit our drug delivery platforms and our ability to enter into sublicenses and to receive royalty and other payments from parties to whom we have sublicensed our technologies;
- our ability to retain members of our management team and our employees;
- our ability to receive federal, state, government or private grants; and
- the competition that may arise in the future.

The foregoing does not represent an exhaustive list of risks. Please see Risk Factors for additional risks which could adversely impact our business and financial performance. Moreover, new risks emerge from time to time and it is not possible for our management to predict all risks, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. All forward-looking statements included in this Report are based on information available to us on the date of this Report. Except to the extent required by applicable laws or rules, we undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained throughout this Report.

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PART I

Item 1. Description of Business.

Overview

We are a specialty biopharmaceutical company that is exploiting its licensed and proprietary patented drug delivery technologies to develop and commercialize, either on our own or in partnerships with third parties, clinically-significant new formulations of proven therapeutics.

Our development strategy focuses on the utilization of the U.S. Food and Drug Administration s 505(b)(2) approval process to obtain more timely and efficient approval of new formulations of previously approved therapeutics which incorporate our licensed drug delivery technologies. Because the 505(b)(2) approval process is designed to address new formulations of previously approved drugs, we believe it has the potential to be more cost efficient and less time consuming than other approval methods of the U.S. Food and Drug Administration, which we refer to herein as the FDA.

Our drug delivery technologies include:

- the patented BEMA (transmucosal, or applied to the inner cheek membrane) drug delivery technology, and
- the patented Bioral® nanocochleate drug delivery technology, designed for a potentially broad base of applications.

Utilizing our licensed delivery technologies, we are currently developing formulations of pharmaceuticals aimed principally at acute (i.e., short term) conditions occurring in cancer and surgical patients such as:

- pain,
- nausea and vomiting,
- insomnia, and
- fungal infections

We also believe our drug delivery technologies have the potential to be applied to other types of pharmaceuticals. In addition to our Bioral® and BEMA platforms, we are also the exclusive U.S. licensee for Emezine®, a treatment of nausea and vomiting.

We currently generate revenue from licensing milestone payments and royalties, and have generated revenue from grants. Ultimately, if we secure approval from the FDA for our licensed and/or proprietary products and formulations, our goal will be to augment these revenues from sales of such products and formulations, on which we will pay royalties or other fees to our licensors and/or third-party collaborators.

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We intend to finance our research and development, commercialization and distribution efforts and our working capital needs primarily through:

- applying our licensed technologies to existing therapeutics to create our own proprietary formulations, which we will then seek to obtain FDA approval for and subsequently commercialize,
- licensing and joint venture arrangements with third parties, including pharmaceutical companies whose own proprietary pharmaceutical products may benefit from our drug delivery technologies,
- partnering with pharmaceutical companies to assist in the distribution of our products, and
- proceeds raised from our public and private financings and strategic transactions.

Our BEMA drug delivery technology consists of a small, dissolvable polymer disc for application to mucosal (inner lining of cheek) membranes. BEMA discs deliver a rapid, reliable dose of drug across mucous membranes for time-critical conditions like breakthrough cancer pain (i.e., episodes of severe pain which break through the medication used to control the persistent pain), or trauma cases where intravenous lines or injections are unavailable or not practical. We license the BEMA drug delivery technology on a worldwide exclusive basis from Atrix Laboratories, Inc. (now a wholly-owned subsidiary of QLT Inc.), which we refer to herein as Atrix.

Our lead BEMA product under development is BEMA Fentanyl, a treatment for breakthrough cancer pain. This product entered into Phase III trials for breakthrough cancer pain in the second half 2005. On July 15, 2005, we entered into a clinical development and licensing agreement with Clinical Development Capital, LLC, which we refer to herein as CDC, which will provide up to $7 million toward the Phase III clinical development of BEMA Fentanyl. On February 16, 2006, we announced that, as a result of our achievement of certain milestones called for under our CDC agreement, CDC made an initial $2 million payment to us, which will be followed by subsequent monthly payments through the BEMA Fentanyl Phase III program. We expect that the funds which we shall receive from CDC will represent a majority of the funds we will need to fund the BEMA Fentanyl Phase III clinical program.

A second product under development, BEMA Long Acting Analgesic, which we refer to herein as BEMA LA, is a BEMA formulation of an already approved product in the U.S. that will target a broader range of pain conditions including post operative and, potentially, chronic pain due to osteoarthritis, lower back disorders and rheumatoid arthritis. In early December 2005, we submitted an Investigational New Drug Application, or IND, with FDA for BEMA LA. We intend to enter clinical development with BEMA LA in the second quarter of 2006 and expect to finalize our Phase III program and prepare for Phase III trials in the fourth quarter of 2006.

A third product under development, BEMA Zolpidem, is a BEMA formulation of the most widely prescribed drug for the treatment of insomnia. We intend to submit an IND on BEMA Zolpidem during the fourth quarter of 2006.

We are also developing Emezine®, a formulation of prochlorperazine, which we believe will be the first drug to be delivered transmucousally for treatment of nausea and vomiting. In February 2005, we announced that we completed the clinical studies required for our New Drug Application, or NDA, on Emezine® and, on April 29, 2005, we submitted such NDA. The FDA accepted our NDA for filing on

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June 30, 2005. On February 28, 2006, however, we received a non-approvable letter from the FDA regarding our Emezine® NDA. The non-approvable letter stated that additional information would be required to address remaining questions. As of the date of this Report, we have requested a meeting with the FDA regarding their notification and will use the outcome of this meeting to evaluate the direction we intend to pursue regarding Emezine®. No assurances can be given that we will be able to satisfy any FDA concerns regarding Emezine®, and we may be forced to abandon this project. Despite the fact Emezine® represents a relatively small portion of our potential future revenues, the failure to achieve FDA approval of Emezine® could have a material adverse effect on our business. We do not, however, expect that such failure would seriously impair our overall potential future revenue growth. We licensed Emezine® from Reckitt Benckiser Healthcare (UK) Limited, which we refer to herein as Reckitt.

Our Bioral® drug delivery technology encapsulates the selected drug in a nanocrystalline structure termed a cochleate cylinder. All of the components of the cochleate cylinder are naturally occurring substances. We believe that the cochleate cylinder provides an effective delivery mechanism without forming a chemical bond, or otherwise chemically altering, the selected drug. We believe this technology will allow us to take certain drugs that were only available by intravenous injection and convert them to formulations that can be taken orally. Our Bioral® drug delivery technology was developed in collaboration with The University of Medicine and Dentistry of New Jersey, which we refer to herein as UMDNJ, and the Albany Medical College, which we refer to herein, collectively with UMDNJ, as the Universities, each of which has granted us the exclusive worldwide licenses under applicable patents.

Our lead Bioral® formulation is an encochleated version of Amphotericin B, an anti-fungal treatment for treating systemic fungal infections. A Bioral® formulation of Amphotericin B would have the potential for oral delivery of a drug that is currently only given by intravenous injection. Bioral® Amphotericin B is currently in the last stages of preclinical testing. Following the completion of this testing, we intend to submit an IND for Bioral® Amphotericin B in second or third quarter of 2006, which will immediately be followed by a Phase I clinical trial.

A second formulation for intranasal administration Amphotericin B to treat chronic rhinosinusitis, or CRS, is now in development. In April 2004, we licensed this second product to Accentia Biopharmaceuticals, Inc., an affiliate of ours which we refer to herein as Accentia, for the use in the treatment of CRS and asthma. Certain of our officers and directors are officers, directors and/or stockholders of Accentia or its subsidiaries.

We have also explored other potential applications of our encochleation technology, including the creation of cochleate formulations of siRNA therapeutics, certain vaccines and important nutrients. In 2005, we entered into agreements with third parties for the evaluation of cochleate formulations of siRNA therapeutics. We believe this may represent a significant opportunity to deliver these therapeutics, which are normally difficult to use and which are easily destroyed in the plasma by the body s natural enzymes, to patients.

During 2005, we actively pursued strategic financing and related partnerships regarding certain of our proposed formulations and products as we attempt to move them through the development, approval and commercialization phases. The FDA non-approvable notification regarding Emezine® means that revenues we had previously projected as potentially being generated upon the launch of Emezine® in 2006 may be delayed or not generated at all. Therefore, in part to offset the potential loss of projected Emezine® revenue, we are continuing our strategic partnership initiatives in 2006 with equal vigor and hope to consummate one or more such transactions in 2006. In particular, we are likely to pursue strategic transactions, such as those with Sigma-Tau and CDC (each described in more detail below), which are designed around a particular product or products.

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Recent and Historical Events

2005 Public Offering

In early October 2005, we announced the consummation of a follow on public offering of 4,400,000 shares of our common stock, resulting in gross proceeds of $8.8 million to us. The public price per share for the offering was $2.00. The offering was underwritten by Ferris, Baker Watts Incorporated, Maxim Group LLC and GunnAllen Financial, Inc. The underwriters were granted an option to purchase up to an additional 660,000 shares of our common stock to cover over-allotments, which option was partially exercised in late October 2005, generating additional gross proceeds of $107,900.

Laurus Financings

On February 22, 2005, we consummated a $2.5 million secured convertible debt financing from Laurus Master Fund, Ltd., which we refer to herein as Laurus. Net proceeds from the financing were used primarily to retire our secured equipment loan with Gold Bank (on which approximately $300,000 was owed and was paid at the closing of the Laurus transaction), to support our research and development opportunities and for general working capital purposes.

The February Laurus investment takes the form of a convertible note secured by certain of our assets. The note has a 3-year term and bears interest at a rate equal to prime plus 2% per annum. The note is convertible, under certain conditions, into shares of our common stock at a price equal to $3.10 per share. As a result of the anti-dilution provisions of the February Laurus note and the pricing of our October 2005 public offering, the conversion price of the February Laurus note is now $2.46.

In connection with this financing, we also issued Laurus a common stock purchase warrant to purchase up to 350,000 shares of our common stock at a price equal to $3.88 per share. A registration statement we filed with the SEC to register the shares of common stock underlying the February Laurus note and the warrant was declared effective on June 20, 2005.

On May 31, 2005, we closed an additional $2.5 million secured convertible debt financing from Laurus. As with the February 2005 Laurus financing, this financing takes the form of a secured convertible note and a warrant to purchase 483,871 shares of our common stock. Net proceeds from the May Laurus financing are to be used to support our research, development and commercialization opportunities and for general working capital purposes. As a result of the anti-dilution provisions of the May Laurus note and the pricing of our October 2005 public offering, the conversion price of the May Laurus note is now $2.46.

In addition, on June 29, 2005, we entered into two separate amendments to our February and May 2005 financing agreements with Laurus under which Laurus agreed to defer payments by us of principal under the February and May 2005 Laurus notes until December 1, 2005. In consideration of Laurus agreement, we issued to Laurus two warrants, one to purchase 22,500 shares of our common stock (in connection with the February amendment) and a second to purchase 7,500 shares of our common stock (in connection with the May amendment). In each case, such warrants are exercisable into shares of our common stock at an exercise price of $.001 per share and expire on June 29, 2012. Except for the exercise price of the warrants, the warrants issued to Laurus in connection with the foregoing amendments are substantially similar to the warrants issued to Laurus on February 22, 2005 and May 31, 2005. We agreed to register the shares of common stock underlying the May note and warrant and the June warrants with Laurus with the SEC, which registration statement was declared effective on July 11, 2005.

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Lastly, on December 28, 2005, we entered into two separate second amendments to our February and May 2005 financing agreements with Laurus under which Laurus agreed to defer payments by us of certain monthly principal amounts, as well as all of the previously postponed principal amounts due to Laurus addressed in our June 29 amendments, until July 1, 2006. In consideration of Laurus agreement to postpone such payments, we issued to Laurus two additional warrants, one to purchase 39,574 shares of our common stock (in connection with the February amendment) and a second to purchase 29,700 shares of our common stock (in connection with the May amendment). In each case, such warrants are exercisable into shares of our common stock at an exercise price of $.001 per share and expire on December 28, 2012. Except for the exercise price of the warrants, the warrants issued to Laurus in December 2005 are substantially similar to the warrants issued to Laurus on February, May and June 29, 2005. We have agreed to register the shares of common stock underlying the December 2005 Laurus warrants with the SEC, pursuant to a registration statement required to be filed by July 10, 2006.

CDC Development and Licensing Agreement

On July 15, 2005, we entered into a clinical development and license agreement with CDC pursuant to which CDC will provide, subject to certain conditions, up to $7 million in funding (including a $2 million upfront payment and subsequent monthly payments over a year) for the clinical development of our BEMA Fentanyl product. The total of the upfront payment and monthly payments shall not exceed, in the aggregate, the lesser of: (i) $7 million or (ii) the costs incurred in conducting the clinical development of BEMA Fentanyl, and such monthly amounts are subject to downward adjustment depending on the achievement by us of patient enrollment targets. All funds made available to us under our transaction with CDC must be repaid to CDC within 60 days of FDA approval of BEMA Fentanyl and therefore will be accounted for as a refundable deposit.

On February 16, 2006, we announced that, as a result of our achievement of certain milestones called for under our CDC agreement, CDC made its initial $2 million payment to us, which will be followed by subsequent monthly payments over a year through the BEMA Fentanyl Phase III program.

Under the agreement, CDC is entitled to receive:

- as referenced above, a milestone fee equal to the lesser of $7 million or the actual amount provided by CDC for development of BEMA Fentanyl;
- royalties based on net sales of BEMA Fentanyl (including minimum royalties); and
- a portion of any licensing revenue received by us prior to FDA approval of BEMA Fentanyl, which will be credited against our initial milestone payment to CDC.

In addition, we granted CDC a warrant exercisable for up to 500,000 shares of our common stock at an exercise price of $3.50 per share. As a result of the anti-dilution provisions of the CDC warrant and the pricing of our October 2005 public offering, the conversion price of the CDC warrant is now $2.91.

Upon execution of the CDC agreement, all data, information, and intellectual property rights concerning BEMA Fentanyl were exclusively licensed to CDC, subject to CDC s return grant of an exclusive license for us to utilize all such information and rights. Further, CDC shall own all data generated in the course of the product development supported by its funds, provided that we shall have an exclusive license to use such data for purposes of our development and commercialization of BEMA Fentanyl.

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Royalties under the CDC agreement are subject to upward adjustments: (i) for delays in obtaining regulatory approval for BEMA Fentanyl, (ii) for the market entry of certain defined competing products in the United States prior to the first commercial sale of BEMA Fentanyl, or (iii) if the average selling price of BEMA Fentanyl is less than that of certain defined competing products. In the event we do not diligently pursue the development and regulatory approval of BEMA Fentanyl or if we encounter certain specified negative circumstances regarding the development of BEMA Fentanyl, CDC has the right to pursue development and commercialization of BEMA Fentanyl pursuant to an exclusive, world-wide, royalty-free license, which includes the right to sublicense, and the assignment of our BEMA Fentanyl assets to CDC, provided that, under certain conditions, we may, despite such negative circumstances, retain our rights to BEMA Fentanyl and continue pursuing its development and/or commercialization itself subject to the reimbursement of all funding provided by CDC and payment of all royalties due, pro rated based on the amount of funding provided by CDC, under the development agreement.

The warrant issued to CDC is currently exercisable at $2.91 per share (originally $3.50, which exercise price was adjusted as a result of our October 2005 public financing) and contains certain anti-dilution provisions with respect to certain issuances of stock (or issuance of securities convertible into stock) at a price per share less than the exercise price stated in the warrant during the six months following its issuance. Also, the number of shares for which the warrant may be exercised are subject to adjustment based on the amount of funding provided by CDC, provided the warrant shall not, in any event, be exercisable for less than 100,000 shares of our common stock. Finally, such warrant expires after the earlier of: (i) 5:00 p.m. Eastern Time on the second anniversary of the approval by the FDA of the first NDA relating to BEMA Fentanyl, (ii) the closing of a sale of all or substantially all of our assets or the acquisition of our company by another entity by means of merger or other transaction as a result of which our stockholders immediately prior to such acquisition possess a minority of the voting power of the acquiring entity immediately following such acquisition, or (iii) any liquidation or winding up of our company.

Pursuant to the CDC development agreement, and concurrently with the timing of CDC s initial $2.0 million payment to us, we entered into a security agreement granting CDC a security interest in assets related to BEMA Fentanyl, which interest terminates upon our payment to CDC of the milestone payment (due within sixty (60) days of FDA approval of BEMA Fentanyl) equal to the lesser of $7 million or the actual amount provided by CDC for development of BEMA Fentanyl.

Acquisition of Arius Pharmaceuticals, Inc.

On August 24, 2004, we consummated the acquisition of Arius Pharmaceuticals, Inc. Arius is a specialty drug delivery company developing products for the acute treatment opportunities such as pain, anxiety, nausea and vomiting, targeted primarily to surgical and oncology patients. In 2004, Arius acquired an exclusive worldwide license to the BEMA delivery technology developed by Atrix, and also acquired the U.S. license rights to a transmucousally delivered tablet formulation of Emezine®.

Simultaneously with the closing of the Arius acquisition, Mark A. Sirgo, Pharm.D., a founder and the President and CEO of Arius, entered into an employment agreement with us and was named Senior Vice President of Commercialization and Corporate Development. Andrew L. Finn, Pharm.D., also a founder and the Chief Operating Officer of Arius, also entered into an employment agreement with us and was named Senior Vice President of Product Development at BDSI. Subsequent to the Arius closing, Dr. Sirgo was promoted through several positions and currently serves as the President and Chief Executive Officer of our company. Dr. Finn was, subsequent to the Arius closing, promoted to the position of Executive Vice President of Clinical Development and Regulatory Affairs of our company.

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Hopkins Capital Group Equity Line of Credit

On September 3, 2004, we entered into an Equity Line of Credit Agreement with Hopkins Capital Group II, LLC, which we refer to herein as HCG, a principal stockholder of our company which is controlled and partially-owned by Dr. Francis E. O Donnell, Jr., our Chairman of the Board. Pursuant to the Equity Line Agreement, HCG will, at our request, invest up to $4.0 million in our company from August 23, 2004 through March 31, 2006 in consideration of shares of a newly created class of Series B Convertible Preferred Stock, or Series B Preferred. On March 30, 2006, we amended our agreement with HCG to extend the commitment period from March 31, 2006 to December 31, 2006. As of the date of this Report, $1.45 million has been drawn under the Equity Line Agreement.

Sigma-Tau License and Stock Purchase Transaction

On January 20, 2005, we signed a definitive licensing agreement with Sigma-Tau Industrie Farmaceutiche Riunite S.p.A., or Sigma-Tau Pharma, for the application of our Bioral® nanocochleate delivery technology to formulate up to four proprietary pharmaceutical compounds currently under development by Sigma-Tau Pharma. Sigma-Tau Pharma is an affiliate of The Sigma-Tau Group, one of Italy s leading pharmaceutical companies. Simultaneously with this licensing agreement, we entered into a stock purchase agreement with, and received a non-refundable upfront payment of US$250,000 from, Sigma-Tau, a holding company of The Sigma-Tau Group. This upfront payment was applied toward the purchase by Sigma Tau of unregistered shares of our common stock priced at $4.25 a share. The stock purchase agreement with Sigma-Tau provides for the purchase by Sigma-Tau, upon the occurrence of specified developmental milestones associated with the license, of additional unregistered shares of our common stock, up to an aggregate potential of $1.5 million worth of such shares. These milestones lead up to and include the submission of product INDs by Sigma-Tau Pharma for one or more of the four subject encochleated compounds. Sigma-Tau, through other holding entities, is currently a stockholder of our company. In addition to the milestone payments, we will receive a royalty on future sales of each of the four products which may arise from the encochleated compounds.

2002 Initial Public Offering

In June 2002, we conducted our initial public offering which consisted of 2 million units, which we refer to herein as Units, with each Unit consisting of: (i) one share of our common stock and (ii) one Class A common stock purchase warrant, or Warrants. Each Warrant entitles the owner to purchase one share of our common stock at a price of $6.30 through June 24, 2007. The net offering proceeds we received were $8,571,397.

Subsequent Events

The following material events occurred subsequent to December 31, 2005:

On March 30, 2006, we amended our agreement with HCG to extend the commitment period of our $4.0 million equity line of credit agreement with HCG from March 31, 2006 to December 31, 2006. Except for the extension of the commitment period, no other terms or conditions of equity line of credit were amended.

