

# MIDDLEBROOK PHARMACEUTICALS, INC.

## FORM 10-Q (Quarterly Report)

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2010

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 000-50414

**MiddleBrook Pharmaceuticals, Inc.**

(Debtor-in-Possession as of April 30, 2010)

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**52-2208264**  
(I.R.S. Employer  
Identification Number)

**7 Village Circle, Suite 100**  
**Westlake, Texas**  
(Address of Principal Executive Offices)

**76262**  
(Zip Code)

**(817) 837-1200**  
(Registrant's Telephone Number, Including Area Code)

**None**  
(Former name, Former address and Former  
Fiscal Year — if Changed Since Last Report)

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

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

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

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

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

As of May 5, 2010, 86,511,898 shares of common stock of the registrant were outstanding.

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**MIDDLEBROOK PHARMACEUTICALS, INC.**

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## PART I — FINANCIAL INFORMATION

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements made under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Quarterly Report on Form 10-Q contain forward-looking statements within the meaning of the Securities Exchange Act of 1934 (the “Exchange Act”) and the Securities Act of 1933, which reflect our current plans, beliefs, estimates and views with respect to, among other things, future events and financial performance. In some cases, forward-looking statements are identified by words such as “believe,” “anticipate,” “expect,” “intend,” “plan,” “potential,” “estimate,” “will,” “may,” “predict,” “should,” “could,” “would” and similar expressions. Specifically, this Quarterly Report on Form 10-Q contains, among others, forward-looking statements regarding the impact and outcome of our filing under Chapter 11 of the United States Bankruptcy Code, our exploration of strategic alternatives, our future financial performance, the sufficiency of our cash resources, the successful commercialization of MOXATAG and its market position and growth, the seasonality of our products, estimated expense savings from our reductions in force, the sufficiency of our existing KEFLEX supply, the status of our product development efforts, the amounts of charge-backs and rebates we record, and the impact of market and foreign currency risk. You should not place undue reliance on these or any other forward-looking statements. The forward-looking statements and any expectations based on such forward-looking statements are subject to risks and uncertainties and other important factors that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including:

- our ability to confirm and consummate a plan of reorganization under Chapter 11 of the United States Bankruptcy Code;
- the failure to obtain market acceptance or to successfully commercialize MOXATAG and any decrease in sales of KEFLEX products;
- the effectiveness of our sales and marketing efforts;
- our ability to continue as a going concern and to meet our anticipated operating needs with our revenues and existing cash, and our ability to identify and consummate a strategic transaction;
- the effect of current market conditions on our products and business;
- our obligations related to product returns;
- our reliance on third parties to provide us with the active pharmaceutical ingredients in our products and product candidates and to perform certain aspects of the manufacturing, packaging and distribution of our products;
- our ability to protect our intellectual property;
- continued pricing pressures;
- reimbursement of our products under managed care programs;
- unsuccessful product development candidates and the effectiveness of the PULSYS technology; and
- our exposure to credit rate, interest rate and exchange rate risk;

as well as other risks and uncertainties identified in Part I, Item 1A. Risk Factors and Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2009 and in Part II, Item 1A. Risk Factors in this Quarterly Report on Form 10-Q.

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We operate in a continually changing business environment, and new risks and uncertainties emerge from time to time. Management cannot predict these new risks or uncertainties, nor can it assess the impact, if any, that any such risks or uncertainties may have on our business or the extent to which any factor, or combination of factors, may cause actual results to differ from those projected in any forward-looking statement. Accordingly, the risks and uncertainties to which we are subject can be expected to change over time, and we undertake no obligation to update publicly or review the risks or uncertainties described in this Quarterly Report on Form 10-Q. We also undertake no obligation to update publicly or review any of the forward-looking statements made in this Quarterly Report on Form 10-Q, whether as a result of new information, future developments or otherwise.

In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

KEFLEX, KEFLEX 250 MG, KEFLEX 500 MG, KEFLEX 750 MG, MiddleBrook, MiddleBrook Pharmaceuticals (stylized), MiddleBrook Pharmaceuticals, Inc., M1 (stylized), MOX-10, MOXAKIT, MOXATAG1 (stylized), MOXATAG, MOXATAG PAK, MOXATAG PAK (stylized), MOXATEN, MOX\_PAK (stylized), MOX-PAK, MOXPAK, MOXPAK- (stylized), and PULSYS are our trademarks and have been registered in the U.S. Patent and Trademark Office or are the subject of pending U.S. trademark applications. Each of the other trademarks, tradenames, or service marks appearing in this document belongs to the respective holder. Except as otherwise indicated by the context, references to “we,” “us,” “our,” “MiddleBrook,” or the “Company,” refer to MiddleBrook Pharmaceuticals, Inc. and its subsidiaries.

## PART I — FINANCIAL INFORMATION

## Item 1. Financial Statements (Unaudited)

**MIDDLEBROOK PHARMACEUTICALS, INC.**  
**CONDENSED BALANCE SHEETS**  
(amounts in thousands, except par values)

	<u>March 31, 2010</u>	<u>December 31, 2009</u>
	(Unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 10,938	\$ 14,798
Accounts receivable, net	—	2,269
Inventories, net	2,948	4,242
Prepaid expenses and other current assets	3,501	4,749
Total current assets	<u>17,387</u>	<u>26,058</u>
Property and equipment, net	1,923	4,555
Other noncurrent assets	678	1,489
Intangible assets, net	9,444	10,073
Total assets	<u>\$ 29,432</u>	<u>\$ 42,175</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,232	\$ 1,031
Co-pay assistance programs	4,905	3,796
Accrued operating lease obligations	5,666	1,103
Accrued expenses and other current liabilities	6,213	9,050
Total current liabilities	<u>19,016</u>	<u>14,980</u>
Deferred contract revenue	11,625	11,625
Long-term lease obligations	—	2,355
Other long-term liabilities	17	162
Total liabilities	<u>30,658</u>	<u>29,122</u>
Commitments and contingencies		
Stockholders' (deficit) equity:		
Preferred stock, \$0.01 par value; 25,000 shares authorized, no shares issued or outstanding at March 31, 2010 and December 31, 2009	—	—
Common stock, \$0.01 par value; 225,000 shares authorized, 86,512 shares issued and outstanding at March 31, 2010 and December 31, 2009	865	865
Capital in excess of par value	312,276	311,428
Accumulated deficit	(314,367)	(299,240)
Total stockholders' (deficit) equity	<u>(1,226)</u>	<u>13,053</u>
Total liabilities and stockholders' (deficit) equity	<u>\$ 29,432</u>	<u>\$ 42,175</u>

The accompanying notes are an integral part of these condensed financial statements.

**MIDDLEBROOK PHARMACEUTICALS, INC**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(amounts in thousands, except per share amounts)

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
	<b>(Unaudited)</b>	
Product sales	\$ 6,046	\$ 8,969
Costs and expenses:		
Cost of product sales	2,113	757
Research and development	378	1,859
Selling, general and administrative	18,686	16,471
Total costs and expenses	21,177	19,087
Loss from operations	(15,131)	(10,118)
Interest income	12	256
Interest expense	(9)	(11)
Other income	2	—
Loss before income taxes	\$ (15,126)	\$ (9,873)
Income taxes	—	132
Net loss	<u>\$ (15,126)</u>	<u>\$ (10,005)</u>
Basic and diluted net loss per share	<u>\$ (0.17)</u>	<u>\$ (0.12)</u>
Shares used in calculation of basic and diluted net loss per share	<u>86,512</u>	<u>86,435</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

**MIDDLEBROOK PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(amounts in thousands, except per share amounts)

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
	<b>(Unaudited)</b>	
<b>Cash flows from operating activities:</b>		
Net loss	\$ (15,126)	\$ (10,005)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	1,836	729
Stock-based compensation	848	829
Deferred rent and credit on lease concession	(145)	(1)
Amortization of discounts on marketable securities	—	(57)
Loss on disposal of fixed assets and existing facility	3,021	—
Gain on termination of capital leases	(22)	—
Deferred tax expense	—	132
<b>Changes in:</b>		
Accounts receivable	2,544	(9,075)
Inventories	1,294	(2,025)
Prepaid expenses and other current assets	2,120	(561)
Deposits and other assets	(61)	(46)
Accounts payable	1,201	(522)
Accrued expenses and other liabilities	(1,214)	1,688
Net cash used in operating activities	(3,704)	(18,914)
<b>Cash flows from investing activities:</b>		
Purchases of marketable securities	—	(188)
Sales and maturities of marketable securities	—	20,817
Purchases of property and equipment	—	(28)
Net cash provided by investing activities	—	20,601
<b>Cash flows from financing activities:</b>		
Principal payments on capital lease obligations	(156)	(246)
Proceeds from exercise of common stock options	—	6
Net cash used in financing activities	(156)	(240)
Net (decrease) increase in cash and cash equivalents	(3,860)	1,447
Cash and cash equivalents, beginning of period	14,798	30,520
Cash and cash equivalents, end of period	\$ 10,938	\$ 31,967
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	\$ 9	\$ 11
<b>Supplemental disclosure of noncash investing and financing transactions:</b>		
Capital lease obligations for leased vehicles	\$ —	\$ 4,898
Cancellation of capital lease obligations	\$ 1,405	\$ —

The accompanying notes are an integral part of these condensed consolidated financial statements.

**MIDDLEBROOK PHARMACEUTICALS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(tabular amounts in thousands except per share data)**

**1. Chapter 11 Bankruptcy Filing**

On April 30, 2010 (the “Petition Date”), MiddleBrook Pharmaceuticals, Inc. (“MiddleBrook,” the “Company”, “we” or “us”) filed a voluntary petition for bankruptcy protection (the “Petition”) under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court in the District of Delaware (the “Bankruptcy Court”), case number 10-11485 (the “Bankruptcy Case”). As a result, we are currently operating as “debtor-in-possession” under the jurisdiction of the Bankruptcy Court and in accordance with the applicable provisions of the Bankruptcy Code. We will continue to manage and operate our business and assets in the ordinary course during the pendency of the Bankruptcy Case, subject to the supervision and orders of the Bankruptcy Court and in accordance with applicable provisions of the United States Bankruptcy Code.

