



## **Bidel Reports Second Quarter Fiscal Year 2010 Financial Results**

### **Conference Call Today at 4:30 PM EDT**

DANBURY, Conn., May 06, 2010 (BUSINESS WIRE) -- Bidel Inc. (Nasdaq: BIOD) today reported financial results for the second quarter ended March 31, 2010.

#### Second Quarter Financial Results

Bidel reported a net loss for the quarter ended March 31, 2010 of \$10.4 million, or \$0.44 per share, compared to a net loss of \$11.6 million, or \$0.49 per share, for the second quarter of fiscal year 2009.

Research and development expenses were \$7.0 million for the three months ended March 31, 2010, compared to \$8.4 million for the same period in the prior year. The decrease in research and development expenses was primarily attributed to reductions in clinical expenses as patients completed the Phase 3 extension trials for VIAject<sup>(R)</sup> in February 2010 and reduced manufacturing expenses due to purchasing of a reduced quantity of recombinant human insulin.

General and administrative expenses totaled \$3.4 million for the three months ended March 31, 2010, compared to \$3.4 million for the same period in the prior year. General and administrative expenses for the quarter ended March 31, 2010 included one-time professional fee expenses associated with the appointment of our new chief executive officer, implementation of our 2010 stock incentive plan and employment agreements. The expenses for the quarter ended March 31, 2009 included a non-recurring (or one-time) severance charge for our former general counsel.

Expenses for the quarter ended March 31, 2009 and 2010 include \$1.4 million and \$1.3 million, respectively, in stock-based compensation expense related to options granted to employees and non-employees.

Bidel did not recognize any revenue during the quarter ended March 31, 2009 or 2010.

At March 31, 2010, Bidel had cash and cash equivalents of \$32.7 million and 23.9 million shares outstanding.

#### Business Review

On March 30, 2010, the company announced the appointments of Dr. Errol De Souza as president and chief executive officer and Dr. Charles Sanders as chairman of the board. Bidel's co-founder and former chairman and chief executive officer, Dr. Solomon Steiner, has been named chief scientific officer to devote his full-time attention to the development of Bidel's pipeline of early-stage product candidates to treat diabetes.

In February, the U.S. Food and Drug Administration (FDA) accepted for review the company's new drug application (NDA) seeking approval to market VIAject<sup>(R)</sup> as a treatment for diabetes. The FDA has notified Bidel that the Prescription Drug User Fee Act action date for the application is October 30, 2010. As part of the normal course of the FDA's review, Bidel has received and responded to the FDA's 74-day letter regarding the NDA and recently submitted a 120-day safety update on patient experience with the drug, including data from the recently completed VIAject<sup>(R)</sup> Phase 3 extension trials. The company will be presenting results from the VIAject<sup>(R)</sup> program at the [Deutsche Diabetes Gesellschaft](#) meeting in Stuttgart, Germany, May 12-15, and will be presenting a number of abstracts on several of the company's product candidates at the American Diabetes Association's annual meeting in June.

#### Conference Call and Webcast Information

Bidel's senior management will host a conference call on May 6, 2010 beginning at 4:30 pm Eastern Daylight Time to discuss these results and provide a company update. Live audio of the conference call will be available to investors, members of the news media and the general public by dialing +1 (877) 303-8028 (United States) or +1 (760) 536-5167 (international). To access the call by live audio webcast, please log on to the investor section of the company's website at [www.bidel.com](http://www.bidel.com). An archived version of the audio webcast will be available at Bidel's website.

#### About Bidel Inc.

Biodel Inc. is a specialty biopharmaceutical company focused on the development and commercialization of innovative treatments for diabetes. Biodel's product candidates are developed using VIAdel™ technology, which reformulates existing FDA-approved peptide drugs. Biodel's new drug application for its most advanced product candidate, VIAject<sup>(R)</sup>, has been accepted for review by the FDA with a Prescription Drug User Fee Act action date of October 30, 2010. Earlier-stage product candidates include VIAtab(TM), a sublingual tablet formulation of insulin, a line of basal insulins, and a stabilized formulation of glucagon. For further information regarding Biodel, please visit the company's website at [www.biodel.com](http://www.biodel.com).