On February 28, 2006, we received a non-approvable letter from the FDA regarding our Emezine® NDA. The non-approvable letter stated that additional information would be required to address remaining questions. As of the date of this Report, we have requested a meeting with the FDA regarding their notification and will use the outcome of this meeting to evaluate the direction we intend to pursue regarding Emezine®.

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On February 16, 2006, we announced that we had received the initial $2 million payment under our agreement with CDC.

On February 2, 2006, we announced our engagement of Addison Whitney, Inc. to develop the brand identity and brand strategy for our BEMA drug delivery technology and BEMA Fentanyl. We believe the branding process is a critical component of our BEMA commercialization strategy.

On January 9, 2006, we announced the appointment of Mark W. Salyer, a former executive with Altana Pharma AG and GlaxoSmithKline, to the newly created position of Executive Vice-President of Sales and Marketing. Mr. Salyer will be designing the commercial strategy around our proposed products and formulations, including BEMA Fentanyl and BEMA LA. He will also work to identify key partnerships including co-promotional agreements worldwide where they are deemed necessary to support our business strategy.

Overview of Specialty Pharmaceuticals and the 505(b)(2) Regulatory Pathway

Since our inception, we have focused primarily on research and development of our licensed Bioral® encochleation technology and the application of such technology to specific drugs. The drug delivery industry develops technologies for the improved administration of certain drugs. These technologies, including our own, have focused primarily on safety, efficacy, ease of patient use and patient compliance.

In 2004, however, and in particular as a result of our acquisition of Arius, we began (and continue) to shift our corporate focus to what we call the area of specialty pharmaceuticals : applying our licensed technologies to existing therapeutics to create our own proprietary formulations, for which we then seek to obtain FDA approval and subsequently commercialize. We believe that focusing our drug delivery technologies for use with existing FDA approved drugs to be less risky than attempting to discover new drugs, sometimes called new chemical entities, or NCEs. This transition in corporate focus continued in 2005 as we continued development of our principal products and formulations toward regulatory submissions.

An important part of our strategy is to attempt to capitalize on the FDA s 505(b)(2) approval process to obtain more timely and efficient approval of our formulations of previously approved therapeutics. Under the 505(b)(2) approval process, we are able to seek FDA approval of a new dosage form, dosage regimen or new indication of a pharmaceutical that has previously been approved by the FDA. This regulation enables us to partially rely on the findings of third parties which the FDA has published on approved pharmaceuticals, including clinical and non-clinical testing, thereby reducing, though not eliminating, the need to engage in these costly and time consuming activities. A typical development program for a 505(b)(2) submission will include:

a single genotoxicity study with the drug substance,

a 14 or 28-day multiple dose toxicity study in a single species,

limited pharmacokinetic evaluation of the new dosage form in humans,

two placebo controlled studies in humans,

stability of drug substance,

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full description of drug product manufacturing process,

1 year stability data on 3 batches at commercial scale, and

special studies specific to the formulation.

This approval program is designed to be significantly less extensive and lengthy and, as a result, we believe, more cost efficient than attempting to gain approval of an NCE. By utilizing this regulatory process and focusing on creating new formulations of established pharmaceuticals that could potentially benefit from association with our delivery technologies, we believe that we will more quickly and efficiently navigate the FDA approval process, and, if such approval is obtained, of which no assurances can be given, move our formulations to market.

As part of our strategy, however, we will also continue to seek partners, such as Sigma Tau, to whom we can license our delivery technologies so that they may be applied to the proprietary products of such partners. Drug delivery technologies can provide pharmaceutical and biotechnology companies with an avenue for developing new drugs, as well as extending existing drug patent protections. Drug delivery companies can also apply their technologies to drugs no longer patent protected. Pharmaceutical and biotechnology companies view new and improved delivery technology as a way to gain competitive advantage through enhanced safety, efficacy, convenience and patient compliance of their drugs, and we will continue to attempt to leverage this desire in the pharmaceutical industry for improved delivery systems.

We have and intend to continue to primarily target drugs that have large established markets for which there is an established medical need. As a result, doctors are familiar with the drug compounds and are accustomed to prescribing them. As with BEMA Fentanyl and Emezine®, we anticipate that many of the drug candidates we target will have been through the regulatory process and therefore the safety and efficacy of the drug has been previously established. Consequently, we believe that our clinical trials would primarily need to show that our Bioral® or BEMA technologies deliver the drug without harming the patient or changing the clinical attributes of the drug. Focusing on drug delivery compared to drug discovery should allow us to potentially form a number of collaborations to deliver a wide variety of medicines without limiting rights to utilize our proprietary technology with additional drug opportunities.

Pipeline of Proposed Formulations and Products

The following table summarizes the status of our currently proposed formulations and products:

Formulation/Product	Indication	Development Status	Commercial Status*
BEMA Fentanyl	Breakthrough cancer pain	Phase III	In-house commercialization for specialty indications
BEMA Long Acting Analgesic	Moderate and Severe Pain	IND Filed	In-house commercialization for specialty indications, primary care rights to be partnered
Bioral® Amphotercin B	Fungal infections	Pre-clinical	In-house commercialization
BEMA Zolpidem	Insomnia	Pre-clinical	In-house commercialization for specialty indications, primary care rights to be partnered
Emezine®	Nausea/Vomiting	FDA non-approvable received; Discussions	Partnered

with FDA ongoing

* Partnership options may be considered for certain of these products on a case by case basis.

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Although we have investigated other projects in the past, including certain of those discussed under Licensing Opportunities and Other Projects below, we are presently dedicating most of our corporate resources toward the development and commercialization of BEMA Fentanyl (the Phase III clinical development of which is being financed through our agreement with CDC), BEMA LA and Biora® Amphotericin B. After these programs, and depending on the availability of corporate resources, we hope to begin to fund the development of BEMA Zolpidem.

Description of Our Drug Delivery Technologies and Proposed Formulations and Products

We have based our estimates of development costs and related matters described below on our market research, third party reports and publicly available information which we consider reliable. However, readers are advised that the projected dates for filing INDs or NDAs, our estimates of developments costs and our projected sales associated with each of our formulations discussed below and elsewhere in this Report are merely estimates and subject to many factors, many of which may be beyond our control, which could cause delays and or cost overruns or otherwise cause us to revise such estimates. Readers are also advised that our projected sales figures do not take into account the royalties and other payments we will need to make to our licensors and strategic partners. Our estimates are based upon our management s reasonable judgments given the information available and their previous experiences, but no assurances can be given that such estimates will prove to be accurate.

BEMA Technology Overview

Licensed to us from a third party, BEMA stands for bioerodible mucoadhesive. BEMA discs are approximately the size of a coin and are composed of an adhesive layer and a non-adhesive backing layer made of polymers, with both layers capable of holding the desired drug. Upon application, the disc adheres to the mucosal surface (inner lining of the cheek) and delivers the dose of medication rapidly and efficiently, making it an excellent delivery system for time-critical conditions such as nausea, vomiting and breakthrough cancer pain, or trauma cases where intravenous lines or injections are unavailable or not practical. The BEMA system permits control of two critical factors allowing for better dose to dose reproducibility: (i) the contact area for mucosal drug delivery, and (ii) the time the drug is in contact with that area, known as residence time.

In contrast to competing transmucosal delivery systems like lozenges and matrix-based delivery systems placed under the tongue or sprayed in the oral cavity, BEMA products:

Adhere to mucosa in seconds and dissolve in minutes;

Permit absorption to be determined by the product, with patients not being required to swish or move the product around in the mouth for absorption;

Have a narrow, reproducible delivery rate, not susceptible to varying or intermittent contact with mucus membranes;

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Dissolve completely, leaving no residual product or waste unlike certain other systems; and

Have relatively inexpensive cost of goods, unlike certain other systems.

Current BEMA Formulations In Development

BEMA Fentanyl

The global market for pain medication is projected to generate $26 billion in 2006. It is estimated that between $2 billion and $4 billion is spent to treat breakthrough pain, and the market for breakthrough cancer pain (the proposed indicated for BEMA Fentanyl) is a subset of this market. The leading product for breakthrough cancer pain is the U.S. market is Actiq®, which had reported sales of $411.8 million in 2005. Cephalon s pain franchise (consisting of Actiq® and OraVescent fentanyl) is projected by Cephalon to obtain sales of $425-$475 million in 2006.

We believe there is a clear need and growing market for additional narcotic agents in alternative dosage forms to provide rapid pain relief. Fentanyl belongs to the group of medicines called narcotic analgesics. Narcotic analgesics are used to relieve pain. The transmucosal form of fentanyl is a powerful narcotic used to treat breakthrough cancer pain. Fentanyl applied with our licensed BEMA technology has the potential to meet the need for new narcotics and, we believe, will be ideal for breakthrough pain in opioid-tolerant patients.

After receiving approval for the initial indication of break-through cancer pain, we may pursue additional indications for BEMA Fentanyl in:

Breakthrough pain in non cancer patients;

Post-operative patients following step-down from intravenous narcotics;

Hospitalized patients or outpatients without intravenous access; and

Emergency room patients where available intravenous lines are limited or impractical.

In March 2005, we announced that we received confirmation from the U.S. Food and Drug Administration that we will be able to utilize the FDA s 505(b)(2) process for regulatory approval consideration of our licensed BEMA Fentanyl formulation.

We began preparing for Phase III clinical studies of BEMA Fentanyl in the fourth quarter of 2005 and in November 2005, we announced the results of a 12 subject study comparing BEMA Fentanyl and Actiq®. The results showed that the BEMA Fentanyl formulation showed greater bioavailability (absorption), higher maximum plasma concentrations (Cmax) and faster concentrations of fentanyl in the plasma (t-first and t-max) compared to Actiq®. In addition, and also in November 2005, we announced that we entered into a supply agreement with Aveva Drug Delivery Systems, Inc., or Aveva, under which Aveva will prepare clinical supplies for our Phase III BEMA Fentanyl trials and provide commercial manufacturing for BEMA Fentanyl. Also, in February 2006, we received our initial $2 million payment from CDC to fund our BEMA Fentanyl Phase III trials. We estimate that the total development costs of this formulation will exceed $8 million.

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We believe that BEMA Fentanyl may have the potential to capture a significant share of the breakthrough cancer pain market in the U.S., which we estimate could result in annual peak sales of approximately $250 million, although no assurances can be given of this estimation.

BEMA Long Acting Analgesic

In addition to our lead BEMA product, BEMA Fentanyl, we are also developing a second analgesic product with a longer duration of action suited for a broad range of pain conditions. In November 2005, we announced our intention to enter clinical development with BEMA LA in the first quarter of 2006 and our expectation of commencing Phase III trials in the second half of 2006. Also, in early January 2006, we announced that we submitted an IND with the FDA for BEMA LA. We estimate that the total development costs of this formulation will be approximately $14 million.

The pain market is well established, with many pharmaceutical companies marketing innovative products as well as generic versions of older, non patent protected products. The global pain market is projected to generate $26 billion in 2006. Of this approximately $7 billion are for opioid therapies. The total market for pain treatment is projected to grow to approximately $33 billion by 2014.

BEMA LA contains a marketed opioid analgesic which has equal potency to morphine but with a lower propensity for adverse reactions and addiction. The lower potential for addiction places BEMA LA as a Schedule III controlled substance versus the majority of the other potent opioids, such as morphine and oxycodone, which are Schedule II. This may help create a broader market opportunity for BEMA LA as doctors are able to call Schedule III prescriptions into the pharmacy whereas the prescription for a Schedule II controlled substance must be obtained by the patient from the doctor s office which the patient then must take to the pharmacy for filling. Since the active ingredient in BEMA LA is a Schedule III controlled substance, physicians will be able to phone or fax in the prescription and also allow for refills to be included on the prescription, thus making chronic therapy easier for both the patient and the physician.

The FDA-approved compound which forms the basis of BEMA LA has been shown to produce comparable pain relief to morphine, with an improved safety profile and extended duration of action, but poor oral bioavailability. The BEMA delivery system may enable us to provide this product in a form suitable for ambulatory care and, because of the safety advantage associated with this product, we believe that BEMA LA will be an ideal next step product for patients with incomplete pain relief on non-narcotic analgesics.

Our proposed BEMA formulation of this long acting analgesic is intended to meet the need for a new narcotic and will be ideally used for:

- Post-operative pain;
- Chronic pain, including lower back, osteoarthritis and rheumatoid arthritis; and
- Non-malignant breakthrough pain.

Compared to currently marketed products and products under development, we believe that BEMA LA will be differentiated based on the following features:

- efficacy equivalent to morphine but unlike morphine is a Schedule III narcotic making it more convenient for physicians to prescribe, pharmacists to dispense, and patients to obtain,

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broad applicability across a wide spectrum of patients with varying types of moderate to severe pain either used in combination with less potent analgesics such as Nonsteroidal anti-inflammatory drugs, or NSAIDS, or used as sole therapy,

a longer half life which allows for less frequent dosing, thus potentially increasing patient compliance,

an established safety profile compared to the agents in development, and

potential for improved safety, including a lower incidence of constipation and, based on its Schedule III designation. a lower propensity for addiction and abuse versus other opioid analgesics.

Due to the ability of BEMA LA to potentially participate in the principal key pain markets (chronic pain, post-operative pain and breakthrough pain), we believe that BEMA LA has the potential to achieve a up to a 2% share of the total worldwide pain market, which is projected to grow to approximately $33 billion by 2014. This would translate into an estimated $500 million in peak annual sales, although no assurances can be given of this estimation.

BEMA Zolpidem

In addition to our two BEMA analgesic products, we intend to commence development of a BEMA formulation of Zolpidem, an FDA-approved compound that has been shown to effectively treat transient and chronic insomnia with few next day residual effects. The standard form of Zolpidem, a swallowed pill, has a typical onset of action 30-45 minutes after taking an oral dose, although this could vary depending on, among other things, the content of the stomach at the time of ingestion. The BEMA delivery system may enable us to provide an onset of action which is in the 10-15 minute range and, since the digestive tract is avoided, potentially provide drug absorption on a more consistent basis. Our proposed BEMA formulation of Zolpidem is intended to meet the need for a product to treat insomnia that has a rapid onset and will be ideally used as a short term treatment for patients with insomnia.

The global insomnia market is well established with many pharmaceutical companies marketing new products as well as generic versions of older, non patent protected products. The global market for insomnia treatments has been projected to be approximately $3.6 billion for 2005 and is estimated to grow to approximately $5.2 billion by 2009 and to approximately $5.5 billion in 2014. BEMA Zolpidem will compete in this market with an indication for the short term treatment of insomnia. Zolpidem is the active ingredient in Ambien®. Ambien® is the world s best selling product for insomnia with 2005 sales of $1.5 billion. Lunesta®, which contains a different active ingredient and was launched in 2005, achieved sales of $329 million in 2005.

Compared to currently marketed products and potential products in development, we believe that BEMA Zolpidem is differentiated based on the following features:

onset of effect in 10-15 minutes versus 30-45 minutes with orally dosed products,

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- no water necessary for administration, reducing the need for elderly patients to urinate during the night, and

- absorption not effected by delayed stomach emptying or first pass metabolism therefore provides for a predictable response every time it is used.

Due to these advantages, we believe that BEMA Zolpidem will effectively compete against current and future insomnia products.

We expect to finalize a formulation for BEMA Zolpidem and file an IND by the end of the fourth quarter of 2006. This will allow us to enter Phase I clinical trials in the first quarter of 2007. Based on the outcome of several Phase I studies to determine the ideal strength and formulation of BEMA Zolpidem, we would anticipate entering into Phase III clinical trials. We estimate that the total development costs of this formulation will be approximately $9.4 million.

Due to the rapid onset characteristics of BEMA Zolpidem, our market research indicates that BEMA Zolpidem has the potential to achieve a 5% share of the total worldwide insomnia market which has a 2010 projected value of approximately $5 billion. This would translate into an estimated $250 million in peak annual sales, although no assurances can be given of this estimation.

Emezine®

We have licensed the U.S. rights to a transmucously delivered formulation of prochlorperazine called Emezine®, an anti-nausea and vomiting medication used for treating nausea and vomiting which occurs after surgeries, chemotherapy and for nausea and vomiting associated with flu and migraines. This is not a BEMA formulation, but rather a formulation administered by placing a tablet between the bridge of the upper front teeth and gum where it dissolves, enabling the active ingredient to be absorbed through the lining of the cheek. We license Emezine® from Reckitt.

On February 28, 2006, we received a non-approvable letter from the FDA regarding our Emezine® NDA. The non-approvable letter stated that additional information would be required to address remaining questions. Our receipt of this non-approvable notification regarding Emezine® was unexpected because:

- We believe we strictly adhered to the FDA sanctioned plan from March 2004 and generated data that, we believe, supported Emezine® s approvability;

- On June 30, 2005, the FDA accepted the Emezine® NDA for filing, meaning that such NDA contained all necessary elements for review by the FDA;

- The review appeared to be normal and customary based on prior experiences of our management and no obvious red flags were presented; and

- Emezine® contains prochlorperazine, which has been on the market in the U.S. for over 40 years in other dosage forms.

As of the date of this Report, we are mapping out our Emezine® defense strategy and hope to have our follow-up meeting with the FDA by no later than the end of May 2006. Although we plan to discuss and better understand the FDA concerns when we meet, no assurances can be given that we will be able to satisfy such concerns regarding Emezine®, and we may be forced to abandon this project. However, given the relatively small outlays we are actually making on this project, and given that our size

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of market projections regarding Emezine® are relatively small compared to other formulations in our pipeline, we do not presently believe that the failure of this project, though damaging to our market reputation and our stock price, among other matters, would seriously impair our overall potential future revenue growth.

In December 2005, we announced the publication of a pharmacokinetic (PK) study in the Journal of Clinical Pharmacology showing that, in the PK study, plasma concentrations of Emezine® s active ingredient, prochlorperazine, were more than twice as high and less variable than those obtained from a standard oral tablet. In March 2005, we received notice from the FDA that it granted, under a small business exception, our request for a waiver of the FDA s human drug application fee in connection with our pending NDA for Emezine®. We believe this fee would have been approximately $672,000.

Anti-nausea, also known as anti-emetic, products are provided as injectable, oral and rectal formulations. Injectable products require that the patient be in a medical facility and have an intravenous injection line in place. Oral products have limitations because delayed gastric emptying that is associated with nausea and vomiting impedes the absorption of the product and actual product ingestion can be nauseating. Rectal suppositories are inconvenient as well as slow and unpredictable in onset. We believe, therefore, that an alternative delivery system is necessary for anti-emetic products, the market for which we estimate to be approximately $2 billion dollars in the United States. Based on our market research, we believe that the Emezine® buccal tablet formulation may be able to participate in the nausea and vomiting markets, including the separate markets for postoperative, chemotherapy induced and general nausea and vomiting. Such research and estimates indicate that Emezine® may be able to achieve peak sales of approximately $30 million annually, although no assurances can be given of this estimation.

Encochleation Technology Overview

Our licensed Bioral® drug delivery technology is based upon encapsulating (or encochleating) drugs to potentially deliver the drug safely and effectively. Over the years, biochemists and biophysicists have studied artificial membrane systems to understand their properties and potential applications, as well as to gain insight into the workings of more complex biological membrane systems. In the late 1960 s, scientists began investigating the interactions of divalent cations with negatively charged lipid bilayers. They reported that the addition of calcium ions to small phosphatidylserine vesicles induced their collapse into discs which fused into large sheets of lipid. In order to minimize their interaction with water, these lipid sheets rolled up into nanocrystalline structures, termed cochleates, after the Greek name for a snail with a spiral shell.

Our licensed Bioral® cochleate technology is based upon components which are believed to be non-toxic. The primary chemical components of our Bioral® cochleate technology are phosphatidylserine, or PS, and calcium. PS is a natural component of essentially all biological membranes, and is most concentrated in the brain. Clinical studies by other investigators (more than 30 have been published of which we are aware) to evaluate the potential of phosphatidylserine as a nutrient supplement indicate that PS is safe and may play a role in the support of mental functions in the aging brain. As an indication of its non-toxic nature, today phosphatidylserine isolated from soybeans is sold in health food stores as a nutritional supplement.