As a result of the Petition, realization of assets and liquidation of liabilities are subject to uncertainty. While operating as a debtor-in-possession under the protection of Chapter 11 of the Bankruptcy Code, subject to Bankruptcy Court approval or as otherwise permitted in the normal course of business, we may sell or otherwise dispose of assets and liquidate or settle liabilities for amounts other than those reflected in the accompanying condensed consolidated financial statements. Further, a plan of reorganization could materially change the amounts and classifications reported in the consolidated historical financial statements, which do not give effect to any adjustments to the carrying value of assets or amounts of liabilities that might be necessary as a consequence of confirmation of a plan of reorganization.

We cannot provide any assurance as to what values, if any, will be ascribed in the bankruptcy proceedings to various pre-petition liabilities or common stock. Accordingly, caution should be exercised with respect to existing and future investments in any securities of the Company.

***Reporting Requirements***

As a result of filing the Petition, we will be periodically required to file various documents with and provide certain information to the Bankruptcy Court, including statements of financial affairs, schedules of assets and liabilities and monthly operating reports in forms prescribed by federal bankruptcy law.

While such materials will accurately provide then-current information required under federal bankruptcy law, they will nonetheless be unaudited and prepared in a format different from that used in our financial statements filed with the Securities and Exchange Commission (the “SEC”). Accordingly, we believe that the substance and format do not allow meaningful comparison with our regular publicly disclosed consolidated financial statements. Moreover, the materials filed with the Bankruptcy Court are not prepared for the purpose of providing a basis for an investment decision relating to our securities, or for comparison with other financial information filed with the SEC.

***First Day Motions***

The Bankruptcy Court has approved various motions for relief designed to allow us to continue normal operations. The Bankruptcy Court’s orders provide MiddleBrook, among other things: (a) the ability to prevent utility providers, on an interim basis pending a final hearing, from altering, refusing, or discontinuing utility services, (b) authority to pay certain taxes and governmental assessments in the ordinary course of business, (c) authority to pay certain pre-petition and post-petition employee wages, (d) authority to pay pre-petition reimbursable business expenses and certain terminated employee obligations, (e) authority to continue paying certain employee wages and salaries, reimbursable expenses, health plan claims, and insurance programs and obligations in the ordinary course of business, (f) authority to make deductions from employees’ paychecks for employees’ portions of certain employee benefits, (g) authority to continue workers’ compensation programs, (h) authority to pay certain pre-petition claims of critical vendors and service providers and certain administrative claimholders, (i) authority directing banks and other financial institutions to honor all checks and electronic payment requests made by us related to items (c)-(h), above, (j) the ability to continue maintenance of existing bank accounts and existing cash management systems, and (k) an interim order establishing notification and hearing procedures for transfers of our equity securities.

### ***Notifications***

Shortly after filing the Petition, we began notifying all known current or potential creditors of the Petition filing. The Petition automatically enjoined, or stayed, the continuation of any judicial or administrative proceeding or other actions against us or our property to recover on, collect or secure a claim arising prior to the Petition Date. Vendors will be paid for goods and services provided after the Petition Date in the ordinary course of business. Under the Bankruptcy Code, we may assume or reject certain unexpired leases, subject to the Bankruptcy Court's approval and certain other conditions.

As of the filing date of this report, we have filed a motion to reject certain of our operating and real property leases. The Bankruptcy Court has not yet held hearings on this motion. Various other filings will be made with respect to third party servicing firms, professional firm engagements and contract approvals.

### ***Basis of Presentation***

The year-end condensed balance sheet was derived from audited financial statements. The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, the unaudited condensed consolidated financial statements do not include all of the information and disclosures required by GAAP for complete financial statements. Therefore, these condensed consolidated financial statements should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2009, as filed with the SEC on March 16, 2010, and our subsequent Current Reports on Form 8-K filed with the SEC. The interim condensed consolidated financial statements reflect all adjustments that, in the opinion of management, are necessary for a fair statement of our financial condition and results of operations for the periods presented. Except as otherwise disclosed, all such adjustments are of a normal recurring nature.

The unaudited condensed consolidated financial statements presented herein reflect the financial position, results of operations and cash flows of MiddleBrook, and have been prepared on the basis of a going concern, although the events leading up to the Petition and the Petition proceedings create uncertainties about our ability to meet our obligations as they become due. As a result of certain events of default, we have reclassified the remaining rent payments associated with our vacated Germantown, Maryland facility as a current liability on our condensed balance sheet (see Note 13 – *Commitments and Contingencies*). The unaudited condensed consolidated financial statements do not include any other adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of these uncertainties.

The unaudited condensed consolidated financial statements do not purport to reflect or provide for the consequences of the Bankruptcy Case, including the accounting requirements under the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 852, "Reorganizations" ("ASC 852"). As a result, the unaudited condensed consolidated financial statements do not segregate liabilities subject to compromise in the condensed balance sheet and reorganization items, net in the condensed consolidated statement of operations, nor do they reflect any of the fresh-start reporting adjustments required by ASC 852, which we expect will be required if and when we emerge from bankruptcy.

### ***NASDAQ De-listing***

In accordance with NASDAQ Listing Rule 5250(b), on April 30, 2010, we notified The NASDAQ Stock Market, ("NASDAQ") that we had filed the Petition. On May 3, 2010, we received notice from NASDAQ notifying us that, due to the filing of the Petition, trading of our common stock will be suspended at the opening of business on May 12, 2010 and that our common stock will be de-listed from the NASDAQ Global Market that same day, pursuant to NASDAQ Listing Rules 5101, 5110(b) and IM-5101-1. At this time, we do not intend to appeal NASDAQ's decision.

## **2. Nature of Business**

We were incorporated in Delaware in December 1999 and commenced operations on January 1, 2000. We are a pharmaceutical company focused on commercializing anti-infective drug products that fulfill unmet medical needs. We have developed a proprietary delivery technology called PULSYS, which enables the pulsatile delivery, or delivery in rapid bursts, of certain drugs. Our PULSYS technology may provide the prolonged release and absorption of a drug, which we believe can provide therapeutic advantages over current dosing regimens and therapies. We currently have 25 U.S. issued patents and seven foreign patents covering our PULSYS technology, which extend through 2020.

Our current PULSYS product, MOXATAG (amoxicillin extended-release) Tablets, 775 mg, received U.S. Food and Drug Administration ("FDA") approval for marketing on January 23, 2008, and is the first and only FDA-approved once-daily amoxicillin. It is approved for the treatment of pharyngitis/tonsillitis secondary to *Streptococcus pyogenes*, commonly known as strep throat, for adults and pediatric patients age 12 and older, and there is no AB-rated equivalent to MOXATAG.



We began marketing MOXATAG on March 16, 2009. We have incurred, and will continue to incur, significant expenses associated with the commercialization of MOXATAG. To date, revenues recognized from our KEFLEX (immediate-release cephalexin) and MOXATAG products have been limited and have not been sufficient for us to achieve or sustain profitability. We believe our existing cash resources will be sufficient to fund our operations through the second quarter of 2010.

### *Liquidity*

We have experienced significant operating losses since our inception in 2000. As of March 31, 2010, we had an accumulated deficit of \$314.4 million. The process of developing and commercializing our products requires significant research and development work, preclinical testing and clinical trials, as well as regulatory approvals, substantial marketing and sales efforts, and manufacturing capabilities. These activities, including the commercialization of MOXATAG, together with our general and administrative expenses, require significant investments and are expected to continue to result in significant operating losses for 2010 and the foreseeable future, if we were to continue as an independent entity.

On March 12, 2010, we announced that we had engaged Gleacher & Company, formerly Broadpoint Gleacher Securities Group, Inc. (“Gleacher”), as our financial advisor to assist our Board of Directors in identifying and evaluating strategic alternatives, including a possible merger or sale. The Board of Directors has not set a definitive timetable for the completion of its evaluation, and there can be no assurance that the process will result in a transaction. We do not intend to disclose developments regarding this process unless and until the Board of Directors has approved a specific transaction. If we are unable to consummate a strategic transaction in the near future, depending on the outcome of the Bankruptcy Case, we may be unable to continue operations as a going concern.

Beginning in April 2010 we ceased making rental payments on our leased facilities in Germantown, Maryland. On April 6, 2010, we received notices of default from the landlords on those leases. The landlords asserted that the default gave them the right to re-possess the leased premises, distrain for rent, apply the security deposit to satisfy amounts due, and claim damages for the loss of rent for the balance of the term of the agreements. On or about April 14, 2010, because of the defaults, the landlords made demand of the letters of credit we had as security deposit, included within other current assets on our condensed balance sheet as of March 31, 2010. These amounts were subsequently paid to the landlords in accordance with the terms of the letters of credit. For further information, see Note 13 – *Commitments and Contingencies*.

Our estimates of future capital requirements are uncertain and will depend on a number of factors, including the outcome of the Bankruptcy Case, the success of our commercialization of MOXATAG, the progress of our research and development of product candidates (which are currently delayed), the timing and outcome of regulatory approvals, cash received from sales of our products, payments received or made under any future collaborative agreements, the costs involved in enforcing patent claims and other intellectual property rights, the status of competitive products, the availability of financing, and our or our potential partners’ success in developing markets for our product candidates. Changes in our commercialization and development plans, partnering activities, regulatory activities and other developments may increase our rate of spending and decrease the period of time our available resources will fund our operations. Insufficient funds will require us to continue to delay, scale back or eliminate some or all of our research, development or commercialization programs, or may adversely affect our ability to operate as a going concern.

On June 29, 2009, we entered into a Loan and Security Agreement, which we refer to as the Loan Agreement, with Silicon Valley Bank for a two-year \$10.0 million revolving line of credit for working capital needs. Effective March 16, 2010, we terminated the Loan Agreement. No balances were outstanding during the term of the Loan Agreement.

### **3. Summary of Significant Accounting Policies**

#### *Use of Estimates*

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

#### *Accounts Receivable*

Accounts receivable represent amounts due from trade customers for sales of pharmaceutical products. Allowances for estimated product discounts, chargebacks and wholesaler rebates are recorded as reductions to gross accounts receivable. When the deductions exceed the gross accounts receivable balance, the resulting net liability is recorded within Accrued expenses and other current liabilities on our condensed balance sheet. Amounts due for returns and estimated rebates payable to third parties are included in Accrued expenses and other current liabilities on our condensed balance sheet.



**Intangible Assets**

Identifiable intangible assets with definite lives are amortized on a straight-line basis over their estimated useful lives. The non-PULSYS KEFLEX assets are being amortized through 2013 to coincide with the estimated economic benefit of the assets, which do not use our PULSYS technology. We have performed an impairment analysis of the intangible assets and have determined that none are impaired at this time. We will continue to monitor the value and life of the assets.