#### Safe-Harbor Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements represent our management's judgment regarding future events. All statements, other than statements of historical facts, including statements regarding our strategy, future operations, future clinical trial results, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The company's forward-looking statements are subject to a number of known and unknown risks and uncertainties that could cause actual results, performance or achievements to differ materially from those described or implied in the forward-looking statements, including, but not limited to, our ability to secure FDA approval for VIAject<sup>(R)</sup> and our other product candidates under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act; our ability to market, commercialize and achieve market acceptance for product candidates developed using our VIAdel<sup>(TM)</sup> technology, particularly VIAject<sup>(R)</sup>; the progress or success of our research, development and clinical programs and the initiation and completion of our clinical trials; the FDA's findings regarding data anomalies observed in India in our Phase 3 clinical trial of VIAject<sup>(R)</sup> for patients with Type 1 diabetes; the possibility that patients taking VIAject<sup>(R)</sup> may experience more injection site discomfort than they experience with competing products; our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; our estimates of future performance; our ability to enter into collaboration arrangements for the commercialization of our product candidates and the success or failure of those collaborations after consummation, if consummated; the rate and degree of market acceptance and clinical utility of our products; our commercialization, marketing and manufacturing capabilities and strategy; our estimates regarding anticipated operating losses, future revenues, capital requirements and our needs for additional financing; and other factors identified in our most recent quarterly report on Form 10-Q for the quarter ended December 31, 2009. The company disclaims any obligation to update any forward-looking statements as a result of events occurring after the date of this press release.

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**Biodel Inc.**  
**(A Development Stage Company)**  
**Balance Sheets**  
**(in thousands, except share and per share amounts)**

	<u>September 30,</u>	<u>March 31,</u>
	<u>2009</u>	<u>2010</u>
		<b>(unaudited)</b>
<b>ASSETS</b>		
Current:		
Cash and cash equivalents	\$ 54,640	\$ 32,716
Taxes receivable	752	766
Other receivables	--	1,406
Prepaid and other assets	482	828
Total current assets	<u>55,874</u>	<u>35,716</u>
Property and equipment, net	3,695	3,255
Intellectual property, net	56	54
Total assets	<u>\$ 59,625</u>	<u>\$ 39,025</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current:		
Accounts payable	\$ 1,007	\$ 2,913
Accrued expenses:		
Clinical trial expenses	5,647	1,777
Regulatory	359	450
Payroll and related	1,117	972

Accounting and legal fees	325	444
Severance	183	46
Other	284	515
Income taxes payable	165	153
Total current liabilities	<u>9,087</u>	<u>7,270</u>
Commitments		
Stockholders' equity:		
Preferred stock, \$.01 par value; 50,000,000 shares authorized, none outstanding	--	--
Common stock, \$.01 par value; 100,000,000 shares authorized; 23,803,672 and 23,889,612 issued and outstanding	238	239
Additional paid-in capital	176,764	179,537
Deficit accumulated during the development stage	(126,464)	(148,021)
Total stockholders' equity	<u>50,538</u>	<u>31,755</u>
Total liabilities and stockholders' equity	<u>\$ 59,625</u>	<u>\$ 39,025</u>

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**Condensed Statements of Operations**  
(in thousands, except share and per share amounts)  
(unaudited)

	Three Months Ended March 31,		Six Months Ended March 31,		December 3, 2003 (inception) to March 31, 2010
	2009	2010	2009	2010	2010
Revenue	\$ --	\$ --	\$ --	\$ --	\$ --
Operating expenses:					
Research and development	8,361	7,014	16,396	15,768	105,819
General and administrative	3,435	3,377	5,716	5,793	42,438
Total operating expenses	<u>11,796</u>	<u>10,391</u>	<u>22,112</u>	<u>21,561</u>	<u>148,257</u>
Other (income) and expense:					
Interest and other income	(78)	(2)	(320)	(7)	(5,496)
Interest expense	--	--	--	--	78
Loss on settlement of debt	--	--	--	--	627
Operating loss before tax provision (benefit)	<u>(11,718)</u>	<u>(10,389)</u>	<u>(21,792)</u>	<u>(21,554)</u>	<u>(143,466)</u>
Tax provision (benefit)	(89)	20	(139)	3	(505)
Net loss	<u>(11,629)</u>	<u>(10,409)</u>	<u>(21,653)</u>	<u>(21,557)</u>	<u>(142,961)</u>
Charge for accretion of beneficial conversion rights	--	--	--	--	(603)
Deemed dividend -- warrants	--	--	--	--	(4,457)
Net loss applicable to common stockholders	<u>\$ (11,629)</u>	<u>\$ (10,409)</u>	<u>\$ (21,653)</u>	<u>\$ (21,557)</u>	<u>\$ (148,201)</u>
Net loss per share -- basic and diluted	<u>\$ (0.49)</u>	<u>\$ (0.44)</u>	<u>\$ (0.91)</u>	<u>\$ (0.90)</u>	
Weighted average shares outstanding -- basic and diluted	<u>23,717,800</u>	<u>23,885,856</u>	<u>23,698,558</u>	<u>23,867,152</u>	

SOURCE: Biodel Inc.

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