Research and development of cochleates has been conducted at the Universities for a number of years. Our scientists, some of whom were former researchers and others who still hold teaching positions with these Universities, supervised their cochleate research programs. As a result of the relationship between our scientists and the Universities, we became the exclusive worldwide licensee to develop this cochleate technology and in some cases co-own the patents with them.

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Potential Advantages

We believe that our licensed Bioral® drug delivery technology represents a potentially important new delivery mechanism. While the characteristics and benefits of this technology will ultimately be established through FDA clinical trials, our research, based upon pre-clinical studies indicates that our Bioral® technology may have the following characteristics:

All-natural ingredients. Our Bioral® drug delivery technology uses phosphatidylserine, which can be sourced from soy beans, and calcium. Phosphatidylserine from soybeans is available commercially as a nutritional supplement with FDA-allowed health promotion claims.

Encapsulation. Our Bioral® drug delivery encapsulates, or entraps within a crystal matrix, the subject drug, rather than chemically bonding with the drug.

Enhanced Availability. Our Bioral® drug delivery technology is being developed to enable oral availability of a broad spectrum of compounds, such as those with poor water solubility, and protein and peptide biopharmaceuticals, which have been difficult to administer. Our Bioral® drug delivery technology also has the potential to be applied to substances which are not currently deliverable by traditional means so that they may be delivered via injection or orally.

Minimizing Side Effects. Our Bioral® drug delivery technology may reduce toxicity, stomach irritation and other side effects of the encapsulated drug.

Cellular Delivery. Our Bioral® drug delivery technology is being developed as membrane fusion intermediates. We believe that, when drugs encapsulated in our Bioral® drug delivery technology come into close approximation to a target membrane, a fusion event between the outer layer of the cochleate cylinder and the cell membrane may occur. This fusion may result in the delivery of a small amount of the encochleated material into the cytoplasm of the target cell. Further, we believe that drugs encapsulated in our Bioral® drug delivery technology may slowly fuse or break free of the cell and be available for another fusion event, either with this or another cell.

Stability. Our Bioral® drug delivery technology employs cochleates which consist of multi-layered structures of large, continuous, solid, lipid bilayer sheets, either stacked or rolled up in a spiral, with little or no internal aqueous space. We believe that our cochleate preparations can be stored in cation-containing buffer, or dried, by freezing in a high vacuum environment, to a powder, which is then stored at room temperature and reconstituted with liquid prior to administration. Our cochleate preparations have been shown to be stable for more than two years in cation-containing buffer, and at least one year as a powder at room temperature.

Resistance to Environmental Attack. Our Bioral® drug delivery technology is being developed to provide protection from degradation of the encochleated drug. Traditionally, many drugs can be damaged from exposure to adverse environmental conditions such as sunlight, oxygen, water and temperature. Since the multilayered structure consists of a series of solid layers, we believe that components within the interior of the cochleate structure remain intact, even though the outer layers of the cochleate may be exposed to these conditions.

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Patient Compliance. We believe that a potential benefit of our cochleate cylinders may include reducing unpleasant taste, unpleasant intestinal irritation, and in some cases providing oral availability.

Release Characteristics. Our cochleate technology may offer the potential to be tailored to control the release of the drug depending on desired application.

Initial Bioral® Products in Development

We believe a diverse pipeline of products can be developed by applying our Bioral® drug delivery technology to a potentially broad array of established and promising pharmaceuticals. Each intended Bioral® product (i.e., drug encapsulated with our drug delivery technology) will, upon completion of development, require separate FDA regulatory approval, and accordingly, will be subject to the uncertainty, time and expense generally associated with the FDA regulatory process. Even though we are targeting FDA approved, market- accepted drugs for encapsulation, each of the products currently in development face development hurdles, regulatory requirements and uncertainty before market introduction. Due to our current availability of corporate resources, in connection with our Bioral® portfolio, we are currently focusing primarily on our Bioral® Amphotericin B formulation, as described below.

Bioral® Amphotericin B

Systemic fungal infections continue to be a major domestic and international health care problem. Amphotericin B, which is delivered intravenously, is an established, commonly used drug to treat these infections. We are currently developing a Bioral® formulation of Amphotericin B for treatment of fungal infections which we expect will be for the treatment of esophageal candidiasis. We plan to submit an IND to the FDA and proceed into clinical trials in second or third quarter 2006.

In late July 2005, we received an indication from National Institute of Allergy and Infectious Diseases, or NIAID, which is affiliated with the National Institutes of Health, or NIH, that the NIAID would, at its expense and following our achievement of certain milestones, conduct pre-clinical studies through an NIH contractor for oral, as well as intravenous, formulations of encochleated Amphotericin B. We believe these studies, if they occur, represent an important third-party validation of our encochleation technology. We also believe these studies will result in cost savings for us as they are being funded by NIAID.

In 2005, we were able to source PS from lecithin derived from soybeans rather than synthetic PS, thereby reducing the costs of goods for our delivery system. In addition, we have simplified our manufacturing approach to Bioral® Amphotericin B, thereby facilitating commercial scale-up. Also, we have changed the ratio of PS to active molecules, thus improving the efficacy while moderating costs. We are currently investigating the pharmacology and toxicology in animals. We estimate that the total development costs of this formulation will be approximately $11 million.

Amphotericin B is often used to treat diseases that frequently strike patients with compromised immune systems. The use of the conventional injectable Amphotericin B to treat these infections is often limited by its propensity to cause kidney damage which we believe our Bioral® products may minimize. Bioral® Amphotericin B may have uses in other diseases such as Leishmaniasis and Chagas disease.

The primary advantage which we are seeking for our proposed Amphotericin B product is an oral formulation of the drug. Additional potential advantages include improved safety, extended shelf life, improved cellular uptake and reduced dosage. Assuming that we complete development of our proposed Bioral® Amphotericin B formulation and that we obtain FDA approval, we believe that Bioral® Amphotericin B may provide an effective orally administered version of Amphotericin B which may be more effective and less toxic.

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According to market research firm Visiongain, the global antifungal market was approximately $6 billion in 2003 and is projected to grow to as much as $8 billion by 2009. According to our market research, annually, there are an estimated 500,000 severe fungal infections globally for which we believe Bioral® Amphotericin B may be an appropriate treatment. Our market research indicates that Bioral® Amphotericin B may be able to achieve peak sales of approximately $400 million annually, although no assurances can be given of this estimation.

In the development of this drug, we have collaborated with the NIH, the Public Health Research Institute of New York and the University of Kentucky. Further, we have been awarded and received all funds under a grant totaling approximately $2.7 million from the NIH to support the further development of this drug formulation.

Separately, on April 12, 2004, we licensed a topical formulation of our encochleated Amphotericin B to Accentia. Accentia is commercializing technology licensed from Mayo Foundation for Medical Education and Research, or the Mayo Foundation, for the treatment of CRS and asthma on a worldwide basis. The technology consists of using low-dose topical antifungals to control the debilitating symptoms of CRS and asthma. Presently, Accentia is developing the encochleated Amphotericin B formulation (which is called BioNasal®) for potential use in a pump spray for the treatment of CRS. Accentia has not yet determined if the application of Amphotericin B to the asthma field is feasible. Accentia will not submit an IND regarding the asthma application of intrapulmonary Amphotericin B, either encochleated or unencochleated, until and if the proof of principle is completed by the Mayo Foundation pursuant to the terms of the Accentia license with the Mayo Foundation.

Our license agreement with Accentia was amended effective June 1, 2004, then modified in September 2004 by the asset purchase agreement with Accentia described below, and was amended with three separate letter amendments in March, April and June 2005, respectively, to make certain clarifications. According to the terms of the license as originally entered into, Accentia was to pay us a running royalty of 12-14% on net sales of covered products in the designated field. Accentia is responsible for all expenses related to the development of an encochleated BioNasal® Amphotericin B for the indication of CRS and asthma on a worldwide basis, including expenses associated with, and the actual provision of, supplies, the submission of an IND and clinical trials. We shall retain world-wide rights to the oral and intravenous formulations of encochleated Amphotericin B.

On September 8, 2004, we entered into a definitive Asset Purchase Agreement with Accentia pursuant to which we sold to Accentia an asset consisting of a royalty revenue stream in consideration of a one-time, irrevocable cash payment of $2.5 million. The royalty revenue stream sold was a fifty percent (50%) interest in the future royalties earnable by us on sales by Accentia for products utilizing our topical formulation of our encochleated Amphotericin B for the treatment of CRS, thus effectively reducing our royalty on the sales of such CRS products by 50%. We agreed with Accentia, however, that the future royalty stream sold shall not include royalty payments that are payable by Accentia based on the sale of encochleated products exclusively intended to treat asthma, and the rights to such royalty payments, as originally set forth in the license agreement, shall remain with us.

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Licensing Opportunities and Other Projects

In addition to the foregoing, we have in the past dedicated resources to other projects. Given our limited resources, we decided during 2004 and 2005 to either focus exclusively on seeking licensing or similar collaborative opportunities for these projects and/or significantly scale back, outsource or place these projects on hold. These projects include:

Bioral® siRNA. Small interfering RNA, or siRNA, is a new class of oligonucleotides that may offer the ability to identify therapeutics directly based on genomic information of the host or pathogens. Like other oligonucleotide candidates such as antisense, siRNA is very susceptible to degradation by plasma enzymes. In 2005, we entered into agreements with third parties for the evaluation of cochleate formulations of siRNA therapeutics, and we will likely continue to search for collaborators and strategic partners in this area. If the results of the collaborations are positive, we intend to pursue the licensing of certain rights associated with the delivery of nucleic acids to these partners.

Bioral® Paclitaxel. Paclitaxel is one of the most commonly prescribed chemotherapies for solid tumors such as breast cancer. Paclitaxel is very insoluble in water and is currently available in either a cremophor formulation, which often has significant vehicle-related toxicities, or in a formulation composed as paclitaxel bound to albumin. Both are available as injections. We are working on an oral form of paclitaxel, making therapy for patients more convenient and reducing the risks associated with intravenous therapies. Evaluation of the formulation will be undertaken in collaboration with an academic center.

Bioral® NSAIDS. In early 2005, we announced that, in laboratory testing, we applied our licensed Bioral® nanocochleate drug delivery technology to aspirin and traditional NSAIDS that are not selective COX-2 inhibitors. We have contracted with an independent testing laboratory to test Bioral® formulations of aspirin and other NSAIDs in a well-established animal model of inflammation. These proof-of-principle animal studies have demonstrated that encochleated NSAIDS enabled a statistically significant reduction in gastro-intestinal toxicity (e.g., ulceration) compared to standard formulations at clinically-relevant high doses of these NSAIDs and aspirin while providing comparable anti-inflammatory effects. Due to limited corporate resources, however, this program has been deemphasized and no further development is anticipated at this point. The rights to this program are available for licensing to third parties.

Autologous HIV Therapy. We have developed and are investigating our patented autologous (patient-specific) HIV therapy for AIDS which uses a cochleate related (proteoliposome) delivery vehicle. In 2005, we investigated the potential cost for the research and administrative efforts that would be necessary to obtain an FDA approved IND necessary to continue this program. We have elected to de-emphasize this program to focus our later stage projects. We do not plan to utilize any resources on this program in the near term. The rights to this program are available for licensing to third parties.

Subunit HIV Vaccine. We are also developing, in conjunction with UMDNJ, a subunit HIV vaccine formulation with our cochleate technology that may have the ability to work following oral administration. This program is currently funded via an NIH grant which expired in January 2006 but was renewed in February 2006 through July 31, 2006. As a result of this extension, we expect to receive approximately $74,000 in additional funds from the NIH for this project. In 2005, we subcontracted the responsibilities under the NIH grant for this project to UMDNJ.

Bioral Nutrient Delivery, LLC. In January 2003, we formed Bioral Nutrient Delivery, LLC to investigate the potential application of our proprietary encochleation technology for use in processed food and beverages and personal care products. While our preliminary findings suggest that, by using our

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encochleation technology, a variety of nutrients, which are substances with potentially beneficial properties, might be protected from degradation during the manufacturing process and delivered with substantially all of the characteristics of the nutrient intact, the BND opportunity is not presently a high priority for us and we do not plan to utilize any corporate resources toward this application of the Bioral® technology.

Relationship with The University of Medicine and Dentistry of New Jersey and Historical Relationship with Albany Medical College

We have had and continue to have critical relationships with UMDNJ and Albany Medical College. Some of our scientists were former researchers and educators at these Universities researching cochleate technology. All of our current research and development is done using facilities provided to us on the campus of UMDNJ, pursuant to a lease, or at the facilities of our contractors or collaborators. Both of these Universities are stockholders in our company and have a substantial financial interest in our business.

In September 1995, we entered into a license agreement with the Universities to be the exclusive worldwide developer and sub-licensor of the cochleate technology. Under the license agreement, we and the Universities have also jointly patented certain aspects of the cochleate technology and co-own such patents with them. Pursuant to the license agreement, we agreed that each University would be issued an equity interest in our capital stock, originally equal to 2% of our outstanding capital stock. These arrangements were subsequently revised in December, 2002. On December 16, 2002, we amended our license agreement with the Universities to provide for a decrease in the royalty payments to be paid to the Universities on sublicenses in consideration of an increase in the royalty on product sales and the issuance to the Universities of options to purchase shares of our common stock. As of December 31, 2005, UMDNJ owned 139,522 shares (including shares issued under a research agreement) and warrants to purchase 9,951 shares of our common stock at $3.06 and 75,000 options to purchase our common stock at a price per share of $2.37. As of December 31, 2005, Albany Medical College owned 2,222 shares of our common stock and warrants to purchase 9,951 shares of our common stock at $3.06 and 75,000 options to purchase our common stock at a price per share of $2.37. There are no further requirements to provide either University any additional equity interests in our company.

The license agreement, as amended, grants us an exclusive license to the cochleate technology owned by these Universities and obligates us to pay a royalty fee structure as follows:

(a) For commercial sales made by us or our affiliates, we shall pay to the Universities a royalty equal to 5% of net sales of cochleate products; and

(b) For commercial sales of cochleate products made by any of our sublicensees, we shall pay to the Universities royalties up to 5% of our revenues received from the sublicensee from the sale of such products.

Our royalty payments to the Universities will be divided equally among them pursuant to the license. In 2004, we accrued a $125,000 royalty payment to the Universities in connection with our $2.5 million asset sale to Accentia.

In April 2001, we entered into a research agreement with UMDNJ whereby we agreed with UMDNJ to share the rights to new research and development that jointly takes place at UMDNJ s facilities until December 31, 2005. We also agreed to provide UMDNJ with progress and data updates and allow its researchers to publish certain projects. We lease our research facilities totaling approximately 8,000 square feet located on their campus pursuant a lease agreement ending December 31, 2005.

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The monthly rent was $3,340 for 2001, $3,840 for 2002, $4,340 for 2003, $4,840 for 2004 and $5,340 for 2005. The lease was renewed in December 2005 for a term of one year at a cost of $144,000 for the year, or $12,000 per month. No assurances can be given that we will be able to extend or renew the lease, and we may decide to relocate, scale back and/or outsource such operations.

In addition to our rent payments, we have also agreed to pay for certain other services provided by UNDNJ. These include two employees from UNDNJ for a total of approximately $119,880, a budget to purchase supplies and chemicals (adjusted to exact cost), and an indirect cost factor constituting 8% for 2001 (12% in 2002, 16% in 2003, 20% for 2004 and 24% for 2005) of the direct costs of the employee costs and chemicals.

Collaborative and Supply Relationships

We are a party to collaborative agreements with universities, government agencies, corporate partners, and contractors. Research collaboration may result in new inventions which are generally considered joint intellectual property. Our collaboration arrangements are intended to provide us with access to greater resources and scientific expertise in addition to our in-house capabilities. We also have supply arrangements with a few of the key component producers of our delivery technology. In addition to our relationship with CDC, our collaborative and supply relationships include:

Atrix Laboratories, Inc. On May 27, 2004, prior to its acquisition by us, Arius entered into a worldwide, exclusive royalty-bearing license agreement with Atrix to develop, market, and sell products incorporating Atrix s BEMA technology, including its BEMA Fentanyl product, and to use the BEMA trademark in conjunction therewith. The BEMA delivery technology consists of an easy to use, dissolvable, dime-sized polymer disc that is applied to the mucus membrane of the mouth. All research and development related to the BEMA technology, including three existing INDs, have been transferred to Arius in accordance with the Atrix license agreement.

Under the terms of the Atrix license agreement, we are required to pay Atrix: (i) an upfront licensing fee of $1 million, which was paid in August 2004, (ii) additional cash payments upon achievement of certain developmental and regulatory milestones, (iii) for reimbursement for research and development support, and (iv) royalties on commercial sales of all BEMA products. A joint development management committee composed of representatives of our company and Atrix oversees product development. We are responsible for the research and development of the products, including costs and expenses, and for their sale, marketing, manufacture and distribution. Atrix retains certain co-promotion rights to the BEMA Fentanyl product.

Reckitt Benckiser Healthcare (UK) Limited. Effective January 6, 2004, Arius entered into an exclusive royalty-bearing license with Reckitt Benckiser Healthcare (UK) Limited to develop, market, and sell Reckitt s Emezine® (buccal prochlorperazine maleate) product for the treatment of nausea and vomiting in the United States, and to use the Emezine® trademark in conjunction therewith. Under the terms of the license agreement, we are required to pay Reckitt: (i) an upfront licensing fee, which has been previously paid in accordance with the Reckitt agreement, (ii) an additional cash payment upon achievement of a certain developmental and regulatory milestone, and (iii) royalties on commercial sales of the licensed product. We are responsible for the development of the product, including costs and expenses, and for its sale, marketing, and distribution in the United States. In addition, we shall be required to obtain from Reckitt, and Reckitt shall be required to supply to us, at our expense, all product to be sold under the license.

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Aveva Drug Delivery Systems. Effective October 17, 2005, we entered into an agreement with Aveva Drug Delivery Systems, Inc. pursuant to which Aveva will supply BEMA Fentanyl product to us for clinical trials and commercial sale. Under the terms of this agreement, Aveva will be the sole supplier of BEMA Fentanyl for the United States and Canada. We will pay for formulation, commercial quantity scale-up, and product development work and the manufacture of clinical supplies, as well as for the cost of commercial supplies of BEMA Fentanyl based on Aveva s fully-burdened cost of manufacturing such supplies. The agreement has an initial term which is subject to automatic renewal for additional terms unless either party provides notice of termination in advance of such renewal. In connection with this agreement, we issued Aveva a warrant to purchase up to 75,000 shares of our common stock (which shares vest based on the occurrence of specified milestones) at a price equal to $3.50 per share.

Sigma-Tau. In January 2005, we signed a definitive licensing agreement with Sigma-Tau Pharma for the application of our Bioral® nanocochleate delivery technology to formulate up to four proprietary pharmaceutical compounds currently under development by Sigma-Tau Pharma. Simultaneously with this licensing agreement, we entered into a stock purchase agreement with, and received a non-refundable upfront payment of US$250,000 from, Sigma-Tau. This upfront payment was made in consideration of unregistered shares of our common stock priced at $4.25 a share. The stock purchase agreement with Sigma-Tau provides for the acquisition by Sigma-Tau, upon the occurrence of specified developmental milestones associated with the license, of additional unregistered shares of our common stock, up to an aggregate potential of $1.5 million worth of such shares. These milestones lead up to and include the submission of product INDs by Sigma-Tau Pharma for one or more of the four subject encochleated compounds.

We continued to work with Sigma-Tau on this project during 2005. Working with Sigma-Tau s immunosuppressant compound, we were able during 2005 to undertake single and multiple dose in vivo efficacy studies versus a subcutaneous formulation of the compound. We anticipate that this Bioral® formulation will enter 28 day toxicology testing in 2006. If the results of this study meet expectation, we believe we will have achieved the next milestone in the collaboration, which is demonstration of proof of principal. If this occurs, a $250,000 payment to BDSI will be triggered, which payment will take the form of a purchase of our common stock by Sigma-Tau at the lesser of: (i) $4.25 and (ii) the average of the closing trade price of our common stock for the ten (10) trading days through and including the applicable payment date, with an absolute floor $3.38 per share.