The KEFLEX brand name and other intangible assets were acquired for marketing purposes, and the related amortization is charged to selling expense. We do not have identifiable intangible assets with indefinite lives.

**Leases — Capital**

We leased vehicles for our field sales force to assist them in performing their responsibilities of calling on physicians and pharmacists. These vehicle leases were accounted for as capital leases. We had recorded an asset within Property and equipment and an offsetting liability for the present value of the minimum lease payments at the inception of the leases. The liability was reduced as the monthly payments were made, with a portion applied to the obligation and the balance recorded as interest expense. During the first quarter of 2010, we eliminated our field sales force, which resulted in the termination of all remaining automobile leases, which had a net book value of \$1.4 million. The net book value of the terminated automobile leases was removed from Property and equipment, net and the associated liabilities were removed from other current and long-term liabilities. As of March 31, 2010, we have no remaining capital leases, and therefore have no assets or associated liabilities recorded for vehicle leases.

**Segment and Geographic Information**

We operate in one business segment and are organized along functional lines of responsibility; we do not utilize a product, divisional or regional organizational structure. The entire business is managed by a single management team that reports to the chief executive officer.

We sell our products to a limited number of pharmaceutical wholesalers and retailers, and all product sales occur in the United States. Long-lived assets, consisting of property and equipment, are located both in the United States and Ireland, as follows:

<b>Geographic Information</b>	<b>Property and Equipment</b>
United States	\$ 371
Ireland	1,552
Total	<u>\$ 1,923</u>

**Recent Accounting Pronouncements**

In December 2009, the FASB issued Accounting Standards Update (“ASU”) No. 2009-17, “Consolidations: Improvements to Financial Reporting by Enterprises Involved with Variable Interest Entities,” which codifies Statement of Financial Accounting Standard No. 167, “Amendments to FASB Interpretation No. 46(R),” issued in June 2009. ASU 2009-17 amends certain provisions of ASC 810 related to the consolidation of variable interest entities (“VIE”). ASU 2009-17 replaces the quantitative-based risks and rewards calculation for determining which enterprise has a controlling financial interest in a VIE with an approach focused on identifying which enterprise has the power to direct the activities of the VIE that most significantly impact the VIE’s economic performance and the obligation to absorb the losses of the VIE or right to receive benefits from the VIE that could potentially be significant to the VIE. ASU 2009-17 requires ongoing reassessments of whether an enterprise is the primary beneficiary. ASU 2009-17 was effective for us beginning January 1, 2010. Its adoption did not have an impact on our consolidated financial statements.

In January 2010, ASU No. 2010-06, “Improving Disclosures about Fair Value Measurements,” was issued and requires new disclosures regarding recurring or nonrecurring fair value measurements. Entities will be required to separately disclose significant transfers into and out of Level 1 and Level 2 measurements in the fair value hierarchy and describe the reasons for the transfers. Entities will also be required to provide information on purchases, sales, issuances and settlements on a gross basis in the reconciliation of Level 3 fair value measurements. In addition, entities must provide fair value measurement disclosures for each class of assets and liabilities and disclosures about the valuation techniques used in determining fair value for Level 2 or Level 3 measurements. ASU 2010-06 is effective for interim and annual reporting periods beginning after December 15, 2009, except for the gross basis reconciliation for the Level 3 fair value measurements, which is effective for fiscal years beginning after December 15, 2010. The adoption of ASU 2010-06 did not have a material impact on our consolidated financial statements. There were no transfers between Level 1 and Level 2 measurements in the fair value hierarchy during the three months ended March 31, 2010.



**4. Revenue**

We record revenue from sales of pharmaceutical products under the KEFLEX brand name and, beginning in the first quarter of 2009, under the MOXATAG brand name.

Beginning July 15, 2009, we implemented a \$20 maximum co-pay program for MOXATAG. The program is designed to keep a patient’s net out-of-pocket co-pay expense for a MOXATAG prescription at no more than \$20. Patients can redeem a voucher at the point-of-sale in conjunction with having a MOXATAG prescription filled. Our estimated future liability for this program is recorded as an offset to our gross sales of MOXATAG as we record sales to our customers.

**5. Other Comprehensive Loss**

Other comprehensive (loss) income consists of unrealized gains and losses on available-for-sale marketable securities and unrealized gains and losses on foreign exchange forward contracts. As of March 31, 2010, we had no unrealized gains or losses, resulting in no adjustment from Net loss to comprehensive loss.

The following table presents the computation of comprehensive loss, net of tax, for the three months ended March 31, 2010 and 2009:

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Net loss	\$ (15,126)	\$ (10,005)
Net unrealized investment losses, net of tax of \$80	—	(127)
Net unrealized losses on forward contracts, net of tax of \$51	—	(82)
Total comprehensive loss	<u>\$ (15,126)</u>	<u>\$ (10,214)</u>

**6. Earnings Per Share**

Basic earnings per share is computed based on the weighted-average number of common shares outstanding during the period. Diluted earnings per share is computed based on the weighted-average shares outstanding adjusted for all dilutive potential common shares. The dilutive impact, if any, of potential common shares outstanding during the period, including outstanding stock options, is measured by the treasury stock method. Potential common shares are not included in the computation of diluted earnings per share if they are antidilutive. We incurred net losses for the three-month periods ended March 31, 2010 and 2009, and accordingly, did not assume exercise of any of our outstanding stock options or warrants.

The following securities could potentially dilute basic earnings per share in the future and were not included in the computation of diluted earnings per share because they would have been antidilutive for the periods presented:

	<b>March 31,</b>	
<b>(Number of Underlying Common Shares)</b>	<b>2010</b>	<b>2009</b>
Stock options	10,775	16,464
Warrants	25,562	25,562
Total	<u>36,337</u>	<u>42,026</u>

**7. Accounts Receivable**

Accounts receivable, net consists of the following:

	<b>March 31,</b>	<b>December 31,</b>
	<b>2010</b>	<b>2009</b>
Accounts receivable for product sales, gross	\$ 872	\$ 3,055
Allowances for rebates, discounts and chargebacks	(1,147)	(786)
Accounts receivable for product sales, net	<u>\$ (275)</u>	<u>\$ 2,269</u>

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The total net accounts receivable balance as of March 31, 2010 is a liability balance and is therefore categorized within Accrued expenses and other current liabilities on our condensed balance sheet for the period. Our largest customers are large wholesalers of pharmaceutical products and retailers. A retailer and two large wholesalers accounted for approximately 36.6%, 17.9% and 15.8%, respectively, of our accounts receivable for product sales as of March 31, 2010.

### 8. Inventories

Inventories, net consists of the following:

	<b>March 31, 2010</b>	<b>December 31, 2009</b>
Finished goods	\$ 3,361	\$ 3,791
Work in process	660	—
Raw materials	602	904
Reserve for slow-moving inventory	(1,675)	(453)
Inventories, net	<u>\$ 2,948</u>	<u>\$ 4,242</u>

During the three-month period ended March 31, 2010, there was a reserve of \$1.4 million recorded primarily for slow-moving MOXATAG inventory, following the elimination of our field sales force during the first quarter of 2010. During the three-month period ended March 31, 2009, there were no amounts recorded for obsolete and slow-moving inventory.

During the three-month period ended March 31, 2010, we put certain bulk tablet batches on hold pending the future direction of MOXATAG, which resulted in work in process inventory as of March 31, 2010.

### 9. Property and Equipment

Property and equipment consists of the following:

	<b>March 31, 2010</b>	<b>December 31, 2009</b>
Computer equipment	\$ 754	\$ 754
Furniture and fixtures	834	834
Equipment	3,514	3,514
Automobiles — capital leases	—	2,502
Leasehold improvements	9,239	9,239
Subtotal	14,341	16,843
Less — accumulated depreciation	(12,418)	(12,288)
Property and equipment, net	<u>\$ 1,923</u>	<u>\$ 4,555</u>

During the three-month period ended March 31, 2010, we terminated all remaining vehicle leases following the elimination of our field sales force. These leases were accounted for as capital leases. As a result of terminating the leases, we removed the assets and associated liabilities associated with these capital leases from our financial statements.

### 10. Intangible Assets

Intangible assets at March 31, 2010 and December 31, 2009 consist of the following:

	<b>March 31, 2010</b>		
	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Amount</b>
KEFLEX intangible assets	\$ 11,758	\$ (2,314)	\$ 9,444
Patents	120	(120)	—
Intangible assets	<u>\$ 11,878</u>	<u>\$ (2,434)</u>	<u>\$ 9,444</u>

	December 31, 2009		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
KEFLEX intangible assets	\$ 11,758	\$ (1,685)	\$ 10,073
Patents	120	(120)	—
Intangible assets	<u>\$ 11,878</u>	<u>\$ (1,805)</u>	<u>\$ 10,073</u>

Identifiable intangible assets with definite lives are amortized on a straight-line basis over their estimated useful lives. Since the re-acquisition of the non-PULSYS KEFLEX intangible assets on September 4, 2008, the assets were being amortized over 12 years to coincide with patents associated with the PULSYS technology.

Beginning in the fourth quarter of 2009, we reduced the remaining life of the KEFLEX intangible assets to four years to better reflect our estimated economic life of the assets, which do not use our PULSYS technology. We performed an impairment analysis of the intangible assets for the end of 2009 and updated it for the first quarter 2010, and we have determined that none are impaired. We will continue to monitor the value and life of the assets.

## 11. Restructuring

Effective March 15, 2010, we eliminated our field sales force and significantly reduced our corporate staff to preserve our cash resources as we explore our strategic options. As part of the reduction-in-force, our president and chief executive officer announced his resignation to further reduce operating expenses. In connection with this reduction-in-force, we recorded an expense of approximately \$3.2 million during the first quarter 2010 associated with the severance benefits for the 125 field-based and 20 office-based employees who were notified that their employment would be terminated by April 15, 2010. This entire expense was recorded within Selling, general and administrative on our condensed statement of operations. Additionally, we recorded \$0.2 million of non-recurring exit costs primarily related to vehicle lease termination expenses and the write-off of the remaining net book value of software licenses specific to our field sales force.

During the second half of 2009, we strategically realigned our field sales force and eliminated corporate staff positions to more aggressively preserve our financial resources. We terminated 142 field-based and 16 office-based employees. All employees were notified and terminated within the period the associated expense was accrued. In connection with the reductions-in-force, we recorded \$2.3 million of severance expense and benefits. Of the total expense, \$1.9 million was recorded in Selling, general and administrative expenses, while the remaining \$0.4 million was recorded within Research and development expenses.

