

Press Release

MiddleBrook Pharmaceuticals Reports Second Quarter 2009 Results

Highlights:

WESTLAKE, Texas--(BUSINESS WIRE)--Aug. 6, 2009-- MiddleBrook Pharmaceuticals, Inc. (Nasdaq: MBRK) today announced financial and operational results for the quarter ended June 30, 2009.

Second Quarter 2009 Financial Results:

MiddleBrook reported second quarter 2009 revenue of \$2.1 million, compared to revenue of \$2.5 million in the second quarter of 2008. Net factory sales of MOXATAG (extended-release amoxicillin) Tablets, 775 mg, totaled \$0.4 million for the 2009 second quarter, and net sales for the KEFLEX® (cephalexin, USP) franchise totaled \$1.7 million.

Net loss was \$19.6 million for the 2009 second quarter, compared to a net loss of \$3.7 million attributable to MiddleBrook in the second quarter of 2008. Net loss per share during the second quarter of 2009 was \$0.23, compared to a net loss per share of \$0.07 in the prior-year quarter.

MiddleBrook reported cost of goods sold in the amount of \$0.3 million for the 2009 second quarter, compared to \$0.4 million in the prior year period. Research and development (R&D) expense in the second quarter of 2009 was \$1.5 million, compared to second quarter 2008 R&D expense of \$3.6 million. Selling, general and administrative expense was \$20.0 million in the second quarter of 2009, compared to \$3.9 million in the prior-year period.

As of June 30, 2009, MiddleBrook's cash, cash equivalents, and marketable securities totaled \$44.5 million, compared to \$55.4 million at the end of first quarter 2009.

"The second quarter represented the first full quarter of our MOXATAG launch, and we achieved steady month-over-month gains in the number of prescriptions throughout the period," said MiddleBrook President and CEO John Thievon. "Most importantly, feedback from the field indicates strong acceptance for MOXATAG by healthcare professionals."

"While the economic environment remains challenging," Thievon continued, "we believe that our improved distribution, increased managed care coverage and new marketing programs will help us increase our market share as we enter the strep throat season."

KEFLEX PULSYS Development Update:

MiddleBrook previously announced that it had planned to start its Phase III clinical trial for its KEFLEX PULSYS product candidate in 2010, contingent upon the success of the MOXATAG launch and the FDA's agreement with MiddleBrook's clinical protocol. MiddleBrook submitted a Special Protocol Assessment (SPA) to the FDA in June for its KEFLEX PULSYS product candidate. The FDA responded to MiddleBrook's SPA on July 30, 2009. At this time, MiddleBrook has not gained agreement with the FDA regarding the non-inferiority design and planned analysis of the study as outlined in MiddleBrook's SPA. Accordingly, MiddleBrook is delaying the development of its KEFLEX PULSYS product candidate. Any future development is contingent upon the successful commercialization of MOXATAG, adequate financial resources, and the FDA's agreement with a revised study design.

Outlook:

MiddleBrook is revising its 2009 annual revenue guidance and expense estimate. The Company now expects combined 2009 net sales for MOXATAG and KEFLEX to be less than \$25 million due to slower-than-anticipated prescription growth and the projected gross margin impact of the new \$20 maximum copay program for MOXATAG. MiddleBrook has also reduced expenses, and the Company now anticipates that total operating expenses for 2009 will range between \$83 and \$88 million, versus its previous estimate of total operating expenses ranging between \$93 and \$100 million.

"MOXATAG's prescription numbers to-date show that we are trending at about 60% of our initial prescription forecast," said Dave Becker, MiddleBrook executive vice president and CFO. "We will continue to focus on controlling expenses while we work to successfully commercialize MOXATAG, and we are eager to see how our enhanced marketing efforts affect prescription growth as we enter the upcoming strep throat season."

"As a result of the FDA's response to our SPA, we have intensified our business development activities in pursuit of product opportunities that would be complementary to MOXATAG," said MiddleBrook President and CEO John Thievon. "Accordingly, we anticipate that additional financing may be necessary to pursue such opportunities and/or to fund operations."

Second Quarter 2009 Conference Call and Webcast

As previously announced, MiddleBrook Pharmaceuticals is releasing its financial and operational results for the second quarter of 2009 today, Thursday, August 6, 2009, before the market opens. At 9:00 a.m. (ET) today, MiddleBrook management will conduct a conference call to review results for the second quarter.

To listen live to the call, dial 1-800-813-8504 or 1-660-422-4526. A replay of the call will be available starting at approximately 11 a.m. on August 6 through 5 p.m. on August 13, 2009. To listen to the replay, dial 1-800-642-1687 or 1-706-645-9291, and enter the conference ID #19864871.

A live audio webcast of the conference call also will be available by going to the Investor Relations section of MiddleBrook's web site, www.middlebrookpharma.com. A replay of the webcast will also be available on the Company's website for approximately one year.