Pharmaceutical Product Development, Inc. On December 31, 2002, we entered into an agreement with Pharmaceutical Product Development, Inc. (NASDAQ:PPDI), which we refer to herein as PPDI, pursuant to which PPDI was granted a license to apply our Bioral® nano-delivery technology to two therapeutic products. In connection therewith, we received a $2 million up-front royalty payment. In addition, the terms of the license require additional royalty payments based on regulatory milestones and a running royalty rate based on worldwide sales.

National Institutes of Health. To investigate the properties of new antifungal cochleate formulations. Grants totaling approximately $2.7 million have been awarded to us by NIH for the development of our proposed Amphotericin B product. Additionally, we are

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conducting anti-fungal studies using our Bioral® drug delivery technology through NIH selected and paid contractors. The NIH has reserved broad and subjective authority over future disbursements under the grant. While no objective or specific milestones for future disbursements have been established by the NIH, we must generally demonstrate to the satisfaction of the NIH that our research and use of proceeds are consistent with the goal of developing a formulation for the oral delivery of Amphotericin B. Furthermore, we are required to submit to the NIH an annual report of activities under the grant.

In 2002, the NIH awarded us a second SBIR grant which we have utilized in our research and development efforts relating to a proposed encochleated HIV subunit vaccine. This grant expired in December 2005 but was extended by the NIH in February 2006 until July 31, 2006, and we believe this will be the final extension for this grant. As a result of this extension, we expect to receive approximately $74,000 in additional funds from the NIH for this project. In 2005, we subcontracted the responsibilities under the NIH grant for this project to UMDNJ.

Additionally, in late July 2005, we received an indication from the NIAID, which is affiliated with the NIH, that the NIAID would, at its expense and following our achievement of certain milestones, conduct pre-clinical studies through an NIH contractor for oral, as well as intravenous, formulations of encochleated Amphotericin B. No assurances can be given that NIAID will proceed with or actually pay for this testing.

Public Health Research Institute of New York. To investigate our proposed Amphotericin B product and other anti-fungal applications of our drug delivery technology. This relationship may involve shared expense reimbursement and shared intellectual property with regard to joint inventions.

We also have agreements with entities that are affiliated with and partially-owned by key members of our board of directors and management to conduct research and license certain proposed drugs. See Certain Relationships and Related Transactions for affiliations with our management.

As of December 31, 2001, our board of directors appointed an audit committee consisting of independent directors. This committee, among other duties, is charged to review, and if appropriate, ratify all agreements and transactions which had been entered into with related parties, as well as review and ratify all future related party transactions. The audit committee independently ratified the agreements described below. At a subsequent meeting of independent board members, with Dr. O Donnell abstaining, and after seeking and reviewing advice from the audit committee and an independent valuation firm and inquiring about the details of the various transactions, the independent board members ratified the below-described related party transactions. During 2004, after compliance with our internal policies and procedures, we also entered into several new related party contracts, some of which were amended in 2005 in accordance with the same policies and procedures. The following are the related-party agreements entered into prior to our initial public offering and subsequently:

Accentia Biopharmaceuticals, Inc. We have several business relationships with Accentia Biopharmaceuticals, Inc. and its affiliates. HCG, which is controlled by Dr. Francis E. O Donnell, Jr., our Chairman of the Board and which owns a significant percentage of our common stock as of the date of this Report, as well as all of our Series B Convertible Preferred Stock, is a significant stockholder of Accentia. In addition, Dr. O Donnell is also the Chairman and CEO of Accentia. Also, James A. McNulty, our Secretary, Treasurer and CFO, is the Treasurer of Accentia.

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Amphotericin B License. On April 12, 2004, we licensed a topical formulation of our encochleated Amphotericin B to Accentia. Accentia is commercializing technology licensed from the Mayo Foundation for the treatment of CRS and asthma on a worldwide basis. The technology consists of using low-dose topical antifungals to control the debilitating symptoms of CRS and asthma. Accentia is responsible for all expenses related to the development of an encochleated BioNasal® Amphotericin B for the indications of CRS and asthma on a worldwide basis, including expenses associated with, and the actual provision of, supplies, the submission of an IND and clinical trials. We shall retain world-wide rights to the oral and intravenous formulations of encochleated Amphotericin B. The license agreement was amended effective June 1, 2004, then modified in September 2004 by our asset purchase agreement with Accentia, and was amended with three separate letter amendments in March, April and June 2005, respectively, to make certain clarifications.

Arius/TEAMM Distribution Agreement. On March 17, 2004, Arius granted exclusive marketing and sales rights in the United States to TEAMM Pharmaceuticals, Inc., or TEAMM, with respect to Arius licensed Emezine® product for the treatment of nausea and vomiting. TEAMM is a specialty pharmaceutical company and wholly-owned subsidiary of Accentia. As part of this agreement, TEAMM has agreed to pay for the development costs of Emezine®. We received development cost reimbursements of $1.0 million in 2004 from Accentia in connection with this agreement. In 2005, we received $300,000 from TEAMM upon the acceptance by the FDA of the Emezine® NDA for filing.

Analytica International Market Studies. During 2004, Analytica International, a provider of research, commercialization, and communications services to the pharmaceutical and biotechnology industries and a subsidiary of Accentia, performed two market studies for us. We paid Analytica $47,800 for these reports, some of which we paid in 2005.

RetinaPharma Technologies, Inc. We previously entered into a license agreement with this development-stage biotechnology company to use our delivery technology in connection with their proposed nutraceutical product with potential application for macular degeneration and retinitus pigmentosa, a disease affecting the retina, and through an agreement with Tatton Technologies, LLC (which subsequently merged into RetinaPharma), certain apoptotic drugs and apoptotic naturally occurring substances to treat certain neuro-degenerative diseases. This exclusive worldwide right to use our Bioral® drug delivery technology in conjunction with their effort to develop, commercialize and manufacture their proposed products, or to sublicense to a third party, is only for the purpose of treating antiapoptotic pharmaceutical and nutraceutical treatment of retinal disease and glaucoma. These licenses shall remain in effect as long as RetinaPharma remains in compliance with the terms of the agreements. HCG, one of our significant stockholders, and Dr. Francis E. O Donnell, Jr., our Chairman of the Board, are affiliated as stockholders and a director of RetinaPharma.

Biotech Specialty Partners, LLC. We have entered into a non-exclusive distribution agreement with Biotech Specialty Partners, LLC, or BSP, a development-stage distribution company, to market and distribute our proposed products once we have

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completed the commercialization of our products. Our financial arrangement with BSP requires us to sell to BSP all of our proposed products, as and when purchased by BSP at a cost which is the lesser of:

(i) ten percent (10%) below the lowest wholesale acquisition cost, inclusive of rebates, quantity discounts, etc.; and

(ii) the lowest cost at which we are then selling the product(s) to any other purchaser. The term of the agreement shall be for a term of five years once a product becomes available for distribution. BSP is a start-up enterprise, which to date has not distributed any pharmaceutical products.

These agreements generally provide that, except for on-going development costs related to our cochleate drug delivery technology, we are not required to share in the costs of the development of the pharmaceutical product or technologies of these companies. In connection with our acquisition of Arius, BSP waived its rights under its distribution agreement with us with respect to all of Arius products.

Under these affiliate agreements, we are entitled to receive the following royalty and other payments:

Accentia Biopharmaceuticals, Inc. Under our license agreement with Accentia as originally entered into, Accentia was to pay us a running royalty of 12-14% on net sales in the U.S. of its CRS products and other products in the designated field. On September 8, 2004, we entered into a definitive Asset Purchase Agreement with Accentia pursuant to which we sold to Accentia an asset consisting of a royalty revenue stream in consideration of a one-time, irrevocable cash payment of $2.5 million. The royalty revenue stream sold was a fifty percent (50%) interest in the future royalties earnable by us on sales by Accentia for products utilizing our topical formulation of our encochleated Amphotericin B for the treatment of CRS, thus effectively reducing our royalty on the sales of such CRS products by 50%. We agreed with Accentia, however, that the future royalty stream sold shall not include royalty payments that are payable by Accentia based on the sale of encochleated products exclusively intended to treat asthma, and the rights to such royalty payments, as originally set forth in the license agreement, shall remain with us.

TEAMM Pharmaceuticals, Inc. Under the distribution agreement with TEAMM, TEAMM: (i) has previously paid to Arius an upfront fee, (ii) has previously paid to Arius an initial milestone payment and shall in the future pay to us certain additional milestone payments upon achievement of certain developmental and regulatory milestones, (iii) shall support our clinical development costs with respect to such product, and (iv) shall pay royalties to us based on the sales of such product. In addition, we shall be obligated to supply TEAMM, at TEAMM s expense, with such products for sale and promotional use. We received development cost reimbursements of $1.0 million in 2004 from Accentia in connection with this agreement.

RetinaPharma Technologies, Inc. We are entitled to 10% of all net revenue from the sale for the authorized use of our technology incorporated into the proposed products with potential application to various neuro-degenerative diseases. The planned RetinaPharma products are in early stage development and no sales of such products or royalty revenue therefrom is anticipated in the foreseeable future. We are also entitled to 10% of all net revenue from the sale for the authorized use of our technology incorporated into

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RetinaPharma s proposed product with potential application to various neuro-degenerative diseases. This latter product (which was transferred to RetinaPharma in its merger with Tatton Technologies, LLC) is in its early stage of development and no sales of such product or royalty revenue therefrom is anticipated in the foreseeable future.

In pursuing potential commercial opportunities, we intend to seek and rely upon additional collaborative relationships with corporate partners. Such relationships may include initial funding, milestone payments, licensing payments, royalties, access to proprietary drugs or potential applications of our drug delivery technologies or other relationships. Our agreements with PPDI, Accentia and Sigma-Tau are examples of these types of relationships, and we will continue to seek other similar arrangements.

Licenses, Patents and Proprietary Information

Our interest in the intellectual property is subject to and burdened by various royalty payment obligations and by other material contractual or license obligations.

In general, the patent position of biotechnology and pharmaceutical firms is frequently considered to be uncertain and involve complex legal and technical issues. There is considerable uncertainty regarding the breadth of claims allowed in such cases and the degree of protection afforded under such patents. While we believe that our intellectual property position is sound and that we can develop our drug delivery technologies, we cannot provide any assurances that our patent applications will be successful or that our current or future intellectual property will afford us the desired protection against competitors. It is possible that our intellectual property will be successfully challenged or that patents issued to others may preclude us from commercializing our drugs.

Other parties could have patent rights which may block our products. We are aware of two issued United States patents dealing with lipid formulations of Amphotericin B products. The first of these patents, United States Patent No. 4,978,654, claims an Amphotericin B liposome product. We do not believe that our patent or technology are in conflict with this existing patent, although there can be no assurance that a court of law in the United States patent authorities might determine otherwise. Our belief is based upon the fact that our cochleate product does not contain liposomes, which is required by the issued claims of this patent. The second of these patents, United States Patent No. 5,616,334, claims a composition of a lipid complex containing Amphotericin B defined during prosecution as a ribbon structure. Our Bioral® nano-encapsulation technology uses cochleates which are not ribbon structures. Accordingly, we do not believe that we require a license under this patent.

We are also aware of United States Patent No. 6,585,997, related to mucoadhesive erodible drug delivery devices. We do not believe that our BEMA Fentanyl product is in conflict with the existing patent, at least because there are limitations recited in the issued claims that are not met by our product. Accordingly, we do not believe that we require a license under this patent for BEMA Fentanyl. We have not, however, conducted any patent searches with respect to our other proposed BEMA -based products. We are further aware of U.S. Patents Nos. 5,948,430, 6,177,096 and 6,284,264, and European Patent No. 949 925, which are owned by LTS Lohmann and which also relate to mucoadhesive erodible drug delivery devices.

If a court were to determine that we infringe any of these patents and that these patents are valid, we might be required to seek one or more licenses to commercialize our Bioral® formulation of Amphotericin B and/or our BEMA products. There can be no assurance that we would be able to obtain such licenses from the patent holders. In addition, if we were unable to obtain a license, or if the terms of the license were onerous, there may be a material adverse effect upon our business plan to commercialize these products.

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Most of the inventions claimed in our cochleate patents were made with the United States government support. Therefore, the United States government has certain rights in the technology, and we have certain obligations to the U.S. government, which could be inconsistent with our plans for commercial development of products and/or processes. We believe to the extent the United States government would have rights in our licensed Bioral® technology due to their funding, we have to either obtain a waiver from the United States government relating to the United States government s rights in the technology, or have agreements with the United States government which would grant us exclusive rights.

We rely on trade secrets and confidentiality agreements with collaborators, advisors, employees, consultants, vendors and other service providers. No assurances can be given that these agreements will not be breached or that our trade secrets will not otherwise become known or be independently discovered by competitors. Our business would be adversely affected if our competitors were able to learn our secrets or if we were unable to protect our intellectual property.

Cochleate Technology

With respect to our cochleate technology and liposome technology related to our autologous HIV therapy, we are the owner and/or the exclusive licensee of nine issued United States patents and five foreign issued patents owned by the parties listed in the chart below. We believe that our licenses to this intellectual property will enable us to develop this new drug delivery technology based upon cochleate and cochleate related technology. Our intellectual property strategy is intended to maximize our potential patent portfolio, license agreements, proprietary rights and any future licensing opportunities we might pursue. With regard to our Bioral® cochleate technology, we intend to seek patent protection for not only our delivery technology, but also potentially for the combination of our delivery technology with various drugs no longer under patent protection. Below is a table summarizing patents we believe are currently important to our business and technology position.

Patent Number	Issued	Expires	Title	Owner
EUR0722338	07/25/2001	09/30/2014	Protein- and peptide cochleate vaccines methods of immunizing using the same	The University of Medicine and Dentistry of New Jersey and Albany Medical College
US06,165,502	12/26/2000	09/11/2016	Protein-lipid vesicles and autogenous immunotherapeutic comprising the same	(same as above)
US06,153,217	11/28/2000	01/22/2019	Nanocochleate formulations, process of preparation and method delivery of pharmaceutical agents	BioDelivery Sciences International, Inc., The University of Medicine and Dentistry of New Jersey and Albany Medical College
US06,592,894	07/15/2003	01/22/2019	(same as above)	(same as above)

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Patent Number	Issued	Expires	Title	Owner
AUS722647	11/23/2000	09/02/2017	Protein-lipid vesicles and autogenous immunotherapeutic comprising the same	The University of Medicine and Dentistry of New Jersey and Albany Medical College
US05,994,318	11/30/1999	11/24/2015	Cochleate delivery vehicles	(same as above)
EUR 812209	05/06/2004	02/22/2016	Cochleate delivery vehicles for biologically relevant molecules	(same as above)
CA 2,246,754	10/22/2002	02/21/2017	Cochleate delivery vehicles	(same as above)
US05,840,707	11/24/1998	11/24/2015	Stabilizing and delivery means of biological molecules	(same as above)
US05,834,015	11/10/1998	9/11/2016	Protein-lipid vesicles and autogenous immunotherapeutic comprising the same	(same as above)
AUS689505	02/02/1998	09/30/2014	Protein- or peptide- cochleate immunotherapeutics and methods of immunizing using the same	(same as above)
US05,643,574	07/01/1997	07/01/2014	(same as above)	(same as above)
US04,871,488	10/03/1989	10/03/2006	Reconstituting viral glycoproteins into large phospholipid vesicles	Albany Medical College

Through Arius, we license from Atrix the following U.S. and foreign patents and patent applications relating to the BEMA technology:

Application Number	Country	Application Date	Patent Number	Grant Date	Expiration Date	Title
08/734,519	US	10/18/1996	5,800,832	09/01/1998	10/18/2016	Bioerodable Film for Delivery of Pharmaceutical Compounds to Mucosal Surfaces
09/144,827	US	09/01/1998	6,159,498	12/12/2000	10/18/2016	(same as above)

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Application Number	Country	Application Date	Patent Number	Grant Date	Expiration Date	Title
09/069,703	US	04/29/1998	Pending			Pharmaceutical Carrier Device Suitable for Delivery of Pharmaceutical Compounds to Mucosal Surfaces
09/684,682	US	10/04/2000	Pending			(same as above)
10/962,833	US	10/12/2004	Pending			(same as above)
11/069,089	US	03/01/2005	Pending			(same as above)
10/763,063	US	01/22/2004	Pending			Bioerodible Film for Delivery of Pharmaceutical Compounds to Mucosal Surfaces
10/706,603	US	11/12/2003	Pending			Adhesive Bioerodible Ocular Drug Delivery System
US04/026531	PCT	08/16/2004	N/A	N/A	N/A	Adhesive Bioerodible Transmucosal Drug Delivery System
US97/18605	PCT	10/16/1997	N/A	N/A	N/A	Pharmaceutical Carrier Device Suitable for Delivery of Pharmaceutical Compounds to Mucosal Surfaces
9747574	Australia	10/16/1997	729516	05/17/2001	10/16/2017	(same as above)
200138924	Australia	10/16/1997	769500	05/13/2004	10/16/2017	
2,268,187	Canada	10/16/1997	Pending		10/16/2017	(same as above)
98519467	Japan	10/16/1997	Pending		10/16/2017	(same as above)
2005182632	Japan	10/16/1997	Pending		10/16/2017	(same as above)
9791047	EP*	10/16/1997	0973497	12/11/02	10/16/2017	(same as above)
US99/09378	PCT	04/29/1999	N/A	N/A	N/A	(same as above)
9939678	Australia	04/29/1999	746339	11/16/99	04/29/2019	(same as above)
2,329,128	Canada	04/29/1999	Pending		04/29/2019	(same as above)

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Application Number	Country	Application Date	Patent Number	Grant Date	Expiration Date	Title
2000545511	Japan	04/29/1999	Pending		04/29/2019	(same as above)
2005233505	Japan	04/29/1999	Pending		4/29/2019	(same as above)
99922753	EP**	04/29/1999	1079813	02/09/05	04/29/2019	(same as above)
US03/11313	PCT	04/11/2003	N/A	N/A	N/A	(same as above)

* Validated in Austria, Belgium, Switzerland, Germany, Denmark, Spain, France, United Kingdom, Greece, Ireland, Italy, Netherlands and Sweden.

** Validated in Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, Switzerland, and United Kingdom.

Emezine®

With respect to Emezine®, we license from Reckitt U.S. Patent No. 4,717,723, issued January 5, 1988, entitled Pharmaceutical Compositions.

Competition

The biopharmaceutical industry in general is competitive and subject to rapid and substantial technological change. Developments by others may render our proposed Bioral® or BEMA technologies and proposed drug formulations (including Emezine®) under development noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition in the industry from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Below are some examples of companies seeking to develop potentially competitive technologies. Many of these entities have significantly greater research and development capabilities than do we, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. In addition, acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors research, financial, marketing, manufacturing and other resources. Such potential competitive technologies may ultimately prove to be safer, more effective or less costly than any drugs which we are currently developing or may be able to develop. Additionally, our competitive position may be materially affected by our ability to develop or successfully commercialize our drugs and technologies before any such competitor.

1,809

Other

185 353 425 418

Total			
$9,711	$7,469	$18,123	$13,733

The Company s collaboration revenue is primarily generated in the United States and grant revenue is generated in Singapore and the United States.

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

The following discussion and analysis should be read together with our condensed consolidated financial statements and the notes to those statements included elsewhere in this Form 10-Q. This Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act, that are based on our management s beliefs and assumptions and on information currently available to our management. The forward-looking statements are contained principally in the sections entitled Risk Factors and this Management s Discussion and Analysis of Financial Condition and Results of Operations. Forward-looking statements include information concerning our possible or assumed future results of operations, business strategies, financing plans, competitive position, industry environment, potential growth opportunities and the effects of competition. Forward-looking statements include statements that are not historical facts and can be identified by terms such as anticipates, believes, could, seeks, estimates, expects, intends, may, plans, potential, predicts, projects, should, will, would or similar expressions and the negatives of those terms.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We discuss these risks in greater detail in Part II, Item 1A, Risk Factors, elsewhere in this Form 10-Q and in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management s beliefs and assumptions only as of the date of this Form 10-Q.

Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future. You should read this Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect.

In this Form 10-Q, we, us and our refer to Fluidigm Corporation and its subsidiaries. We operate on a fiscal year ending December 31.