The liabilities for these reductions-in-force were recorded in current accrued expenses, as all amounts are expected to be paid out within one year of being incurred.

The following table presents a rollforward of the accrued severance and benefits liability associated with the 2009 and 2010 workforce reductions, as discussed above, for the three months ended March 31, 2010:

	2010 Workforce Reduction	2009 Workforce Reduction	Total
Liability as of 12/31/09	\$ —	\$ 825	\$ 825
Expense	3,169	—	3,169
Cash paid	(1,746)	(744)	(2,490)
Adjustment	—	(19)	(19)
Liability as of 3/31/10	<u>\$ 1,423</u>	<u>\$ 62</u>	<u>\$ 1,485</u>

## 12. Income Taxes

Income tax expense or benefit for the year is required to be allocated among continuing operations, discontinued operations, extraordinary items, other comprehensive income, and items charged or credited directly to stockholders' equity. Pursuant to this intraperiod allocation requirement, for the three-month period ending March 31, 2009, \$132,000 of tax expense has been allocated to the loss from continuing operations. This tax expense is reversing a tax benefit recognized during 2008. The expense was recognized in 2009 as the items in other comprehensive income are realized in our net loss. We did not record any tax provision or benefit for the three-month period ending March 31, 2010. We have provided a valuation allowance for the full amount of our net deferred tax assets because realization of any future benefit from deductible temporary differences and net operating loss carry forwards cannot be sufficiently assured at December 31, 2009 and March 31, 2010.



We have federal and state net operating losses, federal research and experimentation tax credit and state tax credit carryforwards available to reduce future taxable income. Under the provisions of Sections 382 and 383 of the Internal Revenue Code, certain substantial changes in our ownership may result in a limitation on the amount of net operating loss and research and experimentation tax credit carryforwards that may be utilized in future years. During 2001, 2005 and 2008, we may have experienced such ownership changes.

We are primarily subject to U.S. federal and Maryland and Texas state corporate income taxes.

Our policy is to recognize interest related to income tax matters, if any, in interest expense and penalties related to income tax matters, if any, in operating expenses. As of March 31, 2010 and December 31, 2009, we had no accruals for interest or penalties related to income tax matters.

### 13. Commitments and Contingencies

#### *Leases — Facilities*

As of March 31, 2010, we have \$5.7 million recorded as a current liability on our condensed balance sheet. This balance represents the present value of the remaining lease payments on our leased facilities in Germantown, Maryland. During the first quarter 2010, we vacated the space and recorded an additional \$3.0 million of expense associated with the facility to increase the liability to reflect all remaining lease payments. Additionally, we moved the entire liability into current liabilities in anticipation of defaulting on the lease. This charge, along with the write-off of the leasehold improvements and furniture abandoned with the building, was recorded in the Selling, general and administrative expense on our condensed statement of operations.

Based on our current liquidity issues, we ceased making any rental payments for our Germantown, Maryland leased facilities beginning in April 2010. On April 6, 2010, we received a notice of default from Minkoff Development Corporation, on behalf of Seneca Meadows Corporate Center III LLLP (“Seneca III”), with respect to default under (1) the Lease #1 Documents (as defined below) entered into in connection with our lease of the premises located at 20443-20445 Seneca Meadows Parkway (the “Lease #1 Premises”) in Germantown, Maryland from Seneca III (“Lease #1”) and (2) that certain Promissory Note, dated May 1, 2009, issued by us for the benefit of Seneca III with an original principal amount of \$606,225.00 (the “Note”). The “Lease #1 Documents” include the following: Agreement of Sublease (“Sublease”), dated August 4, 2004, between us and Large Scale Biology Corporation (“LSBC”); Seneca III’s Consent to Sublease, dated August 2, 2004 (“Consent”); Supplement to Sublease, dated August 24, 2004, between Seneca III and us; Agreement, dated August 11, 2006, between Seneca III and us (where we agreed to attorn to and become the direct tenant of Seneca III under the Sublease, Consent and Prime Lease Agreement, dated July 26, 2000, between Seneca III and LSBC (as assignee)); Amendment to Lease, dated February 4, 2008, between Seneca III and us; and Second Amendment to Lease, dated April 23, 2009, between Seneca III and us.

The notice of default with respect to the Lease #1 Documents and the Note states that the defaults resulted from our failure to remit our scheduled lease payments under Lease #1, totaling \$31,899.55 due on April 1, 2010, and our scheduled principal and interest payment under the Note of \$31,031.71 due on April 1, 2010. The terms of Lease #1 provide that an event of default under Lease #1 could give Seneca III the right to re-possess the Lease #1 Premises, distraint for rent, apply the security deposit to satisfy amounts due, and claim damages for the loss of rent sustained by Seneca III for the balance of the term of Lease #1. In addition, default under the Note could cause the entire unpaid principal balance under the Note, together with accrued interest, to become immediately due and payable. Upon default and acceleration of payment under the Note, the rate of interest would be automatically increased, from the date of default until the Note is paid in full, from eight percent (8%) per annum to fifteen percent (15%) per annum.

Additionally, on April 6, 2010, we received a notice of default from Minkoff Development Corporation, on behalf of Seneca Meadows Corporate Center II LLC (“Seneca II”), our landlord under that certain Lease, dated August 1, 2002, between us and Seneca II with respect to the premises located at 20417-20435 Seneca Meadows Parkway (the “Lease #2 Premises”) in Germantown, Maryland (“Lease #2”). The notice of default states that the default resulted from our failure to make our scheduled lease payment under Lease #2 totaling \$109,550.65, which was due on April 1, 2010. An event of default under Lease #2 could give Seneca II the right to re-possess the Lease #2 Premises, distraint for rent, apply the security deposit to satisfy amounts due, and claim damages for the loss of rent sustained by Seneca II for the balance of the term of Lease #2.

On or about April 14, 2010, because of the defaults, Seneca II and Seneca III made demand of letters of credit that we had as a security deposit included in other current assets on our condensed balance sheet as of March 31, 2010. These amounts were subsequently paid to Seneca II and Seneca III in accordance with the terms of the letters of credit.

***Capital Leases — Automobiles***

In connection with hiring a field sales force during the first quarter of 2009, we entered into leases under a master lease agreement to provide vehicles for the sales force. We accounted for these leases as capital leases, resulting in us recording the present value of the minimum lease payments as an asset within Property and equipment, with an offsetting liability split between other current and long-term liabilities. The value of the vehicle leases was being amortized over the term of each lease, and the lease payments were allocated between a reduction of the outstanding obligation and interest expense.

Effective March 15, 2010, we eliminated our field sales force and terminated all automobile leases, which had a remaining net book value of \$1.4 million. The net book value associated with all terminated automobile leases, along with the remaining current and noncurrent liability balances, were removed from Property and equipment, net and other current and long-term liabilities on our condensed balance sheet. As of March 31, 2010, there are no amounts recorded on our condensed balance sheet associated with capital leases.

For the three-month periods ended March 31, 2010 and 2009, we paid \$9,000 and \$11,000, respectively, for imputed interest on capital leases.

**14. Subsequent Events**

As discussed in Note 13 – *Commitments and Contingencies*, on April 6, 2010, we received a notice of default from Seneca II and Seneca III related to the lease agreements for our Maryland facilities. Seneca II and Seneca III subsequently made demand, and received payments, on letters of credit that we had as a security deposit for the leases.

As discussed in Note 1 – *Chapter 11 Bankruptcy Filing*, on April 30, 2010, we filed a Petition for relief under Chapter 11 of the United States Bankruptcy Code and notified NASDAQ that we had filed the Petition. On May 3, 2010, we received notice from NASDAQ notifying us that, due to the filing of the Petition, trading of our common stock on the NASDAQ Global Market will be suspended at the opening of business on May 12, 2010.

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

The following discussion of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q and the consolidated financial statements and related notes and Management’s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2009, as filed with the Securities and Exchange Commission (“SEC”) on March 16, 2010, and our subsequent Current Reports on Form 8-K filed with the SEC. This discussion contains forward-looking statements, the accuracy of which involves risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements for many reasons, including, but not limited to, those discussed herein and in our Annual Report on Form 10-K for the year ended December 31, 2009. See “Financial Information — Special Note Regarding Forward-Looking Statements.” All tabular amounts are presented in thousands, except per-share data.

**Chapter 11 Bankruptcy Filing**

On April 30, 2010 (the “Petition Date”), we filed a voluntary petition for bankruptcy protection (the “Petition”) under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court in the District of Delaware (the “Bankruptcy Court”), case number 10-11485 (the “Bankruptcy Case”). As a result, we are currently operating as “debtor-in-possession” under the jurisdiction of the Bankruptcy Court and in accordance with the applicable provisions of the Bankruptcy Code. We will continue to manage and operate our business and assets in the ordinary course during the pendency of the Bankruptcy Case, subject to the supervision and orders of the Bankruptcy Court and in accordance with applicable provisions of the United States Bankruptcy Code.

As a result of the Petition, realization of assets and liquidation of liabilities are subject to uncertainty. While operating as a debtor-in-possession under the protection of Chapter 11 of the Bankruptcy Code, subject to Bankruptcy Court approval or as otherwise permitted in the normal course of business, we may sell or otherwise dispose of assets and liquidate or settle liabilities for amounts other than those reflected in our condensed consolidated financial statements. Further, a plan of reorganization could materially change the amounts and classifications reported in the consolidated historical financial statements, which do not give effect to any adjustments to the carrying value of assets or amounts of liabilities that might be necessary as a consequence of confirmation of a plan of reorganization.

We cannot provide any assurance as to what values, if any, will be ascribed in the bankruptcy proceedings to various pre-petition liabilities or common stock. Accordingly, caution should be exercised with respect to existing and future investments in any securities of the Company.

**First Day Motions**

The Bankruptcy Court has approved various motions for relief designed to allow us to continue normal operations. The Bankruptcy Court’s orders provide us, among other things: (a) the ability to prevent utility providers, on an interim basis pending a final hearing, from altering, refusing, or discontinuing utility services, (b) authority to pay certain taxes and governmental assessments in the ordinary course of business, (c) authority to pay certain pre-petition and post-petition employee wages, (d) authority to pay pre-petition reimbursable business expenses and certain terminated employee obligations, (e) authority to continue paying certain employee wages and salaries, reimbursable expenses, health plan claims, and insurance programs and obligations in the ordinary course of business, (f) authority to make deductions from employees’ paychecks for employees’ portions of certain employee benefits, (g) authority to continue workers’ compensation programs, (h) authority to pay certain pre-petition claims of critical vendors and service providers and certain administrative claimholders, (i) authority directing banks and other financial institutions to honor all checks and electronic payment requests made by us related to items (c)-(h), above, (j) the ability to continue maintenance of existing bank accounts and existing cash management systems, and (k) an interim order establishing notification and hearing procedures for transfers of our equity securities.