MiddleBrook Pharmaceuticals Reports Inducement Grants Under NASDAQ Marketplace Rule 4350

MiddleBrook Pharmaceuticals also announced today that on July 31, 2009, it granted options to purchase a total of 17,500 shares of MiddleBrook's common stock to seven (7) new employees as a material inducement for them to join MiddleBrook. The options were granted pursuant to NASDAQ Marketplace Rule 4350(i)(1)(A)(iv) and under MiddleBrook's New Hire Stock Incentive Plan, which was approved by MiddleBrook's Board of Directors on Sept. 26, 2008. The options have a per share exercise price equal to the closing price of MiddleBrook's common stock on the NASDAQ Global Market on the business day immediately preceding the grant date, a ten-year term and vesting over four years, with 25 percent of the options vesting one year from the grant date and 1/48th of the options vesting monthly thereafter. The options have a grant date of July 31, 2009.

About MiddleBrook Pharmaceuticals:

MiddleBrook Pharmaceuticals, Inc. (Nasdaq: MBRK) is a pharmaceutical company focused on developing and commercializing anti-infective products that fulfill unmet medical needs. MiddleBrook's proprietary delivery technology—PULSYS—enables the pulsatile delivery, or delivery in rapid bursts, of certain drugs. MiddleBrook's near-term corporate strategy includes improving dosing regimens and/or reducing frequency of dosing to enhance patient dosing convenience and compliance for antibiotics that have been used and trusted by physicians and patients for decades. MiddleBrook currently markets KEFLEX (cephalexin, USP), the immediate-release brand of cephalexin, and MOXATAG—the first and only FDA-approved once-daily amoxicillin. For more information about MiddleBrook, please visit www.middlebrookpharma.com.

KEFLEX, KEFLEX 250 MG, KEFLEX 500MG, KEFLEX 750 MG, MiddleBrook, MiddleBrook Pharmaceuticals (stylized), MiddleBrook Pharmaceuticals, Inc., M1 (stylized), MOX-10, MOXAKIT, MOXATAG1 (stylized), MOXATAG, MOXATEN, MOXPAK, MOX-PAK 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. trademarks applications. Each of the other trademarks, tradenames, or service marks appearing in this document belongs to the respective holder, as used herein, except as otherwise indicated by the context. References to "we," "us," "our," "MiddleBrook," or the "Company," refer to MiddleBrook Pharmaceuticals, Inc., and its subsidiaries.

About MOXATAG:

MOXATAG (amoxicillin extended-release) Tablets, 775mg, is a once-a-day extended-release formulation of amoxicillin for oral administration consisting of three components: one immediate-release component and two delayed-release components. The three components of MOXATAG are combined in a specific ratio to prolong the release of amoxicillin compared to immediate-release amoxicillin. MOXATAG is intended to provide a lower treatment dose, once-daily alternative to currently approved penicillin and amoxicillin regimens for the treatment of adults and pediatric patients 12 years and older with tonsillitis and/or pharyngitis. For more information about MOXATAG, please visit MOXATAG.com.

About KEFLEX:

KEFLEX (cephalexin, USP) Capsules, is MiddleBrook's immediate-release first-generation cephalosporin antibiotic. KEFLEX has been shown to be active against strains of both gram-positive and gram-negative aerobes in vitro and in clinical infections. KEFLEX is indicated for treatment of the following infections: respiratory tract infections, otitis media, skin and skin structure infections, bone infections, and genitourinary tract infections. More information on KEFLEX and prescribing information are available at KEFLEX.com.

FORWARD-LOOKING STATEMENTS

Some of the statements contained in this press release contain forward-looking statements within the meaning of the Securities Exchange Act of 1934 and the Securities Act of 1933, such as statements about MiddleBrook's future financial performance, growth prospects and need for additional capital, the success of the commercialization of MOXATAG and its market position, and the status of the KEFLEX PULSYS Phase III study. 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. Such forward-looking statements reflect MiddleBrook's current plans, beliefs, estimates and views and involve a number of known and unknown risks, uncertainties and other factors that may cause actual results to differ materially from those expressed or implied by such forward-looking statements. These factors include, but are not limited to, the failure to successfully commercialize MOXATAG or a decline in sales of KEFLEX 750 mg, MiddleBrook's ability to meet anticipated operating needs with revenues, existing cash and the revolving line of credit or to obtain additional financing, further decline in market conditions, MiddleBrook's ability to manage expenses, the FDA's disagreement with a revised study design, and other risks identified in the sections titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors" in MiddleBrook's Annual Report on Form 10-K for the year ended December 31, 2008 and in similar disclosures made by us from time to time in our other filings with the Securities and Exchange Commission. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this press release. MiddleBrook undertakes no obligation to update publicly or review any of the forward-looking statements made in this press release, whether as a result of new information, future developments or otherwise.