Overview

We develop, manufacture and market microfluidic systems for growth markets in the life science and agricultural biotechnology, or Ag-Bio, industries. Our proprietary microfluidic systems consist of instruments and consumables, including chips and reagents. These systems are designed to significantly simplify experimental workflow, increase throughput and reduce costs, while providing the excellent data quality demanded by customers. In addition, our proprietary technology enables genetic analysis that in many instances was previously impractical. We actively market three microfluidic systems including nine different commercial chips to leading pharmaceutical and biotechnology companies, academic institutions, diagnostic laboratories and Ag-Bio companies. We have sold over 400 systems to customers in over 25 countries worldwide through the date of this report.

Our total revenue grew from $15.3 million in 2008 to $33.6 million in 2010 and to $19.3 million in the six months ended June 30, 2011. We have incurred significant net losses since our inception in 1999 and as of June 30, 2011, our accumulated deficit was $213.9 million.

We distribute our microfluidic systems through our direct sales force and support organizations located in North America, Europe and Asia-Pacific and through distributors or sales agents in several European, Latin American, African, Middle Eastern and Asia-Pacific countries. Our manufacturing operations are located in Singapore. Our facility in Singapore manufactures our instruments and fabricates all of our chips for commercial sale and some chips for our own research and development purposes. Our South San Francisco facility fabricates chips for our own research and development purposes.

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Critical Accounting Policies, Significant Judgments and Estimates

Our consolidated financial statements and the related notes included elsewhere in this Form 10-Q are prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, costs and expenses and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Changes in accounting estimates may occur from period to period. Accordingly, actual results could differ significantly from the estimates made by our management. We evaluate our estimates and assumptions on an ongoing basis. To the extent that there are material differences between these estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected.

We believe that certain of our critical accounting policies involve a greater degree of judgment and complexity than our other accounting policies. Accordingly, these are the policies we believe are the most critical to understanding and evaluating our consolidated financial condition and results of operations. There have been no material changes in the matters for which we make critical accounting estimates in the preparation of our condensed consolidated financial statements during the three and six-month periods ended June 30, 2011 as compared to those disclosed in our Annual Report on Form 10-K filed with the SEC on March 28, 2011.

Revenue

We generate revenue from sales of our products, collaboration agreements and government grants. Our product revenue consists of sales of instruments and related services, and consumables, including chips and reagents. We also have entered into collaboration agreements, research and development contracts and have received government grants to conduct research and development activities.

The following table presents our revenue by source for each period presented (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Revenue:				
Instruments	$ 6,434	$ 4,940	$ 11,391	$ 9,059
Consumables	3,277	2,529	6,732	4,674
Product revenue	9,711	7,469	18,123	13,733
Collaboration revenue	754	75	921	75
Grant revenue	111	479	229	931
Total revenue	$ 10,576	$ 8,023	$ 19,273	$ 14,739

The following table presents our product revenue by geography and as a percentage of total product revenue by geography based on the billing address of our customers for each period presented (in thousands):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2011		2010		2011		2010	
United States	$ 5,164	53%	$ 4,401	59%	$ 9,306	51%	$ 7,960	58%
Europe	2,408	25	1,554	21	4,555	25	3,193	23
Japan	1,287	13	100	1	2,187	12	353	3
Asia Pacific	667	7	1,061	14	1,650	9	1,809	13
Other	185	2	353	5	425	3	418	3
Total	$ 9,711	100%	$ 7,469	100%	$ 18,123	100%	$ 13,733	100%

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Grant revenue is generated in Singapore and the United States. Collaboration revenue is primarily generated in the United States. As we expand our business internationally, we expect our product revenue from outside of the United States to increase as a percentage of our total product revenue.

Our customers include pharmaceutical and biotechnology companies, academic research institutions, diagnostic laboratories and Ag-Bio companies worldwide. Revenue from the five largest customers comprised 16% and 12% of our total revenue in the three and six-months ended June 30, 2011, respectively and 20% and 17% of our total revenue for the three and six-months ended June 30, 2010, respectively.

Comparison of the Three Months Ended June 30, 2011 and June 30, 2010

Total Revenue

Total revenue increased by $2.6 million, or 32%, to $10.6 million for the three months ended June 30, 2011 as compared to $8.0 million for the three months ended June 30, 2010.

Product Revenue

Product revenue increased by $2.2 million, or 30%, to $9.7 million for the three months ended June 30, 2011 as compared to $7.5 million for the three months ended June 30, 2010. Consumables revenue increased by $0.7 million, or 30%, resulting from the higher installed base of our instruments, and instrument revenue increased by $1.5 million, or 30%. Our instrument system unit sales volume increased by 21%, primarily driven by increased sales of our Access Array instrument which launched in the second half of 2009. The average selling price for instruments was higher for the three months ended June 30, 2011 compared to the three months ended June 30, 2010 due to increased sales in Japan and Europe where average selling prices are higher, partially offset by increased sales of our Access Array instrument which has a lower average selling price than our BioMark and EP1 instruments.

We expect unit sales of both instruments and consumables to continue to increase in future periods as we continue our efforts to grow our customer base and expand our geographic market coverage. However, we expect the average selling prices of our instruments to fluctuate over time based on product mix and currency fluctuations.

Collaboration Revenue

Collaboration revenue was $0.8 million for the three months ended June 30, 2011 compared to $0.1 million in the three months ended June 30, 2010. The increase in collaboration revenue of $0.7 million is due to the achievement of two milestones from a fixed-fee research and development agreement that we entered into in May 2010. The arrangement provided for an up-front fee of $0.7 million which is being recognized over the term of the agreement, projected to be fifteen months. In March 2011, we amended the collaboration agreement and received an additional $0.3 million payment. Under the amendment, certain milestones and the payment terms associated with satisfaction of the milestones were modified. The total up-front and additional payment of $1.05 million is being recognized on a straight-line basis over the estimated performance period, through September 30, 2011. The arrangement also provides for milestone payments, which payments have been and are expected to be recognized as we achieve milestones.

Grant Revenue

Grant revenue consists of incentive grants from Singapore Economic Development Board, or EDB, and California Institute for Regenerative Medicine, or CIRM. Grant revenue decreased $0.4 million, or 77%, to $0.1 million for the three months ended June 30, 2011 compared to $0.5 million for the three months ended June 30, 2010. The decrease relates to a reduction in activity under the EDB grant agreements as we achieved certain milestones and reached the end of the grant periods.

Under our agreements with EDB, we were eligible to receive incentive grant payments from EDB, provided we satisfied certain agreed upon targets. Our agreements with EDB provided for incentive funding eligibility through May 2011. From January 1, 2008 through December 31, 2010, we recognized $4.3 million of grant revenue from EDB. During the three months ended June 30, 2011, we recognized an additional $4,000 of grant revenue from EDB. These agreements further provided EDB with the right to demand repayment of a portion of past grants in the event that we did not meet our obligations under the applicable agreements. Our first grant agreement with EDB was completed in July 2010 and has been officially closed by EDB with no adjustments. Our second grant agreement was completed in May 2011, and, based on correspondence with EDB, we believe that we have satisfied our obligations applicable to our EDB grant revenue through June 30, 2011.

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We expect total grant revenue for 2011 and future periods to decrease significantly compared to 2010 as the first of our EDB grant agreements was completed in July 2010 and our second EDB grant agreement was completed in May 2011. We expect this decrease will be partially offset by grant revenue from CIRM resulting from a new grant of $1.9 million to be recognized over three years beginning in May 2011.

Cost of Product Revenue

The following table presents the cost of our product revenue and our product margin for each period presented (in thousands, other than percentages):

	Three Months Ended June 30,	
	2011	2010
Cost of product revenue	$ 2,965	$ 2,900
Product margin	69%	61%

Cost of product revenue includes manufacturing costs incurred in the production process, including component materials, assembly labor and overhead; installation; warranty; service; and packaging and delivery costs. In addition, cost of product revenue includes royalty costs for licensed technologies included in our products, provisions for slow-moving and obsolete inventory and stock-based compensation expense. Costs related to collaboration and grant revenue are included in research and development expense.

Cost of product revenue increased $0.1 million, or 2%, to $3.0 million for the three months ended June 30, 2011 from $2.9 million for the three months ended June 30, 2010 due to increased product sales. Cost of product revenue as a percentage of related revenue decreased to 31% for the three months ended June 30, 2011 compared to 39% for the three months ended June 30, 2010. This decrease was due to lower instrument costs, higher average selling prices, higher utilization of chip manufacturing capacity, and improved chip yields.

Operating Expenses

The following table presents our operating expenses for each period presented (in thousands):

	Three Months Ended June 30,	
	2011	2010
Research and development	$ 3,422	$ 3,447
Selling, general and administrative	7,843	5,902
Litigation settlement	3,000	0
Total operating expenses	$ 14,265	$ 9,349

Research and Development

Research and development expense consists primarily of personnel costs, independent contractor costs, prototype and material expenses and other allocated facilities and information technology expenses. We have made substantial investments in research and development since our inception. Our research and development efforts have focused primarily on the tasks required to enhance our technologies and to support development and commercialization of new and existing products and services.

Research and development expense was $3.4 million for each of the three months ended June 30, 2011 and June 30, 2010. During the three months ended June 30, 2011, decreases in compensation costs and related expenses of $0.2 million were offset by increases in consulting and professional fees of $0.2 million, as compared to the three months ended June 30, 2010. We believe that our continued investment in research and development is essential to our long-term competitive position and these expenses may increase in future periods.

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Selling, General and Administrative

Selling, general and administrative expense consists primarily of personnel costs for our sales and marketing, business development, finance, legal, human resources and general management, as well as professional services, such as legal and accounting services.

Selling, general and administrative expense increased $1.9 million, or 33%, to $7.8 million for the three months ended June 30, 2011, compared to $5.9 million for the three months ended June 30, 2010. The increase was primarily due to increased compensation costs and related expenses of $1.5 million resulting from increased headcount to support our business and revenue growth, increased legal and professional fees of $0.6 million, increased other costs of $0.4 million to support our public company requirements, partially offset by lower bad debt expense of $0.3 million and lower rent expense of $0.1 million resulting from our new lease on more favorable terms for our headquarters facility in South San Francisco, California. We expect selling, general and administrative expense to increase in future periods as we continue to grow our sales, technical support, marketing and administrative headcount, support increased product sales, broaden our customer base and incur additional costs to support our expanded global footprint and the overall growth in our business. We also expect legal, accounting and compliance costs to increase as a result of our becoming a public company.

Litigation Settlement

On June 30, 2011, we settled certain litigation and entered into a series of patent license agreements resulting in a net $3.0 million payment by us to Life Technologies and their subsidiary Applied Biosystems, LLC, referred to collectively as Life. The payment was recognized as litigation settlement expense in our June 30, 2011 condensed consolidated statement of operations because the agreement specified that the amount paid by us was principally attributable to resolving Life s litigation claims with respect to a specific expiring U.S. patent and its foreign counterparts. We had no similar settlement in the three months ended June 30, 2010.

Interest Expense and Other Income and Expense, Net

We receive interest income from our cash and cash equivalents and available-for-sale securities. Conversely, we incur interest expense from our long-term debt, bank line of credit, promissory notes and the amortization of debt discounts related to these items. Until the completion of the IPO, we also recognized income or expense as a result of changes in the fair value of outstanding warrants to purchase shares of our convertible preferred stock. The following table presents these items for each period presented (in thousands):

	Three Months Ended June 30,	
	2011	2010
Interest expense	$ (512)	$ (555)
Loss from changes in the fair value of convertible preferred stock warrants		(5)
Other income, net	42	108

Interest expense was $0.5 million for the three months ended June 30, 2011 compared to $0.6 million for the three months ended June 30, 2010. The decrease is primarily due to a reduction in loan principal as we began making principal payments on our long-term debt in March 2011. We expect interest expense to decrease in 2011 as we repay our outstanding debt.

Other income decreased $66,000, to $42,000 for the three months ended June 30, 2011 compared to $108,000 for the three months ended June 30, 2010 primarily due to unfavorable changes in foreign currency exchange gains and losses.

Comparison of the Six Months Ended June 30, 2011 and June 30, 2010

Total Revenue

Total revenue increased by $4.5 million, or 31%, to $19.3 million for the six months ended June 30, 2011 as compared to $14.7 million for the six months ended June 30, 2010.

Product Revenue

Product revenue increased by $4.4 million, or 32%, to $18.1 million for the six months ended June 30, 2011 as compared to $13.7 million for the six months ended June 30, 2010. Consumables revenue increased by $2.1 million, or 44%, resulting from our higher installed base of instruments, and instrument revenue increased by $2.3 million, or 26%. Our instrument system unit sales volume increased by 28%, primarily driven by increased sales of our Access Array instrument. The average selling price for instruments was higher for the six months ended June 30, 2011 compared to the six months ended June 30, 2010 due to increased sales in Japan and Europe where average selling prices are higher partially offset by increased sales of our Access Array instrument which has a lower average selling price than our BioMark and EP1 instruments.

Collaboration Revenue

Collaboration revenue increased by $0.8 million to $0.9 million for the six months ended June 30, 2011 compared to $0.1 million for the six months ended June 30, 2010. The increase in collaboration revenue is due to the achievement of three milestones related to a fixed-fee research and development agreement that we entered into in May 2010. The arrangement provided for an up-front fee of $0.7 million which is being recognized over the term of the agreement, projected to be 15 months. In March 2011, we amended the collaboration agreement and received an additional $0.3 million payment. Under the amendment, certain milestones and the payment terms associated with satisfaction of the milestones were modified. The total up-front and additional payment of $1.1 million is being recognized on a straight-line basis over the estimated performance period, through September 30, 2011. The arrangement also provides for milestone payments, which payments have been and are expected to be recognized as we achieve each milestone.

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Grant Revenue

Grant revenue consists of incentive grants from the Singapore Economic Development Board, or EDB, and the California Institute for Regenerative Medicine, or CIRM. Grant revenue decreased $0.7 million, or 75%, to $0.2 million for the six months ended June 30, 2011 compared to $0.9 million for the six months ended June 30, 2010. The decrease relates to a reduction in activity under the EDB grant agreements as we achieved certain milestones and reached the end of the grant periods.

Under our agreements with EDB, we were eligible to receive incentive grant payments from EDB, provided we satisfied certain agreed upon targets. Our agreements with EDB provided for incentive funding eligibility through May 2011. From January 1, 2008 through December 31, 2010, we recognized $4.3 million of grant revenue from EDB. During the six months ended June 30, 2011, we recognized an additional $31,000 of grant revenue from EDB. These agreements further provided EDB with the right to demand repayment of a portion of past grants in the event that we did not meet our obligations under the applicable agreements. Our first grant agreement with EDB was completed in July 2010 and has been officially closed by EDB with no adjustments. Our second grant agreement with EDB was completed in May 2011 and based on correspondence with EDB, we believe that we have satisfied our obligations applicable to our EDB grant revenue through June 30, 2011.

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Cost of Product Revenue

The following table presents the cost of our product revenue and our product margin for each period presented (in thousands, other than percentages):

	Six Months Ended June 30,	
	2011	2010
Cost of product revenue	$ 5,878	$ 5,545
Product margin	68%	60%

Cost of product revenue includes manufacturing costs incurred in the production process, including component materials, assembly labor and overhead; installation; warranty; service; and packaging and delivery costs. In addition, cost of product revenue includes royalty costs for licensed technologies included in our products, provisions for slow-moving and obsolete inventory and stock-based compensation expense. Costs related to collaboration and grant revenue are included in research and development expense.

Cost of product revenue increased $0.3 million, or 6%, to $5.9 million for the six months ended June 30, 2011 compared to $5.5 million for the six months ended June 30, 2010 due to increased product sales. Cost of product revenue as a percentage of related revenue decreased to 32% for the six months ended June 30, 2011 compared to 40% for the six months ended June 30, 2010. This decrease was due to lower instrument costs, higher average selling prices, higher utilization of chip manufacturing capacity and improved chip yields.

Operating Expenses

The following table presents our operating expenses for each period presented (in thousands):

	Six Months Ended June 30,	
	2011	2010
Research and development	$ 6,642	$ 6,635
Selling, general and administrative	15,285	12,023
Litigation settlement	3,000	0
Total operating expenses	$ 24,927	$ 18,658

Research and Development

Research and development expense consists primarily of personnel costs, independent contractor costs, prototype and material expenses and other allocated facilities and information technology expenses. We have made substantial investments in research and development since our inception. Our research and development efforts have focused primarily on the tasks required to enhance our technologies and to support development and commercialization of new and existing products and services.

Research and development expense was $6.6 million for each of the six months ended June 30, 2011 and June 30, 2010. During the six months ended June 30, 2011, increases in compensation costs and related expenses of $0.1 million and increases in consulting and professional fees of $0.1 million were offset by decreases in equipment related costs and depreciation of $0.2 million as older equipment became fully depreciated, as compared to the six months ended June 30, 2010.

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Selling, General and Administrative

Selling, general and administrative expense consists primarily of personnel costs for our sales and marketing, business development, finance, legal, human resources and general management, as well as professional services, such as legal and accounting services.

Selling, general and administrative expense increased $3.3 million, or 27%, to $15.3 million for the six months ended June 30, 2011, compared to $12.0 million for the six months ended June 30, 2010. The increase was primarily due to increased compensation costs and related expenses of $2.7 million resulting from increased headcount to support our business and revenue growth, increased other costs of $0.6 million to support our public company requirements and increased legal and professional fees of $0.6 million, partially offset by lower bad debt expense of $0.3 million and lower rent expense of $0.3 million resulting from our new lease on more favorable terms for our headquarters facility in South San Francisco, California.

Litigation Settlement

On June 30, 2011, we settled certain litigation and entered into a series of patent license agreements resulting in a net $3.0 million payment by us to Life Technologies and their subsidiary Applied Biosystems, LLC (Life). The payment was recognized as litigation settlement expense in our June 30, 2011 condensed consolidated statement of operations because the agreement specified that the amount paid by us was principally attributable to resolving Life s litigation claims with respect to a specific expiring U.S. patent and its foreign counterparts. We had no similar settlement in the six months ended June 30, 2010.

Interest Expense and Other Income and Expense, Net

We receive interest income from our cash and cash equivalents and available-for-sale securities. Conversely, we incur interest expense from our long-term debt, bank line of credit, promissory notes and the amortization of debt discounts related to these items. Until the completion of our IPO, we also recognized income or expense as a result of changes in the fair value of outstanding warrants to purchase shares of our convertible preferred stock. The following table presents these items for each period presented (in thousands):

	Six Months Ended June 30,	
	2011	**2010**
Interest expense	$ (2,272)	$ (1,080)
Gain (loss) from changes in the fair value of convertible preferred stock warrants	(1,483)	272
Gain from expiration of unexercised warrants	765	
Other income (expense), net	108	(17)

Interest expense was $2.3 million for the six months ended June 30, 2011 compared to $1.1 million for the six months ended June 30, 2010. The increase is primarily due to $1.2 million of non-cash interest expense in connection with a $5.0 million note and warrant agreement entered into in January 2011. We repaid all principal and interest outstanding under this note in February 2011 upon the completion of our IPO. There was no similar transaction or recognition of expense in the six months ended June 30, 2010.

Gain (loss) from changes in the fair value of preferred stock was a loss of $1.5 million for the six months ended June 30, 2011 compared to a $0.3 million gain for the six months ended June 30, 2010. The loss in 2011 was due to an increase in the warrant liability fair value through the completion of our IPO on February 10, 2011. Upon completion of our IPO, our outstanding preferred stock warrants were either converted into warrants to purchase common stock or expired unexercised, or were exercised for shares of our common stock. Liabilities related to the expired warrants were reversed and resulted in a gain reflected in other income; liabilities related to the warrants that were converted into warrants to purchase common stock and warrants that were exercised were reclassified to additional paid-in-capital.

Other income increased $125,000 to $108,000 for the six months ended June 30, 2011 compared to a $17,000 loss for the six months ended June 30, 2010 primarily due to favorable changes in foreign currency exchange gains and losses.