***Notifications***

Shortly after filing the Petition, we began notifying all known current or potential creditors of the Petition filing. The Petition automatically enjoined, or stayed, the continuation of any judicial or administrative proceeding or other actions against us or our property to recover on, collect or secure a claim arising prior to the Petition Date. Vendors will be paid for goods and services provided after the Petition Date in the ordinary course of business. Under the Bankruptcy Code, we may assume or reject certain unexpired leases, subject to the Bankruptcy Court's approval and certain other conditions.

As of the filing date of this report, we have filed a motion to reject certain of our operating and real property leases. The Bankruptcy Court has not yet held hearings on this motion. Various other filings will be made with respect to third party servicing firms, professional firm engagements and contract approvals.

***Basis of Presentation***

The unaudited condensed consolidated financial statements presented herein reflect the financial position, results of operations and cash flows of MiddleBrook, and have been prepared on the basis of a going concern, although the events leading up to the Petition and the Petition proceedings create uncertainties about our ability to meet our obligations as they become due. As a result of certain events of default, we have reclassified the remaining rent payments associated with our vacated Germantown, Maryland facility as a current liability on our condensed balance sheet (see Note 13 – *Commitments and Contingencies*). The unaudited condensed consolidated financial statements do not include any other adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of these uncertainties.

The unaudited condensed consolidated financial statements do not purport to reflect or provide for the consequences of the Bankruptcy Case, including the accounting requirements under the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 852, "Reorganizations" ("ASC 852"). As a result, the unaudited condensed consolidated financial statements do not segregate liabilities subject to compromise in the condensed balance sheet and reorganization items, net in the condensed consolidated statement of operations, nor do they reflect any of the fresh-start reporting adjustments required by ASC 852, which we expect will be required if and when we emerge from bankruptcy.

***NASDAQ De-listing***

In accordance with NASDAQ Listing Rule 5250(b), on April 30, 2010, we notified The NASDAQ Stock Market, ("NASDAQ") that we had filed the Petition. On May 3, 2010, we received notice from NASDAQ notifying us that, due to the filing of the Petition, trading of our common stock will be suspended at the opening of business on May 12, 2010 and that our common stock will be de-listed from the NASDAQ Global Market that same day, pursuant to NASDAQ Listing Rules 5101, 5110(b) and IM-5101-1. At this time, we do not intend to appeal NASDAQ's decision.

***Our Business***

We are a pharmaceutical company focused on commercializing anti-infective drug products that fulfill unmet medical needs. We have developed a proprietary delivery technology called PULSYS, which enables the pulsatile delivery, or delivery in rapid bursts, of certain drugs. Our PULSYS technology may provide the prolonged release and absorption of a drug, which we believe can provide therapeutic advantages over current dosing regimens and therapies. We currently have 25 U.S. issued patents and seven foreign patents covering our PULSYS technology, which extend through 2020.

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Our current PULSYS product, MOXATAG (amoxicillin extended-release) Tablets, 775 mg, received U.S. Food and Drug Administration (“FDA”) approval for marketing on January 23, 2008, and is the first and only FDA-approved once-daily amoxicillin. It is approved for the treatment of pharyngitis/tonsillitis secondary to *Streptococcus pyogenes*, commonly known as strep throat, for adults and pediatric patients age 12 and older, and there is no AB-rated equivalent to MOXATAG. We have two additional PULSYS product candidates. The clinical development programs for these product candidates are currently delayed pending adequate financial resources. We had previously announced our plans to start a Phase III clinical trial for our KEFLEX (Cephalexin) PULSYS product candidate for the treatment of skin and skin structure infections in 2010. We believe the added convenience of improving cephalexin from its typical two-to-four times per day dosing regimen to a once-daily product represents an attractive commercial opportunity. We submitted a Special Protocol Assessment (“SPA”) to the FDA in June 2009 for our KEFLEX PULSYS product candidate. The FDA responded to our SPA on July 30, 2009. At this time, we have not reached agreement with the FDA regarding the non-inferiority design and planned analysis of the study as outlined in the SPA. Any future development is contingent upon the successful commercialization of MOXATAG, the outcome of the Bankruptcy Case, adequate financial resources and the FDA’s agreement with a revised study design. We also intend to conduct a Phase II trial to evaluate various dosing regimens of our amoxicillin pediatric PULSYS product candidate in a sprinkle formulation, for use in pediatric patients more than two years old with pharyngitis/tonsillitis secondary to *Streptococcus pyogenes*. Our Phase II trial for the pediatric PULSYS sprinkle product is currently delayed subject to the availability of additional funds and the successful commercialization of MOXATAG.

We also currently market certain drug products that do not utilize our PULSYS technology and are not protected by any patents. We acquired the U.S. rights to KEFLEX (Cephalexin, USP) capsules, the immediate-release brand of cephalexin, from Eli Lilly and Company (“Eli Lilly”) in 2004.

We have engaged Gleacher & Company (formerly Broadpoint Gleacher Securities Group, Inc.) (“Gleacher”) to assist us in identifying and evaluating strategic options, including a potential sale of the Company. There can be no assurance that we will be able to identify and implement a strategic option that will be beneficial to our investors. If we are unable to consummate a strategic transaction in the near future, depending on the outcome of the Bankruptcy Case, we may be unable to continue operations as a going concern.

In order to more aggressively preserve our financial resources, on September 1, 2009 and December 3, 2009, we announced reductions of approximately 25% and 33%, respectively, in the number of our sales representatives and managers, as well as approximately 20% and 20%, respectively, in our corporate staff. In addition, we announced that, effective March 15, 2010, we eliminated our field sales force and significantly reduced our corporate staff to preserve our cash resources as we explore strategic options. As part of this reduction-in-force, our Chief Executive Officer announced his resignation as an officer and director, effective March 15, 2010, to further reduce operating expenses.

In February 2010, we partnered with DoctorDirectory.com, Inc. (“DoctorDirectory”) to promote MOXATAG through DoctorDirectory’s virtual marketing solution, IncreaseRx<sup>®</sup>, in those areas not covered by our sales force at that time. IncreaseRx<sup>®</sup> performs as a virtual contract sales organization, providing healthcare professionals with access to electronic sampling and online educational tools and information. We now rely entirely on IncreaseRx<sup>®</sup> to market MOXATAG, following the elimination of our field sales force effective March 15, 2010. We also plan to market KEFLEX in the United States through a third party marketer.

Beginning in April 2010, we ceased making rental payments on our leased facilities in Germantown, Maryland. On April 6, 2010, we received a notice of default from the landlords on those leases. The landlords asserted that the defaults gave them the right to re-possess the leased premises, distrain for rent, apply the security deposit to satisfy amounts due, and claim damages for the loss of rent for the balance of the term of the agreements. On or about April 14, 2010, because of the defaults, the landlords made demand of the letters of credit we had as security deposit included in other current assets on our condensed balance sheet as of March 31, 2010. These amounts were subsequently paid to the landlords in accordance with the terms of the letters of credit. See Note 13 – *Commitments and Contingencies* for additional information.

### Management Overview of 2010

The following summarizes the key events that occurred during the first three months of 2010:

- *We engaged Gleacher as our financial advisor to assist the Board of Directors in identifying and evaluating strategic alternatives.*
- *We eliminated our field sales force and significantly reduced our corporate staff, including our former Chief Executive Officer, effective March 15, 2010.*
- *We terminated our Loan Agreement with Silicon Valley Bank, effective March 16, 2010.*
- *We partnered with DoctorDirectory.com, Inc. to promote MOXATAG through DoctorDirectory’s virtual marketing solution, IncreaseRx<sup>®</sup>.*
- *We vacated the remaining portions of our leased space in Maryland.*



***Focus for Remainder of 2010***

Our primary focus for 2010 is the pursuit of strategic alternatives and the preservation of cash, as well as the continued commercialization of our MOXATAG and KEFLEX products. We are working to validate additional active pharmaceutical ingredient providers for our MOXATAG product and negotiating with a new third-party manufacturer for our KEFLEX products. Additionally, we are working to validate production on a 10-count dose pack for MOXATAG.

**Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”). We have based our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

***Revenue Recognition***

We recognize revenue for the sale of pharmaceutical products as follows:

*Product Sales.* Provisions for sales discounts and estimates for chargebacks, service fees, rebates, co-pay assistance and product returns are established as a reduction of product sales revenue at the time revenues are recognized, based on historical experience adjusted to reflect known changes in the factors that impact these reserves.

During the first quarter of 2009, we launched our once-a-day amoxicillin product, MOXATAG. Our MOXATAG customers are almost identical to those that purchase our KEFLEX product. Therefore, we have utilized much of our experience with KEFLEX in order to estimate our provisions associated with sales of MOXATAG. We continue to monitor our estimates and assumptions to determine if a different pattern emerges with MOXATAG and will adjust our provisions accordingly in the period the change is made.

*Product Returns.* Our return policy typically allows product returns for products within an 18-month window, which begins six months prior to the expiration date and continues up to 12 months after the expiration date, which is typically three years from the date of manufacture.

*Distribution Service Fees.* Consistent with industry practice, we enter into distribution and inventory management agreements with our key wholesalers to provide incentives to effectively manage channel inventory and provide timely and accurate data with respect to inventory levels and data regarding sales activity.

*Chargebacks and Rebates.* Chargebacks and rebates represent the difference between the prices at which we sell our products to wholesalers and the sales price ultimately paid under fixed price contracts by third-party payors, including governmental agencies. We record an estimate at the time of sale of the amount to be charged back to us or rebated to the end user. Medicaid rebates in the first quarter of 2010 included an adjustment to account for the increased rebate percentage authorized by the federal government in March 2010.