MIDDLEBROOK PHARMACEUTICALS, INC
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except for Per Share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
	(Unaudited)		(Unaudited)	
Product sales	\$ 2,148	\$ 2,522	\$ 11,117	\$ 4,916
Costs and expenses:				
Cost of product sales	279	374	1,036	996
Research and development	1,525	3,627	3,384	7,355
Selling, general and administrative	20,022	3,937	36,493	8,690
Total costs and expenses	21,826	7,938	40,913	17,041
Loss from operations	(19,678)	(5,416)	(29,796)	(12,125)
Interest income	75	90	330	215
Interest expense	(41)	—	(52)	—
Warrant expense	—	1,680	—	(5,760)
Other income (expense)	49	2	49	(17)
Loss before income taxes	\$ (19,595)	\$ (3,644)	\$ (29,469)	\$ (17,687)
Income taxes	(10)	—	122	—
Net loss	\$ (19,585)	\$ (3,644)	\$ (29,591)	\$ (17,687)
Loss (gain) attributable to noncontrolling interest	—	(63)	—	180
Net loss attributable to MiddleBrook Pharmaceuticals	\$ (19,585)	\$ (3,707)	\$ (29,591)	\$ (17,507)
Basic and diluted net loss per share attributable to MiddleBrook Pharmaceuticals common stockholders	\$ (0.23)	\$ (0.07)	\$ (0.34)	\$ (0.32)
Shares used in calculation of basic and diluted net loss per share	86,482	56,025	86,459	54,660

MIDDLEBROOK PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except Par Values)

June 30,
2009

December
31, 2008

(Unaudited)

ASSETS

Current assets:

Cash and cash equivalents	\$ 39,405	\$ 30,520
Marketable securities	5,142	44,242
Accounts receivable, net of allowances of \$426 and \$379	613	426
Inventories, net	2,223	335
Other current assets	3,899	2,638

Total current assets	51,282	78,161
Property and equipment, net	7,997	4,192
Other noncurrent assets	2,512	1,395
Intangible assets, net	10,953	11,445

Total assets	\$ 72,744	\$ 95,193
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LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable	\$ 1,536	\$ 2,993
Other current liabilities	10,794	6,141

Total current liabilities	12,330	9,134
Deferred contract revenue	11,625	11,625
Other long-term liabilities	4,837	2,503

Total liabilities	28,792	23,262
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Stockholders' equity:

Preferred stock, \$0.01 par value; 25,000 shares authorized, no shares issued or outstanding at June 30, 2009 and December 31, 2008	—	—
Common stock, \$0.01 par value; 225,000 shares authorized, 86,508 and 86,433 shares issued and outstanding at June 30, 2009 and December 31, 2008, respectively	865	864
Capital in excess of par value	309,510	307,705
Accumulated deficit	(266,506)	(236,914)
Accumulated other comprehensive income	83	276

Total stockholders' equity	43,952	71,931
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Total liabilities and stockholders' equity	\$ 72,744	\$ 95,193
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MIDDLEBROOK PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Six Months Ended June	
	30,	
	2009	2008
	(Unaudited)	
Cash flows from operating activities:		
Net loss	\$ (29,591)	\$ (17,687)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,664	1,842
Warrant expense	—	5,760
Stock-based compensation	1,735	792
Deferred rent and credit on lease concession	(3)	(187)
Amortization of premium (discounts) on marketable securities	(26)	(8)
Loss on disposal of fixed assets and existing facility	966	17
Noncash tax expense	122	—
Changes in:		
Accounts receivable	(187)	(16)
Inventories	(1,888)	232
Other current assets	(1,381)	(819)
Deposits and other assets	(117)	63
Accounts payable	(1,457)	(191)
Other liabilities	1,809	(269)
Net cash used in operating activities	(28,354)	(10,471)
Cash flows from investing activities:		
Purchases of marketable securities	(5,206)	(2,364)
Sales and maturities of marketable securities	44,110	—
Purchases of property and equipment	(40)	—
Proceeds from sale of property and equipment	—	332
Change in restricted cash	(1,000)	—
Net cash provided by/(used in) investing activities	37,864	(2,032)
Cash flows from financing activities:		
Principal payments on capital lease obligations	(696)	—
Proceeds from private placement of common stock, net of issue costs	—	19,915
Proceeds from exercise of common stock options	71	726
Proceeds from exercise of common stock warrants	—	164

Net cash (used in)/provided by financing activities	(625)	20,805
Net increase in cash and cash equivalents	8,885	8,302
Cash and cash equivalents, beginning of period	30,520	1,952
Cash and cash equivalents, end of period	\$ 39,405	\$ 10,254

Source: MiddleBrook Pharmaceuticals, Inc.

MiddleBrook Pharmaceuticals, Inc.
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