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Liquidity and Capital Resources

Sources of Liquidity

As of June 30, 2011, we had $10.1 million of cash and cash equivalents and $54.2 million of available-for-sale securities. As of June 30, 2011, our working capital was $63.2 million. In February 2011, we completed our IPO of common stock which resulted in net proceeds to us of approximately $77.0 million, net of underwriting discounts, commissions and offering expenses. Following the completion of our IPO, we paid the balance on our bank line of credit of $3.1 million, which is collateralized by our accounts receivable and provides us the ability to borrow up to $7.0 million, subject to certain covenants and other restrictions, and paid all principal and interest outstanding of $5.0 million on the note and warrant agreement we entered into in January 2011.

As of June 30, 2011, the outstanding balance under our loan and security agreement was $13.0 million. The loan and security agreement has a maturity date of February 2013 and bears interest of 13.5% per annum upon which interest only payments were paid monthly through February 2011. Commencing in March 2011, we began making monthly payments of $0.6 million for principal and interest and will make an additional payment of $2.3 million in March 2012. The additional payment is being accreted as interest expense through the maturity date of February 2013. As of June 30, 2011, we were in compliance with all loan covenants.

The following table presents our cash flow summary for each period presented (in thousands):

	Six Months Ended June 30,	
	2011	2010
Cash flow summary		
Net cash used in operating activities	$ (12,908)	$ (6,027)
Net cash used in investing activities	(54,957)	(527)
Net cash provided by financing activities	72,232	11
Net increase (decrease) in cash and cash equivalents	4,406	(6,533)

Net Cash Used in Operating Activities

We derive cash flows from operations primarily from cash collected from the sale of our products, collaboration and license agreements and grants from certain government entities. Our cash flows from operating activities are also significantly influenced by our use of cash for operating expenses to support the growth of our business. We have historically experienced negative cash flows from operating activities as we have expanded our business and built our infrastructure domestically and internationally and this may continue in the future.

Net cash used in operating activities was $12.9 million during the six months ended June 30, 2011. Net cash used in operating activities primarily consisted of our net loss of $14.5 million, changes in our operating assets and liabilities in the amount of $2.2 million, and non-cash expense items such as stock-based compensation of $1.3 million, depreciation and amortization of our property and equipment of $0.5 million, loss from changes in the fair value of convertible stock warrants of $1.5 million, gain from expiration of unexercised warrants of $0.8 million, write off of debt discounts upon note repayment of $1.2 million and amortization of debt discount and issuance costs of $0.1 million.

Net cash used in operating activities was $6.0 million during the six months ended June 30, 2010. Net cash used in operating activities primarily consisted of our net loss of $10.4 million, changes in our operating assets and liabilities in the amount of $3.0 million, and non-cash expense items such as stock-based compensation of $0.8 million, depreciation and amortization of our property and equipment of $0.6 million, and amortization of debt discount and issuance costs of $0.2 million, partially offset by a gain from changes in the fair value of convertible stock warrants of $0.2 million.

Net Cash Used in Investing Activities

Historically, our primary investing activities have consisted of capital expenditures for laboratory, manufacturing and computer equipment and software to support our expanding infrastructure and work force; and purchases, sales and maturities of our available-for-sale securities. We expect to continue to expand our manufacturing capability, primarily in Singapore, and expect to incur additional costs for capital expenditures related to these efforts in future periods.

We used $55.0 million of cash in investing activities during the six months ended June 30, 2011 to invest a portion of the net proceeds from our IPO in available-for-sale securities of $54.2 million and for purchases of capital equipment to support our infrastructure and manufacturing

operations of $0.7 million.

We used $0.5 million of cash in investing activities during the six months ended June 30, 2010 primarily for purchases of capital equipment to support our infrastructure and manufacturing operations of $0.6 million, partially offset by a decrease in restricted cash of $0.1 million related to the favorable lease negotiations of our headquarters facility in South San Francisco, California.

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Net Cash Provided by Financing Activities

Prior to our IPO, we funded our operations principally through issuances of convertible preferred stock and long term debt.

We generated $72.2 million of cash from financing activities during the six months ended June 30, 2011 primarily from net proceeds from our IPO of approximately $77.0 million and $5.0 million from subordinated secured promissory notes with existing stockholders and proceeds from exercise of stock options of $0.2 million, partially offset by the pay off of our line of credit balance of $3.1 million and repayment of the outstanding principal, interest on the subordinated secured promissory notes of $5.0 million and repayment of long-term debt of $1.8 million.

Capital Resources

At June 30, 2011, our working capital was $63.2 million, including cash, cash equivalents and available-for-sale securities of $64.3 million. We have a bank line of credit agreement that is collateralized by our accounts receivable and provides us the ability to draw up to $7.0 million, subject to certain covenants and restrictions. During the six months ended June 30, 2011, our capital expenditures were $0.7 million. We are estimating capital expenditures to be higher in 2011 compared to 2010 primarily for the expansion of our manufacturing capacity, research and development equipment and sales demonstration and product support instruments to service our global customer base.

We believe our existing cash and cash equivalents will be sufficient to meet our working capital and capital expenditure needs for at least the next 18 months. However, we may need to raise additional capital to expand the commercialization of our products, fund our operations and further our research and development activities. Our future funding requirements will depend on many factors, including market acceptance of our products, the cost of our research and development activities, the cost of filing and prosecuting patent applications, the cost of defending, in litigation or otherwise, any claims that we infringe third-party patents or violate other intellectual property rights, the cost and timing of regulatory clearances or approvals, if any, the cost and timing of establishing additional sales, marketing and distribution capabilities, the cost and timing of establishing additional technical support capabilities, the effect of competing technological and market developments and the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

We may require additional funds in the future and we may not be able to obtain such funds on acceptable terms, or at all. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or additional equity financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets, or delay, reduce the scope of or eliminate some or all of our development programs. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations.

Off-Balance Sheet Arrangements

As of June 30, 2011, we did not have any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K promulgated under the Exchange Act.

Recent Accounting Pronouncements

Information with respect to recent accounting pronouncements is included in Note 2 of the notes to our condensed consolidated financial statements included elsewhere in this Form 10-Q.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in foreign currency exchange rates and interest rates. We do not hold or issue financial instruments for trading purposes.

Foreign Currency Exchange Risk

As we expand internationally our results of operations and cash flows will become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Our revenue is generally denominated in the local currency of the contracting party. Historically, the substantial majority of our revenue has been denominated in U.S. dollars. Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States, with a portion of expenses incurred in Singapore, where our manufacturing facility is located. Our results of operations and cash flows are, therefore, subject to fluctuations due to changes in foreign currency exchange rates. Fluctuations in currency exchange rates could harm our business in the future. The effect of a 10% adverse change in exchange rates on foreign denominated cash, receivables and payables as of June 30, 2011 would not have been material. To date, we have not entered into any material foreign currency hedging contracts although we may do so in the future.

Interest Rate Sensitivity

We had cash and cash equivalents of $10.1 million at June 30, 2011. These amounts were held primarily in cash on deposit with banks, money market funds, and U.S. government agency securities which are short-term. We had $54.2 million in available-for-sale securities at June 30, 2011 held primarily in U.S. government agency securities with maturities of less than twelve months. Cash and cash equivalents and available-for-sale securities are held for working capital purposes. Due to the short-term nature of these investments, we believe that we do not have any material exposure to changes in the fair value of our investment portfolio as a result of changes in interest rates. Declines in interest rates, however, will reduce future investment income. If overall interest rates had decreased by 10% during the period presented, our interest income would not have been materially affected.

As of June 30, 2011, the principal amount of our long-term debt outstanding was $13.0 million and we had no outstanding balance on our bank line of credit. The interest rates on our long-term debt are fixed. If overall interest rates had increased by 10% during the period presented, our interest expense would not have been materially affected.

Fair Value of Financial Instruments

We do not have material exposure to market risk with respect to investments. We do not use derivative financial instruments for speculative or trading purposes. However, we may adopt specific hedging strategies in the future.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and our chief financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our chief executive officer and our chief financial officer concluded that our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and our chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

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Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

On June 29, 2011, we filed suit in the U.S. District Court for the Northern District of California against Life Technologies Corporation and its subsidiary Applied Biosystems LLC (collectively, Life) seeking declaratory judgment of non-infringement and invalidity of certain Life patents, and alleging infringement by Life of a patent owned by us. Later on June 29, 2011, Life filed suit against us in the U.S. District Court for the District of Delaware alleging we infringed two Life patents.

On June 30, 2011, we settled the foregoing suits and entered into a series of license agreements with Life. The agreements resulted in a net $3.0 million payment by us to Life and also provide for various royalty payments on future sales of certain products by each of the parties. Such royalty payments or receipts are not expected to be material to us in the future based on our current expectations.

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Item 1A. Risk Factors.

We operate in a rapidly changing environment that involves numerous uncertainties and risks. The following risks and uncertainties may have a material and adverse effect on our business, financial condition or results of operations. You should consider these risks and uncertainties carefully, together with all of the other information included or incorporated by reference in this Form 10-Q. If any of the risks or uncertainties we face were to occur, the trading price of our securities could decline, and you may lose all or part of your investment.

Risks Related to our Business and Strategy

We have incurred losses since inception, and we expect to continue to incur substantial losses for the foreseeable future.

We have a limited operating history and have incurred significant losses in each fiscal year since our inception, including net losses of $14.5 million, $16.9 million, $19.1 million and $29.5 million during the six months ended June 30, 2011, and the years 2010, 2009 and 2008, respectively. As of June 30, 2011, we had an accumulated deficit of $213.9 million. These losses have resulted principally from costs incurred in our research and development programs and from our selling, general and administrative expenses. We expect to continue to incur operating and net losses and negative cash flow from operations, which may increase, for the foreseeable future due in part to anticipated increases in expenses for significant expansion of our sales and marketing capabilities and research and product development. Additionally, we expect that our selling, general and administrative expenses will continue to increase due to the additional operational and reporting costs associated with being a public company. We anticipate that our business will generate operating losses until we successfully implement our commercial development strategy and generate significant additional revenues to support our level of operating expenses. Because of the numerous risks and uncertainties associated with our commercialization efforts and future product development, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase our profitability.

If our products fail to achieve and sustain sufficient market acceptance, our revenue will be adversely affected.

Our success depends, in part, on our ability to develop and market products that are recognized and accepted as reliable, enabling and cost effective. Most of our potential customers already use expensive research systems in their laboratories and may be reluctant to replace those systems. Market acceptance of our systems will depend on many factors, including our ability to convince potential customers that our systems are an attractive alternative to existing technologies. Compared to some competing technologies, our microfluidic technology is relatively new, and most potential customers have limited knowledge of, or experience with, our products. Prior to adopting our microfluidic systems, some potential customers may need to devote time and effort to testing and validating our systems. Any failure of our systems to meet these customer benchmarks could result in customers choosing to retain their existing systems or to purchase systems other than ours.

In addition, many customers intend to publish the results of their experiments in scientific and medical journals. Therefore, it is important that our systems be perceived as accurate and reliable by the scientific and medical research community as a whole. Many factors influence the perception of a system including its use by leading research groups and the publication of their results in well regarded journals. Historically, a significant part of our sales and marketing efforts have been directed at convincing industry leaders of the advantages of our systems and encouraging such leaders to publish or present the results of their evaluation of our system. If we are unable to continue to induce leading researchers to use our systems or if such researchers are unable to achieve and publish or present significant experimental results using our systems, acceptance and adoption of our systems will be slowed.

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Our financial results may vary significantly from quarter-to-quarter due to a number of factors, which may lead to volatility in our stock price.

Our quarterly revenue and results of operations have varied in the past and may continue to vary significantly from quarter-to-quarter. This variability may lead to volatility in our stock price as research analysts and investors respond to these quarterly fluctuations. These fluctuations are due to numerous factors, including: fluctuations in demand for our products; changes in customer budget cycles and capital spending; seasonal variations in customer operations; tendencies among some customers to defer purchase decisions to the end of the quarter; the large unit value of our systems; changes in our pricing and sales policies or the pricing and sales policies of our competitors; our ability to design, manufacture and deliver products to our customers in a timely and cost-effective manner; quality control or yield problems in our manufacturing operations; our ability to timely obtain adequate quantities of the components used in our products; new product introductions and enhancements by us and our competitors; unanticipated increases in costs or expenses; and fluctuations in foreign currency exchange rates. For example, in 2008, 2009 and 2010, we experienced higher sales in the fourth quarter than in the first quarter of the next fiscal year as a result of one or more of the factors described above. The foregoing factors are difficult to forecast, and these, as well as other factors, could materially and adversely affect our quarterly and annual results of operations. In addition, a significant amount of our operating expenses are relatively fixed due to our manufacturing, research and development, and sales and general administrative efforts. Any failure to adjust spending quickly enough to compensate for a revenue shortfall could magnify the adverse impact of such revenue shortfall on our results of operations. Our results of operations may not meet the expectations of research analysts or investors, in which case the price of our common stock could decrease significantly.

Our future success is dependent upon our ability to expand our customer base and introduce new applications.

Our customer base is primarily composed of pharmaceutical, biotechnology and Ag-Bio companies, academic institutions and life science laboratories that perform analyses for research and commercial purposes. Our success will depend in part upon our ability to increase our market share among these customers, attract additional customers outside of these markets and market new applications to existing and new customers as we develop such applications. Attracting new customers and introducing new applications requires substantial time and expense. For example, it may be difficult to identify, engage and market to customers who are unfamiliar with the current applications of our systems. In addition, certain new applications that we are considering developing are not commonly performed with conventional techniques and therefore may require additional sales efforts to create customer awareness of the utility of these applications. Any failure to expand our existing customer base or launch new applications would adversely affect our ability to increase our revenues.

The life science research and Ag-Bio markets are highly competitive and subject to rapid technological change, and we may not be able to successfully compete.

The markets for our products are characterized by rapidly changing technology, evolving industry standards, changes in customer needs, emerging competition, new product introductions and strong price competition. We compete with both established and development stage life science research and Ag-Bio companies that design, manufacture and market instruments for gene expression analysis, genotyping, PCR, other nucleic acid detection and additional applications using well established laboratory techniques, as well as newer technologies such as bead encoded arrays, microfluidics, nanotechnology, high-throughput DNA sequencing and inkjet and photolithographic arrays. Most of our current competitors have significantly greater name recognition, greater financial and human resources, broader product lines and product packages, larger sales forces, larger existing installed bases, larger intellectual property portfolios and greater experience and scale in research and development, manufacturing and marketing than we do. For example, companies such as Affymetrix, Inc., Agilent Technologies, Inc., Caliper Life Sciences, Inc., Illumina, Inc., Life Technologies Corporation, Luminex Corporation, Roche Applied Science, NanoString Technologies, Inc., QuantaLife, Inc., RainDance Technologies, Inc., Sequenom, Inc. and WaferGen Bio-systems, Inc. have products that compete in certain segments of the market in which we sell our products, including gene expression analysis, genotyping and sequencing. In addition, a number of other companies and academic groups are in the process of developing novel technologies for life science markets.

Competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements. In light of these advantages, even if our technology is more effective than the product or service offerings of our competitors, current or potential customers might accept competitive products and services in lieu of purchasing our technology. We anticipate that we will face increased competition in the future as existing companies and competitors develop new or improved products and as new companies enter the market with new technologies. We may not be able to compete effectively against these organizations. Increased competition is likely to result in pricing pressures, which could harm our sales, profitability or market share. Our failure to compete effectively could materially and adversely affect our business, financial condition and results of operations.

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We have limited experience in marketing, selling and distributing our products, and we need to expand our direct sales and marketing force or distribution capabilities to adequately address our customers needs.

We have limited experience in marketing, selling and distributing our products. Our BioMark and EP1 systems for genomic analysis were introduced for commercial sale in 2006 and 2008, respectively. Our Access Array system for sample preparation was introduced for commercial sale in 2009, and our BioMark HD system for genomic analysis was introduced for commercial sale in 2011. We may not be able to market, sell and distribute our products effectively enough to support our planned growth.

We sell our products primarily through our own sales force and through distributors in certain territories. Our future sales will depend in large part on our ability to develop and substantially expand our direct sales force and to increase the scope of our marketing efforts. Our products are technically complex and used for highly specialized applications. As a result, we believe it is necessary to develop a direct sales force that includes people with specific scientific backgrounds and expertise and a marketing group with technical sophistication. Competition for such employees is intense. We may not be able to attract and retain personnel or be able to build an efficient and effective sales and marketing force, which could negatively impact sales of our products, and reduce our revenues and profitability.

In addition, we may continue to enlist one or more sales representatives and distributors to assist with sales, distribution and customer support globally or in certain regions of the world. If we do seek to enter into such arrangements, we may not be successful in attracting desirable sales representatives and distributors, or we may not be able to enter into such arrangements on favorable terms. If our sales and marketing efforts, or those of any third-party sales representatives and distributors, are not successful, our technologies and products may not gain market acceptance, which would materially impact our business operations.

Our sales may be adversely affected by recent events in Japan.

The recent earthquake and tsunami in Japan and their aftermath have created significant economic uncertainty in that country. Sales to customers located in Japan represented approximately 13%, 9% and 12% of our product revenue for the fiscal years 2009 and 2010 and the six month period ended June 30, 2011, respectively. Although our sales in Japan in the first two quarters of 2011 were not adversely affected by these natural disasters, we can give no assurance that our future operating results will not be adversely affected.

Our business depends on research and development spending levels of pharmaceutical, Ag-Bio and biotechnology companies and academic, clinical and governmental research institutions and any reduction in such spending could limit our ability to sell our products.

We expect that our revenue in the foreseeable future will be derived primarily from sales of our microfluidic systems and chips to academic institutions and biotechnology, Ag-Bio and pharmaceutical companies and life science laboratories worldwide. Our success will depend upon their demand for and use of our products. Accordingly, the spending policies of these customers could have a significant effect on the demand for our technology. These policies may be based on a wide variety of factors, including the resources available to make purchases, the spending priorities among various types of equipment, policies regarding spending during recessionary periods and changes in the political climate. In addition, academic, governmental and other research institutions that fund research and development activities may be subject to stringent budgetary constraints that could result in spending reductions, reduced allocations or budget cutbacks, which could jeopardize the ability of these customers to purchase our system. Our operating results may fluctuate substantially due to reductions and delays in research and development expenditures by these customers. For example, reductions in capital expenditures by these customers may result in lower than expected system sales and, similarly, reductions in operating expenditures by these customers could result in lower than expected sales of our microfluidic systems and chips. These reductions and delays may result from factors that are not within our control, such as:

- changes in economic conditions;
- natural disasters;
- changes in government programs that provide funding to research institutions and companies;

changes in the regulatory environment affecting life science and Ag-Bio companies engaged in research and commercial activities;

differences in budget cycles across various geographies and industries;

market-driven pressures on companies to consolidate operations and reduce costs;

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mergers and acquisitions in the life science and Ag-Bio industries; and

other factors affecting research and development spending.

Any decrease in our customers budgets or expenditures or in the size, scope or frequency of capital or operating expenditures as a result of the foregoing or other factors could materially and adversely affect our operations or financial condition.

We may not be able to develop new systems or enhance the capabilities of our existing microfluidic systems to keep pace with rapidly changing technology and customer requirements.

Our success depends on our ability to develop new applications for our technology in existing and new markets, while improving the performance and cost effectiveness of our systems. New technologies, techniques or products could emerge that might offer better combinations of price and performance than our current or future product lines and systems. Existing markets for our products, including gene expression analysis, genotyping, digital polymerase chain reaction, or PCR, and single cell analyses, as well as potential markets for our products such as high-throughput DNA sequencing and molecular diagnostics applications, are characterized by rapid technological change and innovation. It is critical to our success for us to anticipate changes in technology and customer requirements and to successfully introduce new, enhanced and competitive technology to meet our customers and prospective customers needs on a timely basis. Developing and implementing new technologies will require us to incur substantial development costs and we may not have adequate resources available to be able to successfully introduce new applications of, or enhancements to, our systems. We cannot guarantee that we will be able to maintain technological advantages over emerging technologies in the future. While we typically plan improvements to our systems, we may not be able to successfully implement these improvements. If we fail to keep pace with emerging technologies, demand for our systems will not grow and may decline, and our business, revenue, financial condition and operating results could suffer materially. In addition, if we introduce enhanced systems but fail to manage product transitions effectively, customers may delay or forgo purchases of our systems and our operating results may be adversely affected by product obsolescence and excess inventory. Even if we successfully implement some or all of these planned improvements, we cannot guarantee that our current and potential customers will find our enhanced systems to be an attractive alternative to existing technologies, including our current products.