*Co-Pay Assistance Programs.* Our co-pay assistance program has evolved from our coupon and check programs. The coupon and check redemptions are based on the specific terms of the coupon or check and timing and quantity of distribution, combined with historical redemption rates. We launched our co-pay assistance program in July 2009, which we designed to keep a patient’s net out-of-pocket co-pay expense for a MOXATAG prescription at no more than \$20. The co-pay voucher is available at doctors’ offices or through the MOXATAG website. Patients can redeem the voucher at the point-of-sale in conjunction with having a MOXATAG prescription filled. The estimated liability for the redemption of these vouchers is based on the estimated number of prescriptions that will be filled with a voucher, compared to the number of prescriptions in the channel (i.e., inventory that we have sold to retailers and wholesalers but that has yet to be filled as prescriptions for an end-user patient). In addition to estimating the number of prescriptions to be filled, we also estimate the number of prescriptions remaining in the channel and the value for which each voucher will be redeemed to provide the \$20 maximum co-pay benefit.

*Other Sales Allowances and Reserves.* We also record other sales allowances and reserves that reduce our gross product revenue, including cash discounts and pricing discounts. Cash discount reserves are recorded as an allowance against accounts receivable. Pricing discounts are based on the specific terms of each discount and are recorded at the time of the sale of such discounted product.



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The following table summarizes the activity for the first three months of 2010 associated with accrued returns, distribution fees, chargebacks and other sales allowances:

	<u>Product Returns</u>	<u>Distribution Service Fees</u>	<u>Chargebacks</u>	<u>Cash Discounts</u>	<u>Co-pay Assistance</u>	<u>Rebates and Other Sales Allowances</u>	<u>Total Accrued Sales Reserves &amp; Allowances</u>
<b>Balance at December 31, 2009</b>	<b>\$ 1,684</b>	<b>\$ 512</b>	<b>\$ 220</b>	<b>\$ 55</b>	<b>\$ 3,796</b>	<b>\$ 195</b>	<b>\$ 6,462</b>
Provision made for sales during period	262	594	102	206	2,518	333	<b>4,015</b>
Provision/(benefit) for sales in prior periods	—	—	—	—	(18)	127	<b>109</b>
Payments/credits	(14)	(244)	(54)	(244)	(1,391)	(104)	<b>(2,051)</b>
<b>Balance at March 31, 2010</b>	<b>\$ 1,932</b>	<b>\$ 862</b>	<b>\$ 268</b>	<b>\$ 17</b>	<b>\$ 4,905</b>	<b>\$ 551</b>	<b>\$ 8,535</b>

### Income Taxes

We account for income taxes by the liability method. Under this method, deferred income taxes are recognized for tax consequences in future years based on differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end, which are determined by reference to enacted laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are provided if it is more likely than not that some or all of the deferred tax assets will not be realized. Income tax expense or benefit for the year is allocated among continuing operations, discontinued operations, extraordinary items, other comprehensive income, and items charged or credited directly to shareholders equity. Pursuant to this intraperiod allocation requirement, for the three-month period ending March 31, 2009, \$132,000 of tax expense has been allocated to the loss from continuing operations. We did not record any tax provision or benefit for the three-month period ended March 31, 2010. We have provided a valuation allowance for the full amount of our net deferred tax assets because realization of any future benefit from deductible temporary differences and net operating loss carry forwards cannot be sufficiently assured at December 31, 2009 and March 31, 2010.

### Recent Accounting Pronouncements

In December 2009, the FASB issued Accounting Standards Update (“ASU”), No. 2009-17, “Consolidations: Improvements to Financial Reporting by Enterprises Involved with Variable Interest Entities,” which codifies SFAS No. 167, “Amendments to FASB Interpretation No. 46(R),” issued in June 2009. ASU 2009-17 amends certain provisions of ASC 810 related to the consolidation of variable interest entities (“VIE”). ASU 2009-17 replaces the quantitative-based risks and rewards calculation for determining which enterprise has a controlling financial interest in a VIE with an approach focused on identifying which enterprise has the power to direct the activities of the VIE that most significantly impact the VIE’s economic performance and the obligation to absorb the losses of the VIE or right to receive benefits from the VIE that could potentially be significant to the VIE. ASU 2009-17 requires ongoing reassessments of whether an enterprise is the primary beneficiary. ASU 2009-17 was effective for us beginning January 1, 2010. Its adoption did not have an impact on our consolidated financial statements.

In January 2010, ASU No. 2010-06, “Improving Disclosures about Fair Value Measurements,” was issued and requires new disclosures regarding recurring or nonrecurring fair value measurements. Entities will be required to separately disclose significant transfers into and out of Level 1 and Level 2 measurements in the fair value hierarchy and describe the reasons for the transfers. Entities will also be required to provide information on purchases, sales, issuances and settlements on a gross basis in the reconciliation of Level 3 fair value measurements. In addition, entities must provide fair value measurement disclosures for each class of assets and liabilities and disclosures about the valuation techniques used in determining fair value for Level 2 or Level 3 measurements. ASU 2010-06 is effective for interim and annual reporting periods beginning after December 15, 2009, except for the gross basis reconciliation for the Level 3 fair value measurements, which is effective for fiscal years beginning after December 15, 2010. The adoption of ASU 2010-06 did not have a material impact on our consolidated financial statements. There were no transfers between Level 1 and Level 2 measurements in the fair value hierarchy during the three months ended March 31, 2010.

## Results of Operations

### Three Months Ended March 31, 2010 Compared to Three Months Ended March 31, 2009

*Revenues.* We recorded revenues from net product sales of \$6.0 million and \$9.0 million during the three-month periods ended March 31, 2010 and 2009, respectively. The following table sets forth revenues by product for the three months ended March 31, 2010 and 2009:

	Three Months Ended March 31,	
	2010	2009
MOXATAG 775 mg tablets	\$ 3,536	\$ 7,449
KEFLEX 750 mg capsules	1,660	1,015
KEFLEX 250 mg and 500 mg capsules	850	505
Total	<u>\$ 6,046</u>	<u>\$ 8,969</u>

We began to sell MOXATAG during the first quarter of 2009 in anticipation of its marketing launch on March 16, 2009. During the third quarter of 2009, we launched our \$20 maximum co-pay program designed to keep a patient's net out-of-pocket co-pay expense for a MOXATAG prescription at \$20 or less. The expense for the co-pay assistance program is recorded as a reduction of revenues. The decrease in MOXATAG sales in the first quarter of 2010 is due to a combination of fewer gross sales during the first quarter of 2010 as the traditional strep throat season ended, as compared to the first quarter of 2009, which included initial orders by customers in preparation of the marketing launch, and the negative impact on net sales associated with the co-pay assistance program during the first quarter of 2010.

Sales of KEFLEX products increased during the first quarter of 2010 as compared to the same period in 2009, primarily due to increased sales units combined with increased sales dollars following a January 2010 price increase.

In February 2010, we partnered with DoctorDirectory to promote MOXATAG through DoctorDirectory's virtual marketing solution, IncreaseRx<sup>®</sup>, in those areas not covered by our sales force at that time. We now rely entirely on IncreaseRx<sup>®</sup> to market MOXATAG, following the elimination of our field sales force effective March 15, 2010.

*Cost of Product Sales.* Cost of product sales represents the purchase cost of our MOXATAG and KEFLEX products sold, royalties on the KEFLEX 750 mg product, and any provisions recorded for slow-moving or excess inventory that is not expected to be sold prior to reaching expiration. The following table discloses the major components of cost of product sales for the three months ended March 31, 2010 and 2009:

	Three Months Ended March 31,	
	2010	2009
Product manufacturing costs	\$ 551	\$ 643
Royalty to Eli Lilly	160	114
Provisions for slow-moving/obsolete inventory	1,402	—
Total	<u>\$ 2,113</u>	<u>\$ 757</u>

Cost of product sales increased from \$0.8 million during the three months ended March 31, 2009 to \$2.1 million during the three months ended March 31, 2010, primarily as the result of recording a \$1.4 million reserve primary for slow-moving MOXATAG inventory during the three months ended March 31, 2010.

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*Research and Development Expenses.* Research and development expenses decreased \$1.5 million, or approximately 80.0%, to \$0.4 million for the three months ended March 31, 2010, from \$1.9 million for the three months ended March 31, 2009. The decrease in research and development expenses is primarily attributable to a decline in expenses associated with the development of MOXATAG, which we launched in the first quarter of 2009. The following table discloses the components of research and development expenses for the three-month periods ending March 31, 2010 and 2009:

	Three Months Ended March 31,	
	2010	2009
Third-party direct project costs (consultants & materials)	\$ 341	\$ 496
Legal and consulting expenses	31	285
Depreciation and amortization	6	41
Salaries, stock-based compensation, benefits and related costs	—	810
Facilities and equipment related	—	144
Other expenses	—	83
Total	<u>\$ 378</u>	<u>\$ 1,859</u>

Research and development expenses consist of direct and indirect costs. Direct costs include expenses such as salaries and related costs of research and development personnel, and the costs of consultants, materials and supplies associated with research and development projects, as well as clinical studies and manufacturing validation in advance of our commercial launch of MOXATAG. Indirect research and development costs include facilities, depreciation, and other indirect overhead costs.

During the fourth quarter of 2009, we put our KEFLEX PULSYS research on hold following our review of the FDA's response to our SPA. Subsequent to this decision, we began to classify expenses related to our employees in research and development in Selling, general and administrative expense on our statement of operations. We anticipate these internal costs to remain classified as Selling, general and administrative expenses on our statement of operations.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses increased \$2.1 million, or 13.0%, to \$18.6 million for the three months ended March 31, 2009, from \$16.5 million for the three months ended March 31, 2009, as detailed in the following table:

	Three Months Ended March 31,	
	2010	2009
Salaries, benefits and related costs	\$ 4,538	\$ 6,856
Severance expense	3,169	—
Facilities and equipment related	3,708	555
Marketing costs	2,311	5,445
Depreciation and amortization	1,764	392
Stock-based compensation	848	799
Legal and consulting expenses	676	470
Audit and financial fees	346	206
Selling and distribution expenses	197	169
Other expenses	1,041	1,579
Total	<u>\$ 18,598</u>	<u>\$ 16,471</u>

Overall, selling, general and administrative expenses increased primarily due to severance expense associated with the elimination of our field sales force and significantly reducing our corporate staff, including our former Chief Executive Officer, during the first quarter of 2010 to preserve cash resources, combined with the increase in facility-related expenses driven by recording the liability for the remaining lease payments for the leased facilities in Maryland that we vacated during the first quarter of 2010 and writing off the leasehold improvements associated with those facilities.