Emerging market opportunities may not develop as quickly as we expect.

The application of our technologies to molecular diagnostics, single cell analysis, digital PCR and sample preparation for next generation DNA sequencing are emerging market opportunities. We believe these opportunities will take several years to develop or mature and we cannot be certain that these market opportunities will develop as we expect. Although we believe that there will be applications of our technologies in these markets, there can be no certainty of the technical or commercial success our technologies will achieve in such markets. Our success in the emerging markets of molecular diagnostics, single cell analysis, digital PCR and sample preparation for next generation DNA sequencing may depend to a large extent on our ability to successfully market and sell products using our technologies. In addition, in the case of molecular diagnostics, we will need to obtain regulatory approval for such products in the United States and in overseas markets.

Our research and product development efforts may not result in commercially viable products within the timeline anticipated, if at all.

Our business is dependent on the improvement of our existing products, our development of new products to serve existing markets and our development of new products to create new markets and applications that were previously not practical with existing systems. We intend to devote significant personnel and financial resources to research and development activities designed to advance the capabilities of our microfluidic systems technology. Our technology is new and complex and the behavior of fluids and surrounding compounds in a nanoscale environment is difficult to predict in advance. Though we have developed design rules for the implementation of our technology, these are frequently revised to reflect new insights we have gained about the technology. In addition, we have discovered that biological or chemical reactions sometimes behave differently when implemented on our systems rather than in a standard laboratory environment. As a result, research and development efforts may be required to transfer certain reactions to our systems. In the past, product development projects have been significantly delayed when we encountered unanticipated difficulties in implementing a process on our systems. We may have similar delays in the future, and we may not obtain any benefits from our research and development activities. Any delay or failure by us to develop new products or enhance existing products would have a substantial adverse effect on our business and results of operations.

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Our sales cycles are lengthy and variable, which makes it difficult for us to forecast revenue and other operating results.

The sales cycles for our systems are lengthy, which makes it difficult for us to accurately forecast revenues in a given period, and may cause revenue and operating results to vary significantly from period to period.

Due in part to the high up-front cost associated with our systems, potential customers for our systems typically need to commit significant time and resources to evaluate our technology and their decision to purchase our instruments may be further limited by budgetary constraints and several layers of internal review and approval, which are beyond our control. In addition, the novelty and complexity of our products often requires us to spend substantial time and effort assisting potential customers in evaluating our instruments, including providing demonstrations and benchmarking our products against other available technologies. Even after initial approval by appropriate decision makers, the negotiation and documentation processes for a purchase can be lengthy. As a result of these factors, our sales cycle has varied widely and, in certain instances has been longer than 12 months. The complexity and variability of our sales cycle has made it difficult for us to accurately project quarterly revenues, and we have frequently failed to meet our internal quarterly projections. Moreover, we do not recognize revenue on sales of our systems until the system has been delivered to the customer and our other revenue recognition criteria have been met. This further complicates our ability to project quarterly revenue as we may have entered into a sale agreement with a customer for a system but cannot predict when that customer will take delivery of the system and when we will be able to recognize the revenue. We expect that our sales will continue to fluctuate on a quarterly basis and that our financial results for some periods may be below those projected by securities analysts. Such fluctuations could have a material adverse effect on our business and on the price of our common stock.

We may rely on strategic partnerships for research and development and commercialization purposes.

We have entered into and may continue to enter into strategic partnerships, including collaborations, joint ventures and alliances with other participants in the life science, Ag-Bio and molecular diagnostics industries. For example, in 2010, we entered into a collaboration agreement in molecular diagnostics and a co-marketing agreement in next generation sequencing. If any of our strategic partners were to change their business strategies or development priorities, or encounter research and development obstacles, they may no longer be willing or able to participate in such strategic partnerships which could have a material adverse effect on our business, financial condition and results of operations. In addition, we may not control the strategic partnerships in which we participate. We may also have certain obligations, including some limited funding obligations or take or pay obligations, with regard to our strategic partnerships, joint ventures and alliances. We may be required to relinquish important rights, including intellectual property rights, and control over the development of our product candidates, assume product or other liabilities associated with the use of our products in diagnostic and other applications, agree to restrictions on the use or applications of our products, or otherwise be subject to terms unfavorable to us.

Under our collaboration agreements with Novartis Vaccines & Diagnostics, Inc., or Novartis V&D, our capabilities in digital PCR are being developed for potential in-vitro diagnostics applications, with an initial focus on the development of an NIPD test for fetal aneuploidies. These agreements provide Novartis V&D with an option to exclusively license our technology in the primary field of non-invasive testing for fetal aneuploidies and the secondary field of non-invasive testing of genetic abnormality, disease or condition in a fetus or in a pregnant woman (other than as tested in the primary field), RhD genotyping or carrier status in a pregnant woman and the genetic carrier status of a prospective mother and her male partner. Under these agreements, except with Novartis V&D, we cannot, directly or in collaboration with a third party, use, develop or sell any products or services in the primary field or the secondary field, other than for research applications in the secondary field. The agreements contain technical feasibility milestones in 2011 and may be terminated by Novartis V&D at any time. At Novartis V&D s option, these agreements can be extended to encompass further research, development and commercialization of our products in the primary and secondary fields described above, which could take several years or more to complete. The agreements provide that if a test is commercialized, we would supply the required systems and chips for performance of such test.

Our agreements and efforts with Novartis V&D are in their early stages and are subject to numerous conditions, contingencies, development challenges, milestones, royalty and license fees, indemnification obligations, termination rights, change of control and default provisions and regulatory approvals. There can be no assurance that this collaboration will lead to technology, products or services, that such technology, products or services will receive market acceptance, that we will realize any material revenue or other benefits from this collaboration or that the benefits will exceed our costs.

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If our facility becomes inoperable, we will be unable to continue manufacturing our products and as a result, our business will be harmed until we are able to secure a new facility.

We manufacture and assemble all of our products for commercial sale at our facility in Singapore. No other manufacturing or assembly facilities are currently available to us. Our facility and the equipment we use to manufacture our products would be costly to replace and could require substantial lead time to repair or replace. The facility may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, flooding and power outages, which may render it difficult or impossible for us to perform our research, development and manufacturing for some period of time. The inability to perform our research, development and manufacturing activities, combined with our limited inventory of reserve raw materials and manufactured supplies, may result in the loss of customers or harm our reputation, and we may be unable to reestablish relationships with those customers in the future. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

Our future capital needs are uncertain and we may need to raise additional funds in the future.

We believe that our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements for at least the next 18 months. However, we may need to raise substantial additional capital to:

- expand the commercialization of our products;
- fund our operations;
- further our research and development; and
- acquire and license technologies.

Our future funding requirements will depend on many factors, including:

- market acceptance of our products;
- the cost of our research and development activities;
- the cost of filing and prosecuting patent applications;
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patents or violate other intellectual property rights;
- the cost and timing of regulatory clearances or approvals, if any;
- the cost and timing of establishing additional sales, marketing and distribution capabilities;

the cost and timing of establishing additional technical support capabilities;

the effect of competing technological and market developments; and

the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

We cannot assure you that we will be able to obtain additional funds on acceptable terms, or at all. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or additional equity financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets, or delay, reduce the scope of or eliminate some or all of our development programs.

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If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations. Any of these factors could harm our operating results.

To use our products and our BioMark system in particular, customers typically need to purchase specialized reagents. Any interruption in the availability of these reagents for use in our products could limit our ability to market our products.

Our products and our BioMark system in particular, must be used in conjunction with one or more reagents designed to produce or facilitate the particular biological or chemical reaction desired by the user. Many of these reagents are highly specialized and available to the user only from a single supplier or a limited number of suppliers. Our customers typically purchase these reagents directly from the suppliers, and we have no control over the supply of those materials. In addition, our products are designed to work with these reagents as they are currently formulated. We have no control of the formulation of these reagents, and the performance of our products might be adversely affected if the formulation of these reagents was changed. If one or more of these reagents were to become unavailable or were reformulated, our ability to market and sell our products could be materially and adversely affected.

In addition, the use of a reagent for a particular process may be covered by one or more patents relating to the reagent itself, the use of the reagent for the particular process, the performance of that process or the equipment required to perform the process. Typically, reagent suppliers, who are either the patent holders or their authorized licensees, sell the reagents along with a license or covenant not to sue with respect to such patents. The license accompanying the sale of a reagent often purports to restrict the purposes for which the reagent may be used. If a patent holder or authorized licensee were to assert against us or our customers that the license or covenant relating to a reagent precluded its use with our systems, our ability to sell and market our products could be materially and adversely affected. For example, the current applications of our BioMark system, which represented 34% of our product revenue in the six months ended June 30, 2011 and 43% of our product revenue in 2010, involve real-time quantitative polymerase chain reaction, or real-time qPCR. Leading suppliers of reagents for real-time qPCR reactions include Life Technologies Corporation and Roche Applied Science, who are our direct competitors, and their licensees. These real-time qPCR reagents are typically sold pursuant to limited licenses or covenants not to sue with respect to patents held by these companies. We do not have any contractual supply agreements for these real-time qPCR reagents, and we cannot assure you that these reagents will continue to be available to our customers for use with our systems, or that these patent holders will not seek to enforce their patents against us, our customers, or suppliers.

If we cannot provide quality technical support, we could lose customers and our operating results could suffer.

The placement of our products at new customer sites, the introduction of our technology into our customers existing systems and ongoing customer support can be complex. Accordingly, we need highly trained technical support personnel. Hiring technical support personnel is very competitive in our industry due to the limited number of people available with the necessary biochemistry background and ability to understand our systems at a technical level. To effectively support potential new customers and the expanding needs of current customers, we will need to substantially expand our technical support staff. If we are unable to attract, train or retain the number of highly qualified technical services personnel that our business needs, our business and prospects will suffer.

We are dependent on single source suppliers for some of the components and materials used in our systems, and the loss of any of these suppliers could harm our business.

We rely on single source suppliers for certain components and materials used in our systems. Of these single source suppliers, the loss of any of the following would require significant time and effort to locate and qualify an alternative source of supply:

- The chips used in our microfluidic systems are fabricated using a specialized polymer that is available from a limited number of sources. In the past we have encountered quality issues that have reduced our manufacturing yield or required the use of additional manufacturing processes. We do not have a long term contract with our current sole supplier.

- The reader for our BioMark system requires specialized high resolution camera lenses and other components that are available from a limited number of sources.

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Our reliance on these suppliers also subjects us to other risks that could harm our business, including the following:

- we may be subject to increased component costs;
- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;
- our suppliers may make errors in manufacturing components that could negatively affect the efficacy of our systems or cause delays in shipment of our systems; and
- our suppliers may encounter financial hardships unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements.

We have in the past experienced quality control and supply problems with some of our suppliers, such as manufacturing errors, and may again experience problems in the future. We may not be able to quickly establish additional or replacement suppliers, particularly for our single source components. Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products.

We may experience development or manufacturing problems or delays that could limit the growth of our revenue or increase our losses.

We may encounter unforeseen situations in the manufacturing and assembly of our products that would result in delays or shortfalls in our production. In addition, our production processes and assembly methods may have to change to accommodate any significant future expansion of our manufacturing capacity. If we are unable to keep up with demand for our products, our revenue could be impaired, market acceptance for our products could be adversely affected and our customers might instead purchase our competitors products. Our inability to successfully manufacture our products would have a material adverse effect on our operating results.

All of our commercial products are manufactured at our facility in Singapore. We began commercial production of our chips in Singapore in October 2006 and have transitioned the commercial production of our microfluidic systems to Singapore as well. Production of the elastomeric block that is at the core of our chips is a complex process requiring advanced clean rooms, sophisticated equipment and strict adherence to procedures. Any contamination of the clean room, equipment malfunction or failure to strictly follow procedures can significantly reduce our yield in one or more batches. We have in the past experienced variations in yields due to such factors. Such a drop in yield can increase our cost to manufacture our chips or, in more severe cases, require us to halt the manufacture of our chips until the problem is resolved. Identifying and resolving the cause of a drop in yield can require substantial time and resources.

In addition, developing a chip for a new application may require developing a specific production process for that type of chip. While all of our chips are produced using the same basic processes, significant variations may be required to ensure adequate yield of any particular type of chip. Developing such a process can be very time consuming, and any unexpected difficulty in doing so can delay the introduction of a product.

Our shipments of products to customers are subject to delays or cancellation due to work stoppages or slowdowns, piracy, damage to shipping facilities caused by weather or terrorism, and congestion due to inadequacy of shipping equipment and other causes.

Because all our products are manufactured at our facility in Singapore, we rely on shipping providers to deliver our products to our customers. To the extent that there are disruptions or delays in shipping our products from Singapore or off-loading our products upon arrival at their destination due to labor disputes, tariff or World Trade Organization-related disputes, piracy, physical damage to shipping facilities or equipment caused by severe weather or terrorist incidents, congestion at shipping facilities, inadequate equipment to load, dock and offload our products or energy-related tie-ups or otherwise, or for other reasons, product shipments to our customers will be delayed. Depending on the severity of such consequences, this may have an adverse effect on our financial condition and results of operations.

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If we are unable to recruit and retain key executives and scientists, we may be unable to achieve our goals.

Our performance is substantially dependent on the performance of our senior management and key scientific and technical personnel, particularly Gajus V. Worthington, our President and Chief Executive Officer. We do not maintain fixed term employment contracts with any of our employees. The loss of the services of any member of our senior management or our scientific or technical staff might significantly delay or prevent the development of our products or achievement of other business objectives by diverting management s attention to transition matters and identification of suitable replacements, if any, and could have a material adverse effect on our business. We do not maintain significant key man life insurance on any of our employees.

In addition, our research and product development efforts could be delayed or curtailed if we are unable to attract, train and retain highly skilled employees, particularly, senior scientists and engineers. To expand our research and product development efforts, we need additional people skilled in areas such as molecular and cellular biology, assay development and manufacturing. Competition for these people is intense. Because of the complex and technical nature of our system and the dynamic market in which we compete, any failure to attract and retain a sufficient number of qualified employees could materially harm our ability to develop and commercialize our technology.

Adverse conditions in the global economy and disruption of financial markets may significantly harm our revenue, profitability and results of operations.

The global economy has been experiencing a significant economic downturn, and global credit and capital markets have experienced substantial volatility and disruption. Volatility and disruption of financial markets could limit our customers ability to obtain adequate financing or credit to purchase and pay for our products in a timely manner or to maintain operations, which could result in a decrease in sales volume that could harm our results of operations. General concerns about the fundamental soundness of domestic and international economies may also cause our customers to reduce their purchases. Changes in governmental banking, monetary and fiscal policies to address liquidity and increase credit availability may not be effective. Significant government investment and allocation of resources to assist the economic recovery of sectors which do not include our customers may reduce the resources available for government grants and related funding for life science, Ag-Bio and molecular diagnostics research and development. Continuation or further deterioration of these financial and macroeconomic conditions could significantly harm our sales, profitability and results of operations.

We may be unable to manage our anticipated growth effectively.

The rapid growth of our business has placed a significant strain on our managerial, operational and financial resources and systems. To execute our anticipated growth successfully, we must continue to attract and retain qualified personnel and manage and train them effectively. We must also upgrade our internal business processes and capabilities to create the scalability that a growing business demands.

We believe our commercial manufacturing facility located in Singapore is sufficient to meet our short-term manufacturing needs. The current leases for our manufacturing facility in Singapore expire at various times from August 2011 through July 2013. In order to meet the long-term demand for our microfluidic systems, we believe that we will need to add to our existing manufacturing space in Singapore or move all of our manufacturing facilities to a new location in Singapore in 2012. Such a move will involve significant expense in connection with the establishment of new clean rooms, the movement and installation of key manufacturing equipment and modifications to our manufacturing process and we cannot assure you that such a move would not delay or otherwise adversely affect our manufacturing activities.

Further, our anticipated growth will place additional strain on our suppliers and manufacturing facilities, resulting in an increased need for us to carefully monitor quality assurance. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

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Demand for our technology could be reduced by legal, social and ethical concerns surrounding the use of genetic information and biological materials.

Our products may be used to provide genetic information or analyze biological materials from humans, agricultural crops and other living organisms. The information obtained from our products could be used in a variety of applications, which may have underlying legal, social and ethical concerns, including the genetic engineering or modification of agricultural products, testing for genetic predisposition for certain medical conditions and stem cell research. Governmental authorities could, for safety, social or other purposes, call for limits on or impose regulations on the use of genetic testing or the use of certain biological materials. Such concerns or governmental restrictions could limit the use of our products, which could have a material adverse effect on our business, financial condition and results of operations.

Our products, although not currently subject to regulation by the U.S. Food and Drug Administration or other regulatory agencies as medical devices, could become subject to regulation in the future.

Our products are currently labeled and sold to biotechnology and pharmaceutical companies, academic institutions, and life sciences laboratories for research purposes only, and not diagnostic procedures. As research only products, they are not subject to regulation as medical devices by the U.S. Food and Drug Administration, or FDA, or comparable agencies of other countries. However, if we change the labeling of our products in the future to include diagnostic applications, our products or related applications could be subject to the FDA s pre- and post-market regulations. For example, if we wish to label and market our products for use in performing clinical diagnostics, we would first need to obtain FDA premarket clearance or approval. Obtaining FDA clearance or approval can be expensive and uncertain, generally takes several months to years to obtain, and may require detailed and comprehensive scientific and clinical data. Notwithstanding the expense, these efforts may never result in FDA approval or clearance. Even if we were to obtain regulatory approval or clearance, it may not be for the uses we believe are important or commercially attractive.

Further, FDA may expand its jurisdiction over our products or the products of our customers, which could impose restrictions on our ability to market and sell our products. For example, our customers may use our research use only products in their own laboratory developed tests, or LDTs, for clinical diagnostic use. FDA has historically exercised enforcement discretion in not enforcing the medical device regulations against LDTs. However, the FDA could assert jurisdiction over some or all LDTs, which may impact our customers uses of our products. A significant change in the way that the FDA regulates our products or the LDTs that our customers develop may require us to change our business model in order to maintain compliance with these laws. The FDA held a meeting in July 2010, during which it indicated that it intends to reconsider its policy of enforcement discretion and to begin drafting a new oversight framework for LDTs. Additionally, in June 2011 the FDA issued a draft guidance document intended to clarify the types of in vitro diagnostic products that are properly labeled for research use only. The draft guidance states that merely including a labeling statement that the product is for research purposes only will not necessarily render the device exempt from the FDA s clearance, approval, or other requirements if the circumstances surrounding the distribution of the product indicate that the manufacturer knows its product is offered for additional uses. These circumstances may include written or verbal marketing claims regarding a product s performance in clinical applications and a manufacturer s provision of technical support for such activities. If the FDA imposes significant changes to the regulation of LDTs, or modifies its approach to our research use only tests which may be used by our customers for clinical use, it could reduce our revenues or increase our costs and adversely affect our business, prospects, results of operations or financial condition.

Finally, we may be required to proactively achieve compliance with certain FDA regulations as part of our contracts with customers or as part of our collaborations with third parties. In addition, we may voluntarily seek to conform our manufacturing operations to the FDA s good manufacturing practice regulations for medical devices, known as the Quality System Regulation, or QSR. The QSR is a complex regulatory scheme that governs the methods and documentation covering the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of medical device products. The FDA enforces the QSR through periodic unannounced inspections of registered manufacturing facilities. The failure to take satisfactory corrective action in response to an adverse QSR inspection could result in enforcement actions, including a public warning letter, a shutdown of manufacturing operations, a product recall, civil or criminal penalties or other sanctions, which could in turn cause our sales and business to suffer.

Our products could have unknown defects or errors, which may give rise to claims against us and adversely affect market adoption of our systems.

Our microfluidic systems utilize novel and complex technology applied on a nanoliter scale and such systems may develop or contain undetected defects or errors. We cannot assure you that material performance problems, defects or errors will not arise, and as we increase the density and integration of our microfluidic systems, these risks may increase. While we do not provide express warranties that our microfluidic systems will meet performance expectations or be free from defects, we have done so in the past, and expect to in the future in response to customer concerns in order to preserve customer relationships and help foster continued adoption and use of our systems. We typically do provide warranties relating to other parts of our microfluidic systems. The costs incurred in correcting any defects or errors may be substantial and could adversely

affect our operating margins.

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In manufacturing our products, we depend upon third parties for the supply of various components. Many of these components require a significant degree of technical expertise to produce. If our suppliers fail to produce components to specification, or if the suppliers, or we, use defective materials or workmanship in the manufacturing process, the reliability and performance of our products will be compromised.

If our products contain defects, we may experience:

- a failure to achieve market acceptance or expansion of our product sales;
- loss of customer orders and delay in order fulfillment;
- damage to our brand reputation;
- increased cost of our warranty program due to product repair or replacement;
- product recalls or replacements;
- inability to attract new customers;
- diversion of resources from our manufacturing and research and development departments into our service department; and
- legal claims against us, including product liability claims, which could be costly and time consuming to defend and result in substantial damages.

The occurrence of any one or more of the foregoing could negatively affect our business, financial condition and results of operations.

We generate a substantial portion of our revenues internationally and are subject to various risks relating to such international activities which could adversely affect our international sales and operating performance.

During 2008, 2009, 2010, and the six months ended June 30, 2011, approximately 48%, 46%, 45%, and 49%, respectively, of our product revenue was generated from sales to customers located outside of the United States. We believe that a significant percentage of our future revenue will come from international sources as we expand our overseas operations and develop opportunities in additional international areas. In addition, all of our commercial products are manufactured in Singapore. Our international business may be adversely affected by changing economic, political and regulatory conditions in foreign countries. Because the majority of our product sales are currently denominated in U.S. dollars, if the value of the U.S. dollar increases relative to foreign currencies, our products could become more costly to the international consumer and therefore less competitive in international markets, which could affect our financial performance. In addition, if the value of the U.S. dollar decreases relative to the Singapore dollar, it would become more costly in U.S. dollars for us to manufacture our products in Singapore. Furthermore, fluctuations in exchange rates could reduce our revenue, particularly with respect to grant revenue under agreements in Singapore, and affect demand for our products. Engaging in international business inherently involves a number of other difficulties and risks, including:

- required compliance with existing and changing foreign regulatory requirements and laws;

export or import restrictions;

laws and business practices favoring local companies;

longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;

political and economic instability;

potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;

difficulties and costs of staffing and managing foreign operations; and

difficulties protecting or procuring intellectual property rights.

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If one or more of these risks occurs, it could require us to dedicate significant resources to remedy, and if we are unsuccessful in finding a solution, our financial results will suffer.

We use hazardous chemicals and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development and manufacturing processes involve the controlled use of hazardous materials, including flammables, toxics, corrosives and biologics. Our operations produce hazardous biological and chemical waste products. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. In addition, our microfluidic systems involve the use of pressurized systems and may involve the use of hazardous materials, which could result in injury. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials. We do not currently maintain separate environmental liability coverage and any such contamination or discharge could result in significant cost to us in penalties, damages and suspension of our operations.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

We began operating as a public company in February 2011. As a public company, we are incurring significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as new rules subsequently implemented by the Securities and Exchange Commission and the NASDAQ Global Market, have imposed various new requirements on public companies, including requiring changes in corporate governance practices. Our management and other personnel are devoting a substantial amount of time to these new compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these new rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage.

If we fail to maintain effective internal control over financial reporting in the future, the accuracy and timing of our financial reporting may be impaired, which could adversely affect our business and our stock price.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, with respect to our 2011 fiscal year, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our testing may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues. We currently do not have an internal audit group and we will evaluate the need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the NASDAQ Global Market, the Securities and Exchange Commission or other regulatory authorities, which would require additional financial and management resources.

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Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

In general, under Section 382 of the Internal Revenue Code, a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change net operating losses or NOLs to offset future taxable income. Our existing NOLs may be subject to limitations arising from previous ownership changes, including our initial public offering. If we undergo an ownership change, our ability to utilize NOLs could be further limited by Section 382 of the Internal Revenue Code. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Internal Revenue Code. We may not be able to utilize a material portion of the NOLs reflected on our balance sheet and for this reason, we have fully reserved against the value of our NOLs on our balance sheet.

Risks Related to Intellectual Property

Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain.

Our commercial success depends in part on our ability to protect our intellectual property and proprietary technologies. We rely on patent protection, where appropriate and available, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Our pending U.S. and foreign patent applications may not issue as patents or may not issue in a form that will be sufficient to protect our proprietary technology and gain or keep our competitive advantage. Any patents we have obtained or do obtain may be subject to re-examination, reissue, opposition or other administrative proceeding, or may be challenged in litigation, and such challenges could result in a determination that the patent is invalid or unenforceable. In addition, competitors may be able to design alternative methods or devices that avoid infringement of our patents. To the extent our intellectual property, including licensed intellectual property, offers inadequate protection, or is found to be invalid or unenforceable, we are exposed to a greater risk of direct competition. If our intellectual property does not provide adequate protection against our competitors products, our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive. Furthermore, the laws of some foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States.

The patent positions of companies in the life science and Ag-Bio industries can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies patents has emerged to date in the United States. The laws of some non-U.S. countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. For example:

We might not have been the first to make the inventions covered by each of our pending patent applications;

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We might not have been the first to file patent applications for these inventions;

Others may independently develop similar or alternative products and technologies or duplicate any of our products and technologies;

It is possible that none of our pending patent applications will result in issued patents, and even if they issue as patents, they may not provide a basis for commercially viable products, or may not provide us with any competitive advantages, or may be challenged and invalidated by third parties;

We may not develop additional proprietary products and technologies that are patentable;

The patents of others may have an adverse effect on our business; and

We apply for patents covering our products and technologies and uses thereof, as we deem appropriate. However, we may fail to apply for patents on important products and technologies in a timely fashion or at all.

In addition to pursuing patents on our technology, we take steps to protect our intellectual property and proprietary technology by entering into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, corporate partners and, when needed, our advisors. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets.

We may be involved in lawsuits to protect or enforce our patents and proprietary rights, to determine the scope, coverage and validity of others proprietary rights, or to defend against third party claims of intellectual property infringement that could require us to spend significant time and money and could prevent us from selling our products or services or impact our stock price.

Litigation may be necessary for us to enforce our patent and proprietary rights and/or to determine the scope, coverage and validity of others proprietary rights. Litigation on these matters has been prevalent in our industry and we expect that this will continue. To determine the priority of inventions, we may have to initiate and participate in interference proceedings declared by the U.S. Patent and Trademark Office that could result in substantial legal fees and could substantially affect the scope of our patent protection. Also, our intellectual property may be subject to significant administrative and litigation proceedings such as invalidity, unenforceability, re-examination and opposition proceedings against our patents. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us, and we might not be able to obtain licenses to technology that we require. Even if such licenses are obtainable, they may not be available at a reasonable cost. We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. Further, we could encounter delays in product introductions, or interruptions in product sales, as we develop alternative methods or products.

In addition, if we resort to legal proceedings to enforce our intellectual property rights or to determine the validity, scope and coverage of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if we were to prevail.

Our commercial success may depend in part on our non-infringement of the patents or proprietary rights of third parties. Numerous significant intellectual property issues have been litigated, and will likely continue to be litigated, between existing and new participants in the PCR market and competitors may assert that our products infringe their intellectual property rights as part of a business strategy to impede our successful entry into those markets. Third parties may assert that we are employing their proprietary technology without authorization. For example, on June 4, 2008 we received a letter from Applied Biosystems, Inc., now Life Technologies Corporation, asserting that our BioMark system for gene expression analysis infringes upon U.S. Patent No. 6,814,934, or the 934 patent, and its foreign counterparts in Europe and Canada. In June 2011, we resolved this dispute by entering into a license agreement with Life Technologies Corporation which, among other matters, granted us a non-exclusive license to the 934 patent and its foreign counterparts.

In addition, our competitors and others may have patents or may in the future obtain patents and claim that use of our products infringes these patents. As we move into new markets and applications for our products, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us.

Patent infringement suits can be expensive, lengthy and disruptive to business operations. We could incur substantial costs and divert the attention of our management and technical personnel in prosecuting or defending against any claims, and may harm our reputation. There can be no assurance that we will prevail in any suit initiated against us by third parties. Furthermore, parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us, including treble damages and attorneys fees and costs in the event that we are found to be a willful infringer of third party patents.

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In the event of a successful claim of infringement against us, we may be required to obtain one or more licenses from third parties, which we may not be able to obtain at a reasonable cost, if at all. In addition, we could encounter delays in product introductions while we attempt to develop alternative methods or products to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any required licenses on favorable terms could prevent us from commercializing our products, and the risk of a prohibition on the sale of any of our products could adversely affect our ability to grow and gain market acceptance for our products.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

In addition, our agreements with some of our suppliers, distributors, customers and other entities with whom we do business may require us to defend or indemnify these parties to the extent they become involved in infringement claims against us, including the claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify any of these third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results, or financial condition.

We engage in discussions regarding possible commercial, licensing and cross-licensing agreements with third parties from time to time. There can be no assurance that these discussions will lead to the execution of commercial license or cross-license agreements or that such agreements will be on terms that are favorable to us. If these discussions are successful, we could be obligated to pay license fees and royalties to such third parties. If these discussions do not lead to the execution of mutually acceptable agreements, one or more of the parties involved in such discussions could resort to litigation to protect or enforce its patents and proprietary rights or determine the scope, coverage and validity of the proprietary rights of others. In addition, if we enter into cross-licensing agreements, there is no assurance that we will be able to effectively compete against others who are licensed under our patents.

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We depend on certain technologies that are licensed to us. We do not control these technologies and any loss of our rights to them could prevent us from selling our products.

We rely on licenses in order to be able to use various proprietary technologies that are material to our business, including our core integrated fluidic circuit and multi-layer soft lithography technologies. We do not own the patents that underlie these licenses. Our rights to use the technology we license are subject to the negotiation of, continuation of and compliance with the terms of those licenses. In some cases, we do not control the prosecution, maintenance, or filing of the patents to which we hold licenses, or the enforcement of these patents against third parties. Some of our patents and patent applications were either acquired from another company who acquired those patents and patent applications from yet another company, or are licensed from a third party. Thus, these patents and patent applications are not written by us or our attorneys, and we did not have control over the drafting and prosecution. The former patent owners and our licensors might not have given the same attention to the drafting and prosecution of these patents and applications as we would have if we had been the owners of the patents and applications and had control over the drafting and prosecution. We cannot be certain that drafting and/or prosecution of the licensed patents and patent applications by the licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

Our rights to use the technology we license are subject to the validity of the owner s intellectual property rights. Enforcement of our licensed patents or defense or any claims asserting the invalidity of these patents is often subject to the control or cooperation of our licensors. Legal action could be initiated against the owners of the intellectual property that we license. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent these other companies or institutions from continuing to license intellectual property that we may need to operate our business.

Certain of our licenses contain provisions that allow the licensor to terminate the license upon specific conditions. Our rights under the licenses are subject to our continued compliance with the terms of the license, including the payment of royalties due under the license. Termination of these licenses could prevent us from marketing some or all of our products. Because of the complexity of our products and the patents we have licensed, determining the scope of the license and related royalty obligation can be difficult and can lead to disputes between us and the licensor. An unfavorable resolution of such a dispute could lead to an increase in the royalties payable pursuant to the license. If a licensor believed we were not paying the royalties due under the license or were otherwise not in compliance with the terms of the license, the licensor might attempt to revoke the license. If such an attempt were successful, we might be barred from producing and selling some or all of our products.

We are subject to certain manufacturing restrictions related to licensed technologies that were developed with the financial assistance of U.S. governmental grants.

We are subject to certain U.S. government regulations because we have licensed technologies that were developed with U.S. government grants. In accordance with these regulations, these licenses provide that products embodying the technologies are subject to domestic manufacturing requirements. If this domestic manufacturing requirement is not met, the government agency that funded the relevant grant is entitled to exercise specified rights, referred to as march-in rights , which if exercised would allow the government agency to require the licensors or us to grant a non-exclusive, partially exclusive or exclusive license in any field of use to a third party designated by such agency. All of our microfluidic systems revenue is dependent upon the availability of our chips, which incorporate technology developed with U.S. government grants. As of June 2011, all of our commercial products, including microfluidic systems and chips are manufactured at our facility in Singapore. The federal regulations allow the funding government agency to grant, at the request of the licensors of such technology, a waiver of the domestic manufacturing requirement. Waivers may be requested prior to any government notification. We have assisted the licensors of these technologies with the analysis of the domestic manufacturing requirement, and, in December 2008, one of the licensors applied for a waiver of the domestic manufacturing requirement with respect to certain patents. In July 2009, the funding government agency granted the requested waiver of the domestic manufacturing requirement for a three year period commencing in July 2009. If in the future it were to be determined that we are in violation of the domestic manufacturing requirement and additional waivers of such requirement were either not requested or not granted, then the U.S. government could exercise its march-in rights. In addition, these licenses contain provisions relating to compliance with this domestic manufacturing requirement. If it were determined that we are not in compliance with these provisions and such non- compliance constituted a material breach of the licenses, the licenses could be terminated. Either the exercise of march-in rights or the termination of one or more of our licenses could materially adversely affect our business, operations and financial condition.

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We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our employees former employers.

Many of our employees were previously employed at universities or other life science or Ag-Bio companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or prevent our ability to commercialize certain potential products, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Our Common Stock

We expect that our stock price will fluctuate significantly, and holders may have difficulty selling their shares.

Prior to our initial public offering, there had been no public market for shares of our common stock. Our stock is currently traded on the NASDAQ Global Market, but we can provide no assurance that there will be active trading on that market or any other market in the future. If there is not active trading market or if the volume of trading is limited, holders of our common stock may have difficulty selling their shares. In addition, the trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- actual or anticipated quarterly variation in our results of operations or the results of our competitors;
- announcements by us or our competitors of new commercial products, significant contracts, commercial relationships or capital commitments;
- issuance of new or changed securities analysts reports or recommendations for our stock;
- developments or disputes concerning our intellectual property or other proprietary rights;
- commencement of, or our involvement in, litigation;
- market conditions in the life science, Ag-Bio and molecular diagnostics sectors;
- failure to complete significant sales;
- manufacturing disruptions that could occur if we were unable to successfully expand our production in our current or an alternative facility;
- any future sales of our common stock or other securities;
- any major change to the composition of our Board or management; and

general economic conditions and slow or negative growth of our markets.

The stock market in general, and market prices for the securities of technology-based companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. A certain degree of stock price volatility can be attributed to being a newly public company. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. In several recent situations where the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

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If securities or industry analysts publish unfavorable research about our business or cease to cover our business, our stock price and trading volume could decline.

The trading market for our common stock may rely in part on the research and reports that equity research analysts publish about us and our business. We do not have any control of the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

Future sales of shares could cause our stock price to decline.

If stockholders holding shares of our common stock purchased prior to our public offering sell, or indicate an intention to sell, substantial amounts of their common stock in the public market the trading price of our common stock could decline. As of June 30, 2011 we had outstanding a total of 19,979,565 shares of common stock of which only the 6,392,083 shares of common stock sold in our public offering are currently freely tradable, without restriction, in the public market. Each of our directors and officers, and certain of our stockholders, has entered into lock-up agreements with the underwriter of our initial public offering that restrict their ability to sell or transfer their shares. The lock-up agreements pertaining to our public offering are in effect through August 25, 2011, although they may be extended under certain circumstances. Our underwriters, however, may, in their sole discretion, permit our officers, directors and other current stockholders who are subject to the contractual lock-up to sell shares prior to the expiration of the lock-up agreements. After the lock-up agreements expire, based on shares outstanding as of June 30, 2011, up to an additional 13,587,482 shares of common stock will be eligible for sale in the public market, 2,392,059 of which are held by directors and executive officers and will be subject to volume limitations under Rule 144 under the Securities Act and various vesting agreements. In addition, 2,460,203 shares of common stock that are issuable upon exercise of outstanding options as of June 30, 2011 will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements, the lock-up agreements and Rules 144 and 701 under the Securities Act. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Our directors and executive officers will continue to have substantial control over and could limit your ability to influence the outcome of key transactions, including changes of control.

As of June 30, 2011, our current executive officers, directors and their affiliates beneficially owned or controlled approximately 15% of the outstanding shares of our common stock. Accordingly, these executive officers, directors and their affiliates, acting as a group, can have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of us, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors perception that conflicts of interest may exist or arise.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Provisions in our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control or changes in our management, including provisions that:

- authorize our board of directors to issue, without further action by the stockholders, up to 10,000,000 shares of undesignated preferred stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, the Chairman of the board, the Chief Executive Officer or the President;

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establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;

establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three year terms;

provide that our directors may be removed only for cause;

provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;

specify that no stockholder is permitted to cumulate votes at any election of directors; and

require a super-majority of votes to amend certain of the above-mentioned provisions.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us.

We have broad discretion in the use of the net proceeds from our initial public offering and may not use them effectively.

We have broad discretion in the application of the net proceeds from our initial public offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. We intend to use the net proceeds from our initial public offering for sales and marketing activities, including expansion of our sales force to support the ongoing commercialization of our products; for research and product development activities; for facilities improvements and the purchase of manufacturing and other equipment; and for working capital and other general corporate purposes. We may also use a portion of our net proceeds to acquire and invest in complementary products, technologies or businesses; however, we currently have no agreements or commitments to complete any such transaction. We have not allocated these net proceeds for any specific purposes. We might not be able to yield a significant return, if any, on any investment of these net proceeds. Stockholders will not have the opportunity to influence our management s decisions on how to use the net proceeds, and our failure to apply the funds effectively could have a material adverse effect on our business, delay the development of our product candidates and cause the price of our common stock to decline.

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

We have paid no cash dividends on any of our classes of capital stock to date, have contractual restrictions against paying cash dividends and currently intend to retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be stockholders sole source of gain for the foreseeable future.

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

Use of Proceeds

On February 9, 2011, our registration statements on Form S-1 (Nos. 333-170965 and 333-172146) relating to our IPO were declared effective by the SEC. Our IPO closed on February 15, 2011, and the net proceeds to us after underwriting discounts, commissions, and offering expenses were approximately $77.0 million. Through June 30, 2011, the net proceeds have been applied as follows: $5.0 million for the repayment of promissory notes issued in January 2011, $3.1 million for the repayment of our bank line of credit, $5.0 million for research and development expenses, $14.5 million for general corporate purposes including selling, general and administrative expenses, and $0.7 million for capital expenditures.

There has been no material change in the planned use of proceeds from our IPO from that described in the final prospectus filed with the SEC pursuant to Rule 424(b) on February 10, 2011.

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Item 6. Exhibits.

Exhibit Number	Description	Incorporated by Reference From Form	Incorporated by Reference From Exhibit Number	Date Filed
10.26	Acceptance Letter re Pioneer Incentive dated April 25, 2011 between Singapore Economic Development Board and the Registrant	8-K	10.1	8/5/11
31.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 of President and Chief Executive Officer	Filed herewith		
31.2	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 of Chief Financial Officer	Filed herewith		
32.1(1)	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 of President and Chief Executive Officer	Furnished herewith		
32.2(1)	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 of Chief Financial Officer	Furnished herewith		
101(2)	The following materials from Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Condensed Consolidated Balance Sheets at June 30, 2011 and December 31, 2010, (ii) Condensed Consolidated Statements of Operations for the Six Months Ended March 31, 2011 and 2010, (iii) Condensed Consolidated Statements of Cash Flows for the Six Months Ended June, 2011 and 2010, and (iv) Notes to Condensed Consolidated Financial Statements.	Furnished herewith		

(1) In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 33-8238 and 34-47986, Final Rule: Management s Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-Q and will not be deemed filed for purposes of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

(2) XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Exchange Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

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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.

FLUIDIGM CORPORATION

Dated: August 8, 2011

By: /s/ Gajus V. Worthington
Gajus V. Worthington
President and Chief Executive Officer

Dated: August 8, 2011

By: /s/ Vikram Jog
Vikram Jog
Chief Financial Officer

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EXHIBIT LIST

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