These increases were partially offset by lower marketing expenses during the first quarter of 2010 compared to the prior year first quarter, which included the launch of our MOXATAG product, and lower salary and related expenses due to fewer employees during the first quarter of 2010 compared to 2009.

*Nonoperational Income (Expense).* Nonoperational income (expense) during the three months ended March 31, 2010 included \$12,000 of interest income on cash balances, offset by \$9,000 of interest expense related to the accounting for leased vehicles as capital leases, which allocates a portion of the monthly payment to interest. During the three months ended March 31, 2009, nonoperational income (expense) included interest income of \$256,000 on invested balances, partially offset by \$11,000 of interest expense associated with our capital lease accounting.

## Liquidity and Capital Resources

We have funded our operations principally with the proceeds of \$54.5 million from a series of five preferred stock offerings and one issue of convertible notes over the period from 2000 through 2003, the net proceeds of \$54.3 million from our initial public offering in October 2003, and private placements of common stock for net proceeds of \$19.9 million and \$96.0 million in January 2008 and September 2008, respectively. In addition, we have received funding of \$8.0 million and \$28.3 million from GlaxoSmithKline and Par Pharmaceutical, Inc., respectively, as a result of now-terminated collaboration agreements for the development of new products.

In November 2007, we sold certain of our KEFLEX assets in exchange for \$7.5 million (less a \$0.5 million payment to the purchaser to cover its expenses related to the transaction), while retaining the right to continue operating the KEFLEX business, subject to certain royalty payments to the purchaser and the right to repurchase the assets at a future date at predetermined prices. We repurchased these assets in September 2008.

We have experienced significant operating losses since our inception in 2000. As of March 31, 2010, we had an accumulated deficit of \$314.4 million. The commercialization of our products, including MOXATAG, together with our general and administrative expenses, require significant investments and are expected to continue to result in significant operating losses for 2010 and the foreseeable future, if we were to continue as an independent entity. We believe our existing cash resources will be sufficient to fund our operations through the second quarter of 2010 at our planned levels of activities, including the continued commercialization of MOXATAG.

We have engaged Gleacher as our financial advisor to assist the Board of Directors in identifying and evaluating strategic alternatives, including a possible merger or sale of the Company. The Board of Directors has not set a definitive timetable for the completion of its evaluation, and there can be no assurance that the process will result in a transaction. If we are unable to consummate a strategic transaction in the near future, depending on the outcome of the Bankruptcy Case, we may be unable to continue operations as a going concern.

Beginning in April 2010, we ceased making rental payments on our leased facilities in Germantown, Maryland. On April 6, 2010, we received a notice of default from the landlords on those leases. The landlords asserted that the defaults gave them the right to re-possess the leased premises, distain for rent, apply the security deposit to satisfy amounts due, and claim damages for the loss of rent for the balance of the term of the agreements. On or about April 14, 2010, because of the defaults, the landlords made demand of the letters of credit we had as security deposit included in other current assets on our condensed balance sheet as of March 31, 2010. These amounts were paid to the landlords in accordance with the terms of the letters of credit. See Note 13 – *Commitments and Contingencies* for additional information.

Our estimates of future capital requirements are uncertain and will depend on a number of factors, including the outcome of the Bankruptcy Case, the success of our commercialization of MOXATAG, the progress of our research and development of product candidates (which are currently delayed), the timing and outcome of regulatory approvals, cash received from sales of our products, payments received or made under any future collaborative agreements, the costs involved in enforcing patent claims and other intellectual property rights, the status of competitive products, the availability of financing, and our or our potential partners' success in developing markets for our product candidates. Changes in our commercialization and development plans, partnering activities, regulatory activities and other developments may increase our rate of spending and decrease the period of time our available resources will fund our operations. Insufficient funds will require us to continue to delay, scale back or eliminate some or all of our research, development or commercialization programs, or may adversely affect our ability to operate as a going concern.

To minimize our cash requirements, we have continued our program of cost reductions, including the elimination of our field sales force and significantly reducing our corporate staff.

Our net cash requirements for 2010 will depend on, among other things, the outcome of the Bankruptcy Case, the cash received from sales of MOXATAG and our existing non-PULSYS products (KEFLEX capsules in 250 mg, 500 mg and 750 mg strengths) and the cash expended for (1) cost of products sold, including royalties due to Eli Lilly on KEFLEX 750 mg net revenues, (2) sales and marketing expenses for KEFLEX 750 mg and MOXATAG, and (3) general and administrative expenses. Our cash receipts and cash expenditures assumptions for 2010 include the following: (1) continuation of KEFLEX 750 mg monthly prescriptions at the current 7,000 to 10,000 prescriptions per month rate (end-user demand), which assumes no generic competitive product enters the market in 2010, (2) market acceptance of MOXATAG and associated end-user demand, (3) the expenses associated with and impact of eliminating our internal field sales force and managers, (4) marketing costs associated with the commercial launch of MOXATAG through DoctorDirectory's virtual marketing solution, IncreaseRx<sup>®</sup>, (5) the continued postponement of our research and development programs for PULSYS product candidates, and (6) expenses associated with identifying and evaluation strategic options. These 2010 estimates are forward-looking statements that involve risks and uncertainties, and actual results could vary materially.

### ***Loan Agreement***

On June 29, 2009, we entered into a Loan and Security Agreement, which we refer to as the Loan Agreement, with Silicon Valley Bank for a two-year \$10.0 million revolving line of credit for working capital needs. Effective March 16, 2010, we terminated the Loan Agreement. No balances were outstanding during the term of the Loan Agreement.

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### Cash and Marketable Securities

At March 31, 2010, unrestricted cash and cash equivalents were \$10.9 million compared to \$14.8 million at December 31, 2009, as summarized in the following table:

	<u>March 31,</u> <u>2010</u>	<u>December 31,</u> <u>2009</u>
Cash and cash equivalents	\$ 10,938	\$ 14,798
Total	<u>\$ 10,938</u>	<u>\$ 14,798</u>

Our cash and cash equivalents balance decreased by \$3.9 million during the first three months of 2010 from a balance of \$14.8 million as of December 31, 2009. The decrease is due to cash used in operations during the first three months of 2010, including the severance paid in connection with the elimination of our field sales force and significantly reducing our corporate staff.

Our investment policy requires the selection of high-quality issuers, with bond ratings of AAA to A1+/P1. We do not invest in auction rate securities. Due to our current liquidity needs, we do not anticipate holding any security with a maturity greater than 12 months. We held no marketable securities at either March 31, 2010 or December 31, 2009.

We maintain cash balances with financial institutions in excess of insured limits. However, we do not anticipate any losses with respect to such cash balances.

### Cash Flow

The following table summarizes our sources and uses of cash and cash equivalents for the three-month periods ended March 31, 2010 and 2009:

	<u>Three Months Ended</u> <u>March 31,</u>	
	<u>2010</u>	<u>2009</u>
Net cash used in operating activities	\$ (3,704)	\$ (18,914)
Net cash provided by investing activities	—	20,601
Net cash used in financing activities	(156)	(240)
Net (decrease) increase in cash and cash equivalents	<u>\$ (3,860)</u>	<u>\$ 1,447</u>

Cash used in operating activities decreased primarily as a result of activities associated with the launch of MOXATAG during the prior year first quarter. Decreases in inventory, accounts receivable and other current asset balances, along with an increase in accounts payable during the first three months of 2010, helped decrease the cash used in operations during the period, partially offsetting the larger net loss during the first quarter of 2010 compared to the negative impact these accounts had on the net loss for the first quarter of 2009 as we were launching MOXATAG. Additionally, our net loss for the first quarter of 2010 included more non-cash items that were added back, such as the accrual of the remaining lease payments associated with the facilities in Germantown, Maryland that we vacated and the write-off of the associated leasehold improvements.

Cash provided by investing activities decreased to zero for the three months ended March 31, 2010 as we did not have any marketable securities at any time during the period and did not make any purchases of property or equipment. During the three months ended March 31, 2009, cash provided by investing activities consisted primarily of the sales and maturity of marketable securities, partially offset by small purchases of marketable securities and property and equipment. The majority of sold and matured marketable securities were used to increase cash balances to support our operating activities.

Net cash used in financing activities during the first three months of 2010 and 2009 consisted primarily of payments associated with the capital leases for vehicles, slightly offset in 2009 by stock option exercises. The decrease in the capital lease payments in 2010 compared to 2009 is due to fewer vehicles being leased during the 2010 quarter.

### Contractual Commitments

We continue to have commitments for leased facilities in Maryland that we no longer occupy. During the first quarter of 2010, we vacated the facilities and recorded an additional \$1.4 million of expense associated with the buildings to increase the liability to reflect all remaining lease payments.

Based on our current liquidity issues, we ceased making any rental payments for these leased facilities beginning in April 2010. On April 6, 2010, we received a notice of default from Minkoff Development Corporation, on behalf of Seneca Meadows Corporate Center III LLLP (“Seneca III”), with respect to default under (1) the Lease #1 Documents (as defined below) entered into in connection with our lease of the premises located at 20443-20445 Seneca Meadows Parkway (the “Lease #1 Premises”) in Germantown, Maryland from Seneca III (“Lease #1”) and (2) that certain Promissory Note, dated May 1, 2009, issued by us for the benefit of Seneca III with an original principal amount of \$606,225.00 (“the Note”). The “Lease #1

Documents” include the following: Agreement of Sublease, or the Sublease, dated August 4, 2004, between us and Large Scale Biology Corporation; Seneca III’s Consent to Sublease, dated August 2, 2004; Supplement to Sublease, dated August 24, 2004, between Seneca III and us; Agreement, dated August 11, 2006, between Seneca III and us; Amendment to Lease, dated February 4, 2008, between Seneca III and us; and Second Amendment to Lease, dated April 23, 2009, between Seneca III and us.

The notice of default with respect to the Lease #1 Documents and the Note states that the defaults resulted from our failure to remit our scheduled lease payments under Lease #1, totaling \$31,899.55 due on April 1, 2010, and our scheduled principal and interest payment under the Note of \$31,031.71 due on April 1, 2010. The terms of Lease #1 provide that an event of default under Lease #1 could give Seneca III the right to re-possess the Lease #1 Premises, distraint for rent, apply the security deposit to satisfy amounts due, and claim damages for the loss of rent sustained by Seneca III for the balance of the term of Lease #1. In addition, default under the Note could cause the entire unpaid principal balance under the Note, together with accrued interest, to become immediately due and payable. Upon default and acceleration of payment under the Note, the rate of interest would be automatically increased, from the date of default until the Note is paid in full, from eight percent (8%) per annum to fifteen percent (15%) per annum.

Additionally, on April 6, 2010, we received a notice of default from Minkoff Development Corporation, on behalf of Seneca Meadows Corporate Center II LLC ("Seneca II"), our landlord under that certain Lease, dated August 1, 2002, between us and Seneca II with respect to the premises located at 20417-20435 Seneca Meadows Parkway ("the Lease #2 Premises") in Germantown, Maryland ("Lease #2"). The notice of default states that the default resulted from our failure to make our scheduled lease payments under Lease #2 totaling \$109,550.65, which were due on April 1, 2010. An event of default under Lease #2 could give Seneca II the right to re-possess the Lease #2 Premises, distraint for rent, apply the security deposit to satisfy amounts due, and claim damages for the loss of rent sustained by Seneca II for the balance of the term of Lease #2.

On or about April 14, 2010, because of the defaults, Seneca II and Seneca III made demand of the letters of credit we had as security deposit included within other current assets on our condensed balance sheet as of March 31, 2010. These amounts were subsequently paid to Seneca II and Seneca III in accordance with the terms of the letters of credit.

In connection with the elimination of our field sales force in the first quarter of 2010, we terminated all remaining vehicle leases associated with the master lease agreement that we entered into during 2009. We removed the remaining assets and liabilities associated with the capital lease accounting of those leases, and we accrued the estimated loss that we anticipate to incur as the vehicles are sold. Any expenses above and beyond that estimated loss will be expensed as incurred.

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

#### **Market Risk**

Our exposure to market risk is currently confined to our cash, cash equivalents and restricted cash, which generally have maturities of less than one year. We currently do not hedge interest rate exposure. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments.

#### **Foreign Currency Risk**

Most of our trade payable transactions are conducted in U.S. dollars, or USD, although purchases of our MOXATAG finished product and some services are paid in euros, or EUR, and packaging for our MOXATAG samples is paid in British pound sterling, or GBP. In order to manage the fluctuations in exchange rates between the USD and EUR and USD and GBP, we occasionally enter into foreign currency forward exchange contracts that lock in the exchange rate for which we will buy our inventory. We enter into these exchange contracts solely for hedging purposes and not for trading purposes. These contracts are designated as cash flow hedges of the variability of the cash flows due to changes in foreign exchange rates and marked-to-market with the resulting gains or losses reflected in other comprehensive income (loss). Gains or losses are included in Cost of products sold at the time the products are sold, generally within twelve months. We had no outstanding foreign currency forward exchange contracts as of March 31, 2010.

#### **Inflation**

Our most liquid assets are cash and cash equivalents. Because of their liquidity, these assets are not directly affected by inflation. We also believe that we have intangible assets in the value of our intellectual property. We have not capitalized the value of this intellectual property on our balance sheet. Due to the nature of this intellectual property, we believe that these intangible assets are not affected by inflation. Because we intend to retain and continue to use our equipment, furniture and fixtures and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources.

**Item 4. Controls and Procedures**

Our management, including our principal executive and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2010. Our disclosure controls and procedures are designed to provide reasonable assurance that the information required to be disclosed in the reports 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 management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, our principal executive and principal financial officer concluded that our disclosure controls and procedures, as defined by Rule 13a-15(e) under the Exchange Act, were effective at the reasonable assurance level as of March 31, 2010.

Our management, including our principal executive and principal financial officer, evaluated any changes in our internal control over financial reporting that occurred during the quarterly period ended March 31, 2010 and concluded that there was no change that occurred during the quarterly period ended March 31, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, as defined by Rule 13a-15(f) under the Exchange Act.

**PART II — OTHER INFORMATION**

**Item 1. Legal Proceedings**

On April 30, 2010, we filed a voluntary petition for bankruptcy protection under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court in the District of Delaware, case number 10-11485.

The Bankruptcy Court has approved various motions for relief designed to allow us to continue normal operations. The Bankruptcy Court's orders provide MiddleBrook, among other things: (a) the ability to prevent utility providers, on an interim basis pending a final hearing, from altering, refusing, or discontinuing utility services, (b) authority to pay certain taxes and governmental assessments in the ordinary course of business, (c) authority to pay certain pre-petition and post-petition employee wages, (d) authority to pay pre-petition reimbursable business expenses and certain terminated employee obligations, (e) authority to continue paying certain employee wages and salaries, reimbursable expenses, health plan claims, and insurance programs and obligations in the ordinary course of business, (f) authority to make deductions from employees' paychecks for employees' portions of certain employee benefits, (g) authority to continue workers' compensation programs, (h) authority to pay certain pre-petition claims of critical vendors and service providers and certain administrative claimholders, (i) authority directing banks and other financial institutions to honor all checks and electronic payment requests made by us related to items (c)-(h), above, (j) the ability to continue maintenance of existing bank accounts and existing cash management systems, and (k) an interim order establishing notification and hearing procedures for transfers of our equity securities.

Other than the Bankruptcy Case, we are not a party to any material pending legal proceedings, other than ordinary routine litigation incidental to our business.

**Item 1A. Risk Factors**

In addition to risk factors set forth below and the other information set forth in this Quarterly Report, you should carefully consider the factors discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2009, which could materially affect our business, financial condition or future results. The risks described below and in our Annual Report on Form 10-K are not the only risks we may face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial conditions and/or operating results. The information below amends, updates and should be read in conjunction with the risk factors and information disclosed in our Annual Report on Form 10-K for the year ended December 31, 2009.

***A long period of operations under the Bankruptcy Case may harm our business.***

During the Bankruptcy Case, our senior management will be required to spend a significant amount of time and effort working on the reorganization instead of focusing exclusively on our business operations. A prolonged period of operating under chapter 11 protection may also make it more difficult to attract and retain management and other key personnel necessary to the success and growth of our business. In addition, the longer the Bankruptcy Case continues, the more likely it is that our contractors and suppliers will lose confidence in our ability to successfully reorganize our businesses and seek to establish alternative commercial relationships. Furthermore, so long as the Bankruptcy Case continues, we will be required to incur substantial costs for professional fees and other expenses associated with the administration of the Bankruptcy Case. A prolonged continuation of the Bankruptcy Case may also require us to seek financing. If we require financing during the Bankruptcy Case and we are unable to obtain the financing on favorable terms or at all, our chances of successfully reorganizing our businesses may be seriously jeopardized, and as a result, our liabilities and securities could become further devalued or worthless.



***Adverse publicity in connection with the Bankruptcy Case or otherwise could adversely our results of operations and our business.***

Adverse publicity or news coverage relating to us, including publicity or news coverage in connection with the Bankruptcy Case, may negatively impact our efforts to establish and promote name recognition and may impair our efforts to gain market acceptance for our products with physicians, patients, pharmacists, healthcare payors and the medical community.

***Operating under the Bankruptcy Code may restrict our ability to pursue our business strategies and strategic alternatives.***

Under the Bankruptcy Code, we must obtain Bankruptcy Court approval to engage in actions outside the ordinary course of business, including with respect to any consolidation, merger, sale or other disposition of all or substantially all of our assets. We have engaged Gleacher to assist our Board of Directors in identifying and evaluating strategic options. Any agreement we enter into with respect to a strategic transaction will be subject to Bankruptcy Court approval. If we are unable to consummate a strategic transaction, we may not be able to continue to operate as a going concern.

In addition, if a trustee is appointed to operate our business while we are in bankruptcy, the trustee would assume control of our assets.

***The amount of creditor claims in the Bankruptcy Case could be more than projected.***

The date for filing proofs of claims has not yet passed. The allowed amount of claims could be significantly more than projected, which could significantly dilute the value of distributions to the holders of claims.

***While the Bankruptcy Case is pending, our financial results may be volatile and any disposition of assets could materially change the amounts we reported in our historical financial statements.***

During the Bankruptcy Case, we expect our financial results to continue to be volatile as asset impairments, asset dispositions, restructuring activities, contract terminations and rejections and claims assessments may significantly impact our consolidated financial statements. Further, we may sell or otherwise dispose of assets and liquidate or settle liabilities, with Bankruptcy Court approval, for amounts other than those reflected in our historical financial statements. Any such sale or disposition and any plan of reorganization could materially change the amounts and classifications reported in our historical condensed financial statements, which do not give effect to any adjustments to the carrying value of assets or amounts of liabilities that might be necessary as a consequence of a plan of reorganization.

***NASDAQ has notified us that it will delist our common stock on May 12, 2010, which makes our common stock significantly less liquid. If our common stock is traded on the Over The Counter Bulletin Board or the Pink Sheets, trading may be highly speculative and pose substantial risks.***

Trading prices of our securities are very volatile and may bear little or no relationship to the actual recovery, if any, by the holders under any eventual court-approved plan of reorganization. In such plan, our existing securities, in particular our common stock, may be cancelled and holders may receive no payment or other consideration in return, or they may receive a payment or other consideration that is less than the trading price or the purchase price of such securities.

**ITEM 6. Exhibits**

<u>Exhibit</u>	<u>Description</u>
31.1	Certification of Principal Executive and Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive and Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350.

**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.

MIDDLEBROOK PHARMACEUTICALS, INC.

Dated: May 7, 2010

/s/ DAVID BECKER

David Becker

Executive Vice President, Chief Financial Officer, and  
Acting Chief Executive Officer and President

**EXHIBIT INDEX**

<u>Exhibit</u>	<u>Description</u>
31.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350.

I, David Becker, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2010 of MiddleBrook Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2010

/s/ DAVID BECKER

Executive Vice President, Chief Financial Officer, and  
Acting President and Chief Executive Officer  
(Principal Executive Officer and Principal Financial Officer)

**Certification of Principal Financial Officer  
Pursuant to 18 U.S.C. 1350  
(Section 906 of the Sarbanes-Oxley Act of 2002)**

I, David Becker, Executive Vice President, Chief Financial Officer and Acting President and Chief Executive Officer (Principal Executive and Financial Officer) of MiddleBrook Pharmaceuticals, Inc. (the "Registrant"), certify, based upon a review of the Quarterly Report on Form 10-Q for the period ended March 31, 2010 of the Registrant (the "Report"), that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

/s/ DAVID BECKER

Name: David Becker

Title: Executive Vice President, Chief Financial Officer, and  
Acting President and Chief Executive Officer  
(Principal Executive Officer and Principal Financial Officer)

Date: May 7, 2010